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QUALITY IN MOTION

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FOREWORD

Welcome to the 6th International Conference on Quality Engineering and Management!

It is an honour to welcome you to the vibrant city of Girona, Spain, where the sixth edition of the **International Conference on Quality Engineering and Management** will take place. This biannual event brings together distinguished professionals, academics, and researchers from around the world to share knowledge, experiences, and advancements in the field of quality.

From June 13 to 14, 2014, Girona will become the epicenter of innovation in quality, providing a unique platform for the presentation of theoretical and practical research papers. The diversity of topics addressed reflects the breadth and depth of the discipline, and we are excited to explore the latest trends and developments in quality engineering and management together.

Some of the highlighted themes to be addressed at the conference include Continuous Improvement, Customer Satisfaction, Digital Quality, Management Systems, Operational Excellence, Organizational Excellence Models, Organizational Improvement, Quality 4.0, Quality and Risk Management, Quality Engineering, Quality in Design and Development, Quality Management and Innovation, Quality Tools, Reliability & Maintenance, Six Sigma / Lean-Six Sigma, Standards, Supply Chain Quality Management, The Future of Quality and Organizational Excellence and Total Quality Management.

We are pleased to emphasize the diversity of sectors that will be addressed, from healthcare to higher education, services, and more. Quality is a universal concern, and this conference seeks to explore how we can improve and apply quality principles in different contexts.

We hope you enjoy the conference, establish new connections, and return to your respective institutions with renewed ideas and valuable perspectives. May this 6th International Conference on Quality Engineering and Management be a resounding success!

Welcome to Girona and enjoy the conference!

Sincerely,

Paulo Sampaio, University of Minho – Chair
Marti Casadesús, University of Girona – Local Chair

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SUBMITTED PAPERS

Medical device industry: overview on quality and sustainability

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STRUCTURED ABSTRACT

Purpose – The article aims to evaluate the state of the art of the scientific research on the investigation of quality and sustainability of medical devices to identify trends and main research topics.

Design/methodology/approach- In the first phase, a bibliometric analysis of the literature was performed following the steps proposed by Donthu et al. (2021). 927 papers were included. Then, the systematic literature review analysis was applied adopting a systematic quantitative approach (Pickering & Byrne, 2014; Pickering et al., 2015) and a final number of 20 articles were admitted.

Findings – Through the bibliometric analysis the authors investigated the state of the art of the literature on quality and sustainability of medical devices. The number of citations per year are identified and the journals, countries, and institutions that most frequently published papers on the phenomenon and the articles with the highest number of citations are shown. Moreover, five clusters were identified that correspond to the main themes of interest for the research community. Starting from the previous phase, the systematic literature analysis investigates the articles focused on the medical device supply chain showing that these papers can be further classified into three main groups and identifying the trajectories for future research.

Originality/value – By depicting the state of the art of the literature on the sustainability and quality of medical devices and their supply chain, the authors point out that this market niche should be further investigated mainly with empirical studies to develop sustainable practices that can guarantee patients' safety and quality of life.

Keywords: medical device, quality, sustainability, healthcare.

Paper type: Literature review

INTRODUCTION

The healthcare sector is one of the largest and most important globally. There are different types of healthcare systems worldwide, but all are facing radical changes and common challenges. Firstly, the healthcare sector has to cope with financial cuts and budget deficits in public spending. Secondly, healthcare must address new needs and find innovative and efficient ways to meet them. The population is ageing rapidly, and by 2050, the number of people over 60 is expected to double, from 901 million to almost 2.1 billion (United Nations, 2017). This phenomenon puts great pressure on healthcare systems, increasing the demand for care, services, and technology to prevent and treat diseases and chronic conditions associated with old age. Healthcare must become more effective, efficient, and equitable for all people by controlling spending, improving, and implementing available technology and involving patients in prevention and treatment.

In recent years, it has become increasingly important in the healthcare sector to understand how to ensure a holistic quality of care for all stakeholders (Kumbani et al., 2012). Different stakeholders have different perspectives, and quality of care requires a multidimensional definition encompassing various needs and expectations. Indeed, the perspectives and priorities of different actors need to be considered to define, measure, and improve the quality of healthcare services (Adomah-Afari et al., 2019). Quality has become an increasingly important factor in our lives, and consumers are constantly looking for quality products and services. For this reason, companies and managers worldwide have been driven to consider quality as a strategic objective to achieve competitive advantage. Improved product or service quality leads to lower costs, increased productivity, better products/services for customers and improved organizational performance (Mosadeghrad, 2013).

Moreover, increasing attention from researchers, practitioners, and policymakers has been paid to the concept of "sustainable healthcare". However, the literature shows that there is still no consensus on the definition of this concept (Braithwaite et al., 2019; Fischer, 2014). Many studies seek to identify methods and processes to enable healthcare systems to meet the needs of individuals and populations by achieving optimal healthcare outcomes and responding to present and future cultural, social, and economic conditions.

Medical devices represent an important niche in the healthcare industry, and they are subject to strict quality control to be placed on the market, as they are directly related to patient's health and safety. However, medical devices also contribute to the sector's unsustainability. For these reasons, it is important to understand how to decrease the impacts of these products on sustainability while ensuring the highest quality.

Article 2, Chapter I of the New Regulation 2017/745/EU defines a medical device as “any instrument, apparatus, implant, substance or other product, whether used alone or in combination (including computer software used for its proper functioning) and intended by the manufacturer to be used in human beings for diagnosis, prevention, control, therapy or alleviation of a disease; diagnosis, control, therapy, alleviation or compensation for an injury or handicap; study, replacement or modification of the anatomy or of a physiological process; intervention in conception, the product of which does not exert its principal action, in or on the human body, for which it is intended, by pharmacological or immunological means or by metabolic process but whose function may be assisted by such means."

The following fall under the category of medical devices: i) medical devices, governed by Regulation (EU) 2017/745; ii) in vitro diagnostic medical devices, governed by Regulation (EU) 2017/746.

Furthermore, devices can be classified into four risk classes according to their intended use and the risks involved: I, II a, IIb and III (Ministero della Salute, 2023).

Legislative Decree 137/2022 does not provide for the reprocessing (i.e. the process performed on a used device to allow its safe reuse, which includes cleaning, disinfection, sterilization, and related procedures, testing and restoration of technical and functional safety) of single-use devices and their further use (Ministero della Salute, 2023).

In the European context, the medical device sector is of rising importance. It contributes to improving health levels by developing innovative solutions for diagnosis, prevention, treatment, and rehabilitation (Ministero della Salute, 2023). The manufacturer has multiple responsibilities as it produces a good that directly impacts individuals' health and, therefore, must carry out a careful quality assessment before placing the product on the market. A stringent quality management system must, therefore, be applied, which requires the assurance of product conformity as defined by the regulation throughout the life cycle of the devices. The declaration of conformity is not only a formal document but an assumption of responsibility necessary for CE marking and placing on the market. Moreover, medical devices play a crucial role in pursuing sustainable healthcare, as they are currently one of the main contributors to increased pollution levels and unsustainability in the healthcare sector (Benedettini, 2022).

Against the above backdrop, the present article aims to evaluate the status of research on the investigation of quality and sustainability of medical devices to identify trends, main research topics and trajectories for future studies. Two methodologies were used to achieve this objective. In the first phase, a bibliometric analysis of the literature was performed following the steps proposed by Donthu et al. (2021) and using the Scopus database. After this first exploratory phase, a systematic literature review (SLR) analysis was applied to depict the state-of-the-art literature on quality and sustainability related to the medical device throughout the supply chain. The research adopts a systematic quantitative approach (Pickering & Byrne, 2014; Pickering et al., 2015), and two databases are used, Scopus and Web of Science.

The study highlights the main themes and lines of research that characterize the phenomenon under investigation and identifying a research agenda for the future.

The present paper is organized as follows. First, the research methodology is presented, then the authors illustrate the main results of the research both for the bibliometric analysis and the systematic literature reviews, finally, conclusions are provided.

METODOLOGHY

The current paper aims to provide a picture of the state of the art of literature about the investigation of quality and sustainability of medical devices to identify trends, main research topics and trajectories for future studies. Two methodologies, that are following described, were used to achieve the objective: the bibliometric analysis (a) and the systematic literature review (b).

a) Bibliometric analysis: methodological approach

In the first phase, an exploratory analysis was conducted using the bibliometric analysis of the literature technique with the aim of mapping all the existing knowledge on medical devices' quality and sustainability and identifying the journals, countries, and institutions that most frequently published papers on the phenomenon under investigation and the articles with the highest number of citations as well as number of citations per year. Bibliometric analysis is used to handle a high volume of scientific data, to synthesize a large amount of information, and when the dataset cannot be analyzed manually (Donthu et al., 2021). It enables an assessment of scientific knowledge in a specific field by identifying the development of research trends and supports academics in gaining insight and determining research gaps and new ideas for investigations (Donthu et al., 2021). To carry out the analysis, the four-step process suggested by Donthu et al. (2021) was applied: a) set the purpose and objective of the research that should be broad; b) choose which type of analysis technique to apply. A bibliometric analysis includes the possibility of employing performance analysis and science mapping techniques (e.g. co-occurrence analysis, co-authorship analysis, bibliographic coupling); c) define the keywords to be used, select the database, collect the data and set up the final dataset; d) perform the bibliometric analysis and report the results. Performance analysis and co-occurrence analysis, a science mapping technique, were used in the present research.

The former identifies the contribution of research components (e.g. countries, journals, authors) in a selected field (Cobo et al., 2011; Ramos-Rodrigue and Ruiz-Navarro, 2004; Donthu et al., 2021). Specifically, the temporal distribution of articles, the journals in which publications were published, the authors and articles with the highest number of citations, the institutions (affiliations) and the countries with the largest number of publications were identified.

Co-occurrence analysis is used to determine thematic clusters in the literature by analyzing the keywords provided by the authors in the papers. The idea on which it is based is that the authors choose the same ones to represent the main concepts of the article (Zou et al., 2018; Emich et al., 2020). Co-occurrence analysis calculates the number of times the keywords most frequently appear together and bases the development of thematic relationships on this (Donthu et al., 2021; Cavalcante et al., 2021; Emich et al., 2020). In the present research, co-occurrence analysis is used to identify thematic clusters in the literature published so far.

To perform the analysis, the Scopus database was chosen, and the following keywords were used in the search query: "*medical device", "sustainability", "quality management", "quality improvement", "circular*", "quality certification*", which were chosen considering the objective of the research and covering a broad topic. The data were examined with the support of the software “Biblioshiny” which is powered by “Bibliometrix” (Aria and Cuccurullo, 2017) and uses the “R” language and "VOSviewer" software for the graphic representation of the keyword co-occurrences and the network interactions visualization. At the end of the process, 1.616 documents were collected. The authors set the inclusion criteria: scientific papers and English language, and the final number of records became 927.

b) Systematic literature review: methodological approach

Starting from the results of the bibliometric analysis, in the second phase, the systematic literature review (SLR) was applied to analyze the articles focusing on the medical device supply chain to assess state of the art regarding examining its quality, circularity, and sustainability. The SLR is useful for understanding the relationships between studies and how each contributes to the specific field (Rahman et al., 2020; Booth et al., 2012). The SLR enables the definition of directions for future study (Pasca et al., 2021) and identifies areas that require further study (Snyder, 2019). The research adopts a systematic quantitative approach (Pickering & Byrne, 2014; Pickering et al., 2015), to identify research gaps (Pickering et al., 2015); it defines what is known and what is undiscovered (MacInnis, 2011), and pinpoints essential components of phenomena (Pasca et al., 2021). It makes it possible to summarize the body of knowledge by examining novel findings (Snyder, 2019), and it is considered "systematic" due to the robust, transparent, and repeatable nature of the selection and identification process (Pickering and Byrne, 2014; Tranfield et al., 2003; Mariani et al., 2018). The analysis used Scopus and ISI Web of Science (WoS) databases (Pasca et al., 2021; Ungaro et al., 2024). The keywords *"sustainability", "quality", "medical devices", and "supply chain"* were entered into the two databases, and a total of 268 records emerged (180 from Scopus and 88 from WoS). The following criteria regarding publication characteristics were set (Pickering and Byrne, 2014; Moher et al., 2009): (i) conference papers, book chapters, reviews and articles. (ii) English language. (iii) Studies published in the last ten years. After the duplicate elimination, the initial number of records identified dropped to 192. The studies were collected within an Excel spreadsheet (Følstad and Kvale, 2018). Another inclusion criteria was set to include only articles focusing on the medical devices supply chain's quality, sustainability and circularity. At the end of the process, the final number of items included is 20. Based on Moher et al. (2009), a PRISMA flow chart was developed to illustrate the SLR process (Figure 1). The records were coded through content analysis (Pasca et al., 2021; Rahman, 2021; Eloranta and Turunen, 2015) to identify the main themes of the research field under investigation.

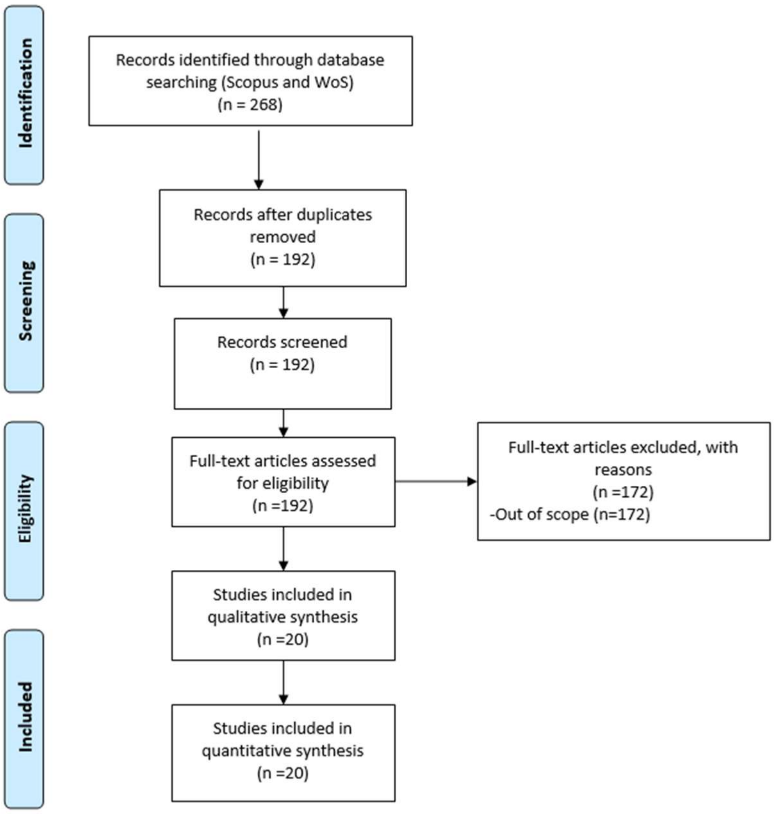

Figure 1 – Prisma diagram.

RESULTS

In the present section, the results of the analysis and their discussion are presented. First, a description is made of the results obtained from the bibliometric analysis (a), and then the categories that emerged from the systematic literature analysis are described (b).

a) Bibliometric analysis of the literature: results

The bibliometric analysis carried out on the 927 records included in the study showed that the scientific community's interest in quality and sustainability within the medical device industry has increased over the years. The first article was published in 1991, but the number of papers has risen constantly since 2012. Considering the journals interested in publishing articles about the phenomenon, it emerged that 468 journals (approx. 50%) published only one article related to the phenomenon analysed, 81 journals (approx. 9%) published only two articles, 31 (approx. 3%) published 3, 14 journals published 4 (approx. 2%), the remainder (18) published more than 5. The three journals with the highest scientific production are Medical Device and Diagnostic Industry, Regulatory Rapporteur and Biomedical Instrumentation and Technology (Table 1).

Table 1 – Distribution of publications per journal.

Journal	Fq
Medical Device and Diagnostic Industry	23
Regulatory Rapporteur	16
Biomedical Instrumentation and Technology	13

The 927 articles collected for the study involve 5203 different authors. Most authors (4.916, around 94%) have published only one article on the research field, 234 have only two publications, 36 have three publications and 17 have published more than four articles. Moreover, the documents included in the analysis received 13.791 citations. Among the articles, 196 did not receive any citations when the dataset was extracted from Scopus, 54 articles have more than 50 citations, and two have more than 400. The article with the highest number of citations (434) is "*Tanaka, M., Motomura, T., Kawada, M., Anzai, T., Kasori, Y., Shiroya, T. & Mochizuki, A. (2000). Blood compatibility aspects of poly (2-methoxyethylacrylate) (PMEA) - relationship between protein adsorption and platelet adhesion on the PMEA surface. Biomaterials, 21(14), 1471-1481*". The number of universities and organisations involved in producing the articles included in this research is 1.333. Table 2 shows which universities are most frequently involved in producing research on the quality and sustainability of medical devices and have more than 20 publications.

Table 2 – Number of publications per organization.

Journal	Fq
Harvard Medical School	36
Yale University School of Medicine	26
University Hospital Heidelberg	25
Griffith University	21
Universitas Indonesia	21

It is relevant to analyse scientific publications by country to understand how the phenomenon is studied globally and which countries are the most productive and therefore most interested in the topic. The United States is the nation with the highest number of records (1,751). The second two most productive nations are the UK (302 articles) and Germany (301 records). The top 10 Countries also include Italy (in fifth place with 262 publications).

Finally, through the co-occurrence analysis, developed using the authors keywords, it was possible to determine the themes that are of main interest for the scientific community and that describe the phenomenon under investigation. Therefore, the keyword analysis allows to highlight the most discussed topics within the literature over the last 22 years.

Specifically, the authors identified five main clusters:

i. *Safety and Quality Improvement:* grouped under this theme are the keywords that relate to the themes of patient safety, control of complications such as infections, and quality improvement in healthcare.

ii. *Technology, Quality, and Risk Management:* This cluster includes articles focused on the study of the technology used in medical devices and on quality management as a strategic approach to increasing customer satisfaction and reducing the risk associated with these products.

iii. *Patient Illness Conditions:* This group includes keywords that refer to factors and conditions that can cause infirmity in patients and related health problems.

iv. *Compliance with Standards and Regulatory Requirements:* the scientific community is also interested in the topics of quality assurance in terms of ensuring that the required quality and safety standards are met and of compliance with regulatory requirements and the authorities' expectations.

v. *Sustainable Supply Chain Management:* this group shows that the focus of researchers is also on the analysis of topics related to the sustainability of medical devices. Specifically, the authors use several keywords that refer to the study of approaches and tools needed to achieve it and the topic of supply chain management that becomes significant to improve product sustainability.

The words with the highest level of occurrence, which were therefore used most often by the authors to summarise the theme of the article, are medical device (94 occurrences), quality improvement (64 occurrences), quality management (48), sustainability (35) and patient safety (32).

b) Systematic literature review: results

Through the bibliometric analysis, it was possible to depict the state of the art of the literature on the study of the sustainability and quality of medical devices. Specifically, through co-occurrence analysis, the most recurring themes were identified. Among these is the examination of the supply chain of medical devices, which has become of particular interest in recent years. For this reason, it was decided to carry out a systematic analysis covering this specific topic, in order to deepen understanding the phenomenon.

At the end of the process, 20 documents were included in the analysis. Specifically, 15 are scientific articles, 3 are reviews, one is a case study and one a book chapter. As showed in table 3 the first article was published in 2014 and the interest of the academics grow during the years. The majority of publications are concentrated in the last three years with 14 publications corresponding to 70% of the analysed documents.

Table 3 – Publications per year.

Year	Fq
2014	2
2015	1
2016	1
2018	2
2020	1
2021	2
2022	7
2023	4

Regarding the methodology used in the articles, 14 are conceptual (70%), while six are empirical (3 qualitative, two quantitative and one mixed method.

After analysing and interpreting the reviewed papers, the authors grouped the documents into three main themes, which represent how to manage the supply chain to ensure the achievement of quality and sustainability in the medical device industry: 1) Sust*ainable Approaches for Supply Chain Management; 2) Procurement; 3) Reconditioning of medical devices and closed-loop* (Table 4).

Table 4 – SLR categories.

Theme	Fq	References
Sustainable approaches for the supply chain management	5	*Brown & Gilbert (2014); Izadikhah & Saen (2016); Abad et al. (2023); Waqas et al. (2023); Choudhary et al. (2023)*
Procurement	4	*Ghadimi et al. (2018); ForouzeshNejad (2023); Rostami et al. (2023); Ghadimi & Heavey (2014).*
Reconditioning of medical devices and closed-loop	11	*Unger & Landis (2016); Kane et al (2018); Akano et al. (2021); Lepasepp & Hurst (2021); Benedettini (2022); Hennein et al. (2022); Taheri & Moghaddam, (2022); Lantada et al. (2022); Williams et al. (2022); Nayeri et al. (2022); MacNeill et al. (2020);*

The three themes are related articles are below illustrated:

1. *Sustainable approaches for supply chain management:* this category comprises 6 articles, four conceptual and two empirical (one qualitative and one quantitative). The documents included in this group aim to understand which types of sustainable approaches can be applied to the

supply chain management of medical devices. The authors of the articles focused on investigating how to minimise environmental impacts of medical devices and total costs and maximise social impacts by considering the resilience and responsiveness of the supply chain. The aim is to highlight strengths and weaknesses in implementing a sustainable supply chain. It shows how the manufacturing process of medical devices impacts sustainability. An important element is the skills of personnel, which are an enabling factor in ensuring sustainability, as tools require skills that need personnel and infrastructure linked to structures, systems, and roles. The supply chain's responsiveness can improve sustainability by leading to more job opportunities and safety, lower CO2 emissions, and economic growth. The use of responsible and sustainable behaviour by manufacturing companies can reduce their costs. Factors affecting the creation of a sustainable chain include lack of initial capital, logistics and inventory management, and customer relations. Additive technology has been highlighted as a useful tool for achieving sustainability because it reduces resource use and CO2 while ensuring worker safety and patient health. Thus, sustainability can be stimulated by collaboration between different actors, including governments and policymakers, by using appropriate technology and information systems, and by improving personnel skills.

2. *Procurement:* in this cluster are grouped 4 articles, 2 conceptual and 2 empirical (one quantitative and one mixed method). The objective of the papers included in the category is to analyse the role of supplier in the medical device supply chain due to their fundamental role for ensuring quality and sustainability. The correct functioning of the supply chain can be ensured by the adequate selection of suppliers. The main factors that should be considered are their green reputation, waste management, quality of materials, costs, services offered, social responsibility, and worker safety. Moreover, important aspects are flexibility, reliability, and the use of technology. the ability to choose and manage its suppliers correctly can lead to benefits for the company, such as improved efficiency and lower costs, enhanced performance in terms of social sustainability, optimised timing, the creation of a correct flow of information and increased profitability.
3. *Reconditioning of medical devices and closed loop*: The category contains 12 articles, 9 conceptual, and 3 empirical (all qualitative). The aim of the documents is to understand barriers and enablers to the reconditioning of medical devices and the development of a closed-loop approach applying the circular economy theories on medical disposals. The analysis of the articles shows that the main factors preventing the adoption of a circular economy supply chain are the perceptions that single-use products are safer for patients than

reprocessed ones, the higher profits from high-volume consumption, the lack of clear guidelines and policies regarding the reprocessing procedure and the lack of understanding regarding the key factors influencing the acceptance of reprocessed medical devices by customers. The information provided by product quality certification and eco-labelling, on the other hand, plays an important role in consumer decision-making. Furthermore, product quality is among the most critical factors influencing the acceptance of remanufactured devices along with price. The establishment of a circular economy in medical device manufacturing will require a complex transformation through the involvement of several stakeholder such as: device users, device manufacturers (who must provide accurate and transparent life cycle assessments of reprocessed medical devices), regulators (who have to implement appropriate policies), accreditors and professional standards organisations. The circulation of products and materials, the creation of environmental and financial value through closed-loop chains, must ensure that the functionality and hygienic conditions of the product are not compromised, as any increase in risk can negatively affect the health of the patient.

CONCLUSIONS

The aim of the present article is to analyse the state-of-the-art regarding the quality and sustainability of the medical devices, a crucial niche of the healthcare industry. When the focus is on the healthcare sector and products such as medical devices, special challenges arise compared to other sectors and products, as strict hygiene, safety, and quality requirements must be met to protect the health of patients (Van Boerdonk et al., 2021). Two methodologies were applied to achieve this goal: a bibliometric analysis and a systematic literature review. The bibliometric analysis identified that the topic has become particularly interesting to the scientific community in recent years, particularly since 2012. It emerged that countries that were most interested in publishing articles on this phenomenon are the United States, followed by the UK and Germany. In Italy the discussion is not so rich probably to the laws and regulation's constraints. Future research could investigate why researchers in the United States are more interested in studying the topic and why there has been a considerable increase in publications since 2012. Legislative changes that may have favoured the rising of research and studies could also be investigated. At the same time, collaborations with academics from underrepresented countries could be stimulated to increase research on the quality and sustainability of medical devices in other places in the world. Analysing the keywords made it possible to identify the topics on which the scientific community has focused the most. This allows researchers in the future to identify where to position their scientific study and which areas need to be explored more or have emerged more recently. Among these, one topic that has become particularly interesting in recent years is sustainable supply chain management. Based on this, a systematic literature analysis was conducted to investigate the research published on this topic. The study showed that the number of articles has increased in the last two years (2022-2023) and that most of the research is conceptual. Future research should, therefore, increase empirical studies. Through the systematic analysis, three themes were identified that represented the topics of major interest to academics in the study of medical device supply chain quality and sustainability. The topic in which most of the articles were categorised is reprocessing, this indicates that the scientific community is particularly interested in understanding how to make the sector more sustainable by investigating how to design products that can be reused and recycled to help reduce environmental impacts on a circular economy perspective. Furthermore, the researchers investigated the role of the procurement and suppliers' selection in managing a quality and sustainable supply chain and which approaches can be used to achieve these results. What emerges from the analysis is that there should be increased collaboration between multiple stakeholders, including regulators who should develop regulations to foster greater sustainability in the industry while maintaining the high quality required, consumers who should be more responsible in their purchasing choices, and producers who should engage in the correct choice of their suppliers, raw materials, and management of the entire supply chain. Therefore, there is a gap of empirical studies and future research could focus on each actor's role in achieving this common goal. Finally, two databases (Scopus and WoS) were used in the present study, and future studies could use other databases, and additional keywords could be included in the search query.

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Coopetition-Driven Excellence: Enhancing Product Quality and Innovation in Manufacturing SMEs through IoT-Enabled Networks

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STRUCTURED ABSTRACT

Purpose: This study explores the impact of coopetition—strategic collaboration amidst competition—on product quality standards in Small and Medium Enterprises (SMEs).

Methodology: Using a quantitative approach, the research analyzes improvements on KPIs related to product quality within a group of stone manufacturing SMEs engaged in Internet of Things (IoT)-enabled coopetition networks.

Findings: Results demonstrate a significant 10.8% improvement in product quality standards and a 41,1% increase in quality consistency after adopting coopetition practices. These enhancements highlight the potential of coopetition to boost standard quality in the manufacturing sector.

Research limitations: The study is specific to stone manufacturing SMEs, suggesting a need for further investigation into the long-term viability of coopetition and its applicability across various industries and global markets.

Originality/value: This research quantitatively substantiates the benefits of coopetition in enhancing product quality and consistency, offering a valuable perspective on strategic collaborations through IoT networks. It underscores coopetition's role in driving innovation and maintaining competitive advantage in the rapidly evolving manufacturing landscape, thereby providing a foundation for future studies and practical implementations in diverse industry settings.

Keywords: Coopetition, Stone Industry, SMEs, Quality, Internet of Things

INTRODUCTION

In Small and Medium Enterprises (SMEs), the quest for sustainable growth and a competitive edge in the market is ceaseless (von der Leyen, 2019). Amidst this quest, coopetition—strategically blending collaboration with competition—emerges as a novel paradigm poised to redefine success for SMEs (Xie *et al.*, 2023). This study is about coopetition technology-enabled networks, focusing on their impact on the quality standards of products developed by SMEs (Rouyre, Fernandez and Bruyaka, 2024). Despite the intuitive appeal of coopetition to spur innovation and operational excellence, the literature remains nascent in quantitatively demonstrating its effects, especially concerning product quality within the SMEs (European Commission, 2020). This research gap signals a compelling need for empirical evidence to validate the efficacy of coopetition in enhancing product quality and consistency.

This study uses quantitative methodology to analyze key performance indicators (KPIs) related to product quality. This approach facilitates an assessment of the innovation outcomes stemming from SMEs participation in coopetition networks (Arora and Brintrup, 2021). By bridging the existing research gaps in qualitatively assessing the coopetition impacts, this paper aims not only to contribute to the academic discourse on coopetition but also to provide actionable insights for SMEs contemplating the integration of coopetition into their strategic framework. In doing so, it aspires to pave the way for SMEs to harness the full capabilities of coopetition, fostering a competitive advantage in the rapidly evolving manufacturing sector.

THE ROLE OF THE INTERNET OF THINGS (IOT) IN ENHANCING COOPETITION

The Internet of Things (IoT) stands at the forefront of technological innovations transforming the industrial landscape. By interconnecting a vast array of devices, machinery, and systems through the internet (Latif *et al.*, 2023), IoT enables an unprecedented level of data collection, analysis, and automation. In coopetition, where strategic collaboration meets competition, IoT technologies play a pivotal role in amplifying the benefits and facilitating the processes that define this novel business strategy (Khan, Solvang and Yu, 2024).

IoT technologies may contribute to coopetition in several ways. First, they enhance operational transparency among competing firms by enabling real-time data sharing and communication (Mosch, Majocco and Obermaier, 2023). This transparency fosters trust and collaboration, allowing SMEs to jointly identify opportunities for improvement, innovation, and efficiency gains without compromising their competitive edge (Büyüközkan and Göçer, 2018). For example, in the manufacturing sector, IoT-enabled machinery can share performance data with all parties in a coopetition network, helping to pinpoint bottlenecks, reduce downtime, and improve product quality standards (Khan, Solvang and Yu, 2024). Second, IoT facilitates a more dynamic and responsive production process. By leveraging IoT sensors and analytics, SMEs can better predict and adapt to market changes, customer preferences, and supply chain disruptions (Tjahjono *et al.*, 2017). This agility is crucial for maintaining high quality and consistency in products, as demonstrated by the significant improvements observed in the study's participating stone manufacturing SMEs. Moreover, IoT technologies support the development of new business models and innovation pathways central to coopetition (Yazdinejad *et al.*, 2023). They enable firms to collaboratively explore new markets, develop complementary products, and integrate services, thereby creating additional value for customers and differentiating themselves in the marketplace (Salih *et al.*, 2022).

METHODOLOGY

The study utilizes a case study methodology to explore the influence of coopetition on product quality in the industrial sector, emphasizing small and medium-sized enterprises (SMEs). At the heart of the analysis are key performance indicators (KPIs) that are directly linked to quality standards, specifically First Time Through (FTT) (Rohac and Januska, 2015), Customer Complaint Ratio (CcR) (Pakdil and Leonard, 2013), and On-Time Delivery Ratio (OtD) (Rohac and Januska, 2015). Through a quantitative examination of these KPIs, the research seeks to evaluate the efficacy of coopetition strategies deployed by SMEs. The aim is to uncover actionable insights that can significantly improve product quality and promote competitive growth within this sector.

First Time Through KPI (KPI_{FTT}) measures the proportion of products meeting quality and compliance standards on the first attempt, highlighting process efficiency and reducing waste (Table 1, Eq. 1). Customer Complaint Ratio (KPI_{CcR}), a vital metric, calculates the frequency of customer complaints, providing insights into product or service quality and customer service effectiveness (Table 1, Eq. 2). On-Time Delivery (KPI_{OtD}) ratio assesses the timeliness of deliveries to customers, reflecting a company's operational efficiency and reliability (Table 1, Eq. 3).

Table 1. Formulation of the Key Performance Indicators

Equation	KPIs	Description	Calculation
Eq.1	KPI_{FTT} (%)	FFT Quantitative KPI	$\sum_1^n\left(\frac{\sum parts\ produced - defective\ parts\ _{(daily)}}{\sum parts\ produced_{(daily)}}\right).\ 100\%$
Eq.2	KPI_{CcR} (%)	MvA Quantitative KPI	$\sum_1^n\left(\frac{\sum total\_complained\_parts\ _{(daily)}}{\sum parts\_delivered)_{(daily)}}\right).\ 100\%$
Eq.3	KPI_{OtD} (%)	PoR Quantitative KPI	$\sum_1^n\left(\frac{parts\_delivered\_on\_time_{(daily)}}{\sum parts\_delivered)_{(daily)}}\right).\ 100\%$
Eq.4	$KPI_{(\sigma)}$	Dispersion KPI	$\sqrt[2]{\frac{\sum_1^n[KPI(FTT;CcR;OtD)_{(daily)} - \overline{KPI(FTT;CcR;OtD)_{(daily)}}\ ]^2}{(Observations(FTT;CcR;OtD)_{(test\ period)})}}$

Analyzing these KPIs allows for a nuanced understanding of how coopetition networks influence product quality standards and consistency (Table 1, Eq. 4), offering actionable insights for SMEs. The study further integrates the concept of Innovation Outcomes (IO) (Bouncken and Fredrich, 2012) (Silva, Rabadão and Capela, 2020) to quantify the effects of innovative practices, like joining coopetition networks or adopting new technologies, on operational metrics (Table 2, Eq. 5 - 12).

Table 2. Formulation of the Innovation Outcomes

Equation	IOs	Description	Calculation
Eq.5	$IO_{(QTT)FFT}$	FFT Quantitative gains	$\frac{KPI_{(FTT\_COO.N)} - KPI_{(FTT\_CBP)})}{KPI_{(FTT\_COO.N)}}.100\%$
Eq.7	$IO_{(\sigma)FFT}$	FFT Consistency gains	$\frac{KPI_{(\sigma FTT\_COO.N)} - KPI_{(\sigma FTT\_CBP)})}{KPI_{(\sigma FTT\_COO.N)}}.100\%$
Eq.8	$IO_{(QTT)CcR}$	CcR quantitative gains	$\frac{KPI_{(CcR)CN.P} - KPI_{(CcR)CB.P)}}{KPI_{(CcR)CN.P}}.100\%$
Eq.9	$IO_{(\sigma)\ CcR}$	CcR Consistency gains	$\frac{KPI\sigma_{(CcR)CN.P} - KPI\sigma_{(CcR)CB.P})}{KPI\sigma_{(CcR)CN.P}}.100\%$
Eq.10	$IO_{(QTT)OtD}$	OtD Quantitative gains	$\frac{KPI_{(PoR)CN.P} - KPI_{(PoR)CB.P})}{KPI_{(PoR)CN.P}}.100\%$
Eq.11	$IO_{(\sigma)\ OtD}$	OtD Consistency gains	$\frac{KPI\sigma_{(OtD)CN.P} - KPI\sigma_{(OtD)CB.P}}{KPI\sigma_{(OtD)CB.P}}.100\%$
Eq.12	$IO_{(QTT)Quality}$	Quality Drivers Quantitative gains	$\frac{IO_{(QTT)FTT} + IO_{(QTT)CcR}\ IO_{(QTT)OtD}}{4}.100\%$

Through this methodology, the research aspires to contribute to the discourse on the Internet of Things (IoT), emphasizing the potential of these technologies to redefine industrial capabilities and foster value creation within manufacturing environments.

EMPIRICAL CONTEXT

The selection of the empirical context for this study aligns with the stringent criteria of quantitative research methodologies, as delineated by Johnson & Onwuegbuzie (2004). The decision regarding the specific sector and its companies was made through a pragmatic lens, emphasizing the necessity of data collection while also considering the financial implications of data gathering and analysis (Johnson and Onwuegbuzie, 2004). This approach ensured that the chosen context was feasible and pertinent, facilitating the collection of data that accurately reflects the impact of coopetition networks within the designated environment.

The study zeroes in on the Portuguese ornamental stone sector, exploring the influence of coopetition networks on determinants of quality standards in SMEs, focusing on service innovation (Silva and Pata, 2022). It capitalizes on the capabilities of an Internet of Things (IoT) platform, supported by funding from the European Union, to delve into quality enhancements and the evolving competitive dynamics within the manufacturing SME domain. This case study investigates the transformative potential of IoT in conventional sectors and sheds light on the strategic benefits of fostering competitive dynamics among SMEs.

Population and Sample

The dataset for this study was sourced from the Portuguese Association of the Mineral Resources Industry (ASSIMAGRA) in 2022, focusing on Portugal's Ornamental Stone (OS) sector. This sector plays a crucial role in Portugal's economy, employing over 16,600 people and exporting to 116 countries, making Portugal the eighth largest exporter globally in this market (Almeida and Silva, 2022). The introduction of an IoT system, supported by the European Union, marks a pioneering effort in this sector, enhancing digital connectivity and integrating competing firms into a cohesive coopetition framework (Silva, Rabadão and Capela, 2020).

For this research, three ornamental stone producers were selected to examine the IoT-enabled coopetition network's technological and competitive benefits. The study was conducted in two phases: an initial assessment of operations and a subsequent evaluation post-IoT implementation. The research began with informal discussions with company directors, leading to formal participation and a confidentiality agreement to protect proprietary information. This agreement provided access to detailed company data, including analytical and financial records, order histories, and management and production process insights.

The research team closely monitored operational activities, ensuring data integrity and security. Data collected from digital machinery and databases underpins the analysis of the IoT-enabled cooperative network's impact, offering a comprehensive evaluation of its benefits for the ornamental stone producers involved.

Data Collection Procedures

This study employs a safe data collection methodology to assess operational efficiencies before and after the implementation of Coopetition Practices (CN.P), juxtaposed with the framework of Current Best Practices (CB.P). The methodology is structured around two 54-day periods, facilitating a detailed comparison between conventional operations and those enhanced by coopetition principles. To ensure confidentiality, participating companies were designated as "A", "B", and "C":

Phase 1 - Current Best Practices (CB.P): This initial phase, spanning from April 17th, 2023, to June 10th, 2023, captured existing operational metrics under the CB.P model. They established a foundational baseline during this period, enabling a subsequent comparison with coopetition practices.

Phase 2 - Coopetition Production Practices (CN.P): Following the baseline assessment, this phase, from September 9th, 2023, to November 14th, 2023, focused on the integration of coopetition. This approach emphasized fostering collaborative and competitive dynamics among the participant companies, using the same duration and methodology as the CB.P phase to ensure a balanced comparison.

Data management protocols were stringently followed, and confidentiality agreements were in place to guarantee the secure and uniform processing of data for comprehensive analysis. This systematic approach is designed to highlight the operational and competitive advantages of embedding collaboration practices within SMEs, particularly in the Ornamental Stone sector, thereby offering insights into the tangible benefits of such strategic collaborations.

RESULTS AND DISCUSSION

The study's analysis, drawing from data under Current Best Practices (CB.P) and Coopetition Technology-Enabled Networks, reviewed ten performance indicators (KPIs) to assess the impact of coopetition on quality standards. This evaluation, with results detailed in Table 5, contrasts the performance under CB.P and coopetition, providing insights into coopetition's influence on various quality standards dimensions.

Key Performance Indicators (KPIs)

KPI_{FTT} is a metric indicative of operational quality within manufacturing organizations. According to data presented in Table 3, the average daily production was reported at 369.9 parts, with 31.3 of those failing to meet the initial quality criteria. Consequently, the KPI_{FTT} was calculated at 90.9%, demonstrating that, on average, 90.9% of the parts manufactured met the quality standards on their first pass. The same FTT KPI was observed as companies transitioned to adopting Coopetition network practices, as detailed in Table 4. This consistency suggests that integrating coopetition strategies keeps the quality output intact.

Table 3. Data packages collected in Current Best Practices (CB.P)

Data ID	Description	Current Best Practices (CB.P)	Average daily
Data 1	Parts Produced	∑parts_produced(CB.P)	369.9
Data 2	Defective Parts Found	∑defective_parts(CB.P)	31.3
Data 3	Total complained parts	∑ total_complained_parts	15
Data 4	Parts delivered	∑ parts_delivered	339
Data 5	Parts delivered on time	∑ parts_delivered_on_time	240
Data 6	Parts delivered	∑ parts_delivered	339

Table 4. Data packages collected in Coopetition Network Practices (CN.P)

Data ID	Description	Coopetition Networks (CN.P)	Average daily
Data 7	Parts produced	∑parts_produced(CN.P)	454.3
Data 8	Defective parts	∑defective_parts(CN.P)	38.5
Data 9	Total complained parts	∑ total_complained_parts	17
Data 10	Parts delivered	∑ parts_delivered	454
Data 11	Parts delivered on time	∑ parts_delivered_on_time	358
Data 12	Parts delivered	∑ parts_delivered	454

The KPI_{CCR} measures the proportion of customer complaints relative to the total number of products provided within a given timeframe. Under the Current Best Practices, the analysis showed an average of 17 parts rejected daily from 339 dispatched, resulting in a KPI_{CCR} of 6.3%, as outlined in Table 5.

Table 5. KPI assessment in Current Practices (CN.P) and Coopetition Practices (CN.P)

KPIs	CB.P	CN.P
KPI - First Time Through (%)	KPI_{FTT}: 90.9 % $KPI_{(\sigma)FTT}$: 0.0235	KPI_{FTT}: 90.9 % $KPI_{(\sigma)FTT}$: 0.0169
KPI – Customer Complain Ratio	KPI_{CcR}: 6.3 % $KPI_{(\sigma)CcR}$: 0.03	KPI_{CcR}: 4.4 % $KPI_{(\sigma)\ CcR}$: 0.02
KPI - On-Time Delivery	KPI_{OtD}: 67.1 % $KPI_{(\sigma)OtD}$: 0.05	KPI_{OtD}: 77.5 % $KPI_{(\sigma)OtD}$: 0.03

Transitioning to the Coopetition Production Practices led to an increase in daily production to 454 parts, with rejections holding steady at 17. This escalation in production, while maintaining the number of rejections, highlights the efficiency of scaling up under coopetition. Remarkably, this transition saw the KPI_{CCR} improve to 4.4%, indicating a significant reduction of 1.9% in customer complaints, as demonstrated in Figure 1.

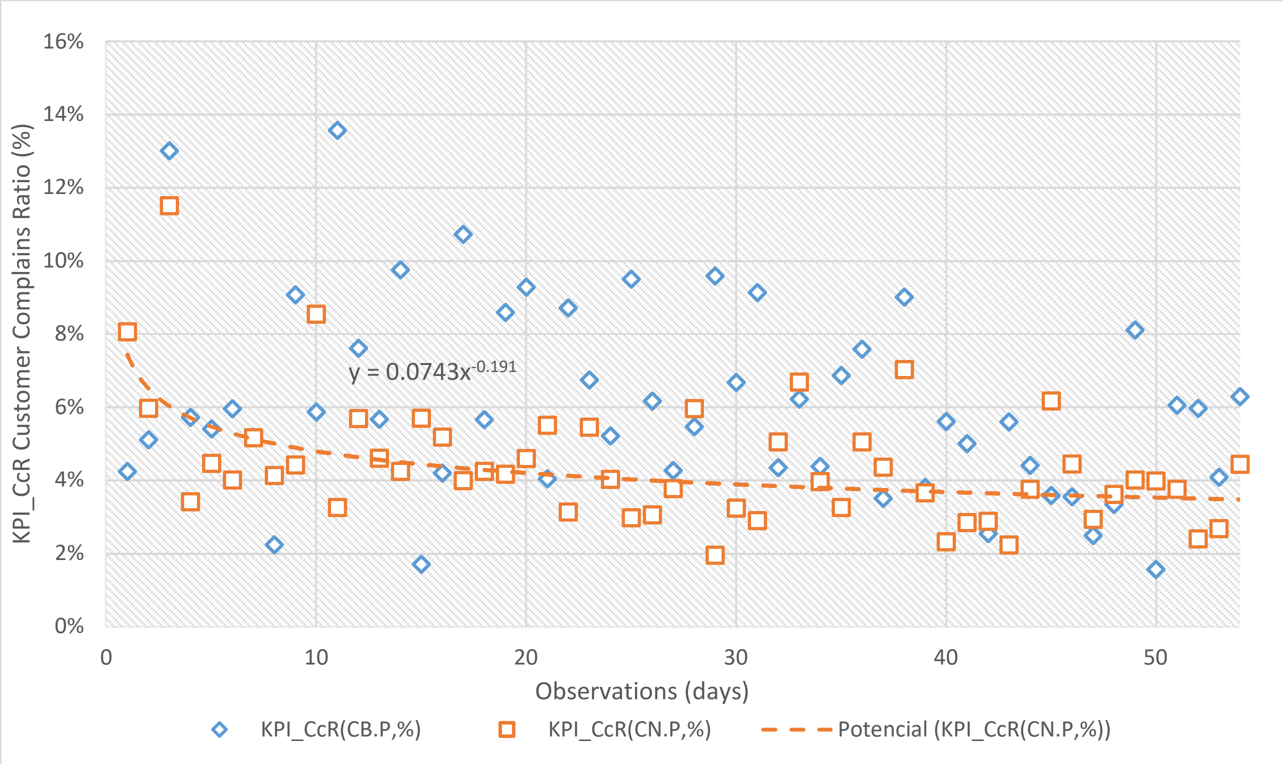

Figure 1. Trend in Customer Complaint Ratio for Stone SMEs Transitioning to Coopetition Networks

Additionally, the variance indicator $KPI(\sigma)_{CcR}$ was recorded at 0.001, signaling a decrease in variability and, thus, a boost in production consistency and stability.

The On-Time Delivery (KPI_{OTD}) measures the percentage of products or services delivered to customers within the agreed-upon delivery timeline. Under the Current Best Practices, analysis shows an on-time delivery of 240 out of 339 parts dispatched daily, resulting in a KPI_{OTD} of 67.1%. This figure is based on data in Table 3. The shift to Coopetition Production Practices markedly enhanced the On-Time Delivery Ratio. With consistent production levels, the number of parts delivered on time rose to an average of 358 parts per day, boosting the KPI_{OTD} to 77.5%. This improvement demonstrates the CN.P strategy's effectiveness in increasing delivery reliability to customers.

Innovation Outcomes (IOs)

Innovation Outcomes (IOs) are crucial for evaluating the concrete benefits derived from participation in cooperative competition, or coopetition, networks, demonstrating marked enhancements in key factors influencing quality standards of the stone SMEs. Table 6 offers a detailed examination of these benefits, presenting measurable progress and associated reductions in variability across different innovation outcomes.

Table 6. Innovation Outcomes assessment: Transition from CB.P to CN.P

Innovation Outcome (IO)	**Quantitative Gains ($IO_{(QTT)}$)**	**Consistency Gains ($IO_{(\sigma)}$)**
IO - First Time Through (%)	$IO_{(QTT)FFT}$: 0.00 %	$IO_{(\sigma)RMY}$: 28.18%
IO - Cust. Complaint Ratio	$IO_{(QTT)\ CcR}$: 29.3 %	$IO_{(\sigma)CcR}$: 44.9 %
IO – On Time Delivery	$IO_{(QTT)OtD}$: 15.6 %	$IO_{(\sigma)OtD}$: 43.9 %
IO - Quality	$IO_{(QTT)Quality}$: 18,8 %	$IO_{(\sigma)Cust.\ Satisf.\ Det}$: 41,1 %

The analysis highlights explicitly the Customer Complaint Ratio (CCR) within the context of IOs, revealing a direct positive impact on customer satisfaction. This is evidenced by a significant 29.3% reduction in customer rejections of parts and a 44.9% improvement in the uniformity of production processes. Such enhanced consistency underscores the effective streamlining and increased predictability that coopetition networks bring to the manufacturing sector. It underscores the strategic value of embracing a model of collaborative competitiveness, pointing to its ability to refine operational procedures and, by extension, bolster overall customer satisfaction.

The On-Time Delivery Ratio has seen a remarkable increase of 15.6%, indicating significant strides in optimizing production capabilities. This development highlights the advantages of weaving coopetition— the fusion of cooperation and competition— into the fabric of operational strategies. The resulting synergy fosters a highly predictable and efficient operational landscape. Coopetition grants access to a pooled repository of expertise, technological advancements, and capabilities, enhancing individual firms' productivity and elevating the entire network's collective competitiveness.

Further analysis of innovation outcomes reveals a positive impact on KPIs related to quality standards, showcasing an 18.8% improvement as stone SMEs integrate coopetition practices, as depicted in Figure 2. This improvement is amplified by a 41.1% rise in the uniformity of quality enhancements. These findings highlight the significant role of coopetition in expanding operational capacity and scale, supporting a strategic shift towards these hybrid competitive-collaborative networks as a pivotal move to enhance operational capabilities and consolidate market standing.

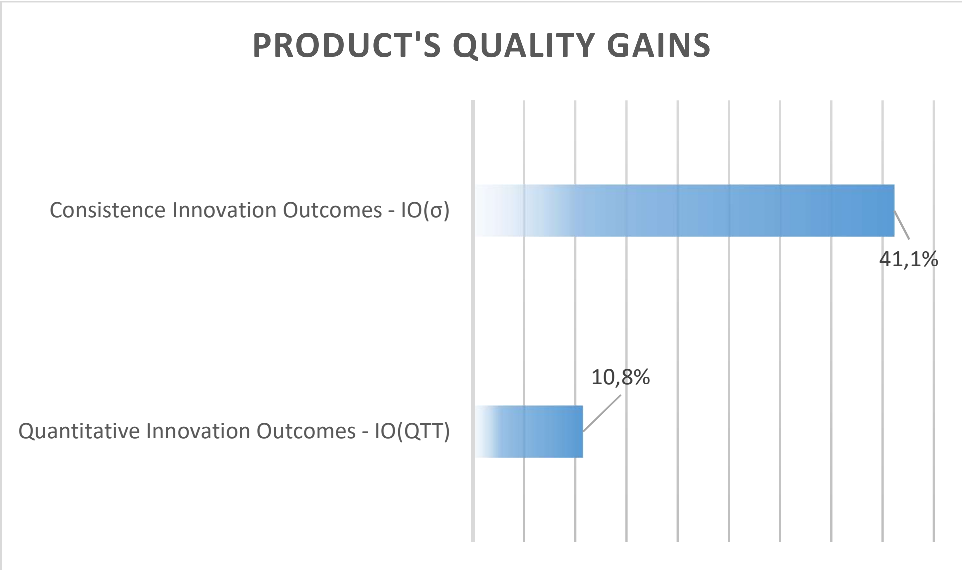

Figure 2. Enhancing Product Quality through the Adoption of Coopetition Network Practices

Figure 3. Product Quality Innovation Outcomes from the transition to coopetition network practices.

This evidence compellingly demonstrates the strategic value of coopetition as a framework that effectively meets customer expectations regarding quality and ensures consistent and predictable performance across various metrics. The insights detailed in Table 6 robustly affirm the substantial advantages of engaging in coopetition networks. These networks foster a unique blend of collaboration and competition, creating an optimal environment for OS SMEs—specifically stone companies—to thrive. Through strategically sharing strengths and resources among peers, stone companies within these networks can significantly enhance the quality of their products, elevate the product's quality, and minimize costs.

CONCLUSION

The study examined the impact of coopetition—a synergistic amalgamation of cooperation and competition—on the quality standards of products within the stone SME sector. An analysis of KPIs from Current Best Practices and Coopetition IoT-Enabled Networks demonstrated that coopetition seems to boost product quality. Key findings, such as improvements in the First Time Through metric, the Customer Complaints Ratio, and the On-Time Delivery Ratio, underscore the substantial benefits that coopetition networks offer to manufacturing processes. Incorporating coopetition into operational frameworks fosters an environment conducive to enhancing product quality, optimizes production capabilities, streamlines operations, and minimizes costs. This strategic integration positions stone SMEs for increased market competitiveness and sustainable growth, highlighting the pivotal role of coopetition in creating a dynamic and innovative manufacturing landscape.

The conducted study, while insightful, is subject to certain limitations. Its focus on the stone SME sector might restrict the applicability of its conclusions to other industries, which may exhibit different characteristics and competitive dynamics. The emphasis on quantitative metrics to assess quality standards may overlook broader impacts of coopetition, such as its effects on organizational culture, innovation, and employee morale. Furthermore, the study presupposes a stable competitive environment, potentially overlooking industry shifts, technological advancements, or market changes that could influence the effectiveness and sustainability of coopetition strategies over time.

Future research should broaden its scope to assess the impact of coopetition across various industries, enhancing the generalizability of the current study's findings. Longitudinal studies would provide invaluable insights into the long-term effects of coopetition, especially considering evolving technologies and fluctuating market conditions. Moreover, integrating IoT within coopetition networks also presents challenges, including the need for robust cybersecurity measures, data privacy considerations, and the management of technology integration across different firms. Addressing these challenges is essential for harnessing the full potential of IoT in enhancing coopetition strategies.

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Customer order management in lens production

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STRUCTURED ABSTRACT

Introduction - Through this paper, quality tools such as 5 why, SWOT and SMART objectives will be implemented to address customer order management in lens manufacturing. The role of these methods is to identify non-conformities present in the company, but also to solve them. Mapping the objectives is a starting point for the work, to be transformed into SMART objectives that help to define them more clearly, becoming specific, measurable, approachable, relevant and within the allotted time. The transformation provides a solid basis for observing how achievable are the proposed objectives; the strengths, weaknesses, opportunities and threats that may appear after the application of the possible solution found and, finally, the objective comparison of concrete data currently measured with the data that appeared after the changes applied in the organization.

Purpose - This paper describes a real case about customer order management in lens manufacturing.

Methodology - The Methodology used was the Case Study.

Findings - The use of methods ensures that customer expectations are met and exceeded, which leads to customer satisfaction and increased loyalty to the company.

The study of the paper includes the adoption of a solution that consists in the creation of a software and its concrete implementation. More precisely, following the adoption of the proposed solution, organizational performance was developed by increasing the degree of information accessibility by any department involved and optimizing production by eliminating dead times that came from manual activities, but which can be done more efficiently in a system computer thus avoiding human errors.

Therefore, the main value brought to the company lies in increased customer satisfaction and, directly proportionally, a better position in the market. Also, value is brought to the company by reducing costs or eliminating downtime.

Keywords: Customer satisfaction, lens production, quality methods.

Paper type: Case study.

1. INTRODUCTION

The concept of customer satisfaction, according to the SR EN ISO 9000/2015 standard, focuses on the level at which customer needs have been met. Another approach to customer satisfaction states that it is directly proportional to the company's ability to improve the quality achieved. A leading name in total quality management, Joseph M. Juran, addresses this topic by emphasizing the importance of prioritizing customer satisfaction in achieving quality in an organization.

In this paper, 3 quality methods were used to identify the level of customer satisfaction: 5 why, SMART objectives and SWOT analysis.

- Numerous interpretations and developments have been assigned over time to the concept of SMART goals, as well as what the acronym SMART actually stands for. Transforming general objectives into SMART objectives. The concept of SMART objectives was mainly introduced by George T. Doran in 1981 in volume 70, issue 11 of Management Review. This is defined as a goal of principles that help us achieve the desired results.

- The founder of the 5 why method was Sakichi Toyota, who developed the mentioned technique for Toyota Industries Corporation. The method is used to identify the root cause of a problem and develop effective solutions. At the organizational level, applying the 5 Why technique can bring a number of limitations and challenges by repeatedly asking the why question. Some of these limitations can be addressed by SWOT analysis.

- The Swot analysis represents a quality strategic tool through which it is possible to evolve performance, competition, risk and potential of the organization. It is a powerful tool used to evaluate any department of the company, regardless of their size. Also, the method represents a tool for strategic planning of the organization that intersects the strengths with the identified opportunities and the weaknesses with the perceived potential threats.

Next, the paper is structured as follows: chapter 2 presents the research methodology and includes both the description of the quality methods used and their application in the management of lens orders. Chapter 3 states the findings to which the case study led. Chapter 4 highlights the limitations that appeared during the implementation of the project, and chapter 5 presents the conclusions.

2. RESEARCH METHODOLOGY

The main purpose of the methods used is to identify the weak points that lead to the loss of clients: The study was carried out using 3 quality methods:

- 5 why: The 5 why quality method involves the application of successive questions that lead to the main cause of the identified problem.

- SMART objectives: The main definition of SMART objectives presents them as specific, measurable, approachable, relevant and within the allotted time. They are designed to draw a framework for realizing the identified and proposed solution for monitoring downtime and improving company performance.

- Swot analysis: The acronym SWOT comes from the words Strengths, Weaknesses, Opportunities and Threats and highlights the clear identification of both positive and negative aspects of a project, but also of the organization. We consider strengths (S) and weaknesses (W) as internal factors and Opportunities (O), Threats (T) as external factors. The difference between these two factors being: The organization can control the weak points and the strong points, after they are properly mapped, while the threats and opportunities are considered external factors that are constantly changing, which the company cannot fully control.

3. CASE STUDY

3.1 Application of the 5 why method

Identifying the problem and finding the root cause was accomplished using the 5 why method. The main complaint came from customers. Specifically, complaints began to appear because their orders were being delayed. The company, trying to resolve the complaints, started conducting research activities to discover the main source of the problem by applying the 5 why method.

1. Why do customers report/complain?
Because it delays their orders. The estimated time for each order is 3-7 working days, but they expect to receive them as soon as possible, which is 3 days.

2. Why are orders delayed?
Orders from customers are divided into 2 categories: online orders and orders manually entered into the system.

Manual orders account for 52% and are collected through multiple methods such as fax or phone call to the customer service department, while online orders account for 48%. In total, approximately 1500 orders/day are processed.

The online orders are printed directly in the production department, but they are also printed in the data entry department, although there is no need for them, this generates the main problem. We will call these duplicate orders. At the same time, in the data entry department, the orders entered manually into the system are also printed. These are called good orders.

Therefore, both duplicates and good orders are printed in the same department. Here an employee intervenes to sort everything that is printed. Sorting took place over a period of about 40 min/day and meant that printed duplicates were sent to recycling and good orders were sent to the production department. Human errors were also made during sorting. Thus, certain good orders arrived in recycling and certain duplicates were sent to production.

3. Why were duplicates printed in the data entry department?
Duplicates were printed automatically, without being able to interfere with the schedule because that would also block the printing in the production department.

4. Why were mistakes not reported by employees?
Mistakes were noticed, but late. The maximum time an order needs to leave the production department is 48h. Thus, if after 48 hours an order was in the same department, or at least that's how it appeared in the system, an error was reported. To solve the reported problem, the order that did not advance in the system was printed and sent to production.

Another problem that came from this sometimes missorting was that, as it was mentioned, the order would be reprinted and sent to production thinking it wasn't there, only to find out later that it was there, but due to issues (such as being a complicated order to carry out from a technical point of view) it took more than 48h. Thus, it ended up that, in the end, there was a product made 2 times, which represents an economic loss for the company.

5. Why couldn't the duplicate printing be stopped?
Currently, stopping the printing of duplicates meant stopping the printing of orders received online from both departments. A more extensive program modification was required to solve the problem.

After applying the method, it was concluded that the main source of the problem was the duplicates printed in the data entry department and the impossibility of blocking their printing.

3.2 Transforming general objectives into SMART objectives

Mapping the objectives is an essential process that was carried out after the identification of the non-conformity. The objectives adopted at the level of the work are:

1. Eliminating the time needed to manually sort the duplicate printed forms from the correctly printed ones by implementing an IT system capable of blocking the printing of duplicates.
2. Reduction of paper consumption,
3. Eliminate human errors by eliminating the possibility of loss due to the elimination of the sorting process. Everything printed after the solution is implemented will be correct and must reach the production department
4. Cost optimization
5. Increase customer satisfaction and loyalty

The transformation of the initially addressed objectives into SMART objectives is presented in tables 1-5.

Table 1: Transforming objective 1 into a SMART objective

SMART 1. Eliminating the time needed to manually sort the duplicate printed forms from the correctly printed ones by implementing an IT system capable of blocking the printing of duplicates	
S	Implementation of an IT system to reduce the time required for manual sorting by developing a functionality to block printed duplicates.
M	Eliminating the 48 h required to identify a problem by eliminating the occurrence of the problem. More precisely, the implementation of the computer system excludes the possibility of orders disappearing during manual sorting.
A	Establishing a detailed action plan for implementing software to block duplicate printing.
R	Creating and developing a program using Excel. Its functionality is ensured by means of a macro-command.
T	The time required to collect approvals, develop and implement is 5 months. During the development, it was taken into account that the specific part of the objective should be fulfilled within the established term. Also, the created interface was modified until it became an intuitive, user-friendly one.

Table 2: Transforming objective 2 into a SMART objective

SMART 2. Reduction of paper consumption	
S	Reduction of paper consumption by more than 48% in the data entry department in the next 12 months by implementing the computer system for the management and electronic storage of customer orders, thus replacing the manual work of sorting documents.
M	Monitoring the amount of paper used before and after implementing the solution.
A	Implementation of a follow-up plan for the evolution of digital sorting.
R	Improving sustainability and operational efficiency by reducing paper consumption by 48 % in the data entry department. This objective is relevant because it aligns with the purpose of the project, promoting sustainable practices and improving performance for the future of the company and its employees.
T	The monitoring of the project will be carried out in the next 12 months.

Table 3: Transforming objective 3 into a SMART objective

SMART 3 . Eliminate human error by eliminating the possibility of loss due to the elimination of the sorting process. Everything printed after the solution is implemented will be correct and must reach the production department.	
S	Reducing the rate of human errors to zero and eliminating losses is achieved by implementing the digital system for management and electronic storage, replacing the manual work of employers. This will minimize human errors and employee dissatisfaction with sorting duplicates that lead to waste.
M	The measurement in this case will be made by comparing the number of human errors and losses before and after the implementation of the digital solution. Thus, human errors can be quantified before and after, allowing a clear assessment of the progress of the implemented project and of the company's performance by reaching

	the objective. More precisely, the sorting time will be reduced from 40 min to 0 min.
A	After implementing the information system, the company will allow employees to gradually adapt until they manage to use the new program. It maximizes the chances of success by avoiding sorting problems.
R	The impact of achieving this objective is a positive one on the employees, saving them from the time lost in the sorting process, but also from the complaints arising from the notification of the mistakes made. This objective, in a broad sense, is beneficial and tangible to the project.
T	The implementation of the IT system to achieve the proposed objective will be done in the specific time.

Table 4: Transforming objective 4 into a SMART objective

SMART	
1.	Cost optimization
S	Eliminating the costs necessary for the purchase, storage and handling of paper, but also the costs of the personnel who sort the papers printed in duplicate from the correct orders by using a macro in Excel.
M	On a daily basis, the flow of incoming orders has been optimized by 48%, this is the percentage of orders received online that are now printed only in the production department.
A	The objective is achievable because the program can be developed with the resources that the company has. The optimization of costs comes from several sources: the implementation of the system, the elimination of the costs necessary to pay for the work done by the employee in order to sort, but also those from the purchase of paper.
R	The objective fits very well with the company's principles and vision, becoming relevant to it.
T	Over the course of a calendar year, 5% lower production costs can be observed.

Table 5: Transforming objective 5 into a SMART objective

SMART	
5	Increasing customer satisfaction and loyalty
S	The proposed objective can be easily achieved due to the fact that the root cause leading to this problem has been identified, knowing where corrective measures need to be applied.
M	Customer satisfaction is measured by decreasing complaints and increasing positive feedback, while their loyalty remains reflected in the increased number of orders placed.
A	The implementation of the new software ensures that the objective is achievable, customer satisfaction and loyalty being increased by the orders reaching them in the shortest possible time.
R	Customer satisfaction is the number 1 priority of the company, so any goal that wants to participate or increase their satisfaction becomes relevant, worth the time and effort given in this regard.
T	The time from placing the order to its delivery, in most cases, has been reduced to 3 days.

3.3 Application of SWOT analysis

In the organizational context, the application of SWOT analysis in the project of managing customer orders in the production of lenses, is beneficial to evaluate as correctly as possible the relevant aspects for starting the project and to develop suitable strategies for its implementation, thus observing both strong/weak points and and external opportunities/threats**.**

After the objectives have been clarified, the SWOT identification can clarify the directions of action necessary for the implementation of the project that means the prioritization of problems, the definition of strategies, the involvement of the team, its promotion and the adaptability regarding the changes and circumstances that have arisen.

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Strenghs

- Using a software speeds up the order management process and reduces the time required for manual sorting.
- The software eliminates human errors associated with manual sorting, ensuring greater accuracy in the order management process.
- The risk of duplicates is reduced, because the automation capability intervenes through the macro used.
- Much easier monitoring, efficiency of order status and much faster identification of possible delays or problems.
- Orders are carried out much more correctly and their delays are reduced, and customers are much more satisfied with the waiting/delivery time.

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Weaknesses

- The implementation of an IT system may involve initial acquisition and training costs.
- Employees need training to use the IT tool, they may be initially reluctant to adopt a new technology, this implies additional support and adaptability to change.
- The IT tool requires regular maintenance and updates to remain effective, leading to additional costs.

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Opportunities

- The use of an IT system means a much better and correct management of the orders received from customers, a much faster and more precise communication and a better connection between several departments (production, data entry, customer service, Shipping, order management).
- The efficiency of the project implemented in the order management process allows the organization to expand into new markets/directions to offer quality products/services and finally, a very important aspect is increasing customer satisfaction and increasing their loyalty.
- Attracting potential partners/collaborators interested in innovation in order to implement a modern organizational software.

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Threats

- From the point of view of competition, other companies can also adopt similar technologies to increase their efficiency and performance, which can intensify the market.
- Data security is a main element in the use of an IT system in order not to expose the company to risks and cyber attacks.
- Rapidly advancing technology.

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Like any valuable tool for evaluation and strategic planning in the organizational and decision-making context, it represents both advantages and disadvantages:

a) The main advantages are:

1. The identification and analysis of strengths and opportunities leads to obtaining competitive advantages and increases the performance of the organization.

2. Awareness of weak points and threats allows the identification of negative, external factors that affect the organization and the project.

3. By means of this analysis, strategic decisions can be made more easily, representing a solid basis for decision-making because it has a clearer understanding of the context and the options.

b) The following can be listed as disadvantages:

1. The listed ideas can be influenced by the individual perceptions of the involved parties that are part of the process, being subjectivistic and this can omit important or relevant aspects.

2. The SWOT analysis may not provide enough details for an exact planning and for certain specific actions.

3. A direct limitation is the quality and veracity of the entered data, they can influence the quality of the analysis and the decisions made based on the SWOT analysis

3.4 Theoretical Depth

The findings from the application of the 5 Whys, SMART objectives and SWOT analysis challenges the existing theories in quality management and customer satisfaction to an in-depth analysis of any problem that arises. Specifically, there are 3 perspectives that require attention:

- The root cause that led to the appearance of the problem was identified by successively applying several questions specific to the encountered problem. In a first perspective of analyzing a problem, a series of possible causes can be observed, but an expansion of the research is necessary to identify the main cause from which all the others are derived.

- Identifying the objectives towards which the solution of the problem tends. Concretely, the transformation of general objectives into specific, measurable, approachable, relevant and within the allotted time, helping to draw a concrete direction towards the best solution.

- The way in which it is desired to achieve them accompanied by the degree of their feasibility. The deepening of the current situation resulting from the application of SMART objectives and 5 whys helps to evaluate the strengths, weaknesses, opportunities, and threats and provides concrete ideas for software development but also future strategies for better competitiveness on the market.

4. FINDING

4.1 Data Collection Process

After the complaints received from the customers, the repeated manual work carried out by the employees of the data entry department regarding the sorting of the orders manually entered into the system from the orders received online was noticed.

The collected data was entered into an excel on a sample of 1500 orders that were made every day. Out of the 1500 orders processed daily, there were about 200 complaints/day. This data was monitored for 30 days. Figure 1 shows several frames made during the process of making orders.

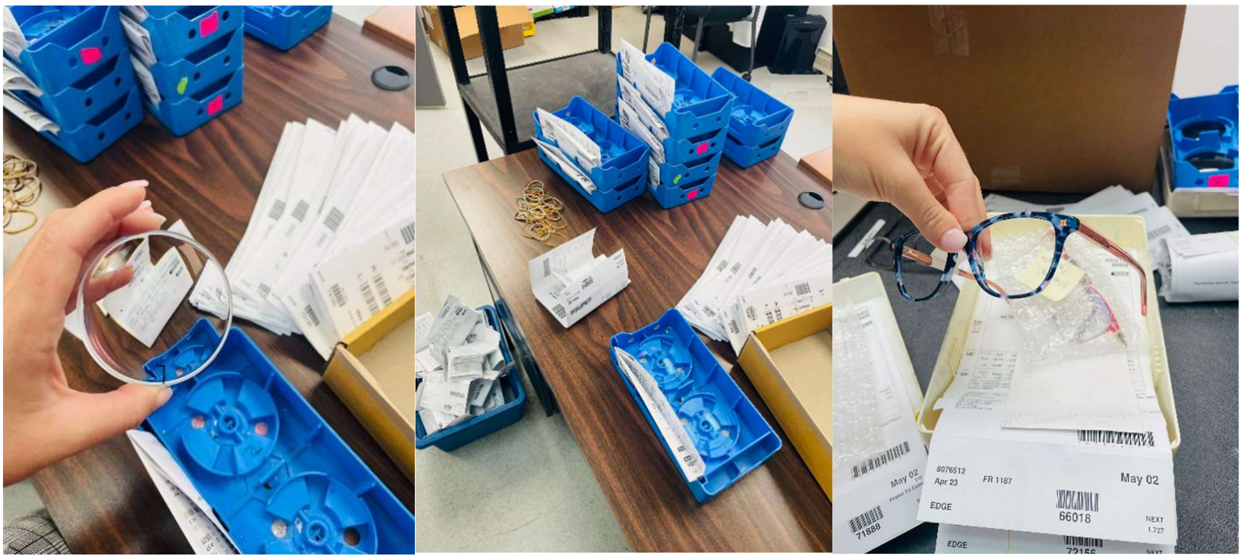


Fig 1: Order processing

At the end of the monitoring period, after a thorough analysis, it was concluded that it is necessary to introduce an automated program capable of replacing manual work. It has several purposes, including reducing mistakes due to human error, eliminating the time required for sorting, but also reducing paper consumption for a healthier planet. However, the main goal remains to increase the level of customer satisfaction by improving the flow of order management.

4.2 Development of the solution

After analyzing the previously mentioned aspects, both the problem and the proposed objectives, the company decided that a new system was needed and the creation of a fairly advanced macro, with many conditions, based on the basic data of the program already used by the company, OptiFast.

The need to create and implement the new system became more and more as it was found that it can be used in several departments of the company, thus it is worth its development because the benefits are increasing.

Several investigations led to the realization that the data entry department is not the only one affected, the project could be extended over several departments: customer service/customer relations, error works, shipping.

In the mentioned departments, printed papers could be excluded that were printed unnecessarily and soon ended up being recycled:

- Customer service: information such as customer names, contact details and orders that they used to print on both contactable and non-contactable customers remain in pdf format, managing to have all the necessary information in one easy-to-access place such as an online report.
- Error work: like the activities carried out in the previous department, information about error orders handled by opticians can be kept in an online report without the need to print them.
- Shipping: after the lenses are produced, they are transported to the other branches along with a printed invoice. The invoice was useless because immediately after delivery it was sent to recycling, but printing, folding and pairing them with the lenses was, again, wasted time and paper.

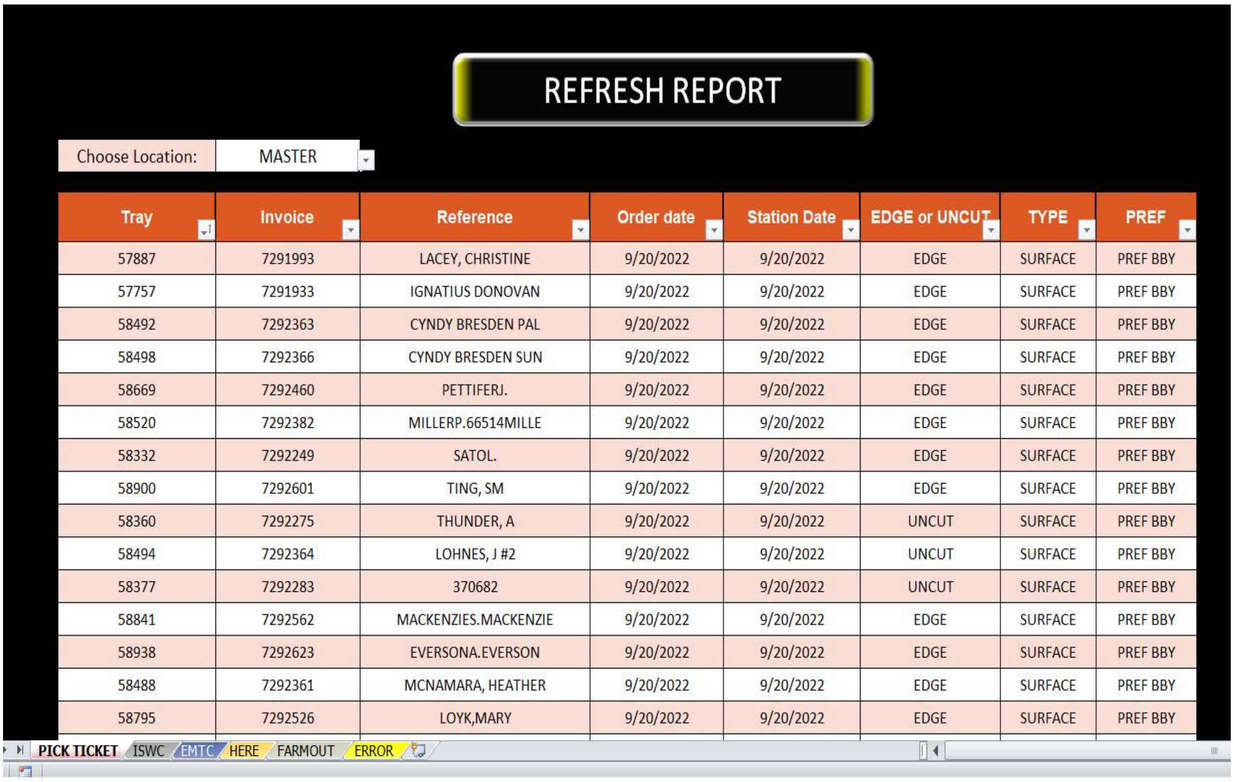
The steps that have been taken from the idea to the proper implementation are:

1. Development and familiarization with Macros for one of the 3 branches of the companies – Excel training
2. Development and familiarization with Macros for the 2nd branch of the company – Excel training
3. Start date of creating the report at the technical support department
4. Standardize the flow to facilitate the creation of the report
5. Manual lite-up creation – Do not print
6. Adding other departments to the project

In addition to eliminating dead times, reducing paper consumption, optimizing the accessibility of order data and their degree of fulfillment, project implementation also helps to avoid human errors such as lost work. In the print job selection process, there is a chance that the correct jobs that should go into production end up in recycling. More precisely, at least 3-4 work/day did not reach production until after 48 h, which is the time after which a report shows that the job has not started to be processed. Delivery dates from the company are between 3-7 days, which means that 48h cannot be lost just because the work was sent for recycling by mistake. In the remaining 24 h, the work cannot be completed in its entirety, which leads to customer dissatisfaction.

In addition to blocking duplicates, the project also brings another improvement. Centralization of 7 reports into one. A multi-page macro with all the necessary data in one place making it much easier to find when you need it. For example, when there is a non-conformance with a work it is much easier to search in a program than in several departments among hundreds of sheets.

The developed macro provides visibility into several aspects related to orders, such as the date it was received, the order number, the customer's requirements (for example: diopters, reflections and/or protections), the date it entered processing, what is the status current status of the work, which department it is in, and what is the next step needed to fulfill the order. Thus the work flow is optimized, the orders reaching the customers much faster. This macro is shown in figure 2.



Tray	Invoice	Reference	Order date	Station Date	EDGE or UNCUT	TYPE	PREF
57887	7291993	LACEY, CHRISTINE	9/20/2022	9/20/2022	EDGE	SURFACE	PREF BBY
57757	7291933	IGNATIUS DONOVAN	9/20/2022	9/20/2022	EDGE	SURFACE	PREF BBY
58492	7292363	CYNDY BRESDEN PAL	9/20/2022	9/20/2022	EDGE	SURFACE	PREF BBY
58498	7292366	CYNDY BRESDEN SUN	9/20/2022	9/20/2022	EDGE	SURFACE	PREF BBY
58669	7292460	PETTIFERJ.	9/20/2022	9/20/2022	EDGE	SURFACE	PREF BBY
58520	7292382	MILLERP.66514MILLE	9/20/2022	9/20/2022	EDGE	SURFACE	PREF BBY
58332	7292249	SATOL.	9/20/2022	9/20/2022	EDGE	SURFACE	PREF BBY
58900	7292601	TING, SM	9/20/2022	9/20/2022	EDGE	SURFACE	PREF BBY
58360	7292275	THUNDER, A	9/20/2022	9/20/2022	UNCUT	SURFACE	PREF BBY
58494	7292364	LOHNES, J #2	9/20/2022	9/20/2022	UNCUT	SURFACE	PREF BBY
58377	7292283	370682	9/20/2022	9/20/2022	UNCUT	SURFACE	PREF BBY
58841	7292562	MACKENZIES.MACKENZIE	9/20/2022	9/20/2022	EDGE	SURFACE	PREF BBY
58938	7292623	EVERSONA.EVERSON	9/20/2022	9/20/2022	EDGE	SURFACE	PREF BBY
58488	7292361	MCNAMARA, HEATHER	9/20/2022	9/20/2022	EDGE	SURFACE	PREF BBY
58795	7292526	LOYK,MARY	9/20/2022	9/20/2022	EDGE	SURFACE	PREF BBY

Fig 2: Excel macro

Another relevant aspect presents us with the fact that the internal processes have been improved as follows:

1. Accelerated identification of erroneous orders: faster customer feedback, reduction of production costs because production is stopped faster, gain of customer delivery data.

2. Environmental and financial impact: 400,000 works per year (52 trees per year) and $10,000 per year on paper.

3. Stopped printing invoices on transfer lenses: 24,000 invoices per year (3 trees), 2 hours less waiting time per month, $1,600 per year in printing (rental), customer delivery data gain.

4. Stopped printing invoices for mailing to the other branches: 144,000 invoices per year, Eliminated unnecessary folding and unfolding, Improved processing flow.

5. Combine 7 different reports in 1: improved management of updates, improvement of existing reports (faster, fewer calls to the database).

5. LIMITATION

In order to implement an IT system for a correct management of orders in lens production, the following types of limitations appear:

First, the adopted solution also includes the development of employees' skills by training them on the use of the program. Training employees requires both time and additional resources. In addition to these two aspects, there is also the reluctance of employees to learn new technologies and reduced adaptability. In order to overcome these limits, an effective training strategy is planned and implemented, to address the needs of everyone and the work teams.

The current study shows that, despite training courses conducted to train employees on the newly implemented software, users encountered difficulties. Thus, it was necessary to identify new solutions with the goal of training employees regarding the novelty brought by the software. The new implemented solutions led to the following solutions: modifying the software interface so that it is more intuitive for the user, stimulating them through different methods such as providing concrete information regarding the benefits brought by the implementation of the software both regarding the accuracy offered by software, the ease brought to the work carried out by them but also to increase the level of customer satisfaction. Another important aspect shows us the importance brought by taking into account the opinion that the employees have. Their feedback should be heard and considered.

It is desired to maximize the efficiency of the use of the system in the long term, so that after the complaints of the employees regarding the use of the new program, its interface has been modified so that it becomes more user-friendly, more intuitive.

The type of IT system approached and implemented also requires continuous updating and maintenance in order to remain efficient over time. This may incur additional costs or additional resources.

From an IT point of view, the implementation of a macro can lead to the risk of incompatibility or various IT errors existing in connection with other systems or work processes. We want a high efficiency in order to implement and an assured quality in the order management process, thus rigorous testing will be taken into account before implementation to identify and fix possible errors, such as the description of a realistic use scenario, even and integrated with other existing systems, such as macros in Excel, the recurrent updating of the Microsoft type and the existence of a close relationship with the IT or technical support departments .

6. CONCLUSIONS

Following the adoption of the proposed solution, organizational performance was developed by increasing the degree of accessibility of information by any department involved and optimizing production by eliminating dead times that came from manual activities, but which can be done in an IT system. Also, the following results contributed to the organizational improvement: the reduction of the costs related to the purchase of paper, its transportation, handling and storage and the increase of customer satisfaction through a short time of receiving orders (from the moment they placed the order until they received it).

A first benefit resulting from the implementation of the project is the reduction of the processing time of orders received from customers, because the software processes orders faster and more correctly, reducing manual sorting time and increasing operational efficiency.

Also, this is closely related to positive aspects such as: orders delivered on time, without delays, so happy customers and satisfied with delivery times. Feedback, being a key element and a link between the client and the organization, is provided much faster by clients and can be processed for continuous improvement.

Automating the sorting process greatly reduces the risk of human errors associated with manual sorting. The process itself is programmed to detect and correct errors, which leads to a consistent processing of orders, separating them from duplicates that may appear, therefore from possible products manufactured twice and without meaning.

The implementation of the project has increased organizational performance both in terms of increasing customer satisfaction and prompt response to customer needs as well as in terms of the positive impact it has on the environment, thus promoting sustainable practices such as: reducing

consumption of paper, by eliminating the paper used as a result of duplicates, reducing waste - eliminating human errors and unnecessary packaging, automatic sorting contributing to the conservation of natural resources.The originality of the project is given by the developed program. Although it uses aspects that the company already had about orders, the program is new and able to sum up in one place all the essential aspects about an order from its inception stage to completion and delivery.
Implementing the macro also brings value by improving the service, thus:
1. Eliminating non-value-added steps for the customer: Speeding up the process of processing a work (sorting JOB Tickets/ scanning, etc.)
2. Improve job identification: Gaining team efficiency
3. Standardization of processes: Remote work becomes possible for tasks that require printing and the possibility of replacing interprofessional staff appears
4. Facilitated Audits: Comment audits and better feedback to the sales team
5. New lens handling method: Gain customer delivery data, Avoid duplicate orders and Centralize information.

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Systematic Literature Review on Performance Measurement Systems for Power Distribution Companies

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STRUCTURED ABSTRACT

Purpose - This paper aims to present the findings of a systematic literature review on performance measurement systems (PMSs) for power distribution companies.

Design/methodology/approach - The research design is systematic literature review applying a search string in the Scopus scientific index, analysing the gathered data using bibliometric analysis, and developing a content analysis in a specific set of articles that adhere to the PMS.

Findings - The authors' keywords reveal the research interests moving from Data Envelopment Analysis application to Balanced Scorecard implementation until recently to applications of artificial intelligence and machine learning associated with some aspects of performance. The findings also reveal a lack of seminal authors and a fragmented publication landscape, suggesting the field's nascent maturity. Additionally, the systematic review identifies a gap in frameworks that effectively address the complex demands of stakeholders in the power distribution sector, indicating a significant opportunity for future research to develop tailored PMS frameworks.

Research limitations/implications- The main implication is the necessity of developing more investigation on the issue in the field and researchers' interests moving from company's performance to specific facets of performance in power distribution companies. Research in the field could benefit from the knowledge of the performance measurement systems domain.

Practical implications - Practitioners can identify their interests in the literature quickly.

Originality/value - No systematic literature review on performance measurement systems for electricity distribution companies were observed in the literature.

Keywords: Performance measurement systems, Power distribution, Performance measures, Literature review.

Paper type: Literature review

INTRODUCTION

Electricity plays a crucial role in the modern economy, with the electric sector consisting of three main stages: generation, transmission, and distribution. Among these stages, electricity distribution is the most intricate due to the diverse demands of stakeholders (Wanderley, Cullen and Tsamenyi 2022; Gunnarsdottir et al., 2022), the integration of various energy sources (Strojny et al., 2023), diversity of technologies, and the challenges posed by demand forecasting, low prices, customer satisfaction, and climate change (Géremi and Ferreira, 2020). Furthermore, in regulated private monopoly markets, government regulations further complicate the landscape (Wanderley, Cullen and Tsamenyi, 2022). Consequently, managing performance in electricity distribution companies becomes a complex issue. To effectively handle power distribution operations, the design, implementation, and utilisation of performance measurement systems (PMSs) are vital.

PMSs play a central role in managing performance across all organisations, with their evolution influenced by economic, technical, and commercial environments (Bourne 2021). Therefore, it is crucial for PMSs to continuously adapt and provide valuable performance information to decision-makers at different levels within the organisation (Melnyk et al. 2014; Bourne 2021). In essence, an effective PMS should align with the organisation's environment and strategic goals, translating the strategy into metrics that influence people's behaviour (Melnyk et al. 2014). However, the widely recognized Balanced Scorecard (BSC), despite its reputation, may not be suitable for every organisation, as it primarily focuses on customers and shareholders, disregarding other stakeholders. For instance, companies operating in regulated private monopoly markets must comply with government regulations to obtain a licence to operate, but BSC is in dissonance with the regulatory logic (Wanderley, Cullen and Tsamenyi 2022).

During the 1990s, the field of performance management (PM) focused on exploring the relationship between performance management systems (PMS) and strategy (Melnyk et al. 2014). However, in the early 2000s, the focus shifted to ensuring that PMS kept up with strategic changes. In the past decade, the emphasis has further shifted from simply translating strategy into action, to also informing and challenging strategy. This shift is necessary to ensure the resilience of PMS in the face of the dynamic and turbulent environments in which organisations operate (Franco-Santos et al. 2012; Melnyk et al. 2014). One of the most notable outcomes of the 1990s is the Balanced Scorecard (BSC), which translates strategy into performance measures in order to motivate individuals to implement strategic goals. However, it should be noted that the BSC framework may not be suitable for all types of organisations, as it is more appropriate for stable environments (Melnyk et al., 2014).

Despite the dominance of the BSC in the 2000s, an alternative framework called the Performance Prism (PP) has emerged. The PP considers all stakeholders, taking into account both their satisfaction and their contributions. Strategy, in this framework, is seen as a means to meet stakeholders' requirements by allocating resources such as processes and capabilities (Neely, Adams and Kennerly 2002).

No review has been published in the academic literature on performance measurement systems for power distribution companies. As a result, there is a lack of comprehensive mapping and analysis of the existing literature, which would provide a valuable resource for researchers and practitioners in this field. This study aims to address this gap by exploring three research questions:

1. What are the most productive authors in the field and what is their contribution?
2. What are the documents which cause a major impact outside and into the field?
3. What are the main sources in the field?

This paper aims to present the findings of a systematic literature review on performance measurement systems for power distribution companies. The findings can help scholars and practitioners in developing new research venues as well as improving the performance measurement in companies.

RESEARCH DESIGN

A systematic literature review, using bibliometric analysis, can provide a comprehensive map of scientific knowledge from multiple angles (Cobbo et al., 2011; Zuppic and Carter, 2015; Öztürk et al., 2024). Additionally, it can identify gaps in the existing literature, offering insights for new research streams (Cobbo et al., 2011). In this study, we applied the following research string ("performance measur*" OR "performance metric*" OR "performance indicato*" OR kpi* OR "performance manage*") AND ("power distribution" OR "electric* distribution" OR "energy distribution") on the Scopus scientific index on 28th of February 2024. This yielded 465 results. Following the collection of data, before reading the documents' content, bibliometric analysis was applied to map the domain of PMSs for power distribution companies. We selected a collection of documents for the purpose of content analysis. For bibliometric analysis, we used the R package R-Bibliometric (Aria and Cuccurullo, 2017). The paper research design follows the proposed method by Lopes and Martins (2021) and Santos and Martins (2020).

RESULTS

The bibliometric analysis revealed a steady increase in scientific production (articles/year) since 2002, despite the first article being published in 1978. Figure 1 displays the evolution of the field, showing scientists' productivity through published papers and the impact of scientific production through mean total citation per year. The total of documents in the sample is 455 documents (papers, papers in conference proceedings) in timespan from 1978 to 2024 with an annual growth rate of 6.21%.

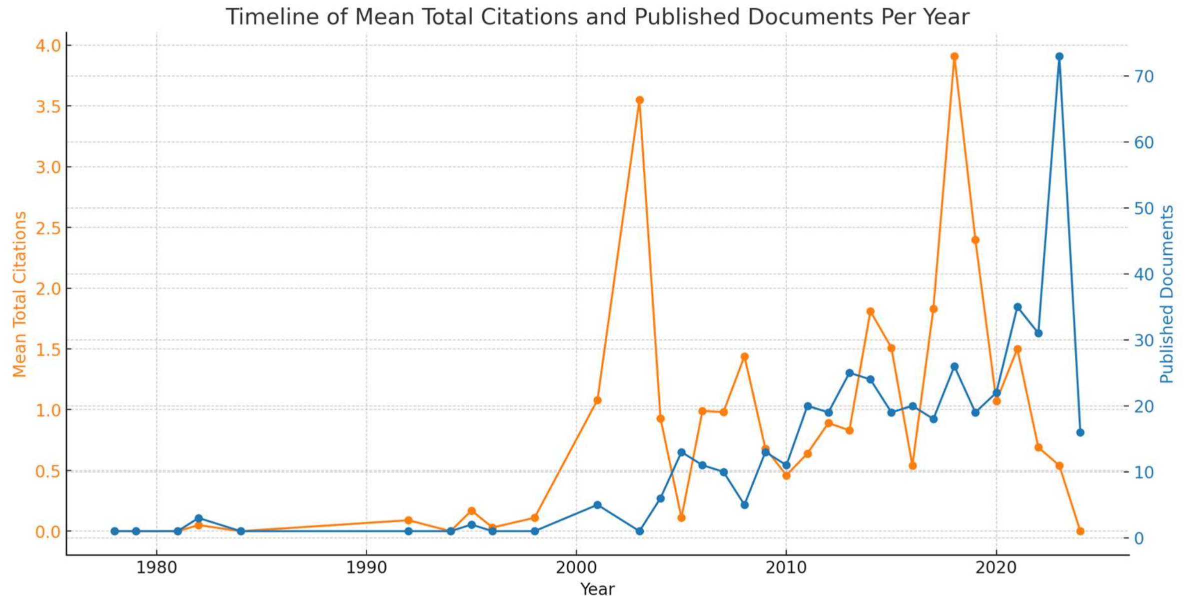

Figure 1 – Evolution of the field.

Figure 1 illustrates the increasing productivity of the authors, with notable peaks in 2003 and 2018. The peaks are influential papers with regular citations over the years. Wamukonya (2003) argues the validity of performance measures used to justify the power sector reforms during the beginning of the 2000s in the developing world. While the reform had solid financial metrics, it was lacking in social and environmental metrics. Various documents published in 2018 have earned many citations. We highlight the two most cited. Messinis and Hatziargyriou (2018) categorised non-technical loss detection into three main clusters: data oriented, network oriented, and hybrids. Pereira and Nunes (2018) present a comprehensive review of datasets, metrics, and tools used to evaluate non-intrusive load monitoring systems.

The most productive and influential authors in the field are highlighted in Figure 2, featuring the top 13 authors with a minimum of three published papers. The bubble size represents the productive (number of published documents) and colour the citations (impact). Even though T. Muthuramalingam and A. W. Umrani appear as productive and influential authors in the search, their research interests are energy distribution in materials science. The term “energy distribution” in the search string caused this misinformation. Nonetheless, there are other authors in Figure 2 who have published in the field.

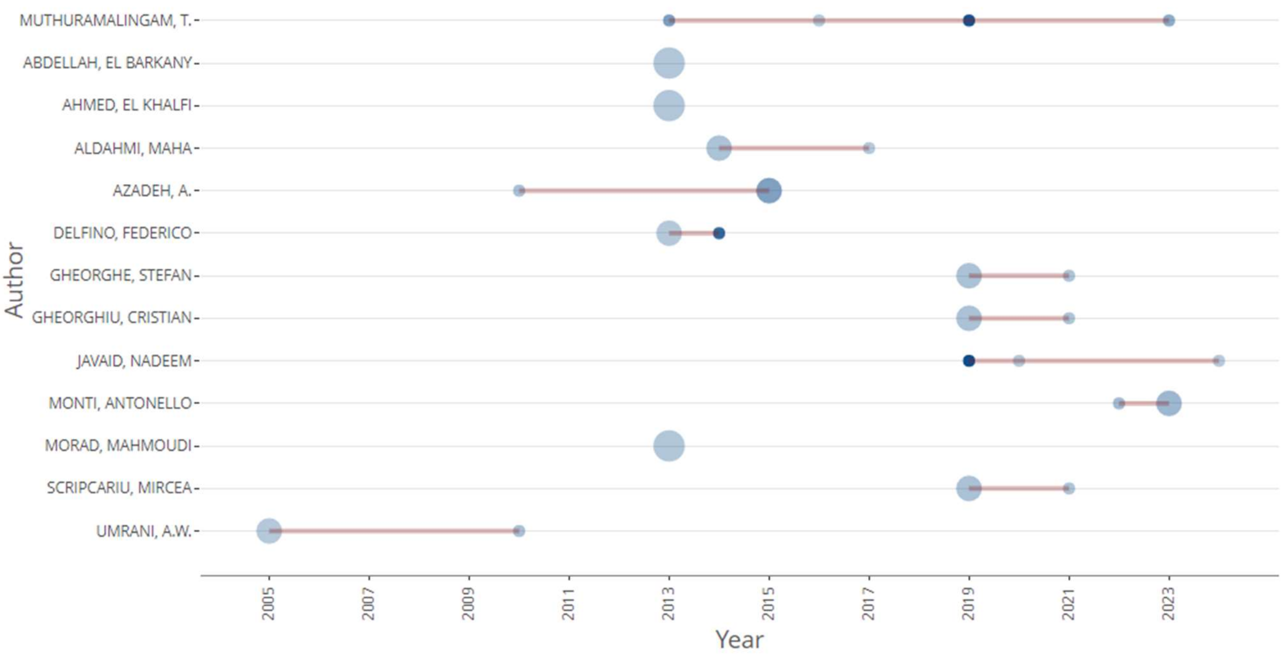

Figure 2 – Most productive and influential authors.

El Barkany Abdellah, El Khalfi Ahmed, and Mahmoudi Morad focus on electrical network maintenance, Maha Aldahmi researches incidents and on how to improve protection of distribution networks. A. Azadeh applies Data Envelopment Analysis (DEA) to measure electricity distribution companies’ performance. Federico Delfino investigates how to measure sustainability in transmission grids focusing on performance indicators. Stefan Gheorghe, Cristian Gheorghiu, and Mircea Scripcariu investigate energy performance indicators of the power distribution grids from different aspects, such as efficiency, quality, and environmental sustainability. Nadeem Javaid applies machine learning for detecting anomalies and frauds in power grids. Monti Antonello also uses a cloud-based platform to support managing power grids. The most productive and influential authors have changed from the application of DEA, a traditional nonparametric technique for analysing performance to measuring performance broadly and using technologies for supporting measuring and managing power grids.

Still regarding authors, Figure 3 poses the result of Lotka’s Law application, another perspective on scientists’ productivity. The Lotka’s Law predicts that a few authors publish many articles in a domain. This typically happens when the field matures and influential authors emerge (Leimkuhler and Chen, 1986). The dash line is the expected behaviour and continuous is the result that unveils the authors in the field are not frequent and, consequently, the maturity is low.

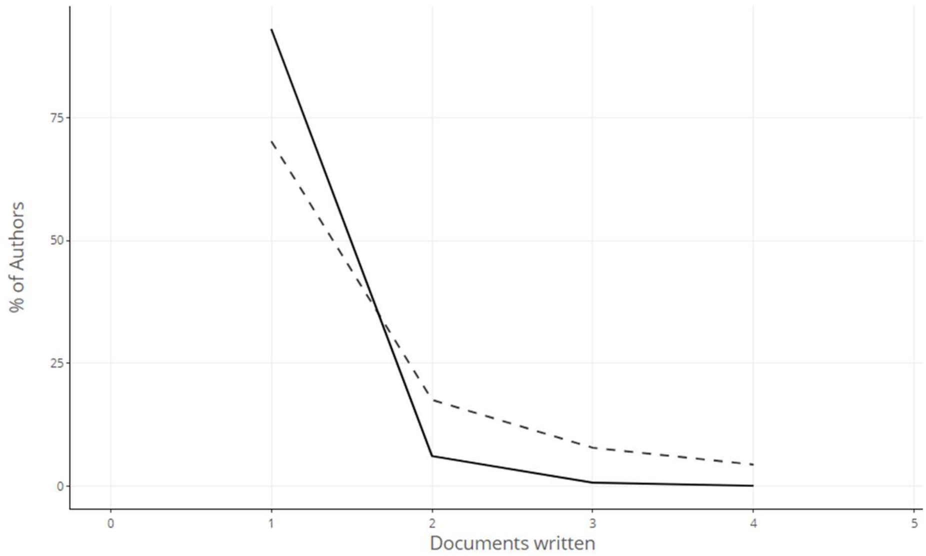

Figure 3 – Application of Lotka's Law to the sample.

Moving to the documents, Figure 4 exhibits the most global cited documents. Zhang et al. (2014) propose a comprehensive performance measure for evaluating microgrids, considering electricity price, emissions, and service quality, assigning a specific weight to ensure a balanced measure. We have previously cited the other two most cited articles by Messinis and Hatziargyriou (2018) and Pereira and Nunes (2018) in this article.Despite their impact on the scientific community, the documents in Figure 4 do not have the same influence on sample documents. Yan and Lu (2006) is the document with the highest number of local citations, earning three. Yan and Lu (2006) introduce an alternative DEA method for analysing the benchmarks, resource allocation, and efficiency of electricity distribution districts in Taiwan Power Company.

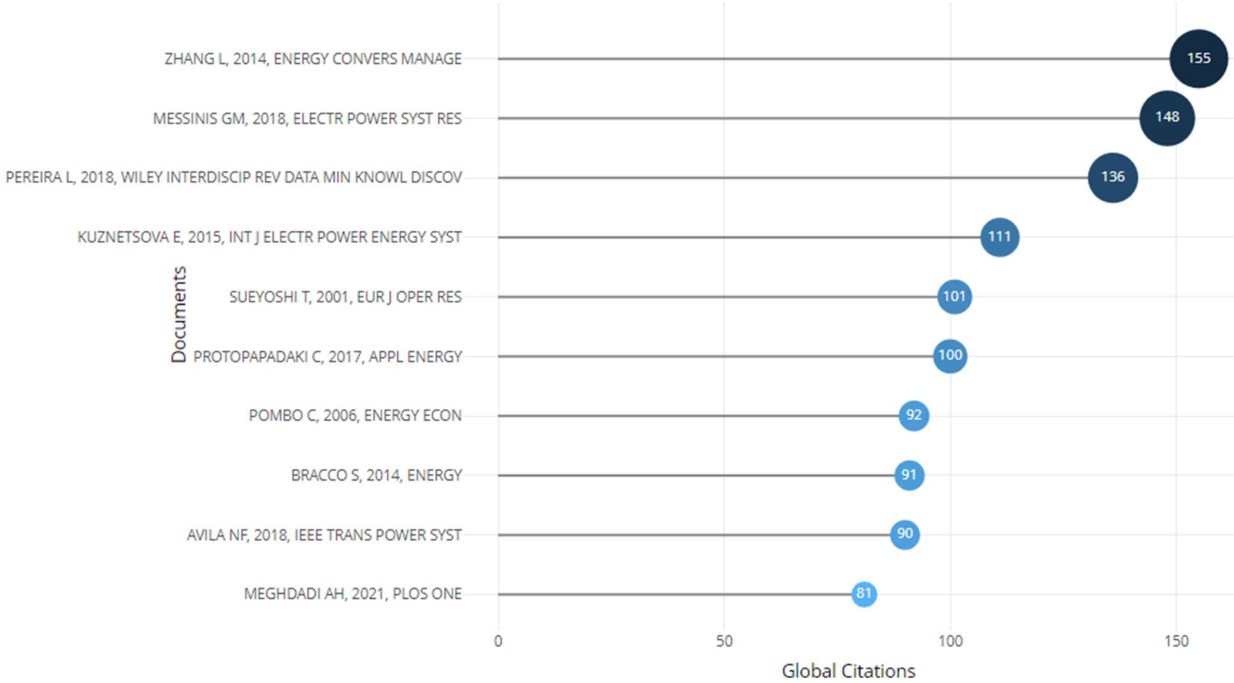

Figure 4 – Most global cited documents.

The authors' keywords are another important metadata of documents. Figure 5 offers an evolutive perspective with a maximum of three terms per with a minimum frequency of five occurrences. The most cited keywords are “distribution network” and “smart grid” which represent the operations whose performance calls researchers’ interest. Following the timeline in the bottom of Figure 5, the researchers’ focus has changed from performance measurement systems (metrics, framework, methods) to aspects of performance (quality, reliability, efficiency) to renewable energy and sustainability. More recently, artificial intelligence and machine learning have been applied to measure and manage performance.

Figure 6 displays the 11 main sources used by the authors for published documents. Journals and conference proceedings focused on energy and power systems have published 60 documents, which accounts for 13.19% of the total 455 articles. A total of 347 sources have published 455 papers. The 11 top sources represent 3.17% of the sample. It is worth noting that 86.81% of production in the field is distributed to 96.83% of sources. Indeed, the conference proceedings have a significant role in disseminating scientific knowledge. Regarding the 11 top sources, the authors chose to share their knowledge on performance measurement publishing in sources associated with the operations systems they are interested in.

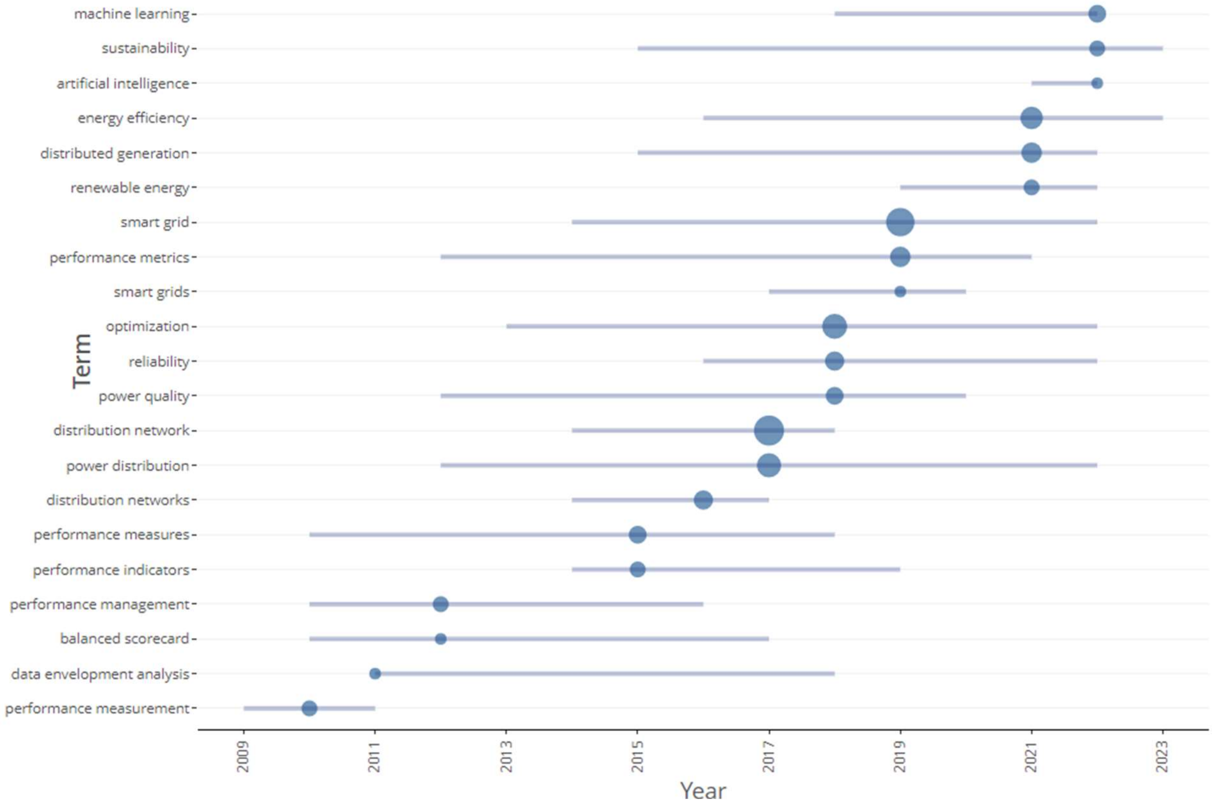

Figure 5 – Trend of authors' keywords.

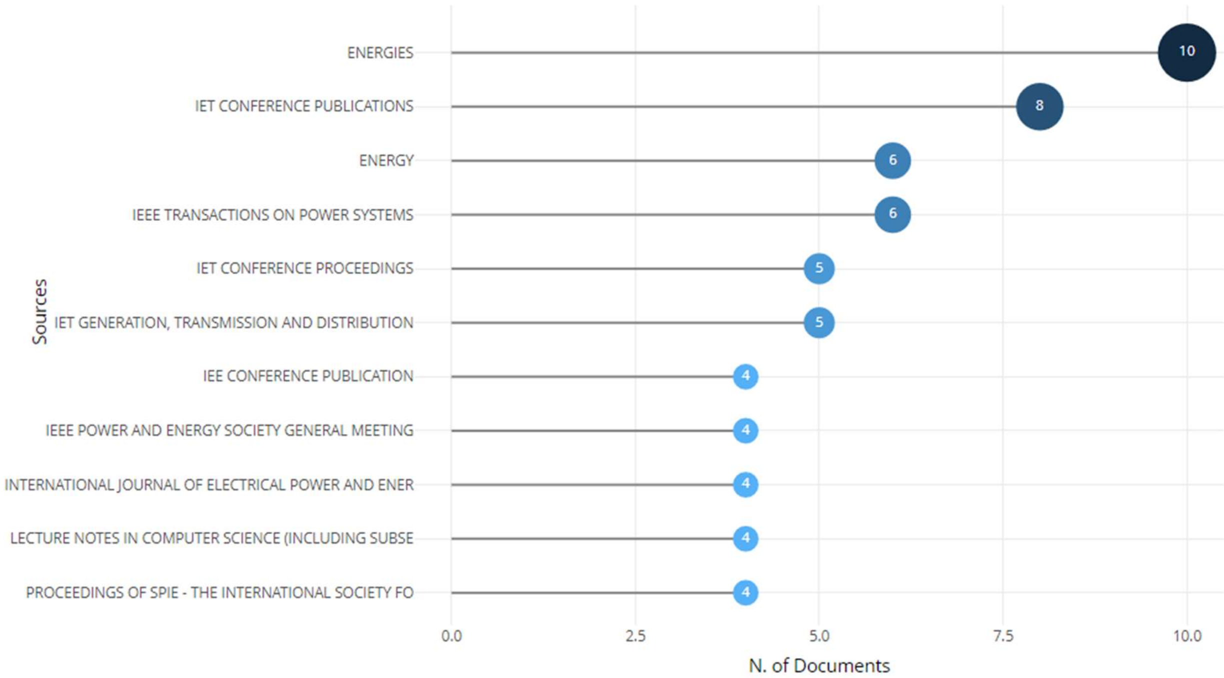

Figure 6 – Most relevant sources of the field.

Finally, Figure 7 provides a summary of the relationship between authors, keywords, and sources, focusing on the top 20 in each category. Authors focusing on performance management, measurement, and metrics publish their articles in the International Journal of Energy Sector Management, IEEE Transactions on Power Systems, and Power Systems. he sample articles on topics artificial intelligence and machine learning appear in the International Journal of Energy Sector Management and IET Conference Proceedings. Because of the publication of just one paper, there are no authors connected to the keywords artificial intelligence and machine learning.

The necessity of content analysis becomes evident when considering the findings in Figure 5, which focus on articles with the highest frequencies of authors' keywords citations. The citation form of those keywords can be classified into three clusters: Balanced Scorecard, DEA, and applications of artificial intelligence and machine learning. Table 1 summarises these articles strictly associated with the three major clusters mentioned previously.

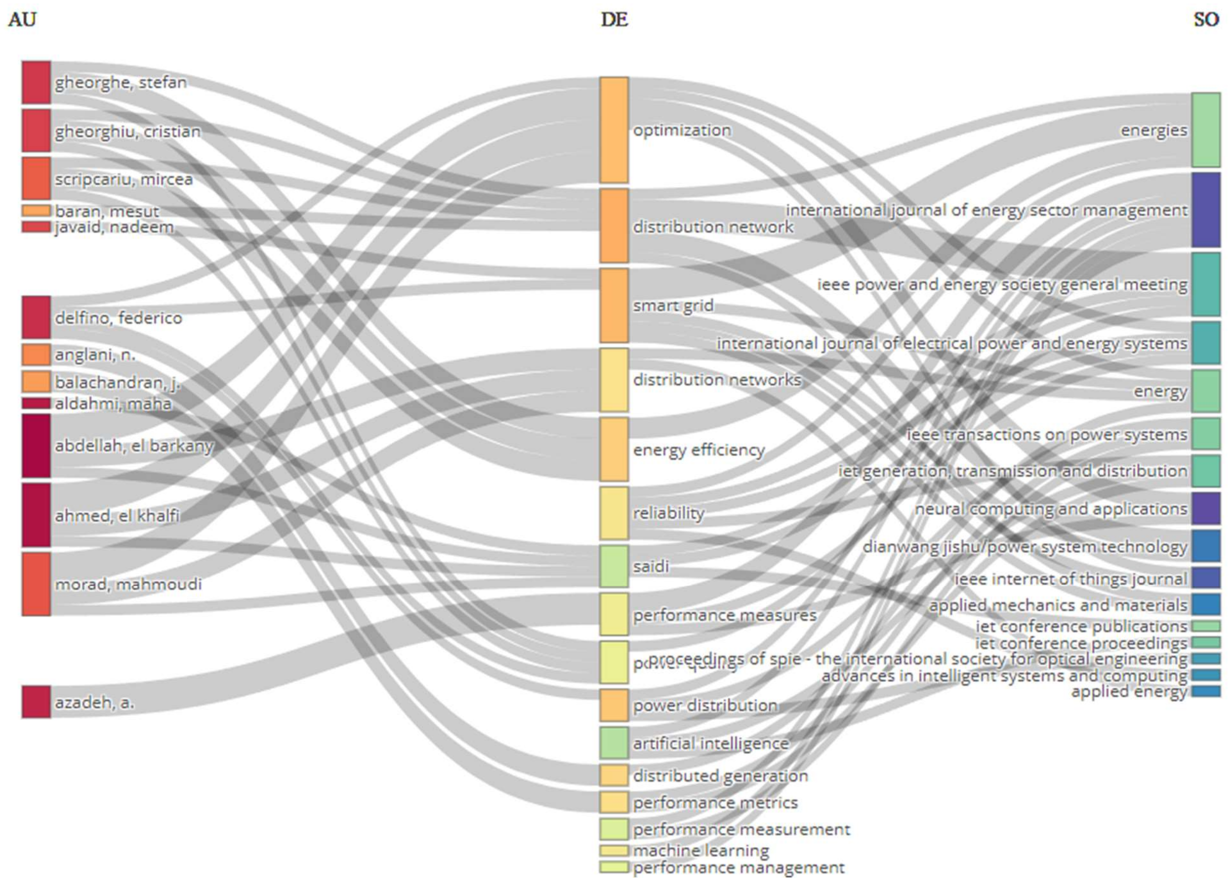

Figure 7 – Relationship between authors, keywords, and sources.

Table 1 – Articles on Balanced Scorecard, DEA, and Artificial Intelligence

Authors	Title	Source title	Year	Author Keywords	Cluster	Summarised Abstract
Platts K.W.; Sobótka M.	When the uncountable counts: An alternative to monitoring employee performance	Business Horizons	2010	Balanced scorecard; gas and electricity distribution; performance management	Balanced Scorecard	The article presents an alternative viewpoint to the accepted wisdom that detailed performance measurement of individual employees is necessary to achieve superior performance
Chopra M.; Gupta V.; Chhabra B.	Strategic Management Using Balanced Scorecard - A Case Study on Tata Power	South Asian Journal of Business and Management Cases	2017	Balanced scorecard; performance management; power distribution; strategic management	Balanced Scorecard	The article aims to present an analysis to develop a deep understanding of the concept of balanced scorecard as a tool for strategy mapping, alignment and measurement of performance in a leading firm in power distribution sector
Aceituno-Rojo M.R.; Condori-Alejo H.I.; Alzamora G.S.	Server monitoring model based on Balanced Scorecard and SNMP of an electric power company	Proceedings of the IEEE 28th International Conference on Electronics, Electrical Engineering and Computing	2021	Balanced scorecard; incident detection; server monitoring; SNMP protocol	Balanced Scorecard	An organisation must be efficient and effective, to accomplish its strategic objectives and growth, technological infrastructure being a critical element in their performance, where servers play an important role, as they allow host and process large volumes of data
Sobótka M.; Platts K.W.	Managing without measuring: A study of an electricity distribution company	Measuring Business Excellence	2010	Balanced scorecard; electric power systems; gas industry; performance measures	Balanced Scorecard	The paper aims to present an exception to the common belief "If you can't measure it, you can't manage it" showing how in certain situations particular practices, attitudes and cultures can remove the need for individual performance measurement
Rosa C.B.; Rigo P.D.; Rediske G.; Moccellin A.P.; Mairesse Siluk J.C.; Michels L.	How to measure organisational performance of distributed generation in electric utilities? The Brazilian case	Renewable Energy	2021	Analytical hierarchy process; balanced scorecard; distributed generation	Balanced Scorecard	The paper proposes measurement system for determination of the overall performance index of electric utilities related to decentralised generation services

Singhania M.; Venkatesh R.	Tata Power Delhi Distribution Ltd: measuring beyond the metrics	Emerald Emerging Markets Case Studies	2012	Balanced scorecard; partnership; performance management systems; strategic alignment; sustainability	Balanced Scorecard	The focus is on a performance management system and its strategic alignment using a Balanced scorecard in a Public Private Partnership framework
Cotilla-Sanchez E.; Eseonu C.I.	Toward a sustainable, smarter power grid: In search of effective performance measures, evaluation schemes, and related policy	International Annual Conference of the American Society for Engineering Management 2013	2013	Performance management; smart grid; sustainability	Balanced Scorecard	The paper applies the balanced scorecard methodology to identify preliminary alternatives for performance measurement, effective policy and organisational management of the existing power grid, and plans for future development
Pourhabib A.; Kordrostami S.; Amirteimoori A.; Matin R.K.	Performance measurement in data envelopment analysis without slacks: An application to electricity distribution companies	RAIRO - Operations Research	2018	Data envelopment analysis; efficiency; input/output weights	Data Envelopment Analysis	In performance measurement of the firms using tools such as data envelopment analysis models, weak efficient units are almost appeared as reference points in the models
Korpela J.; Lehmusvaara A.; Elfvengren K.; Tuominen M.	Supporting distribution network design by combining AHP and DEA	Conference Proceedings 21st International Conference on Production Research,	2011	AHP; analytic hierarchy process; data envelopment analysis; distribution network	Data Envelopment Analysis	The paper proposes a decision support system for strategic distribution network design based on combining two well-known methodologies: the Analytic Hierarchy Process and Data Envelopment Analysis.
dos Santos L.C.B.; Medeiros G.O.S.; Lima L.M.M.; de Queiroz A.R.; Alvares J.E.; Gomes R.; Barbosa M.A.; Marangon Lima J.W.	Efficiency analysis for performance evaluation of electricity distribution companies	Proceedings of the 32nd International Conference on Efficiency, Cost, Optimization, Simulation and Environmental Impact of Energy Systems	2019	Data envelopment analysis; electricity distribution; ratio-based efficiency analysis; weight limits	Data Envelopment Analysis	The power distribution segment has characteristics of natural monopoly requiring proper regulation to guarantee the tripod: power supply security; tariff modicity; and universal service

Omrani H.; Azadeh A.; Ghaderi S.F.; Aabdollahzadeh S.	A consistent approach for performance measurement of electricity distribution companies	International Journal of Energy Sector Management	2010	Data analysis; electricity; electricity industry; performance measures	Data Envelopment Analysis	The paper aims to present an integrated algorithm composed of data envelopment analysis, corrected ordinary least squares and principal component analysis to estimate efficiency scores of electricity distribution units
Mullarkey S.; Caulfield B.; McCormack S.; Basu B.	A framework for establishing the technical efficiency of Electricity Distribution Counties (EDCs) using Data Envelopment Analysis	Energy Conversion and Management	2015	Data envelopment analysis; electricity distribution; performance measurement	Data Envelopment Analysis	European Energy market liberalisation has entailed the restructuring of electricity power markets through the unbundling of electricity generation, transmission and distribution, supply activities and introducing competition into electricity generation
Yang C.; Lu W.-M.	Assessing the performance and finding the benchmarks of the electricity distribution districts of Taiwan power company	IEEE Transactions on Power Systems	2006	Benchmark; data envelopment analysis; performance measurement	Data Envelopment Analysis	The paper proposes an alternative data envelopment analysis method to explore the efficiency, the resource allocation, and the benchmarks of the electricity distribution districts
Azadeh A.; Motevali Haghighi S.; Zarrin M.; Khaefi S.	Performance evaluation of Iranian electricity distribution units by using stochastic data envelopment analysis	International Journal of Electrical Power and Energy Systems	2015	Electricity distribution units; performance measures; stochastic data envelopment analysis	Data Envelopment Analysis	The paper introduces an approach based on stochastic data envelopment analysis for performance assessment of electricity distribution units
Chen L.-C.; Lu W.-M.; Yang C.	Does knowledge management matter? Assessing the performance of electricity distribution districts based on slacks-based data envelopment analysis	Journal of the Operational Research Society	2009	Data envelopment analysis; performance measurement; slacks-based measure	Data Envelopment Analysis	The study uses slacks-based data envelopment analysis to examine the performance of electricity distribution districts

Santos S.P.; Amado C.A.F.; Rosado J.R.	Formative evaluation of electricity distribution utilities using data envelopment analysis	Journal of the Operational Research Society	2011	Data envelopment analysis; electricity distribution; performance measurement	Data Envelopment Analysis	The use of Data Envelopment Analysis in the electricity distribution sector has been prolific in the number of papers published in research journals
Ali A.; Khan L.; Javaid N.; Aslam M.; Aldegheishem A.; Alrajeh N.	Exploiting machine learning to tackle peculiar consumption of electricity in power grids: A step towards building green smart cities	IET Generation, Transmission and Distribution	2024	Artificial intelligence; losses; smart meters; smart power grids	Artificial Intelligence and Machine Learning	The increasing demand for electricity in daily life highlights the need for Smart Cities to use energy efficiently
Wu L.; Kaiser G.; Rudin C.; Anderson R.	Data quality assurance and performance measurement of data mining for preventive maintenance of power grid	Proceedings of the 1st International Workshop on Data Mining for Service and Maintenance	2011	Data mining; machine learning; performance measurement; power grid; preventive maintenance	Artificial Intelligence and Machine Learning	Ensuring reliability as the electrical grid morphs into the "smart grid" will require innovations in how we assess the state of the grid, for the purpose of proactive maintenance, rather than reactive maintenance
Siebert LC..; Bianchi Filho J.F.; Silva Júnior E.J.; Kazumi Yamakawa E.; Catapan A.	Predicting customer satisfaction for distribution companies using machine learning	International Journal of Energy Sector Management	2019	Artificial intelligence; customer satisfaction; machine learning; performance measurement; power distribution;	Artificial Intelligence and Machine Learning	The study aims to support electricity distribution companies on measuring and predicting customer satisfaction
Maamar A.; Benahmed K.	Machine learning techniques for energy theft detection in AMI	ACM International Conference Proceeding Series	2018	Advanced metering infrastructure; energy theft detector; machine learning; smart meter data	Artificial Intelligence and Machine Learning	Advanced Metering Infrastructure (AMI and smart meter) is considered as the basic building block for the development of smart grid in the power distribution system
Singh K.; Mistry K.D.; Patel H.G.	Regression learner machine learning approach to predict wind speed	Australian Journal of Electrical and Electronics Engineering	2024	Loss minimisation; machine learning algorithm (MLA)	Artificial Intelligence and Machine Learning	The escalating global demand for electricity is driving a significant expansion in the size and complexity of electric power systems

	considering various parameters and integration of DG in mesh distribution system through GWO					
Ghadiali S.; Zaveri N.; Ghadiali Z.	Detection and Prevention of Electrical Power Theft by Artificial Intelligence and Machine Learning”	13th International Conference on Advances in Computing, Control, and Telecommunications Technologies	2022	Advanced metering infrastructure; artificial intelligence; machine learning; non-technical loss	Artificial Intelligence and Machine Learning	The gradual rise in electricity theft is one of the foremost concerns for the electric power distribution system and the poor economic state of the short voltage consumer side
Alberti C.; Dura F.; Ceci M.; Pio G.	Development of an advanced planning tool for supporting the choice of optimal investments aimed at optimising the infrastructure of power distribution systems in future scenarios	IET Conference Proceedings	2021	Artificial intelligence; multi-objective optimization; network planning	Artificial Intelligence and Machine Learning	Given the decarbonization objectives set at the European level, the evolutionary scenarios of the electric system envisage a significant paradigm shift in the use of electricity
Alhmoud L.; Marji W.	Optimization of Three-Phase Feeder Load Balancing Using Smart Meters	IEEE Canadian Journal of Electrical and Computer Engineering	2022	Artificial intelligence; power distribution; smart meter	Artificial Intelligence and Machine Learning	Power losses in distribution systems are among the most important performance indicators of electricity distribution companies' economic operations

The seven articles in the Balanced Scorecard cluster focus on different applications of the famous PMS framework in the power distribution companies. Four articles present cases in companies, one poses specific application on data servers, other suggests application in decentralised generation services, and one argues that practices, attitudes, and cultures can remove the need of individual performance measurement.

The nine papers in the DEA cluster focus on different techniques combined or changed for data envelopment analysis like stochastic DEA or slacks-based DEA or a combination with Analytic

Hierarchical Process (AHP). All articles compare the performance of several companies or company's distribution units or districts.

The eight articles in the Artificial Intelligence and Machine Learning cluster focus on applying AI and ML to solve problems in the operations of electricity distribution. The papers show applications reducing losses (2 articles), proactive maintenance (1), predicting customer satisfaction (1), smart meters (2) and distribution optimisation (2).

CONCLUSIONS

This paper used bibliometrics analysis to select and map articles for content analysis, providing an overview of performance measurement systems in electricity distribution companies. This is a step towards closing the identified gap of lack of reviews on the issue.

One significant result indicates how the topics have changed over time in the field. There has been a shift in measuring performance in different areas or organisations, moving from methods like data envelopment analysis to incorporating multiple performance measures, such as financial and non-financial indicators, sometimes using the Balanced Scorecard framework or not. The DEA application involves differences between the traditional method and newer approaches, including stochastic DEA. Although BSC does not work properly under regulation of government agents (Wanderley, Cullen and Tsamenyi, 2022), some authors either describe cases of implementation in electricity distribution companies or advocate the use for solving performance measurement problems or improving performance measurement. In recent times, artificial intelligence and machine learning have been employed by researchers for tasks related to performance measurement in different sectors of companies. The findings demonstrate the utilisation of artificial intelligence and machine learning in proactive maintenance, customer satisfaction prediction, theft detection and minimization, smart meter usage for precise consumption data, and distribution optimization. The emphasis in this final stage is on non-financial performance measures (both external and internal), rather than the company's overall performance. This is a distinctive difference from the previous stages. The absence of integration among these clusters is an important issue that should be addressed in future research by scholars. When it comes to sustainability, most articles focus on technical aspects rather than managerial issues. One paper that stands out is the case study on implementing the Balanced Scorecard at Tata Power Delhi Distribution in India. In their description, the authors highlight the application of BSC in gauging sustainability and performance across multiple dimensions.

The evidence from Lotka's Law suggests a low level of field maturity and a lack of influential authors. The reason is that numerous eventual authors only publish one or two articles. The sources the authors published their articles reinforces the previous finding - 3.17% of sources have published 13.79% of papers. In addition, the top sources (Figure 6) mainly consist of energy or electricity or power distribution outlets or conference proceedings, even though the International Journal of Energy Sector Management, which emphasises energy sector management, publishes the most articles. The operations and quality management journals have a weak presence. Another result that reinforces the field situation is the published documents impact. Although the global citation of the set of documents is satisfactory, the authors' sample do not cited them. These findings demonstrate the importance of developing more investigations that take into account authors' awareness of each other's work.

Nonetheless, the systematic literature review did not find any framework that effectively incorporates the broad and complex demands of stakeholders within the power distribution companies using financial and non-financial performance measures. This gap provides scholars with the opportunity to explore new research avenues by adapting or creating frameworks specifically for the power distribution sector. Moreover, the researchers in the field of performance measurement for the electricity distribution companies could benefit from existing knowledge in the field of performance measurement systems for enriching their research.

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An np chart for reducing sustainability cost of monitoring manufacturing processes

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STRUCTURED ABSTRACT

Purpose (Mandatory) - This research proposes a model for optimizing the np chart and achieving sustainable monitoring of manufacturing processes. The proposed model incorporates sustainability considerations by minimizing both inspection costs and CO_2 emissions.

Design/methodology/approach (Mandatory) - This study presents a model that optimizes the np chart parameters to minimize the sustainability cost of monitoring manufacturing processes, while ensuring adherence to allowable limits for inspection and false alarm rates. A comparative analysis was conducted with the standard np chart using a case study on fire extinguisher inspections.

Findings (Mandatory) - Results revealed a 69% improvement with the proposed optimal np chart.

Originality/value (Mandatory) - In the literature, statistical monitoring of manufacturing processes has been excessively applied to reduce the variability and associated costs. However, sustainability pillars such as environmental and economic aspects have rarely been considered directly while monitoring manufacturing processes.

Keywords: Sustainable monitoring, Statistical process control, np control charts, Sustainability cost.

Paper type: Case study

INTRODUCTION

Manufacturing processes positively contribute to the wealth of the economy globally. Meanwhile, the emissions emitted during the manufacturing and quality monitoring processes, such as inspection, are harmful to the environment. In the same context, Chontanawat (2020) proved that inspection processes usually need additional consumption of energy and resources that led to an increase in the inspection cost and CO_2 emissions, especially if the test is destructive. Therefore, proposing sustainable monitoring models that consider environmental and economic aspects of sustainability is becoming a necessity nowadays to reduce the CO_2 emissions that harm the environment and to decrease the associated costs of inspection processes.

In quality control, several statistical tools can be used to monitor the quality of the products and the state of the process. Control charts are one of the most used tools and can be categorized into two main categories, variable control charts and attribute control charts. The first charts are used when the monitoring statistic is based on numerical variables such as length. These charts are more accurate and precise. However, they are more time- and cost-consuming. In contrast, attribute control charts can be performed to study more than one quality characteristic at one time and classify if the product is conforming or nonconforming. These charts are preferable when it is needed to save time and cost (Haridy et al. 2014).

An np chart is a commonly used attribute chart to monitor the number of nonconforming items (d) found in every inspected sample (n). The widespread use of the np chart is attributable to several reasons, such as the easiness of communicating the data among people at different levels. Haridy et al. (2021) developed optimized np charts for detecting COVID-19 instances in airports. It was discovered that optimal np chart outperforms the regular np chart throughout a variety of infection rate shifts, using the average number of infections as a performance indicator. Similarly, Alamassi et al. (2023) devised an algorithm for the economic design of the np chart from an economic standpoint. The goal was to reduce the total expected cost. Under many conditions, the developed np chart outperformed the regular one.

Many researchers aimed to enhance the performance of control charts by adopting different optimization algorithms that increased the detection effectiveness of the charts (Haridy et al., 2022; Nawaz et al., 2021; Shamsuzzaman et al., 2015). Environmental quality can be negatively impacted by industrial carbon emissions since the industrial sector contributes significantly to Greenhouse Gas emissions (GHGs) such as CO_2 emissions (Mani et al., 2014). According to Gilbert (1987), using quality control charts and techniques for monitoring environmental pollution is an effective way to enable sustainability monitoring. Zhou et al. (2015) combined control charts to effectively control carbon loads in tourism or attractive areas by guiding tourist shunting. The created design successfully monitored the CO_2 load rate over time and managed it to keep it at an acceptable level in the area. Haridy et al. (2011) proposed an approach for evaluating the capability of cold rolling process that that undergo dynamic behavior. In the same context, Ajadi et al. (2021) reported that control charts can successfully detect average levels of air pollution and major points of change in time series of air pollutants on a busy route in the center of London.

Despite the fact that many studies have taken economic and statistical perspectives into account when optimizing control charts for monitoring purposes, environmental impacts such as CO_2 emissions that harm the environment from the inspection and monitoring processes have not been adequately addressed. Even though there are significant efforts and attempts, they did not consider emission costs while monitoring production operations particularly. This research proposes an optimized np chart that takes into consideration the environmental and economic aspects of monitoring processes.

IMPLEMENTATION AND DESIGN OF np CHART

The np chart is implemented as shown in Fig. 1.

1. At the end of each sampling interval h, sample size n units are collected, and the number of nonconforming units d in this sample is counted.
2. The d of each n is plotted on the np chart.
3. If d > UCL, then out-of-control will be signaled, and further investigation is required.
4. If d ≤ UCL, then the process is considered in-control and go back to the first step, to monitor the next sample.

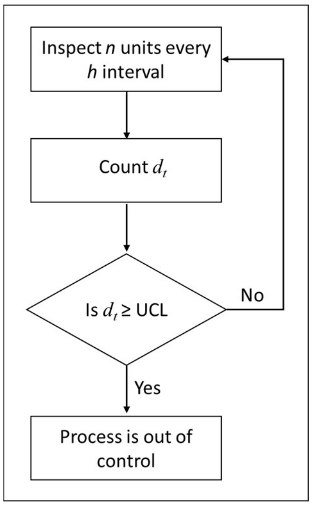

Fig. 1. Implementation procedure of np chart.

In normal quality control procedure, as shown in Fig. 2, when the process is declared to be out-of-control, the production process is terminated. The process is then investigated, and remedial actions are implemented to bring it back under control. The costs considered are the inspection costs, whereas the CO_2 emissions costs are neglected in most cases.

Optimizing np control chart based on the inspection costs and CO_2 emissions costs can guarantee a reduction in the nonconforming items produced by detecting the shift in an early stage. Consequently, this results in the reduction of the overall cost, or what we called Sustainability Cost (SC), which consists of the economic cost (inspection cost) and the environmental cost (CO_2 emissions cost), during the monitoring process, namely, in-control and out-of-control phases illustrated in Fig. 3.

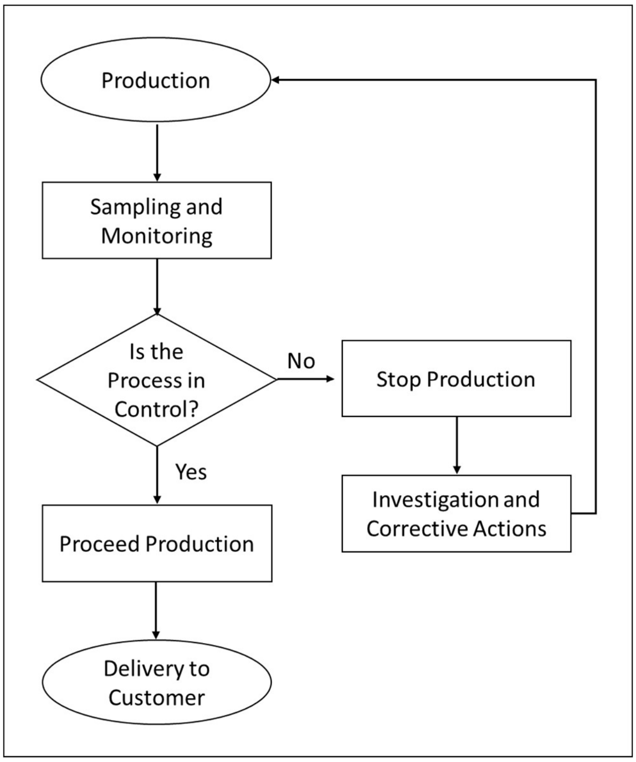

Fig. 2. Quality control monitoring process with in-control and out-of-control phases.

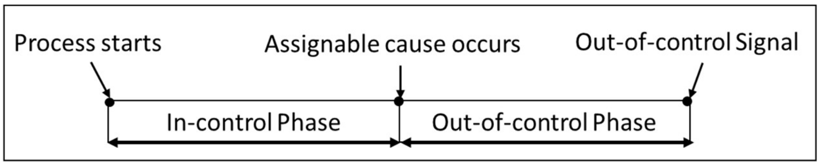

Fig. 3. Phases of sustainable monitoring.

DEVELOPMENT OF OPTIMIZATION MODEL

Design specifications

First, there are five process parameters and two cost parameters to be known before conducting the optimization model of np chart. For the process specifications, initially, the in-control fraction nonconforming, p_0, which is to be known based on in-control historical data. Then, the inspection rate ($r = n/h$), and it is determined by the resources available. Then τ, the minimum allowable in-control Average Time to Signal (ATS_0), and it is determined based on the ability of handling the false alarm rate. ATS_0 is the average time it takes the control chart to produce an out-of-control alert while the process is actually in control. The produced signal is called false alarm. Therefore, it is advised that the value of ATS_0 to be increased to be at least equal to τ. The last two parameters are the maximum shift in fraction nonconforming that is the maximum shift the user is concerned in detecting, δ_{max}. And lastly, the frequency with which the assignable causes occur, $\mathcal{E}$. Consequently, $1/\mathcal{E}$ is the estimated in-control time. The cost parameters, in dollar, are the inspection cost per item, c_i, and CO_2 emission cost per item, c_o.

Assumptions:

1. The production cycle begins with an in-control phase, then moves to an out-of-control phase (if a shift happens).
2. The number of nonconforming units in a sample is considered to follow a binomial distribution.
3. The shift is assumed to be random and uniformly distributed.
4. Only upward fraction nonconforming p shifts are taken into account, because decreasing p indicates improvement.

Optimization model

In this paper, the objective of optimization model is to minimize the Sustainability Cost (SC) that will be detailed in Section C. It consists of the inspection cost and CO_2 emissions cost during monitoring a process.

Objective: Minimize SC

Constraints:

$$\mathrm{ATS_0} \geqslant \tau \tag{1}$$

$$\mathrm{r} = \frac{\mathrm{n}}{\mathrm{h}} \tag{2}$$

Design variables: n, h, and UCL

This model aims to find the optimal values of the charting parameters of np chart, n, h, and UCL that minimize SC throughout a shift wide of ($1 < \delta \leq \delta_{max}$). Setting the inspection rate r and the ATS_0 as constraints to specific values ensures that all available resources are used to improve the control chart detection effectiveness while minimizing the occurrence of the false alarms. $\mathrm{ATS_0}$ can be calculated as follows:

$$ATS_0 = \frac{h}{\alpha} \tag{3}$$

where $\alpha = \Pr\{\mathrm{d} > \mathrm{UCL}\} = 1 - \sum_{\mathrm{i=0}}^{\mathrm{UCL}} \mathrm{C_i^n} (1 - \mathrm{p_0})^{\mathrm{n-i}} \mathrm{p_0}^{\mathrm{i}}$ (4)

The optimization algorithm, as depicted in Fig. 4, begins with specifying the parameters, (r, τ, p_0, δ_{max}, $\mathcal{E}$, c_i, c_o), then initializing the variable SC_{min} as a large value. This variable is used to store the SC's minimum value. The algorithm starts to calculate SC in an iterative way to find the optimal charting parameters that will generate the least SC value and satisfy constraints (1) and (2).

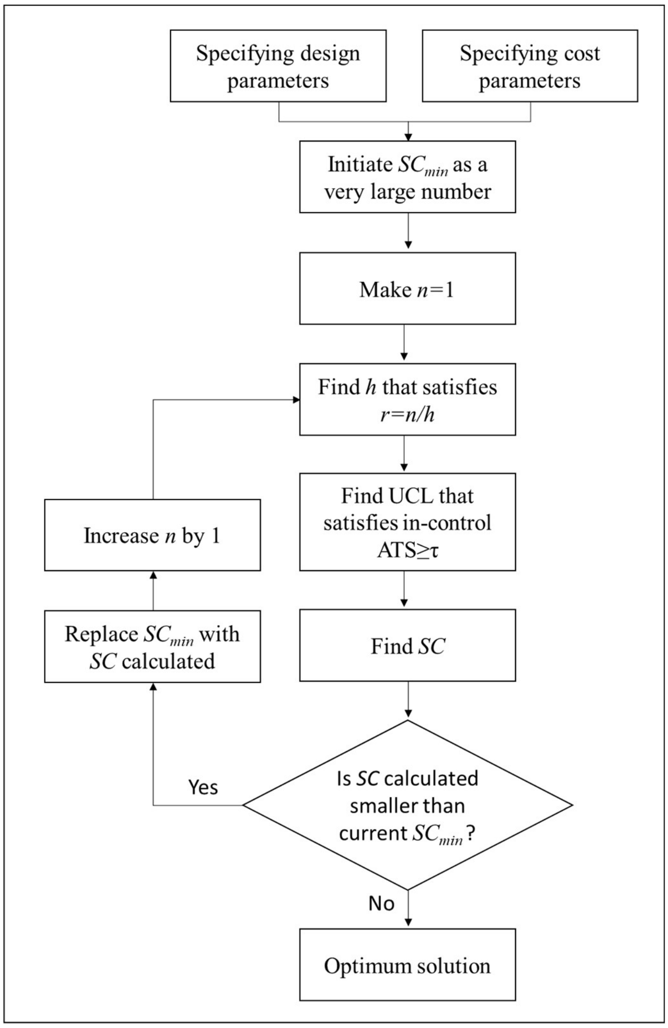

Fig. 4. Optimization Algorithm.

Formulation of the objective function

The SC is the summation of the expected costs of in-control and out-of-control phases, taking into consideration the inspection and CO_2 emission costs.

SC = ECIC + ECOC (5)

The expected cost of the in-control phase (ECIC) represents the costs of inspection and CO_2 emissions for all items inspected during the in-control phase, whereas the expected cost of the out-of-control phase (ECOC) estimates the costs of inspection and CO_2 emissions for all items inspected during the out-of-control phase. These expected costs can be calculated as follows:

$$\text{ECIC} = \left(\frac{n}{h}\right) \times \frac{1}{\varepsilon} \times (c_i + c_o) \quad (6)$$

$$\text{ECOC} = \left(\frac{n}{h}\right) \times (c_i + c_o) \int_1^{\delta_{max}} \text{ATS}(\delta) \times f_\delta(\delta) d\delta \quad (7)$$

Consequently, SC can be formulated as follows:

$$\text{SC} = \left(\frac{n}{h}\right) \times \frac{1}{\varepsilon} \times (c_i + c_o) + \left(\frac{n}{h}\right) \times (c_i + c_o) \int_1^{\delta_{max}} \text{ATS}(\delta) \times f_\delta(\delta) d\delta \quad (8)$$

The out-of-control $\text{ATS}(\delta)$ in Equation (8) represents the average time the control chart takes to signal an out-of-control alarm while the process is truly out-of-control. The goal is to keep the $\text{ATS}(\delta)$ value as low as possible over the entire range of shifts ($1 < \delta \leq \delta_{max}$) to detect shifts as soon as they occur. It can be calculated as follow:

$$\text{ATS}(\delta) = \frac{h}{(1 - \beta)} \quad (9)$$

where $\beta = \Pr\{d \leq \text{UCL}\} = \sum_{i=0}^{\text{UCL}} C_i^n (1-p)^{n-i} p^i \quad (10)$

$f_\delta(\delta)$ is the shift distribution density function that is assumed to follow a uniform distribution in this research and is calculated as follows:

$$f_\delta(\delta) = \frac{1}{\delta_{max} - 1} \quad (11)$$

COMPARATIVE STUDIES

In this section, a comparison between the proposed optimized np chart and the regular np chart is conducted considering an increasing shift in fraction nonconforming using a case for the fire extinguisher monitoring process.

In the process of producing fire extinguishers, it is crucial to ensure the quality of the produced extinguishers to attain high safety standards for the users. One of the conducted tests is performed by filling the extinguisher with gas until explosion, in order to check if there is any leakage or holes in the body of the extinguisher. This kind of tests is a destructive one, which incur a high loss in terms of economic cost, since the tested extinguisher will be considered as a waste, or will be recycled. Additionally, it will cause environmental cost, due to the CO_2 emissions that will be emitted from the inspection process into the environment.

The used design specifications were set based on consultations with the quality engineers and professionals in the extinguisher factory. The two charts are evaluated based on the same following design specifications:

Process parameters:

$p_0 = 0.01$, $\tau = 300$, $r = 20$, $\delta_{max} = 10$, $\varepsilon = 0.05$

Cost parameters:

$c_i = 2$, c_o 0.7

The factory uses a regular np chart where 20 extinguishers are inspected daily. On the other hand, the optimal np chart will use the optimal n and h resulted from the optimization model to ensure the best detection effectiveness. The charting parameters and SC for both charts are found as below:

Regular np chart: UCL = 2, n = 20, h = 1,

SC = 2562.52

Optimal np chart: UCL = 4, n = 168, h = 8.4,

SC = 1516.37

A ratio $SC_{regular}$ / $SC_{optimal}$ is calculated to compare the performance of the regular np chart to that of the optimal np chart. In this case, 2562.52 / 1516.37 = 1.69. It means that the optimal np chart excels the regular one by 69% over the specified shift range ($1 < \delta \leqslant 10$).

Table 1 displays the ATS values for both charts recorded throughout the shift range. Subsequently, the normalized ATS is determined by dividing the ATS value of the regular np chart at a certain shift point by that of the optimal np chart at the same shift point. Fig. 5 shows the normalized ATS curves of the charts.

Table 1. ATS values for both np charts.

	ATS	
δ	$\mathbf{np_{regular}}$	$\mathbf{np_{optimal}}$
1	996.437	303.894
2	140.969	29.780
3	47.100	10.556
4	22.298	6.227
5	12.748	4.869
6	8.198	4.411
7	5.711	4.262
8	4.216	4.217
9	3.251	4.204
10	2.595	4.201

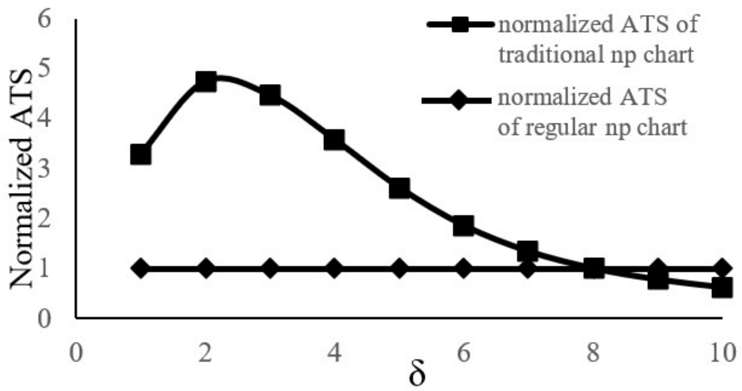

Fig. 5. Normalized ATS values for both charts.

Table 1 and Fig. 5 can lead to the following conclusions:

1. Both charts produce an ATS_0 greater than τ for $\delta = 1$. This ensures that false alarm rate constraint (1) is met by both charts.
2. The ATS values for both charts show that the optimal np chart excels the regular np chart throughout most of the tested shifts. It can be noted that the optimal np chart is more sensitive to small and moderate shifts than the regular np chart.
3. The optimal np chart has the greatest superiority over the regular one at a shift size of $\delta = 2$. Then the difference in performance between the charts begins to lessen as the shift increases.
4. For large shift where $\delta = 7$ and more, both charts have nearly similar detection effectiveness. This is expected since the np chart, in general, is well-known for its ability to detect big shifts.

CONCLUSION

Manufacturing is a critical driver of economic prosperity. Concurrently, emissions from manufacturing industries pose significant challenges to achieving sustainability. Furthermore, the inspection of manufactured items, particularly through destructive tests, exacerbates CO_2 emissions. This research optimizes an np chart by considering both environmental (CO_2 emission costs) and economic (inspection costs) aspects of sustainability. A case study on fire extinguisher inspections demonstrates that the optimized np chart surpasses the standard one by 69% in reducing emissions and costs.

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Remote STEM Education: Gap Analysis from the Perspectives of Students and Faculty

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STRUCTURED ABSTRACT

Purpose: This study aims to assess the current critical aspects (or *gaps*) in remote STEM education, from the dual perspectives of students and faculty from different European universities. Initiated about four years after the onset of the COVID-19 pandemic, the study explores the critical aspects affecting educational outcomes, in the context of the ongoing EU-funded REMOTE project.

Methodological approach: The research involved the design and implementation of structured questionnaires through the LimeSurvey platform, focusing on various critical aspects of remote learning and assessment, such as *resource availability*, *training adequacy*, *technical responsiveness*, *online assessment feedback*, and *social dynamics*. Data were collected from over five hundred students and nearly two hundred faculty members, from four different European universities.

Findings: The results show some discrepancies between student and faculty perceptions regarding the *adequacy of assessment feedback*, which is particularly critical for students but not for faculty, and *student-faculty interaction*, which is particularly critical for faculty but not for students. On the other hand, a consensus emerged between the two counterparts on the intrinsic challenges to *educational quality* and *academic integrity*. In addition, the analysis revealed a general agreement among the universities involved in the questionnaires, despite their different geographic and cultural contexts, with a substantial absence of gender bias for both students and faculty.

Practical/social implications: These insights may be relevant for educational policymakers and institutions to continue to refine online teaching strategies and assessment methods.

Keywords: Quality of education, Remote learning/assessment, Gap analysis, Questionnaire.

Paper type: Research paper

INTRODUCTION

The global shift to remote learning, accelerated by the COVID-19 pandemic, has profoundly impacted educational paradigms, particularly within the STEM (science, technology, engineering, and mathematics) disciplines. Today, more than four years after the start of the pandemic, both faculty and students have significantly increased their awareness and training for remote learning. Numerous digital platforms with advanced tools have emerged, facilitating customised learning paths that respond to the specific needs of students and give the possibility to choose content and delivery modes more flexibly than in the past. Lecturers – thanks to continuous training, both external and autonomous – have also developed advanced skills in the use of educational technologies (Broadbent et al., 2023; Casadesús et al., 2024). Remote learning is increasingly complementing, rather than replacing, in-presence teaching, as demonstrated by the growing use of hybrid teaching techniques. For example, the use of innovative digital tools allows, subsequent to theoretical in-person lectures, virtual visits to laboratories or research environments that are often difficult to access physically.

However, despite the significant progress made within higher education institutions (HEIs) worldwide in adapting to remote teaching and assessment methods, critical issues and intrinsic difficulties remain. These challenges continue to raise significant questions about the effectiveness of remote learning in promoting essential educational outcomes, such as knowledge acquisition, critical thinking, problem-solving skills, and collaborative learning (Iglesias-Pradas et al., 2021; Lockee, 2021; Wang et al., 2021). Remote learning, while offering additional opportunities for students and faculty, has introduced new challenges, including reduced social interactions, emerging technological barriers, and an increased demand for student autonomy in learning (Palvia, et al., 2018). These challenges underscore the necessity of a thorough evaluation of remote learning practices to gauge their effectiveness and identify areas for improvement, aiming to ensure optimal student engagement and learning outcomes (Guangul et al., 2020; Carter et al., 2020).

Research in this area has pinpointed several crucial aspects for the effective implementation of remote learning: student engagement, teaching methodologies, the role of academic staff, and the integration of information technology. Students in remote settings are expected to exert greater control over their learning, utilizing various technology-mediated forms of assessment that serve not only to measure their academic progress but also to enhance their digital literacy (Fidalgo et al., 2020; Ho et al., 2021). However, there remains a substantial gap in understanding how to effectively adapt teaching methodologies to the specificities of remote teaching and assessment (Gupta et al., 2020; Flores et al., 2022). Academic staff certainly play a critical role in the transition to online education, responsible for designing engaging content and employing pedagogical strategies that promote active learning and student participation. Concurrently, the role of advanced computing technologies and platforms, fundamental to the delivery and management of remote education, warrants further exploration to better integrate these tools with effective teaching practices (Reedy et al., 2021).

The present study, conducted approximately four years after the onset of the pandemic, seeks to systematically investigate the prevailing challenges and to identify potential *gaps* in remote STEM education, from the dual perspectives of students and faculty members. In particular, it aims to answer some main research questions:

- "*What are the current challenges of remote STEM education, as perceived by students and lecturers?*";
- "*What are the main discrepancies between perceptions of students and lecturers regarding the effectiveness of remote learning and assessment?*";
- "*Are any differences observed between the partner universities involved in the survey?*".

This study is an integral part of the project "Assessing and evaluating remote learning practices in STEM" (REMOTE), financed by the European Union under the "Cooperation partnerships in higher education" action of the Erasmus+ program. It involves four universities – Universitat de Girona (UdG) from Spain, Politecnico di Torino (PoliTO) from Italy, Universitat Internacional de Catalunya (UIC) from Spain, Universidade do Minho (UMinho) from Portugal – and three external agencies for quality assurance in higher education – AQU Catalunya (Spain), ANVUR (Italy), and A3ES (Portugal). Starting with a comprehensive literature review and dozens of interviews with academic experts conducted in the early part of the project, a series of potentially critical aspects of remote teaching and assessment in the STEM field emerged for both students and teachers (Casadesús et al., 2024). These aspects serve as the starting point for the development and dissemination of structured questionnaires across the aforementioned European partner universities, aimed at illuminating the peculiarities of remote teaching, learning, and assessment experiences, focusing on resource availability, technical responsiveness, training adequacy, online assessment methods, and social dynamics. A preliminary analysis of the data collected through these questionnaires will focus on identifying significant gaps in remote education, discerning any systematic differences between students' and faculty perceptions, and exploring the impact of various demographic and institutional factors. Data from a relatively large sample of respondents (i.e., several hundred students and lecturers from the above four European universities) will be analysed.

The rest of this article is organized into four sections. The first one provides a description of the methodology, divided into two parts pertaining to the construction and administration of questionnaires. The second section illustrates and comments on the preliminary results. Then, the conclusions summarize the main findings of the analysis, practical implications, limitations and insights for future developments. Finally, the appendix section contains additional more detailed material on the questionnaires.

METHODOLOGY

Construction of questionnaires

A thorough analysis of the scientific literature allowed to identify a set of potentially problematic aspects (or *constructs*), which characterise remote learning/teaching in STEM areas (see Table 1). It can be seen that the majority of the aspects are common to both students (S) and lecturers (L), while other more specific aspects apply only to one or the other part. For each construct, a “triplet” of different *items* (i.e., questions relevant to the construct itself) were formulated (e.g., items 2.3.1, 2.3.2 and 2.3.3 for construct 2.3). This sort of redundancy will be used to provide robustness to the results of the study.

The answers to each item are expressed on a 7-level scale with increasing direction in terms of gap (the higher the level, the wider the gap). The constructs were developed separately for student and lecturers. Each questionnaire has an initial part of demographic information, which is here omitted for simplicity. Tables A.1 and A.2 (in the Appendix section) show the items of both the questionnaires. Even for the several overlapping aspects/constructs in the two questionnaires (cf. the last two columns of Table 1), the items were customised to suit the respective target populations.

Administration of questionnaires

Both questionnaires were administered to the four partner universities of the REMOTE project and each university identified appropriate samples of lecturers and students. The questionnaires were administered through the LimeSurvey platform and were completed during the month of February 2024. Table 2 shows the number of respondents who completed the relevant questionnaires. Some disparities in participation can be observed, partly commensurate with the size of the universities involved, and partly related to other contingent factors (e.g., differences in terms of incentives for completion, dissemination channels used, respondents' sensitivity, etc.). In general, the overall number of respondents can be considered in line with expectations and acceptable for the intended statistical analysis (Ross, 2017; Franceschini et al., 2022).

Table 1 – List of aspects/constructs considered potentially problematic, based on a literature review. Some aspects apply to both students (S) and lecturers (L), while others apply to only one of the two respondent parties.

Dimension	Aspect / Construct	Description	Applicable to (S)	Applicable to (L)
1. Resource availability and accessibility	**1.1** Accessibility to materials	Ease of access to teaching materials from any location.	✓	✗
	1.2 Accessibility to evaluation resources	Ease of access to resources (software and hardware) for an effective online evaluation.	✓	✓
	1.3 Access equity	Equal access to technological resources for online teaching and assessment.	✓	✓
2. Technical responsiveness	**2.1** Connection and web platform adequacy	Technological stability and reliability of online platforms for lectures and exams, in addition to the quality of the Internet connection.	✓	✓
	2.2 Student-lecturer interaction	Effectiveness of communication, mutual interaction and support in an online learning context.	✓	✓
	2.3 Technical problem solving	Ability to manage technical problems during online lectures and exams.	✓	✓
3. Training	**3.1** Preparation and training for managing lectures	Preparation and training of lecturers on the use of online technologies to conduct exams and online evaluation.	✗	✓
	3.2 Preparation for managing the evaluation	Preparation and training of lecturers on the use of online technologies to conduct online exams effectively, including the creation of assessment materials.	✗	✓
	3.3 Institutional support to lecturers	Level of support and assistance provided to lecturers by the institution for online teaching and evaluation.	✗	✓
4. Online assessment	**4.1** Adequacy of assessment methods	Adequacy of assessment methods in use to the online context.	✓	✓
	4.2 Adequacy of evaluation feedback	Promptness and quality of feedback provided to students following exams.	✓	✓
	4.3 Quality of education	Online activities can undermine the achievement of the expected learning outcomes.	✓	✓
5. Social dynamics	**5.1** Gender diversity	Online activities can for some reason undermine gender equality.	✓	✓
	5.2 Community	Online activities can undermine the sense of belonging to the university community.	✓	✗
	5.3 Academic integrity (honesty)	Extent to which online exams maintain high ethical standards, including anti-fraud measures.	✓	✓

Table 2 – Number of respondents that completed the questionnaires administered at the four European partner universities: Politecnico di Torino (PoliTO), Universitat de Girona (UdG), Universitat Internacional de Catalunya (UIC), and Universidade do Minho (UMinho).

Questionnaire	European universities				Overall
	PoliTO	UdG	UIC	UMinho	
Students (S)	248	137	136	32	**553**
Lecturers (L)	89	18	28	41	**176**

PRELIMINARY RESULTS

The results were subjected to an analysis – still in progress – of which here are some preliminary results. First of all, a pre-processing of the answers given by the individual respondents was carried out, based on two elaborations:

1. *Aggregation of the answers (expressed on a rating scale from 1 to 7) of each triplet of items referring to the same aspect/construct, through the median operator***.** For example, assuming that a certain respondent gives the following answers to a certain triplet of items:

   $$1.1.1 \rightarrow 6, 1.1.2 \rightarrow 7, \text{and } 1.1.3 \rightarrow 4, \tag{1}$$

   the median associated with aspect/construct 1.1 will be 6. This aggregation gives robustness to the results, filtering out possible outliers. Furthermore, the median is a central tendency indicator compatible with the *ordinal* scale properties of ratings (Franceschini et al., 2022).

2. *Transformation of the (median) ratings for all aspects/constructs of the questionnaire into a single ranking and, subsequently, association of a rank with each aspect/construct.* With reference to the ratings in the first two columns of Table 3, the following ranking would be obtained:

   $$1.3 \prec (1.1 \sim 2.3 \sim 4.1 \sim 5.1 \sim 5.3) \prec (1.2 \sim 2.2 \sim 4.2 \sim 4.3) \prec 2.1 \prec 5.2, \tag{2}$$

   where the symbol "≺" means "*less critical than*", and the symbol "~" means "*indifferent to*". So, aspects/constructs are ranked in order of increasing *criticality* (understood as the width of the gap).

   Table 3 – Example of transforming (median) ratings, obtained from the scale levels into (mean) ranks. The ranking in Eq. 2 was then converted into the specific ranks shown in the last column of the table.

Aspect/construct	(Median) rating	Rank
1.1	2	4
1.2	3	8.5
1.3	1	1
2.1	4	11
2.2	3	8.5
2.3	2	4
4.1	2	4
4.2	3	8.5
4.3	3	8.5
5.1	2	4
5.2	5	12
5.3	2	4

   The rank of the individual aspects/constructs within the ranking is then determined, i.e. their relative position (e.g., 1st, 2nd, 3rd); if several values have the same rank (i.e., they are tied in the ranking), the so-called *mean rank* is conventionally used (Franceschini et al., 2022). The resulting rank of each aspect/construct will be used as a variable of interest for subsequent analyses. The transformation of questionnaire ratings into ranks was introduced to facilitate comparability between the results of different questionnaires[1].

Data were then subjected to statistical analysis (still ongoing), of which some preliminary results are provided here. Table 4 contains the average values of the variable of interest (rank) for the aspects/constructs of interest, both at a general level ("Overall" in the last column) and at a university-disaggregated level. The Pareto diagram in Fig. 1 shows that the most critical constructs at a general level are: *community* (5.2), *academic integrity* (5.3), *adequacy of evaluation feedback* (4.2), *quality of education* (4.3) and *adequacy of assessment methods* (4.1). Considering the data disaggregated by university, it can be seen that – apart from a few small variations – they seem to confirm the general trend. In other words, there is a good degree of agreement among the respondents, regardless of which university they belong to. This impression can also be appreciated quantitatively, considering the Pearson product-moment-correlation coefficients in Table 5.

Table 4 – Summary of the student-side questionnaire results. The table shows average values of the response variable (rank) for the aspects/constructs of interest, both at an overall level and at a university-disaggregated level. "PoliTO" stands for Politecnico di Torino, "UdG" stands for Universitat de Girona, "UIC" stands for Universitat Internacional de Catalunya, and "UMinho" stands for Universidade do Minho.

Aspect/Construct	European universities				Overall
	PoliTO	UdG	UIC	UMinho	
1.1	4.8	5.0	4.9	4.9	**4.9**
1.2	5.7	5.6	5.7	6.4	**5.7**
1.3	4.7	4.6	4.7	6.4	**4.8**
2.1	5.9	5.3	5.5	6.0	**5.6**
2.2	6.3	6.1	6.2	6.1	**6.2**
2.3	5.4	5.6	6.0	6.0	**5.6**
4.1	7.5	7.2	6.9	7.3	**7.3**
4.2	7.9	7.9	7.7	6.8	**7.8**
4.3	7.2	7.9	8.1	7.4	**7.6**
5.1	4.1	5.3	5.7	4.3	**4.8**
5.2	10.3	8.9	8.4	8.4	**9.4**
5.3	8.1	8.6	8.2	7.8	**8.3**

[1] Rating scales may be used subjectively, as there is no absolute reference shared by all respondents. For example, let us consider the seven-level ordinal scale representing the width of the gap: *very low*, *low*, *moderately low*, *intermediate*, *moderately high*, *high*, and *very high*; "indulgent" respondents will tend to assign higher levels whereas "severe" respondents will tend to assign lower ones. For this reason, it would be questionable to aggregate ratings by different respondents through indicators of central tendency.

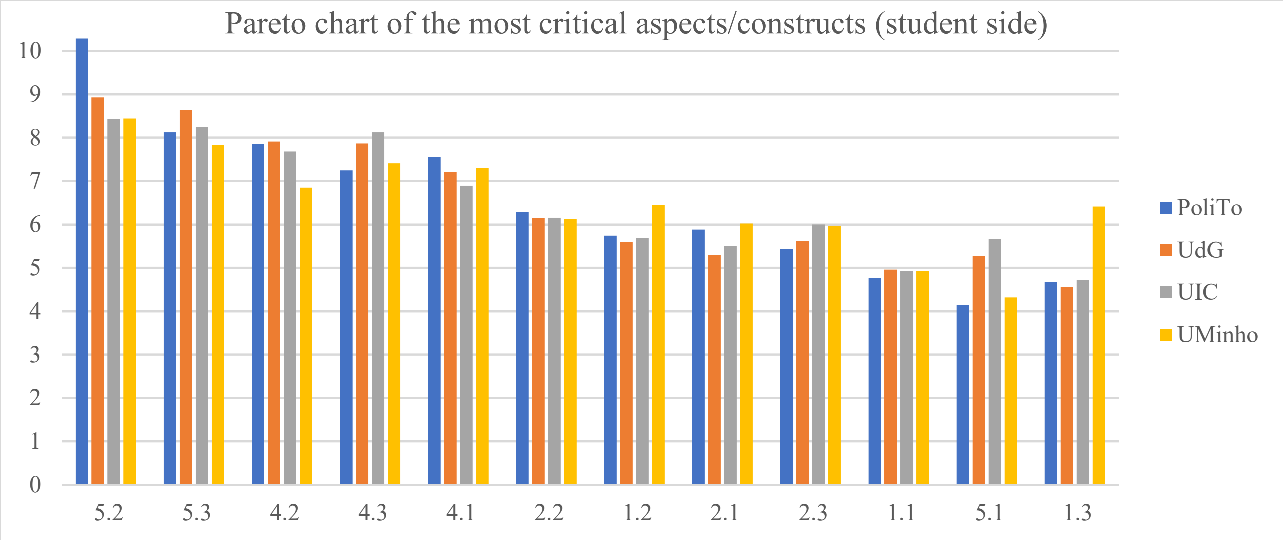


Figure 1 – Pareto chart relating to the summary data in Table 4, resulting from the analysis of the student-side (S) questionnaires. Aspects/constructs are ordered in descending order with respect to the “Overall” values in the last column of Table 4. “PoliTO” stands for Politecnico di Torino, “UdG” stands for Universitat de Girona, “UIC” stands for Universitat Internacional de Catalunya, and “UMinho” stands for Universidade do Minho.

Table 5 – Pearson product-moment-correlation coefficients (and relevant *p*-values in brackets), related to the university-disaggregated data in Table 4 (student-side analysis) (Ross, 2017). “PoliTO” stands for Politecnico di Torino, “UdG” stands for Universitat de Girona, “UIC” stands for Universitat Internacional de Catalunya, and “UMinho” stands for Universidade do Minho. The analysis was conducted using Minitab® statistical software.

(S) Correlations: PoliTO; UdG; UIC; UMinho

	PoliTO	UdG	UIC
UdG	0.938 (0.000)		
UIC	0.897 (0.000)	0.987 (0.000)	
UMinho	0.901 (0.000)	0.834 (0.001)	0.801 (0.002)

A similar study was carried out for the questionnaires administered to lecturers. In particular, a certain alignment is confirmed in the answers given by respondents from the different universities (cf. Table 6, Fig. 2, and Table 7). However, the most critical aspects/constructs are somewhat different from those ones resulting from the student-side questionnaires. On the lecturer side, the aspects perceived as most problematic in general are: *student-lecturer interaction* (2.2), *quality of education* (4.3), *preparation for managing the evaluation* (3.2), and *academic integrity* (5.3). Let us note that aspect 2.2 has little criticality on the student side (cf. Fig. 1); on the other hand, aspect *adequacy of evaluation feedback* (4.2), while critical on the student side, is not critical on the lecturer side.

Table 1 – Summary of the lecturer-side questionnaire results. The table shows average values of the response variable (rank) for the aspects/constructs of interest, both at an overall level and at a university-disaggregated level. "PoliTO" stands for Politecnico di Torino, "UdG" stands for Universitat de Girona, "UIC" stands for Universitat Internacional de Catalunya, and "UMinho" stands for Universidade do Minho.

Aspect/Construct	European universities				Overall
	PoliTO	UdG	UIC	UMinho	
1.2	6.5	5.1	6.1	6.7	**6.4**
1.3	5.7	7.1	5.2	6.5	**5.9**
2.1	5.0	4.8	5.4	5.9	**5.2**
2.2	9.3	8.1	8.2	9.3	**9.0**
2.3	4.5	5.4	4.9	6.1	**5.0**
3.1	8.4	7.5	8.3	7.5	**8.1**
3.2	8.8	9.1	9.3	8.1	**8.7**
3.3	5.5	5.6	6.7	6.7	**6.0**
4.1	8.0	7.9	6.8	7.5	**7.7**
4.2	4.7	4.7	4.7	4.0	**4.6**
4.3	9.2	8.4	8.6	8.0	**8.7**
5.1	7.3	7.5	6.3	6.0	**6.9**
5.3	8.0	9.9	10.1	8.8	**8.7**

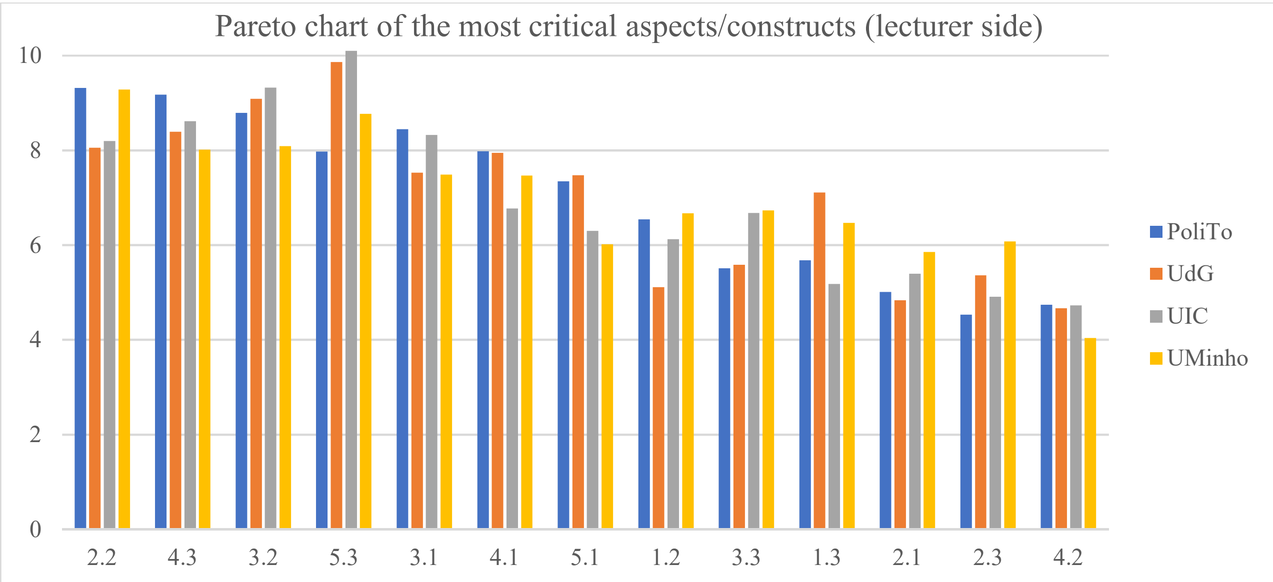


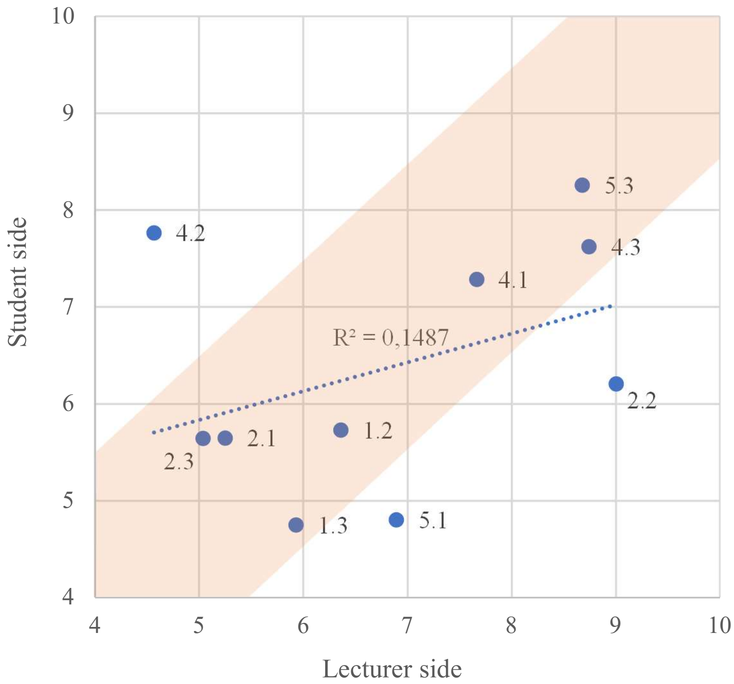
Figure 2 – Pareto chart relating to the summary data in Table 6, resulting from the analysis of the lecturer-side (L) questionnaires. Aspects/constructs are ordered in descending order with respect to the "Overall" values in the last column of Table 6. "PoliTO" stands for Politecnico di Torino, "UdG" stands for Universitat de Girona, "UIC" stands for Universitat Internacional de Catalunya, and "UMinho" stands for Universidade do Minho.

To better grasp this diversity of views between the student and lecturer populations, let us consider the two-dimensional map in Fig. 3, which positions the aspects/constructs of interest according to the overall indicators in Table 4 (S) and Table 6 (L). The map shows no correlation ($R^2 \approx 15\%$) between the two populations of respondents. The only aspects/constructs considered problematic for both populations are (5.3) and (4.3), in top-right position. On the other hand, the aspects positioned near the bottom-right corner – e.g., (2.2) – are considered problematic on the lecturer side but not on the student side, while those positioned near the top-left corner – e.g., (4.2) – are considered problematic on the student side but not on the lecturer side.

Table 2. Pearson product-moment-correlation coefficients (and relevant *p*-values in brackets), related to the university-disaggregated data in Table 6 (lecturer-side analysis) (Ross, 2017). "PoliTO" stands for Politecnico di Torino, "UdG" stands for Universitat de Girona, "UIC" stands for Universitat Internacional de Catalunya, and "UMinho" stands for Universidade do Minho. The analysis was conducted using Minitab® statistical software.

(L) Correlations: PoliTO; UdG; UIC; UMinho

	PoliTO	UdG	UIC
UdG	0.840 (0.000)		
UIC	0.852 (0.000)	0.863 (0.000)	
UMinho	0.836 (0.000)	0.808 (0.001)	0.859 (0.000)



Aspect / Construct
1.2 Accessibility to evaluation resources
1.3 Access equity
2.1 Connection and web platform adequacy
2.2 Student-lecturer interaction
2.3 Technical problem solving
4.1 Adequacy of assessment methods
4.2 Adequacy of evaluation feedback
4.3 Quality of education
5.1 Gender diversity
5.3 Academic integrity (honesty)

Figure 3 – Map of the positioning of the analysed aspects/constructs, from the dual perspective of students (vertical axis) and lecturers (horizontal axis). The numerical values are the "Overall" ones from Table 4 and Table 6 respectively, which represent the average values of the response variable (i.e., rank) for the aspects/constructs of interest.

The study found no evidence of a significant gender effect in the responses, suggesting that of remote-learning issues affect all students and lecturers, regardless of gender. For instance, Fig. 4 illustrates the results for students, where the percentages of female and male respondents are nearly equal at 46.5% and 53.5%, respectively. Similarly, for lecturers the results show no significant gender effect, although the percentages of female and male respondents differ to a greater extent (34.1% and 65.9%, respectively).

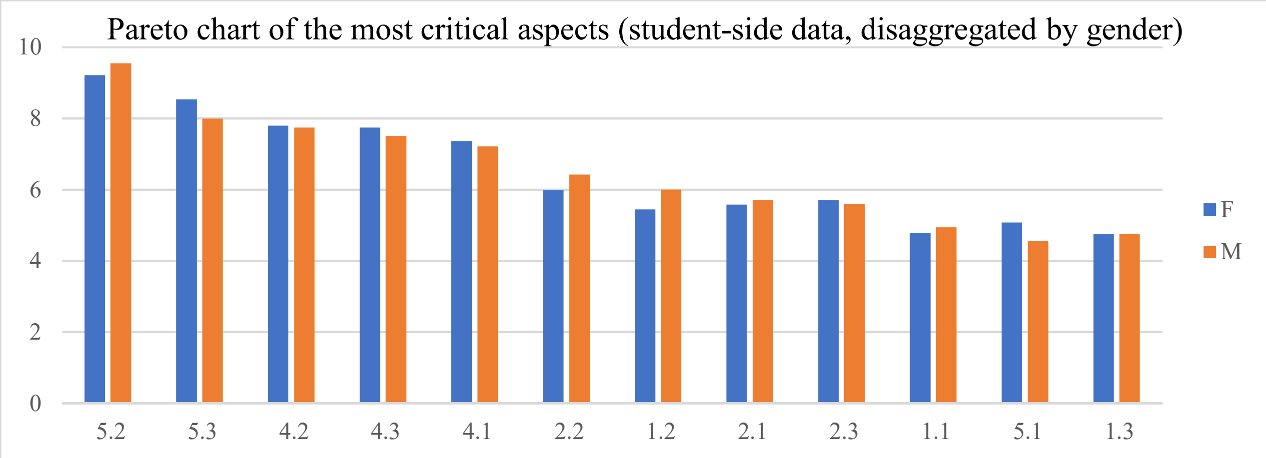


Figure 4 – Pareto chart relating to the summary data in Table 4, resulting from the analysis of the student-side (S) questionnaires.

CONCLUSIONS

This research was conducted under the EU-funded project REMOTE, exploring the most significant challenges currently facing online teaching and assessment, from the dual perspectives of students and lecturers. The initial phase of the analysis involved the design of two questionnaires to probe potentially critical aspects of remote learning and assessment, identified through an extensive review of the scientific literature. With the collaboration of all project partners (i.e., universities and agencies for quality assurance), these aspects were pinpointed, leading to the implementation of the questionnaire via the LimeSurvey online platform. Subsequently, questionnaires were distributed across the four European universities involved in the project. Respondent samples varied in size due to inevitable differences in the number of faculty and students and other contingent factors (e.g., possible incentives for completion, promotional activities, questionnaires issued during vacation periods, exam sessions, or other potentially challenging times for respondents, etc.). Nevertheless, an acceptable overall sample size was achieved, including more than five hundred students and nearly two hundred faculty members.

The analysis of the questionnaire results revealed that the most problematic aspects of online teaching and assessment for students include *sense of belonging to the university community* (5.2), *academic integrity* (5.3), *adequacy of evaluation feedback* (4.2), *quality of education* (4.3), and *adequacy of assessment methods* (4.1). On the other hand, the most critical issues for lecturers are *student-lecturer* *interaction* (2.2), *quality of education* (4.3), *preparation for managing evaluation* (3.2), and *academic integrity* (5.3). Interestingly, both students and lecturers identified *quality of education* (4.3) and *academic integrity* (5.3) as among the most critical aspects. However, discrepancies between the two groups were noted: students deemed *adequacy of evaluation feedback* (4.2) particularly relevant, whereas it was less critical for lecturers; conversely, *student-lecturer interaction* (2.2) was perceived as more critical by lecturers compared to students.

A relevant aspect of the analysis is the general agreement found among the partner universities involved in the questionnaires, which span diverse geographic and cultural realities; this lends a certain generality to the results obtained. Furthermore, a substantial absence of gender bias was observed in the questionnaire responses, both among students and lecturers. In addition, it is worth noting that the questionnaire ratings were transformed into corresponding ranks, which were then used as response variables; this approach prevented (i) inappropriate *promotions* of scale properties (from *ordinal* to *cardinal*), and (ii) questionable comparisons between respondents using somewhat heterogeneous rating scales (Franceschini et al., 2022).

Regarding the outcomes of this research, the debate will continue within the REMOTE project, involving experts and high-profile individuals from the academic world. It will also be interesting to consider the perspective of the agencies for quality assurance, to understand their interpretation of the results. The focus may also broaden to include collateral phenomena such as the rise of private online universities, which, often driven by opportunistic reasons, do not always provide educational services at the level of traditional universities, despite seeking accreditation for an increasing number of courses of questionable quality (Cunha et al., 2020).

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APPENDIX

Table A.1 – Student-side questionnaire, entitled "Challenges in remote learning: your experience as a student".

Dimension	Aspect/Construct	Item	Scale
1. Resource availability and accessibility	**1.1** Accessibility to materials	**1.1.1** How often do technical issues prevent you from accessing online teaching materials?	1 - Never … 7 - Always
		1.1.2 Assess the likelihood of facing challenges in accessing teaching materials due to compatibility issues with your devices or software.	1 - Very unlikely ... 7 - Very likely
		1.1.3 To what extent do the available teaching materials meet your diverse learning needs?	1 - Fully meets needs … 7 - Not at all
	1.2 Accessibility to evaluation resources	**1.2.1** How frequently do you encounter technical issues with software or platforms during online assessments?	1 - Never ... 7 - Always
		1.2.2 Rate the adequacy of the resources (like software, hardware) provided for conducting online evaluations.	1 - Fully adequate … 7 - Completely inadequate
		1.2.3 Assess the likelihood of encountering insufficient or outdated evaluation resources in future online assessments.	1 - Very unlikely ... 7 - Very likely
	1.3 Access equity	**1.3.1** How often do you perceive disparities in access to online learning resources among different student groups?	1 - Never ... 7 - Always
		1.3.2 Rate the extent to which you believe your own access to technological resources for online learning is equal to that of your peers.	1 - Completely equal … 7 - Not equal at all
		1.3.3 To what extent do you think the problem of the "digital divide" (e.g. unequal levels of Internet connectivity) hinders equal access to online education?	1 - Not at all … 7 - To a great extent
2. Technical responsiveness	**2.1** Connection and web platform adequacy	**2.1.1** Rate the reliability of the online platforms used for lectures and exams in terms of uptime and accessibility.	1 - Very reliable … 7 - Very unreliable
		2.1.2 How adequate do you find the user interface and overall user experience of the online learning platforms?	1 - Very adequate ... 7 - Very inadequate
		2.1.3 Evaluate the impact of technical issues on the online platforms on your overall learning experience.	1 - No impact ... 7 - Major impact
	2.2 Student-lecturer interaction	**2.2.1** How often do you experience difficulties in reaching out to lecturers for assistance in an online setting?	1 - Never ... 7 - Always
		2.2.2 Rate the effectiveness of the communication channels used for interacting with lecturers online.	1 - Very effective ... 7 - Very ineffective
		2.2.3 Evaluate how supported you feel by your lecturers in the online learning context.	1 - Fully supported … 7 - Not supported at all

Dimension	Aspect/Construct	Item	Scale
	2.3 Technical problem solving	**2.3.1** How frequently do you encounter technical issues that disrupt your participation in online classes or exams?	1 - Never ... 7 - Always
		2.3.2 Rate the effectiveness of the support provided when encountering technical issues during online learning.	1 - Very effective ... 7 - Very ineffective
		2.3.3 How often do technical issues remain unresolved for prolonged periods, affecting your learning experience?	1 - Never ... 7 - Always
4. Online assessment	**4.1** Adequacy of assessment methods	**4.1.1** Rate the level of fairness of the online assessment methods in comparison to traditional in-person exams.	1 - Just as fair … 7 - Much less fair
		4.1.2 How often do the online assessment methods fail to accurately evaluate your understanding of the course material?	1 - Never ... 7 - Always
		4.1.3 Rate the extent to which the online assessments encourage critical thinking and problem-solving skills.	1 - To a great extent … 7 - Not at all
	4.2 Adequacy of evaluation feedback	**4.2.1** Rate the timeliness of the feedback provided after completing online assessments.	1 - Very prompt … 7 - Extremely delayed
		4.2.2 Evaluate the extent to which feedback on online assessments helps you understand your mistakes and learn from them.	1 - Extremely helpful … 7 - Not helpful at all
		4.2.3 Rate the level of detail provided in the feedback for understanding your performance in online assessments.	1 - Highly detailed … 7 - Very superficial
	4.3 Quality of education	**4.3.1** Rate the effectiveness of the online course format in facilitating deep understanding of the subject matter.	1 - Highly effective … 7 - Not effective at all
		4.3.2 How often do you feel that online courses fail to provide the same level of education quality as in-person courses?	1 - Never ... 7 - Always
		4.3.3 Assess the adequacy of resources (like libraries, laboratories) available to you in an online learning format.	1 - Fully adequate … 7 - Completely inadequate
5. Social dynamics	**5.1** Gender diversity	**5.1.1** To what extent do you believe that online activities promote gender equality?	1 - To a great extent … 7 - Not at all
		5.1.2 Evaluate the extent to which gender biases affect the learning experience in your online courses.	1 - Not at all ... 7 - To a great extent
		5.1.3 How inclusive do you find the online learning environment in terms of gender representation?	1 - Very inclusive ... 7 - Not inclusive at all
	5.2 Community	**5.2.1** Rate the effectiveness of online platforms in facilitating a sense of community among students.	1 - Highly effective … 7 - Not effective at all
		5.2.2 Rate the sense of belonging to the university or academic community you experience in an online learning setting.	1 - Feel a strong sense of belonging … 7 - Do not feel a sense of belonging at all
		5.2.3 To what extent do you feel connected to your peers in the online learning environment?	1 - Very connected ... 7 - Not connected at all
	5.3 Academic integrity (honesty)	**5.3.1** How frequently do you encounter situations in online exams where academic integrity is compromised?	1 - Never ... 7 - Always

Dimension	Aspect/Construct	Item	Scale
		5.3.2 Assess the likelihood of students engaging in dishonest behaviors due to the perceived ease of cheating in online environments.	1 - Very unlikely ... 7 - Very likely
		5.3.3 Evaluate the extent to which you believe online exams maintain principles of ethical conduct (e.g., faireness, honesty, integrity, etc.).	1 - To a great extent … 7 - Not at all

Table A.2 – Lecturer-side questionnaire, entitled “Challenges in remote teaching and assessment: your experience as a faculty member”.

Dimension	Aspect/Construct	Item	Scale
1. Resource availability and accessibility	**1.2** Accessibility to evaluation resources	**1.2.1** How much do hardware/software limitations affect your ability to conduct effective online evaluations?	1 - Not at all ... 7 - Extremely
		1.2.2 How often do you have to compromise on evaluation quality due to resource accessibility issues?	1 - Never ... 7 - Always
		1.2.3 How adequate are the evaluation tools provided to you for assessing students online (e.g., Moodle, Google Classroom, Zoom, Survey Monkey, etc.)?	1 - Perfectly adequate … 7 - Completely inadequate
	1.3 Access equity	**1.3.1** Considering students' personal financial constraints, how fair do you find the availability/accessibility of digital tools and resources at your university, on campus?	1 - Very equitable … 7 - Not equitable at all
		1.3.2 How equitable do you believe the distribution of digital tools and resources is for students, when accessing them from outside your university (e.g., from home or other external locations)?	1 - Very equitable … 7 - Not equitable at all
		1.3.3 To what extent do you perceive a disparity in technological resource access among students, which affects their ability to participate in online learning?	1 - No perceived disparity ... 7 - Extreme perceived disparity
2. Technical responsiveness	**2.1** Connection and web platform adequacy	**2.1.1** How would you rate the quality of audio and video streaming on your current online platform?	1 - Excellent … 7 - Very poor
		2.1.2 How often do you find that the web platform's features limit the types of remote teaching/assessments you can perform?	1 - Never ... 7 - Always
		2.1.3 How frequently do you experience interruptions due to connectivity issues in online teaching?	1 - Never ... 7 - Always
	2.2 Student-lecturer interaction	**2.2.1** How would you rate the overall quality of interaction you have with students in an online teaching environment?	1 - Excellent … 7 - Very poor
		2.2.2 How often do you feel that the online platform hinders meaningful dialogue with students?	1 - Never ... 7 - Always
		2.2.3 How frequently do you encounter barriers to providing immediate feedback to students during online assessment?	1 - Never ... 7 - Always

Dimension	Aspect/Construct	Item	Scale
	2.3 Technical problem solving	**2.3.1** In instances of technical difficulties, how promptly do you receive support from the IT department?	1 - Very promptly … 7 - Not promptly at all
		2.3.2 How often do you encounter technical problems that disrupt online teaching or assessment?	1 - Never ... 7 - Always
		2.3.3 How effectively can you communicate technical issues to the relevant support team to get them resolved?	1 - Very effectively … 7 - Not effectively at all
3. Training	**3.1** Preparation and training for managing lectures	**3.1.1** How adequate do you find the provided training for conducting online lectures? (If no training was provided at all, answer "Completely inadequate")	1 - Very adequate … 7 - Completely inadequate
		3.1.2 How relevant do you find the training content to your actual teaching needs? (If no training was provided at all, answer "Not relevant")	1 - Highly relevant … 7 - Not relevant
		3.1.3 How much do you feel that the training enhances your effectiveness as an online lecturer? (If no training was provided at all, answer "Does not enhance")	1 - Greatly enhances … 7 - Does not enhance
	3.2 Preparation for managing the evaluation	**3.2.1** How effectively does the training prepare you for creating online assessment materials? (If no training was provided at all, answer "Not effectively at all")	1 - Very effectively … 7 - Not effectively at all
		3.2.2 How sufficient do you find the training for using online tools and technologies in assessments? (If no training was provided at all, answer "Insufficient")	1 - Very sufficient … 7 - Insufficient
		3.2.3 How relevant is the training content to the specific types of assessments you administer? (If no training was provided at all, answer "Not relevant")	1 - Highly relevant … 7 - Not relevant
	3.3 Institutional support to lecturers	**3.3.1** How responsive is the institution to your needs and challenges in online teaching?	1 - Very responsive ... 7 - Not responsive at all
		3.3.2 How effectively does the institution facilitate access to necessary online teaching resources?	1 - Very effectively ... 7 - Not effectively at all
		3.3.3 To what extent do you feel supported by the institution in developing your online teaching skills?	1 - Fully supported … 7 - Not supported at all
4. Online assessment	**4.1** Adequacy of assessment methods	**4.1.1** How effective do you find the current online assessment methods in accurately evaluating student knowledge?	1 - Very effective ... 7 - Not effective at all
		4.1.2 How confident are you in the reliability of the results obtained through online assessments?	1 - Very confident … 7 - Not confident at all
		4.1.3 How well do the assessment methods align with the learning objectives of your courses?	1 - Perfectly align … 7 - Do not align at all
	4.2 Adequacy of evaluation feedback	**4.2.1** How timely do you provide feedback to students following online assessments?	1 - Very timely … 7 - Extremely delayed
		4.2.2 How clear and understandable do you believe your feedback is to students?	1 - Very clear … 7 - Not clear at all

Dimension	Aspect/Construct	Item	Scale
		4.2.3 How effective is the feedback you provide in enhancing student learning and understanding?	1 - Very effective … 7 - Not effective at all
	4.3 Quality of education	**4.3.1** To what extent do you believe online teaching methods engage students as effectively as in-person methods?	1 - To a great extent … 7 - Not at all
		4.3.2 How effective do you find online activities in achieving the expected learning outcomes?	1 - Very effective … 7 - Not effective at all
		4.3.3 How adequate do you find the online course materials in covering the course curriculum comprehensively?	1 - Very adequate … 7 - Completely inadequate
5. Social dynamics	**5.1** Gender diversity	**5.1.1** How effective do you think online platforms are in fostering an environment of gender equality?	1 - Very effective … 7 - Not effective at all
		5.1.2 To what extent do you believe that online education addresses the specific needs and perspectives of all genders?	1 - Fully addresses … 7 - Does not address at all
		5.1.3 To what extent do you think online learning environments can contribute to reducing gender disparities in education?	1 - Greatly contribute … 7 - Do not contribute at all
	5.3 Academic integrity (honesty)	**5.3.1** How prevalent do you believe cheating or dishonest practices are in online assessments?	1 - Not prevalent ... 7 - Very prevalent
		5.3.2 How effective are the current measures implemented to ensure academic integrity in online exams?	1 - Very effective … 7 - Not effective at all
		5.3.3 How sufficient do you find the institutional policies and support in addressing academic integrity issues in online learning?	1 - Very sufficient … 7 - Insufficient

Quality of Bibliometric Databases: Accuracy in Classification of Document Types

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STRUCTURED ABSTRACT

Purpose: Scholarly publications are usually classified into *document types* (DTs), which are predefined categories outlining their nature (e.g., *research articles*, *conference proceedings*, *reviews*, *short notes*, *letters*, *book chapters*, etc.). This research presents a new semi-automated methodology to assess the accuracy of DT classification in bibliometric databases, such as Scopus and Web of Science (WoS). The methodology can handle a relatively large amount of documents (on the order of tens/hundreds of thousands) and is adaptable to the different classes of DTs covered by the databases in use, without requiring an *a priori* definition of a correspondence between their DTs.

Methodological approach: The first phase of the proposed methodology is automated and exploits discrepancies in DT classifications by two competing databases (e.g., Scopus and WoS), in order to identify a subset of potentially misclassified documents, i.e., with possible DT-classification errors. The second phase involves the manual analysis of this subset of documents, resulting in the identification and attribution of DT-classification errors. The novel methodology is illustrated through a realistic application example.

Findings: The methodology is shown to be effective in identifying DT-classification errors, suggesting a path to improve the quality and reliability of bibliometric databases. With reference to the application example provided, Scopus and WoS have overall error rates around 1.7% and 1.2%, respectively. A similar analysis based on a larger sample of documents is still in progress.

Practical/social implications: By improving database accuracy, the academic community can benefit from more reliable bibliometric indicators, which can affect (at least to some extent) research funding, decision making and academic reputation.

Keywords: Bibliometric databases, Document type, Semi-automated analysis, Database accuracy.

Paper type: Research paper

INTRODUCTION

Scientific publications are typically categorized into *document types* (DTs), i.e., predefined categories that outline their nature and primary characteristics (Harzing, 2013; Yeung, 2021). Common DTs include *research articles*, *conference proceedings*, *surveys*, *letters*, *book chapters*, etc. The classification of publications into significant DTs is a task performed by the publishers and/or bibliometric databases indexing them, so as to serve multiple purposes (Donner, 2017). Firstly, it contributes to the organisation of knowledge, aiding researchers in efficiently selecting and retrieving relevant information. Additionally, it plays a crucial role in research evaluation, differentiating scientific contributions for the construction of bibliometric indicators and assessments, e.g., DTs that are usually subject to less scrutiny during acceptance, such as *conference proceedings*, *short notes* and *letters*, may be excluded from some evaluations. Furthermore, most bibliometric indicators relating to scientific journals, like the well-known *impact factor*, are constructed by considering the DT of indexed documents (García-Pérez, 2010).

Unfortunately, DT classification is not always accurate, leading to instances where scientific contributions are mislabelled. The literature documents common mislabelling scenarios, such as misclassifying *research articles* as *reviews*, *letters* and *conference proceedings* as *research articles*, which indicates that some types of errors tend to be more frequent than others (Sigogneau, 2000; Yeung, 2019; Mokhnacheva, 2023). The misclassification of DTs can be somewhat fed by the absence of standardized rules, which results in subjectivity. The distinction between a *research article*, a *review*, or a *short note*, for example, can be quite subtle. Moreover, the DT-classification rules used by both bibliometric databases and publishers are not completely transparent, nor the metadata they exchange. Furthermore, there are quite often discrepancies in the nomenclature and definitions of DTs between different publishers and databases. These discrepancies become evident when comparing the official DT lists from major generalist databases, like Scopus and Web of Science (WoS) (Clarivate, 2024; Elsevier, 2024).

Relatively few studies on DT-classification errors are documented in the literature, forming a part of the broader category of research on errors in bibliometric databases (Donner, 2023; Franceschini et al., 2013; 2015; 2016; García-Pérez, 2010; Moed, 2005; Olensky et al., 2016; Valderrama-Zurián et al., 2015). These studies indicate that DT-classification errors are significant for both Scopus and WoS, amounting to a few percentage points (Yeung, 2021). It was also noted that specialized databases – like PubMed in the medical field – tend to have fewer errors compared to generalist databases such as Scopus and WoS, possibly due to a smaller and more homogenous set of indexed documents (Yeung, 2019). The few existing studies on DT-classification errors unfortunately have (at least) a couple of limitations. First, they generally limit the investigation to relatively small samples of a few hundred or thousand documents. In addition, they only involve manual analysis of the documents of interest.

This research introduces a novel semi-automated methodology to investigate DT-classification errors on large quantities of documents. The methodology includes an initial phase to determine a relatively large *corpus* of publications, simultaneously indexed by the (competing) generalist Scopus and WoS databases. Having determined the DTs assigned by the aforementioned databases to each publication, a subset of publications with potentially inconsistent/discordant DTs is determined. Manual analysis of this subset is then performed, identifying any DT-classification errors and attributing them to the responsible database. The new methodology, which can be classified as "adaptive" since it requires no *a priori* correspondence between the DTs covered by one database and those covered by the other, is described through an application example.

NEW METODOLOGY

The following pseudo-code summarizes the basic steps of the new methodology for identifying DT-classification errors, which is described in detail in the rest of the section.

Start

1. **Identify a *corpus* of scientific publications.** Use specific criteria to select a relatively broad group of scientific publications (e.g., scientific output from research groups, institutions, scientific journals, etc., within a certain time window).
2. **Query Scopus and WoS.** Conduct separate queries in the Scopus and WoS databases using criteria that define the *corpus* of publications at step (1).
3. **Determine the "intersection" of publications indexed by both databases.** Using suitable unique identifiers (e.g., DOI code), identify the subset of publications resulting from the queries in step (2), indexed in both databases.
4. **Determine the DTs for each publication at step (3), according to both Scopus and WoS.** For each publication in the intersection subset, identify the DTs classified by Scopus and WoS respectively.
5. **Construct the concordance matrix.** Create a so-called *concordance matrix* (described later) to compare the DTs assigned by the two databases of interest. Arrange the relevant DTs (in columns for Scopus and in rows for WoS), in order to maximize the amount of (concordant) publications in the diagonal.

6. **Identify publications with discordant DTs.** Focus on the scientific publications outside the diagonal of the concordance matrix, as their DT-classifications are potentially discordant.
   6.1 *Manual analysis.* Manually analyse each discordant publication and identify the most plausible DT for it (i.e., the "true" DT).
   6.2 *Determine a DT-classification error for Scopus or WoS.* Determine which of the two databases is responsible for the (presumed) DT-classification error and record it.
   6.3 *Return to step (6.1).* Repeat the manual analysis until all publications with discordant DTs have been analysed.
7. **Determine error statistics.** Process the results of the analysis and construct database-error statistics.
   7.1 *Consider each specific database separately and report the relevant DT-classification errors in a so-called error table (described later).*
   7.2 *Determine different kinds of error statistics*, both from the overall perspective of a database of interest (ε) and from the perspective of a specific DT (contemplated by the database itself), i.e., calculate the rate of *false exclusions* (α) and the rate of *false classifications* (β) related to that DT.
   7.3 *Return to step (7.1).* Repeat the calculation of error statistics for the other database.

End

First, it is necessary to identify a relatively large sample of scholarly publications (*step 1*). By way of example, let us assume that the governing bodies of the two major universities in Turin (Italy) – Politecnico di Torino (a technical university of engineering and architecture) and Università di Torino (a generalist university) – have decided to undertake a campaign to verify the accuracy of the data reported in the Scopus and WoS databases, in anticipation of a forthcoming national evaluation exercise of the scientific output produced in 2019-2023. To this end, the publications produced in the five-year period of interest by the more than two thousand researchers affiliated with the two universities are considered. Then, both Scopus and WoS databases are queried (*step 2*) to extract data on the publications of interest (e.g., using co-author affiliation and issue years). This yields two sets of publications: one returned by Scopus and one returned by WoS. About 34 thousand articles were obtained from Scopus and 38 thousand from WoS. Let us note that the two sets are not of identical size because the two databases differ in terms of source coverage (e.g., one database may index some journals or conference proceedings that are not necessarily indexed by the other database and *vice versa*).

The "intersection" (*step 3*) between the above two sets, i.e., the subset of common documents, is then determined. The identification of these common documents can be accomplished using the relevant *digital object identifier* (or DOI code); therefore, documents without a DOI code are necessarily excluded from the analysis. In the application example, we restricted the analysis to the DTs of *research article* (or more simply *article*), *conference proceeding*, *letter*, and *review*, neglecting for simplicity the other DTs (e.g., *book chapters*, *monographs*, etc.). Returning to the application example, cross-referencing the two sets of documents returned by Scopus and WoS yields an intersection subset, consisting of 26,405 total documents, classified by each database into corresponding DTs, as shown in Table 1.

Table 1 – Summary of DTs classified by Scopus and WoS with reference to the "intersection" subset, in the application example.

Scopus DTs		WoS DTs	
Article	21,793	*Article*	21,800
Review	2,445	*Review*	2,472
Conference paper	1,810	*Proceedings paper*	1,756
Letter	357	*Letter*	377
Total	**26,405**	**Total**	**26,405**

In this case the DT labels of the two databases are coincident, except for *conference paper*, as contemplated by Scopus, and *proceedings paper*, as contemplated by WoS[1]. The amounts of articles classified in the DTs of the two databases are very close, although the differences indicate possible discrepancies in the classification of the DTs, as better evidenced in the so-called concordance matrix (step 5). This matrix (exemplified in Table 2) is nothing more than a contingency table showing in column the DTs assigned by Scopus and in row the DTs assigned by WoS for the publications of interest. The rows and columns are sorted in such a way that the row totals and column totals are both sorted in descending order. In this way the matrix is *diagonal*, that is, with most of the papers placed on the main diagonal. At the same time, this sort of diagonalization establishes an empirical correspondence between the DTs covered by one and the other database. This correspondence can be called "adaptive" in that it does not require any *a priori* link between Scopus and WoS DTs (Owen, 2001). In other words, among the possible permutations between Scopus and WoS DTs, the proposed diagonalization ensures the highest degree of concordance. Off-diagonal elements indicate discordant DT classifications, denoting potential errors by (at least) one database. For this reason, these elements can be classified as "discordant" (and by extension the documents involved in them).

[1] In fact, expanding the study to other more specialized DTs, the differences between the databases would be more pronounced. For example, DTs covered by one database but not the other, such as *biographical-item*, *book review*, *expression of concern*, *fiction*, *meeting abstract*, *retraction*, *data paper*, and many others, can be observed (Clarivate, 2024; Elsevier, 2024).

Table 2 – Example of *concordance matrix* related to data collected for the application example. While the elements in the diagonal (in square brackets) denote DT classifications that are concordant between competing databases, those off-diagonal denote possible DT-classification errors.

DT classifications →		by Scopus				
↓		*Article*	*Review*	*Confer. paper*	*Letter*	**Row total**
by WoS	*Article*	[21,418]	297	71	14	**21,800**
	Review	323	[2,146]	2	1	**2,472**
	Proceed. paper	19		[1,737]	-	**1,756**
	Letter	33	2	-	[342]	**377**
	Column total	**21,793**	**2,445**	**1,810**	**357**	**26,405**

Manual analysis of each of the discordant publications (sub-step 6.1) is performed using all available information, such as abstract, data on the publisher's site, "fulltext", etc. This analysis is aimed at identifying the "true" DT and, consequently, detect the possible DT-classification error of the databases. Figure 1 exemplifies the heading of a paper classified by Scopus as a *conference paper* and by WoS as an *article*. Manual analysis revealed that the "true" DT is *article*, since the paper is a (complete) research contribution unrelated to any conference. The DT classification error is therefore attributed to Scopus in this case.


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Decision Support

On the usefulness of soft OR models in decision making: A comparison of Problem Structuring Methods supported and self-organized workshops

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ABSTRACT

Applications of Problem Structuring Methods (PSMs) are extensively reported in the literature; however, their evaluation remains challenging. Moreover, scholars' disagreement on how to evaluate and compare PSMs constrains research that seeks to show whether certain PSMs are more useful than others within particular contexts and 'better than doing nothing'. Drawing on scholars' suggestion to evaluate PSMs through a link between action, outcomes and context, we address this gap by adopting an exploratory, quasi-experimental research design with MSc students to evaluate and compare three workshops supported by the use of (i) Strategic Choice Approach, (ii) Soft Systems Methodology and (iii) a non-PSM supported approach, and report on the findings of a quantitative and qualitative analysis. We explore the *usefulness* of PSMs for achieving outcomes that can support decision making. Our findings show variation in the usefulness of the three approaches and the different workshop outcomes.

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Figure 1 – Example of document misclassified by Scopus as *conference paper* instead of *article* (https://doi.org/10.1016/j.ejor.2018.12.016).


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Biological control of invasive stink bugs: review of global state and future prospects

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Key words: biocontrol, chemical ecology, Hemiptera, invasive species, landscape management, pre-emptive classical biological control, semiochemicals, parasitoid, Pentatomidae, risk assessment, Tachinidae, Scelionidae

Abstract

Invasive stink bugs (Hemiptera: Pentatomidae) are responsible for high economic losses to agriculture on a global scale. The most important species, dating from recent to old invasions, include *Bagrada hilaris* (Burmeister), *Halyomorpha halys* (Stål), *Piezodorus guildinii* (Westwood), *Nezara viridula* (L.), and *Murgantia histrionica* (Hahn). *Bagrada hilaris*, *H. halys*, and *N. viridula* are now almost globally distributed. Biological control of these pests faces a complex set of challenges that must be addressed to maintain pest populations below the economic injury level. Several case studies of classical and conservation biological control of invasive stink bugs are reported here. The most common parasitoids in their geographical area of origin are egg parasitoids (Hymenoptera: Scelionidae, Encyrtidae, and Eupelmidae). Additionally, native parasitoids of adult stink bugs (Diptera: Tachinidae) have in some cases adapted to the novel hosts in the invaded area and native predators are known to prey on the various instars. Improving the efficacy of biocontrol agents is possible through conservation biological control techniques and exploitation of their chemical ecology. Moreover, integration of biological control with other techniques, such as behavioural manipulation of adult stink bugs and plant resistance, may be a sustainable pest control method within organic farming and integrated pest management programs. However, additional field studies are needed to verify the efficacy of these novel methods and transfer them from research to application.

Figure 2 – Example of a paper incorrectly classified by Scopus as an *article* and by WoS as a *review*, instead of *conference/proceedings paper* (https://doi.org/10.1111/eea.12967).

Very rarely, simultaneous errors of both databases can be observed. As an example, let us consider the document in Figure 2, classified by Scopus as an *article* and by WoS as a *review*. Manual analysis found that this document is in fact a *conference paper* on a journal special issue, resulting in an error for both databases. Probably the Scopus classification error (i.e., *article* instead of *conference paper*) stems from the fact that this *conference paper* is published in a journal special issue. On the other hand, the WoS error (i.e., *review* instead of *proceedings paper*) stems from the fact that the word "review" is used both in the title and within the conclusions to say that the paper actually reviews more than a century of research on the biological control of invasive stink bugs. Additionally, an extensive reference list is presented (more than 200 references).

For the diagonal elements (in square brackets), the DT classifications in both databases are automatically assumed to be correct, given the general agreement between the counterpart databases. To test the plausibility of this assumption, a sampling of 0.5 percent of these concordant documents (i.e., $\lceil 0.5\% \cdot 25{,}643 \rceil = 129$) was conducted, without detecting any DT-classification error. This confirms the plausibility of the hypothesis of validity of DT assignments for these publications, in line with the concepts of *convergent validity*, and *wisdom of crowds* (Franceschini et al., 2022).

Having completed the manual analysis of the discordant documents (cf. step 6 and relevant sub-steps), the DT-classification errors found for each database are summarized in an *error table*, i.e., a contingency table illustrating in the columns the DT assignments made by the database of interest and in the rows the "true" (or correct) DTs resulting from the manual analysis. In practice, the main diagonal of the error table contains the correct DT classifications while the off-diagonal elements correspond to the incorrect DT classifications. Tables 3 and 4 show the error tables related to Scopus and WoS, with reference to the application example. Let us note that for a small portion of the DT-classification errors, the "true" DT is *other DTs*, which is different from the four DTs considered in this simplified study. In fact, this DT class includes all other DTs not covered in this study (e.g., *book review*, *note*, *short survey*, etc.). For example, Figure 3 exemplifies a publication in the field of forensic psychiatry, containing a brief report of a clinical case with some references to existing literature on the subject. The contribution lacks the consistency and originality to be considered a (research) *article*, nor does it provide a sufficiently thorough review of the state of the art to be considered a *review*. Unsurprisingly, it is classified by the journal as a *case report*. This publication is misclassified by Scopus as an *article* and by WoS as a *review*, whereas our manual analysis showed that the most plausible Scopus and WoS DTs would respectively be *note* and *other*, which would converge in the class *other DTs* in the present simplified analysis (Clarivate, 2024; Elsevier, 2024). Furthermore, it was noted that Scopus tends to classify *case-report* publications as *articles*, whereas WoS tends to classify them as *reviews*, resulting in a systematic classification error.

Table 3 – Example of *error table* for Scopus, with reference to the application example. Error statistics (see Eqs. 1, 2, and 3) are bolded.

		DT classification by Scopus					
		Article	*Review*	*Confer. paper*	*Letter*	Row total	$\alpha_{\text{Scopus}, DT}$
"True" DT classification	*Article*	[21,503]	102	53		21,658	**0.7%**
	Review	233	[2,331]			2,564	**9.1%**
	Confer. paper	20	5	[1,757]		1,782	**1.4%**
	Letter	30	2		[357]	389	**8.2%**
	Other DT(s)	7	5			12	-
	Column total	21,793	2,445	1,810	357	26,405	
	$\beta_{\text{Scopus}, DT}$	**1.3%**	**4.7%**	**2.9%**	**0.0%**		$\varepsilon_{\text{Scopus}} \cong 1.7\%$

Table 4 – Example of *error table* for WoS, with reference to the application example. Error statistics (see Eqs. 1, 2, and 3) are bolded.

		DT classification by WoS					
		Article	*Review*	*Confer. paper*	*Letter*	Row total	$\alpha_{\text{WoS}, DT}$
"True" DT classification	*Article*	[21,584]	75		3	21,662	**0.4%**
	Review	176	[2,386]			2,562	**6.9%**
	Proc. paper	23	3	[1,756]		1,782	**1.5%**
	Letter	16	1		[374]	391	**4.3%**
	Other DT(s)	5	7			12	-
	Column total	21,804	2,472	1,756	377	26,405	
	$\beta_{\text{WoS}, DT}$	**1.0%**	**3.5%**	**0.0%**	**0.8%**		$\varepsilon_{\text{WoS}} \cong 1.2\%$

Next, some indicators depicting database errors are constructed. An overall indicator of the DT-classification errors by a certain database (ε_{db}) is expressed by the ratio of the total number of off-diagonal elements (i.e., depicting erroneous DT classifications resulting from manual analysis) to all elements in the *error table* (i.e., the total number of DT classifications):

$$\varepsilon_{db} = \frac{\sum_{\forall(i,j)\,|\,i\neq j} d_{db,(i,j)}}{\sum_{\forall(i,j)} d_{db,(i,j)}}, \tag{1}$$

being $d_{db,(i,j)}$ the number of documents reported in the *i*-th row and *j*-th column of the error table, for the database of interest (*db*).

The ε_{db} values resulting from the analysis, also shown in the lower right vertex of the error tables, are $\varepsilon_{\text{Scopus}} \cong 1.7\%$ and $\varepsilon_{\text{WoS}} \cong 1.2\%$. Although aware that these results are difficult to generalize as they relate to a rather small sample of documents, it is interesting to note some general trends. First, the ε_{db} values are very close for the two databases, denoting a slightly higher error rate for Scopus with respect to WoS. In both cases, the most frequent DT-classification errors involve *reviews* misclassified as *articles* and *vice versa*. *Letters* misclassified as *articles* are also fairly frequent for both databases. In addition, while Scopus has an erroneously categorized some *articles* as *conference papers* (cf. the example in Figure 1), WoS did not incur this error.


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CASE REPORT

Check for updates

The risk of assault against mental health professionals: a fatal case report and literature review

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Abstract
Assaults by patients against healthcare providers are an increasing phenomenon worldwide. Mental health professionals in acute facilities and rehabilitation wards have the highest risk of being attacked at work. Verbal abuse or intimidating behaviors represent the most common types of violence. Fatal assault by psychiatric patients has been rarely reported in the literature. We present a case of a female psychiatrist who was fatally stabbed in her office in a Mental Health Center. At autopsy seventy stab wounds were found: four wounds of the neck, fifty penetrating wounds of the thorax, three wounds of the abdomen, six wounds of the lumbar region, and seven wounds of the upper arms including defense injuries. The cause of death was massive blood loss due to multiple stab wounds. The perpetrator was a 44-year-old male patient who had been referred to the victim after a previous admission to hospital following experiences of suicidal ideation and confusion. The extreme and unmotivated violence in a non-acute setting were notable. A borderline-antisocial personality disorder was later diagnosed by forensic experts. This case emphasizes the significant occupational risk for mental healthcare staff to sustain life threatening injuries or death, with implications for training of clinicians, and strategies for preventing aggressive behaviors.

Keywords Workplace violence · Psychiatry · Violence · Stab wounds

Figure 3 – Example of a paper incorrectly classified by Scopus as an *article* and by WoS as a *review* (https://doi.org/10.1007/s12024-019-00105-6). The article is actually defined by the publisher (Springer Nature) as a *case report* in the field of forensic psychiatry. Manual analysis revealed that the most plausible DT for Scopus would be *note* and for WoS would be *other* (Clarivate, 2024; Elsevier, 2024).

Next, other more detailed database-error statistics can be constructed from the perspective of individual DTs. In this regard, a *null hypothesis* (H_0) is defined as: "*The DT assigned by the database in use is correct*". Next, two DT-related error types are defined, as described below.

1. The *Type-I error* corresponds to the probability of wrongly rejecting H_0 when it is true, i.e. the probability of a document belonging to a specific DT being wrongly classified into another DT (i.e., *false exclusion from the DT of interest*):

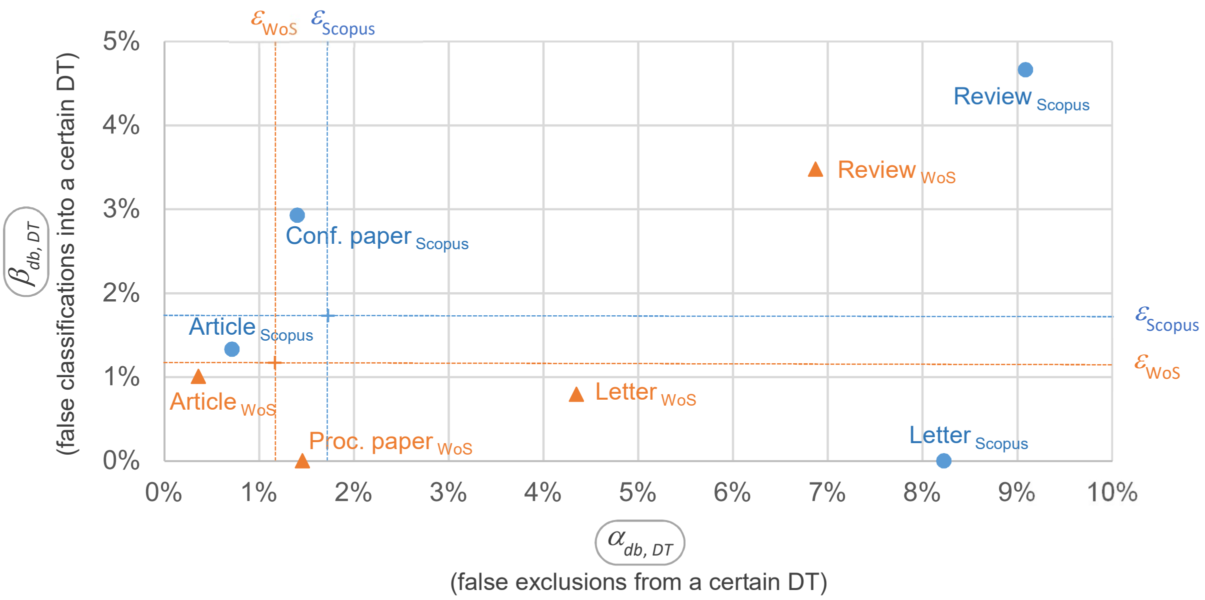
$$\alpha_{db,\,DT} = \frac{\sum_{\forall j \mid j \neq DT} d_{db,\,(DT,j)}}{\sum_{\forall j} d_{db,\,(DT,j)}}, \tag{2}$$

   DT being the DT of interest for the database (*db*) in use. $\alpha_{db,\,DT}$ is actually calculated on a row-by-row basis by means of the ratio of misclassifications (i.e., false exclusions from the DT of interest) to the row total.

2. The *Type-II error* corresponds to the probability of failing to reject H_0 when it is false, i.e. the probability of misclassifying a document into a specific DT of interest (i.e., *false classification into the DT of interest*):

$$\beta_{db,\,DT} = \frac{\sum_{\forall i \mid i \neq DT} d_{db,\,(i,\,DT)}}{\sum_{\forall i} d_{db,\,(i,\,DT)}}, \tag{3}$$

$\beta_{db,\,DT}$ is actually calculated on a column-by-column basis by means of the ratio of misclassifications (i.e., false classifications into the DT of interest) to the column total. Interestingly, the same element ($d_{db,\,(i,j)}$) in the error table contributes to both of these two types of error. With reference to the application example, the values of $\alpha_{db,\,DT}$ and $\beta_{db,\,DT}$ are reported respectively in the right and lower parts of the corresponding error tables (Tables 3 and 4). Again, some similarity is observed between the results obtained for the two databases. The map in Figure 4 provides a graphical representation of the above error statistics. The dashed lines represent $\varepsilon_{\text{Scopus}}$ and ε_{WoS} values, which can be read on both



the horizontal and vertical axes. In addition, for each of the DTs covered by a certain database, a corresponding point of coordinates ($\alpha_{db,\,DT}$, $\beta_{db,\,DT}$) is plotted.

Figure 4 – Map of error statistics, referring to the application example.

CONCLUSIONS

This paper proposed a new methodology for semi-automated analysis of a relatively large amount of scientific publications, which is useful in identifying DT-classification errors in the Scopus and WoS databases. Taking advantage of the discordance in DT classification between the two databases, the proposed methodology directly targets a subset of potentially misclassified documents for manual analysis. In the application example provided, against a total *corpus* of 26,405 documents in both databases, only the 762 off-diagonal documents in the concordance matrix – corresponding to about 2.9% of the total – were manually analysed. Additionally, 0.5% of the 25,643 diagonal documents (i.e., 129) were analysed randomly, finding no DT-assignment error and confirming the plausibility of the working hypothesis that concordant DT classifications are unlikely to be erroneous.

This methodology could be used by individual scientists, institutions and even database managers to detect (and correct) DT-classification errors relatively quickly. Having license to use both databases, the novel methodology can be simply implemented using spreadsheets and/or pivot tables. In the future, the possibility of assisting the time-consuming manual analysis with AI-based techniques will be explored. In addition, a similar investigation based on a larger sample of publications is underway to determine more representative results of DT-classification errors from the two databases under consideration.

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The use of Quality Tools to support a SMED implementation

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STRUCTURED ABSTRACT

Purpose - This work discusses a SMED implementation carried out in the assembly department of a sanitary components' factory, located in Aveiro, Portugal, with the support of quality tools. The case study focused on the process of changing production codes, for cistern structures manufacturing cells.

Methodology – The first step of the study was the development of a SIPOC diagram to represent the production process. The next step was to identify the tasks required by the setup, whenever a new production order starts. The data needed to define and analyze the initial state of the setup was collected on the shop floor, which helped to identify problems and opportunities for improvement. The relevance and causes of the problems were explored using quality tools such as a Pareto Chart and an Ishikawa Diagram, and then improvement actions were proposed and implemented. To standardize the setup, a procedure was defined, which required the use of additional quality tools, namely 5Whys, 5S and *Kamishibai*.

Findings - The implementation of these actions resulted in an 18% reduction in the average time of the setup. There is also a positive balance in terms of the standardization of processes and the maintenance of tools and equipment, which are crucial in ensuring that no waiting and no inappropriate or extraneous activities occur during setup.

Originality/value - This work showed how quality tools can be integrated in a SMED process, assisting in identifying improvement opportunities and in involving workers in the process, which leads to more lasting results.

Keywords: SMED, Quality Tools, Continuous Improvement.

Paper type: Case Study

INTRODUCTION

The case study described in this work focused on the application of SMED to the process of changing production codes within the in-wall cistern structures manufacturing cells, that are part of the assembly department of a sanitary components' factory, located in Aveiro, Portugal. The use of SMED was supported by several quality tools, such as Pareto Diagrams, Ishikawa Diagrams, SIPOC and 5 Whys, in order to identify the major wastes and, subsequently, the improvement opportunities in the setup process.

For the company, the need for this work derived from the market they operate in, where customer needs are constantly changing and increasingly diverse. An effective strategy to overcome this situation is to customize the products according to the specificities of each customer, so this company tries to present different solutions with unique characteristics for the particular needs of each client.

In this context, the company needs to increase its production capacity as well as its agility, considering the greater variability of products, the greater the number of setups to be carried out. Thus, one of the options to provide companies with the necessary flexibility to respond to the demand for more diverse products is to reduce setup times, thus allowing them to be carried out more often and reduce their impact on productivity (Yash & Nagendra, 2012).

A setup corresponds to the set of tasks necessary to configure and prepare a given production system for the manufacture of a different product (Silva et al., 2020), and thus setup time is defined as the time elapsed from the time the machine finishes the last good product of a given production order (PO) until the first OK product of the next PO is obtained (Lopes et al., 2015; Silva et al., 2020).

When it comes to reducing setup times, the most referenced methodology is SMED (Single Minute Exchange of Die). SMED was created in the 1950s by Shigeo Shingo and makes it possible for a setup to take less than 10 minutes (Shingo, 1985). Although it is not always feasible to reduce the time so as to achieve this target, the success of this method has been proven in several application areas over the years (Bhade & Hegde, 2020; Ribeiro et al., 2019).

According to Shingo (1985) there are 4 stages in the SMED implementation process: Stage 0: the setup time is not separated into internal setup (operations that involve the equipment stoppage) and external setup (operations that can be performed without interrupting production); Stage 1: the separation between internal and external setup is made; Stage 2: the aim is to convert internal setups into external setups; Steg 3: simplify all setup tasks (internal and external).

Throughout these stages, it is necessary to consider several factors that can contribute to the success of the implementation of the SMED, which are explained in several studies such as Ribeiro et al., 2022; Otero & Lopes, 2018; Simões & Tenera, 2010; Parwani & Hu, 2021; Lopes et al., 2015.

These same studies refer various benefits of implementing SMED such as: reduction of setup times to up to 70 to 90%, increase in equipment utilization rates, increase in the capacity of bottleneck processes, increase in production flexibility which allows the reduction of batch sizes and improvement of the production flow, reduction of lead time, reduction of stocks and associated costs, and improvement of safety conditions.

Thus, SMED was the methodology used for analyzing and solving the problem identified in the company, which motivated the application of several quality tools, that are briefly described below.

Pareto analysis is a statistical technique used to decide where to focus attention and improvement efforts based on the selection of a limited number of factors or causes that have a substantial overall effect (Ahmad et al., 2018; Ahmed & Rezouki, 2020). This is known as the Pareto principle or as the 80:20 rule (Ahmad et al., 2018; Jana & Tiwari, 2021; Kent, 2016), that states that 80% of outcomes are controlled or determined by 20% of activities or factors (Jana & Tiwari, 2021). The Pareto chart is a bar graph where the factors being studied are represented, in descending order of incidence (e.g. costs, number of defects, number of complaints, number of equipment stoppages).

Another tool used was the Ishikawa Diagram (Ahmed & Rezouki, 2020; Doggett, 2005), which allows for a structured approach to finding the possible root causes of a problem (Ahmed & Rezouki, 2020; Barsalou, 2023). These diagrams are designed to illustrate the potential factors that may contribute to a problem, categorizing them and organizing causal relationships between them (Ahmed & Rezouki, 2020; Doggett, 2005).

A tool that is also frequently used, specifically in brainstorming contexts, and that helps to find the root cause of a given problem, is the 5 Whys, which consists of successively asking "Why?" (Ahmed & Rezouki, 2020; Vijay & Prabha, 2021). The goal is to ask "Why" a sufficient number of times to go through the symptoms or effects of a problem until its true root cause is reached (Ahmed & Rezouki, 2020; Braglia et al., 2017). Vijay & Prabha (2021) argue that this technique is accepted and successfully practiced in various sectors, such as health, safety, environment, reliability, quality, and production. In this work, this tool is effectively integrated into the SMED methodology, specifically in its stage 3.

The 5S were developed in Japan by Sakichi Toyoda, Kishiro Toyoda and Taiichi Ohno in the 1960's (Oliveira et al., 2017) and consists of a method to organize the workplace through the improvement of the layout, the integration of visual management and the standardization of work (Rodrigues et al., 2020), and it can be applied to any type of business or operation (Lopes et al., 2015). The 5S designation derives from five Japanese words that correspond to the 5 sequential steps of this tool: *Seiri* (Sort), *Seiton* (Set in order), *Seiso* (Shine), *Seiketsu* (Standardize), *Shitsuke* (Sustain) (MĺKva et al., 2016; Oliveira et al., 2017; Lopes et al., 2015). Although simple in theory, the practical application of the 5S can be challenging, as its success is determined by the involvement of employees, through the change of their habits and behaviors, as well as the commitment of management (Lopes et al., 2015).

Finally, in a production context, *Kamishibai* refers to a visual management system that uses cards to systematically review and control certain critical points in a process, usually related to evaluation metrics such as safety, quality, productivity, or costs (Knop & Ulewicz, 2018; Niederstadt, 2018). According to Niederstadt (2018), when a tool is implemented and is not sustained, it will eventually have to be reimplemented. A way to avoid this waste is by auditing, using tools such as *Kamishibai* that help to create, support and sustain the implemented processes and their stability (Niederstadt, 2018). Its implementation involves the creation of *Kamishibai* cards that are placed on a *Kamishibai* board and that visually indicate, through a color system, what has been evaluated positively (green) or negatively (red). Both the cards and the board can have different structures and modes of execution (Knop & Ulewicz, 2018). They can include daily, weekly, monthly, semi-annual, or annual tasks; safety, quality, 5S's, standardized work, etc (Niederstadt, 2018).

In the following sections the methodology and the results of the case study are presented.

RESEARCH METODOLOGHY

The application of the SMED methodology involved four main steps, namely:

1. Analysis and diagnosis of the initial state, in order to identify its main problems and opportunities for improvement;
2. Analysis of the causes of the identified problems;
3. Planning and implementation of improvement actions to eliminate or reduce the problems;
4. Standardize and control the processes through the creation and updating of standards.

In the first step of the study a SIPOC diagram to represent the production process in the manufacturing cells was developed. Next the tasks required by the setup, that occurs whenever a new work order starts, were identified. It should be noticed that, in this case, the setup process involves the same two workers assigned to the production tasks.

The data needed to define and analyze the initial state of the process was collected directly on the shop floor, through informal interviews with the workers and the team leader, and through the recording of 10 setups. It was then possible to identify and understand all the tasks performed during the setup, obtain the time that each one takes and also identify problems and opportunities for improvement.

The next step involved developing a Pareto Chart to identify the tasks that presented greater opportunities for improvement, in terms of time reduction.

In addition to a statistical analysis of the quantitative data collected, several brainstorming meetings were used that resulted in an Ishikawa Diagram regarding the causes that could be at the origin of the problems identified.

Once these causes were analyzed, the third step was initialized and improvement actions were planned, proposed and implemented.

Finally, in order to standardize the setup, a procedure was defined, and training was given to the workers and team leaders of the three shifts (each worker was accompanied a total of eight times, four times at each workstation).

During the standardization phase, it was again necessary to employ quality tools, namely the 5 Whys, the 5S and the *Kamishibai*.

RESULTS

The company where this work was developed is dedicated to the design, industrialization, production and marketing of sanitary solutions with a focus on the production of indoor and outdoor cisterns and flushing mechanisms, and exports to more than 80 countries in the world.

The company's general production process is shown in Figure 1.

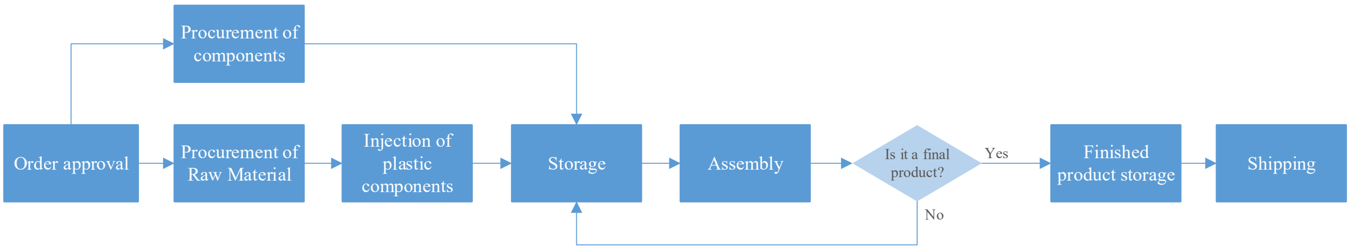


Figure 1 – Production process of the company.

The manufacturing process starts with the customer's order. After its approval, the procurement of raw materials follows, as well as the procurement of any other necessary components from external suppliers.

This is followed by the transformation of the raw materials through an injection molding process, that takes place in two departments.

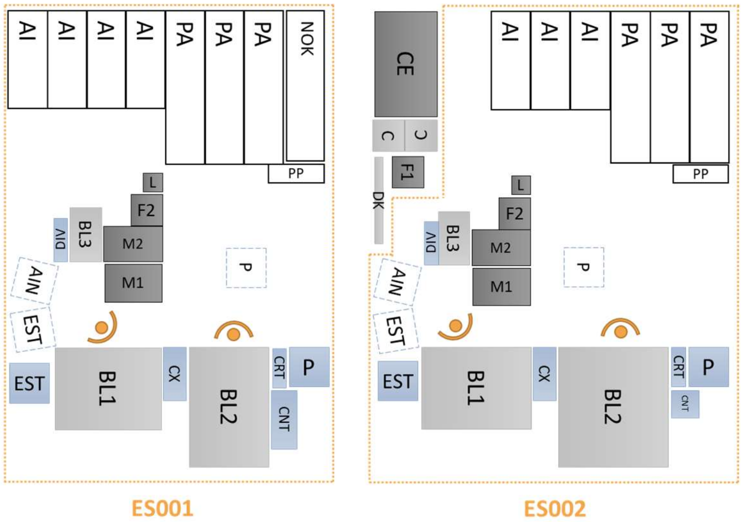
The next step is entirely the responsibility of the Assembly Department and consists of assembling the injected and purchased components. The assembly may result in intermediate codes that will serve as input to other work centers of the Assembly Department, or finished product. In the case of a finished product, it goes to the respective warehouse and is then shipped to the customer or transported to logistics centers.

The Assembly Department has about 250 employees divided among areas: Exterior, Interior, Mechanisms, Plates, Taps and Twins, which are subdivided into twenty work centers.

This study focused on the work center dedicated to metal structures, specifically its two manufacturing cells. These two cells (called ES001 and ES002) operate three 8 hours shifts per day, 5 days a week. In each shift, two workers are required per cell: the first one is responsible for assembling the product and the second one for its packing.

The layout of the two cells is presented in Figure 2.

Figure 2 – Layout of cells ES001 and ES002.



AI – Buffer of intermediate product	BL1 – Assembly line side
PA – Finished product area	BL2 – Packing line side
NOK – NOK area	BL3 – Support line side
PP – Pallet truck	M1 – Worktable
CE – Team Leader area	M2 – Side table
DK – Daily Kaizen Board	AIN – Products in use
C – Computer	EST – Structures
F1 – Shared tool cabinet	CX – Box supply area
F2 – Cell tool cabinet	CRT | CNT – Cardboard supply area
P – Pallets	DIV – Car with partitions

In general, the production process of the cells mentioned above can be represented by the SIPOC diagram depicted in Figure 3.

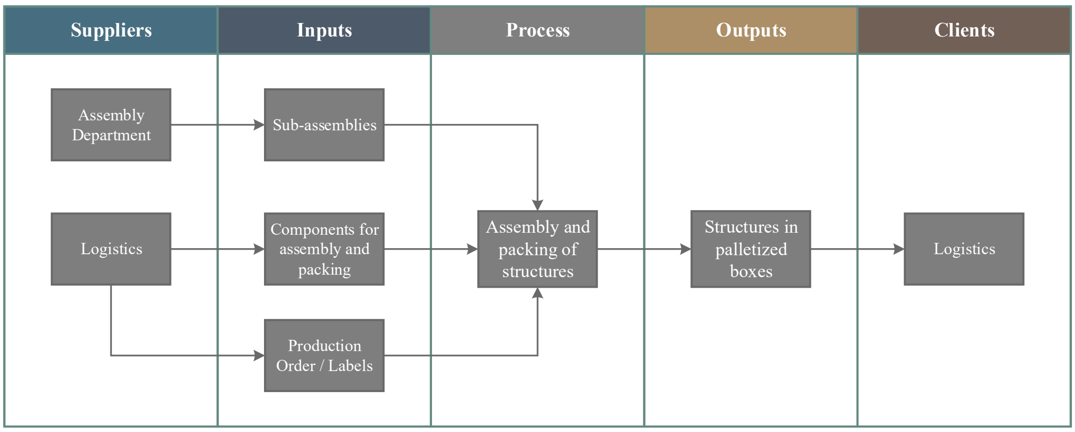


Figure 3 – SIPOC of the assembly and packing process of structures in ES001 and ES002 cells.

The inputs to the process are the indoor cisterns, stored in the cistern area (AI), the components for assembly and packing, supplied by logistics and, finally, the PO and the necessary labels that, despite being printed by the team leader, are also supplied at the line side by logistics. The output of this process are the structures already assembled and packed in palletized boxes that are collected by the logistics workers and stored in the finish product warehouse.

Setup Process Analysis

A code change is a setup process that happens when a new product is going to be produced and occurs whenever a new PO is initiated. The code changes are performed by the two workers assigned to the production in the cells.

The data needed to define and analyze the initial state of the code change process was collected directly from *Gemba*, as mentioned previously, through informal interviews with workers and with the team leader, as well as the recording of 10 videos. It was then possible to identify and understand the tasks performed during the code change, determine the time that each one takes and also identify problems and opportunities for improvement. Table 1 summarizes the statistics calculated using the data collected.

Table 1 – Statistics of the initial sample for the setup (min).

Sample Size	Minimum Time	Maximum Time	Average Time	Standard Deviation
10	12,50	21,75	16,55	3,35

Considering the large number of tasks identified (46 in total), in order to facilitate the analysis, it was decided to classify the tasks into ten categories specific to the process in question:

a. Palletizing: tasks performed after placing on the pallet the last box of the current PO until all the pallets of that order are prepared;
b. Return: tasks related to the return of components from the previous PO;
c. Supply: tasks related to the placement of the components of the next PO in the respective area;
d. Components: tasks related to the preparation of components for assembly, packing and palletizing of the next PO;
e. Tools: tasks related to the preparation of the required tools for the assembly, packing and palletizing of the next PO;
f. Records: tasks related to the required records regarding production as well as stoppage time for code change;

g. Documentation: tasks related to all documentation that must be prepared before starting the new PO;
h. Audit: tasks related to the audit that ensures that the necessary components are stocked for the next PO;
i. Picking: tasks related to programming the pick-by-light system of the line side, as well as the console used for counting the output;
j. 1st part OK: tasks related to obtaining the 1st part OK, including the assembly and packing of the first structure and its audit.

The application of SMED requires the distinction between internal and external setup, so this was the next step in the analysis of the tasks required for the code change. Because it is a manual production cell it is not possible to distinguish internal and external tasks based on the state of the machine (stopped or working), so the classification was made by equating the cell workers to a machine.

Thus, for the 46 tasks, organized according to the 10 defined categories, a distinction was made between internal and external setup, as well as the calculation of the respective statistics, based on the initial sample.

These values are summarized in the following tables, firstly separated by category (Table 2) and then by type of setup (Table 3).

Table 2 – Statistics, by category, of the initial sample for the setup (min).

Category	Minimum Time	Maximum Time	Average Time	Standard Deviation
Audit	2,70	10,42	5,03	2,62
Palletization	1,85	7,32	4,34	1,89
1st part OK	1,45	5,30	3,61	1,08
Documentation	0,45	5,28	2,51	1,38
Components	0,92	3,53	2,28	0,93
Return	0,40	3,87	1,85	1,09
Records	0,73	2,63	1,44	0,82
Supply	0,65	1,88	1,26	0,40
Tools	0,10	2,08	0,91	0,71
Picking	0,10	1,68	0,62	0,47

Table 3 – Statistics, by type of setup, of the initial sample for the setup (min).

Setup	Minimum Time	Maximum Time	Average Time	Standard Deviation
Internal	8,75	25,42	14,74	4,49
External	2,80	11,98	7,46	3,18

Analyzing the values recorded by type of setup, it was possible to verify that external tasks represented about 34%, and internal tasks 66% of the total time obtained in the initial sample.

Regarding the analysis of the categories, since both the "1st piece OK" and the "Documentation" tasks correspond to organizational standards and, in the case of the latter, there was already an improvement action in progress related to the implementation of the MES (Manufacturing Execution System), these were removed from the analysis and the Pareto Diagram was elaborated considering only the remaining 8 categories (Figure 4).

The diagram showed that the best opportunities for improvement would come from reducing the time of tasks such as “Auditing” and “Palletizing”, which together make up more than 50% of the total setup time, considering the data of the initial sample. It can be seen that the “Audit”, “Palletizing”, “Components”, and “Return” categories account for nearly 80% of that time.

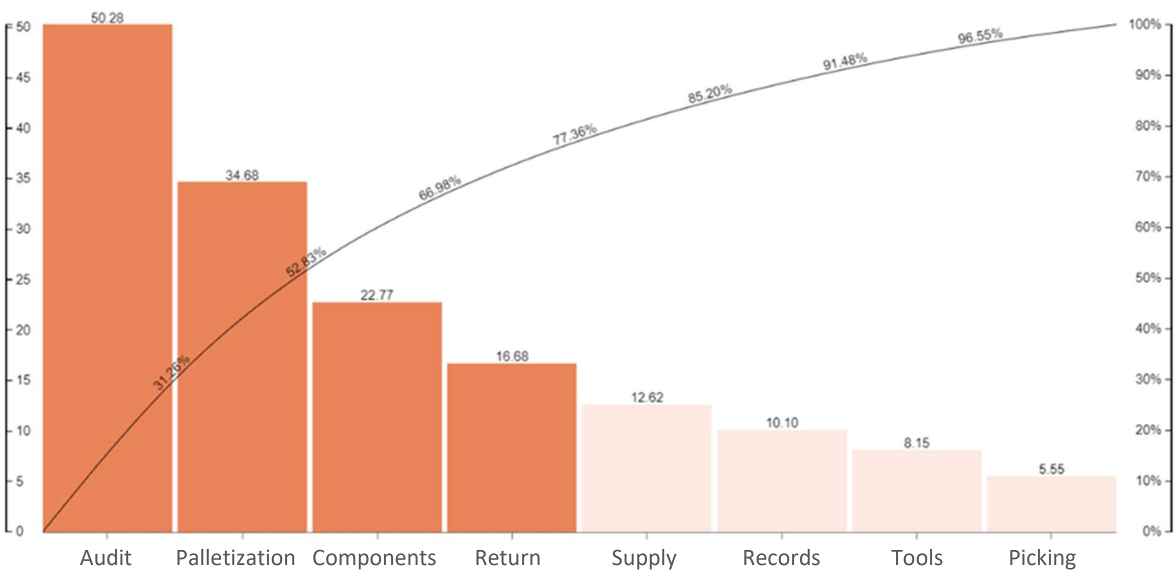


Figure 4 - Pareto Diagram for setup tasks categories.

From the code changes observed, it was also possible to recognize a high variability in relation to the worker allocated to each of the tasks and to the sequence of their execution, which resulted in an inefficient distribution of tasks and led to waiting times between workers. In the chart in Figure 5, for each of the observations, the columns represent the time each worker is occupied by tasks required to change the code, and the dashed line represents the total time of the change, so the distance between the line and the columns corresponds to the time of Non-Value Added (NVA) activities.

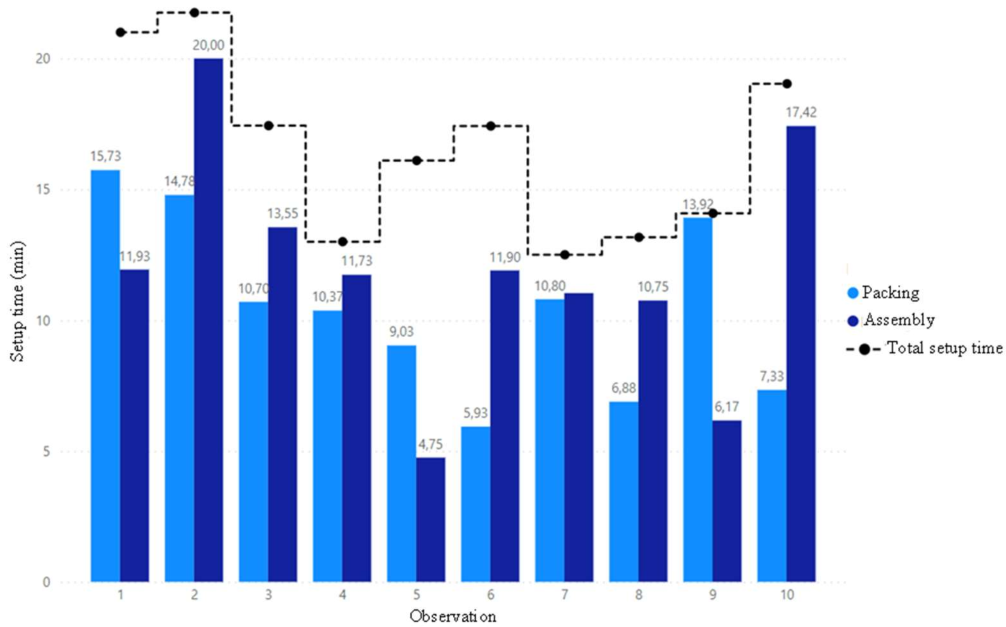


Figure 5 – Comparison of setup time with the occupation of each worker.

It is possible to understand the need to define a better allocation and sequencing of tasks in a standard procedure, that reduces the code change time and balances the workload between the two workers.

So, considering the inputs of the workers and team leaders, and after several brainstorming meetings with the person responsible for this area of the Assembly Department, the Ishikawa Diagram of Figure 6 was elaborated.

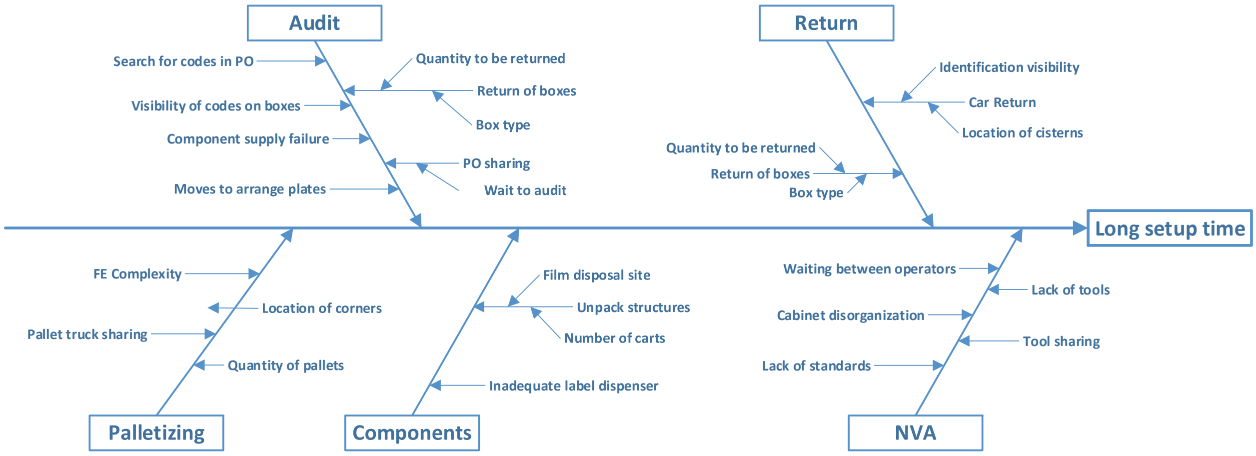


Figure 6 – Ishikawa Diagram for long setup time.

Improvement Actions

Based on this analysis, several improvement actions were identified, within the categories considered most critical, whether through the analysis of the Pareto Diagram and/or the Ishikawa Diagram.

The main improvements made were developed within the scope of the SMED cycle and were included in its different stages.

In stage 1 (distinguishing internal setup from external setup) three tasks were identified that could be eliminated from the setup process in code changes. The first was the configuration of a labeling equipment, which was moved to the beginning of the shift, before starting production, instead of being done during the setup process.

The second and third tasks were related to unpacking some components and materials used in assembly, as well as arranging/disposing of packaging materials, and both became the responsibility of logistics workers.

In stage 3 of SMED (simplify all internal and external setup tasks), two improvement actions were defined.

The first was to organize the list of components of the Production Order (PO), to facilitate the audit task that is carried out whenever there is a code change, to confirm that all the materials needed for the new PO are available at the line sides (namely BL1 – Assembly Line Side, and BL2 – Packing Line Side). These audits, both to BL1 and BL2, are bottleneck tasks, not only because of the long time they take, but also because many of the other tasks depend on them.

As specified in the Ishikawa Diagram in Figure 6, one of the causes identified for the delay in the audit was the "Search for component references in the PO". Another waste that occurred in this step was the over-processing because, many times, when the worker did not find the reference at first glance, he restarted the search, and sometimes the reference was not actually in the list because it was not necessary for the production that was being started.

The main problem of this task was related to the random order given to the list of components in the PO, and thus the way of issuing the list of components of the PO was changed, so that they appear in the same order as they are stored on the line sides (BL1 and BL2), simplifying the verification of all materials.

To test the solution, 15 prototypes of PO were prepared and the solution was tested in the *Gemba*, obtaining the results of Table 4 for the audit time at each line side, which can be compared with the times previously obtained.

Table 4 – Statistics for the audit test organized by line side (min).

Line Side	Sample Size	Minimum Time	Maximum Time	Average Time	Standard Deviation
Before					
BL1	10	0,77	5,83	2,29	1,59
BL2	10	1,35	4,68	2,62	1,31
After					
BL1	15	0,52	1,48	1,07	0,26
BL2	15	0,63	1,02	0,83	0,11

Within the scope of the second action, specific locations were defined for the tools used recurrently in the worker's activities, namely the pneumatic screwdrivers. In addition, the cabinet where the remaining tools, used in more sporadic cases, are stored, was organized (see Figure 7). This reduced the time spent by workers picking up the screwdrivers, as well as searching for the other tools when they need to use them.

Figure 7- Before and After of the tool cabinet.

The preparation time of the screwdrivers, after this improvement, only includes changing the tips or storing them in the respective holder, and it is estimated that the time of this task will be reduced by around 34%.

In the final phase of the SMED, the final procedure for changing the code was defined, in order to standardize this process, create a work instruction and provide training to the workers and team leaders of the three shifts.

The process of defining the procedure underwent multiple iterations followed by the respective test on the shop floor, in order to simplify the tasks and to incorporate several practical aspects detected in those tests. In this manner, it was possible to reduce the number of tasks from 46 to 22.

Following, with the help of the area manager, the team leader and the workers, the precedence diagram was established for this list of standard tasks (see Figure 8). It should be noted that tasks 0 and 0.5 were added to the list, and are related to assembly and packing tasks of the last good part.

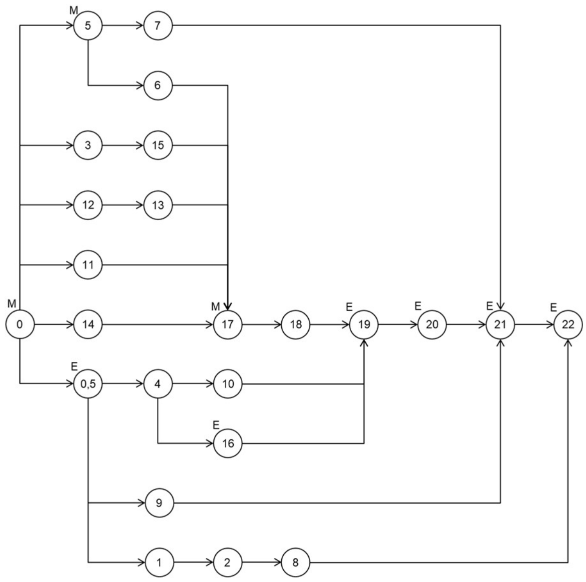


Figure 8 - Precedence Diagram of the final standard setup tasks.

Based on the precedence diagram, and also considering the time of the tasks, the sequencing and allocation of the tasks to the two workers was done, with the objective of reducing the total time of the setup. Thus, a heuristic algorithm adapted from Kolisch & Hartmann (1999) was used, defining the priority of the tasks according to the respective Ranked Positional Weight (RPW).

The Gantt Chart (Figure 9) shows the allocation and sequencing of operations.

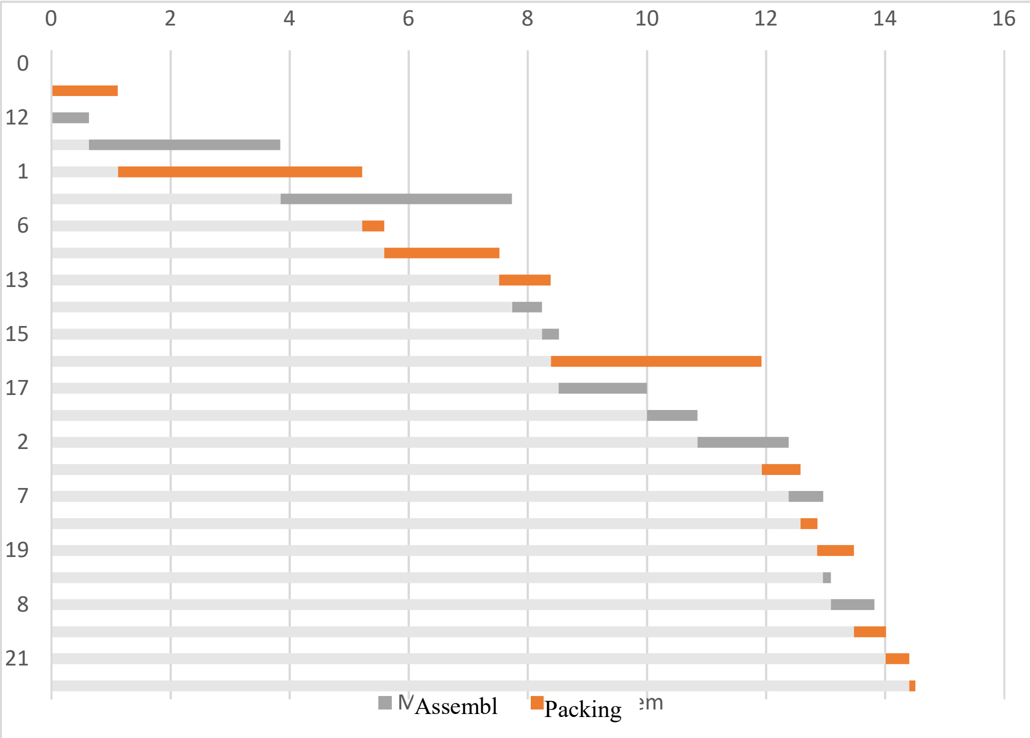


Figure 9 – Gantt Chart of the solution for the allocation and sequencing of setup tasks.

By using SMED methodology, it was also possible to identify other wastes associated with the two workers. Specifically, unnecessary movement, which was often done to return or obtain tools. Following the 5 Whys methodology (Figure 10), the root cause of this problem was identified: the recurrent loss of tools, which meant that there were not enough tools for everyone and that the existing ones were kept away from the workplace. The lack of tools also caused some workers to use their personal ones, which could jeopardize the quality of production.

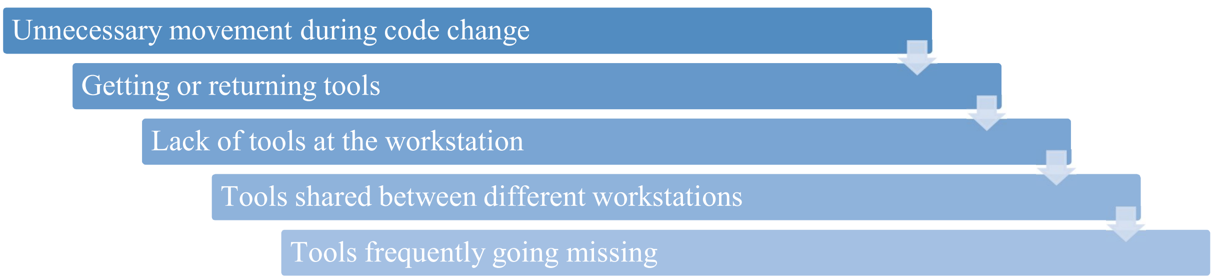


Figure 10 - Applying the 5 Whys to the problem of unnecessary movement during setup.

It was decided to apply the 5S methodology to organize the tools and standardize the way they were used. Figure 11 shows the main steps performed in each of the 5S stages.

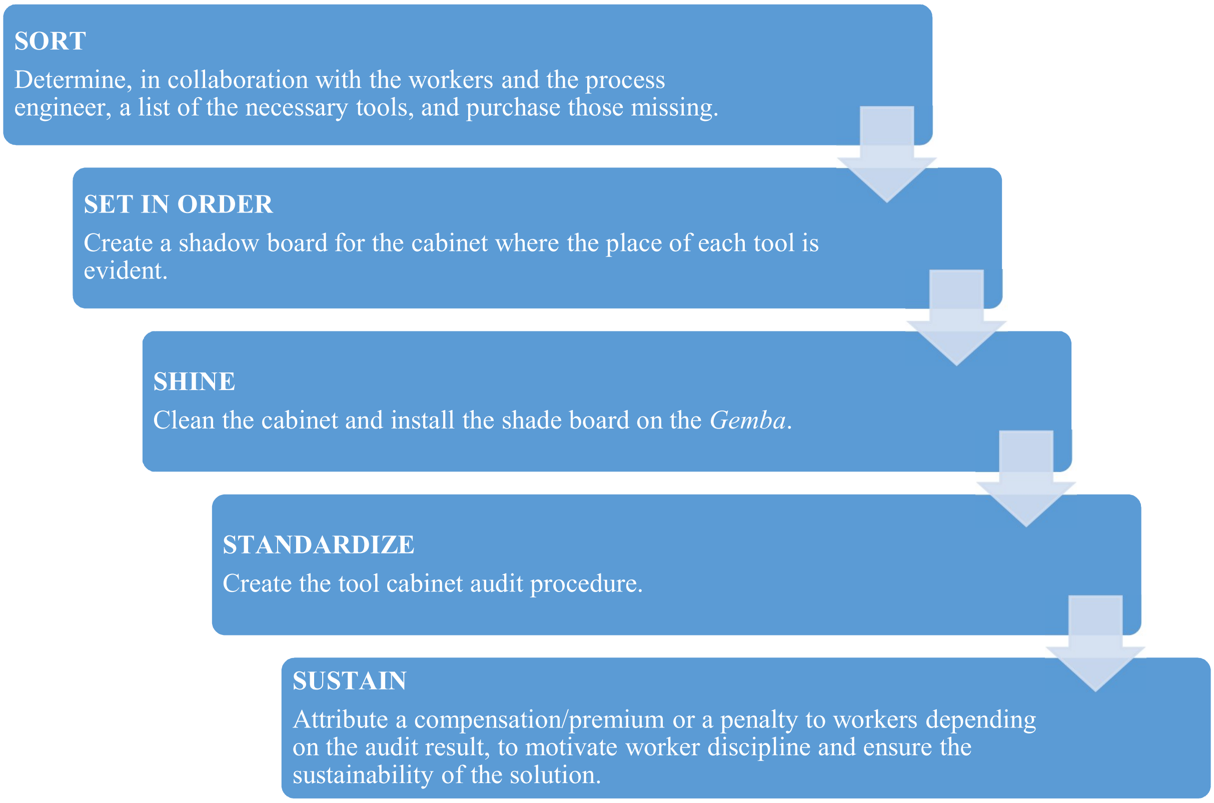


Figure 11- Application of the 5S methodology to the problem of the loss of tools.

The audit of the tool cabinet, which contributes to the 5S Sustain stage, should be done by the Tool Master (who is one of the cell workers), at the beginning of the shift, in order to ensure that all tools are in the indicated place and in perfect condition to start production. To register the result of the audit, the Tool Master should use the green *Kamishibai* if it is positive and the red one if any tool is missing or has a problem (see figure 12).

In this way, the tracking of the tools is done daily in each shift and the workers are held accountable immediately.

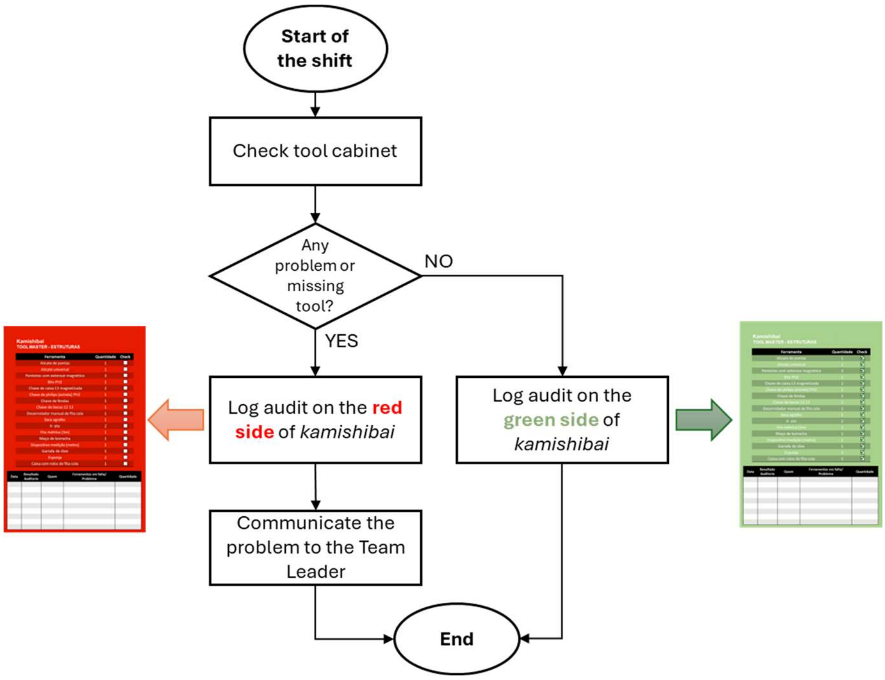


Figure 12 – Tool cabinet audit procedure.

Overall Results

After the end of the training period, a small sample (15 observations) was extracted through direct observation, to evaluate the improvements implemented.

The data reveals a reduction of about 3 minutes (18%) in the average setup time compared to the initial situation (see Table 5).

Table 5 – Structures' code change setup

	Code change
Initial setup time (minutes)	16,53
Final setup time (minutes)	13,50
Reduction (minutes)	3,03
Reduction (%)	18%

In Figure 13 it is possible to see the boxplots of the data regarding the two samples: before and after the improvement actions implementation. It noticeable that not only the setup time shows a reduction, but also its variability has decreased.

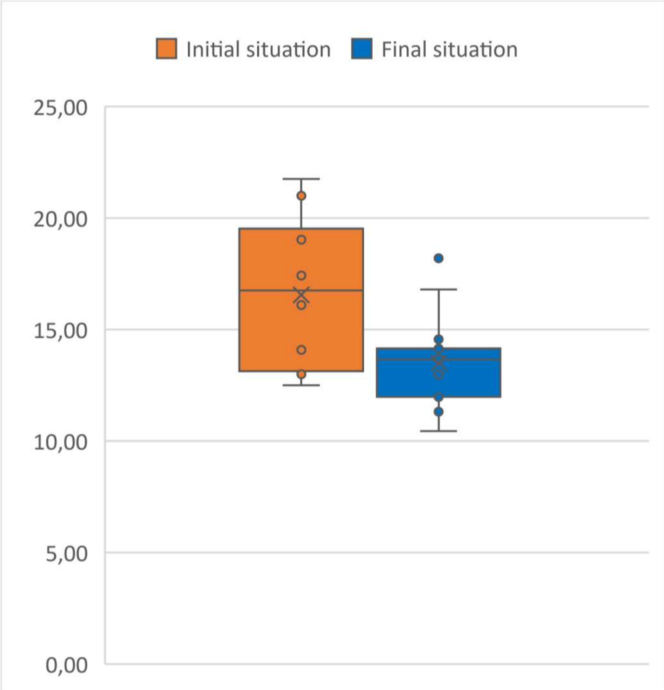


Figure 13 – Boxplots of the setup times.

Taking into account the high pace of these cells (36 parts/hour) and the average number of setups, which is around 70 setups per cell in a month, this reduction in setup time represents an increase in cell output of about 127 units/month.

In general, although the results of the implemented actions indicate improvements, the variability in the process can still be reduced. During the final data collection it was possible to identify some factors that contribute to this problem, namely the manual nature of all tasks that makes their execution time very dependent on the worker's experience, which can be overcome with more training.

CONCLUSIONS

The work developed contributed to the reduction of the setup times of the code change process in the manufacturing cells responsible for making structures.

To solve these problems, actions were developed through the adaptation of SMED, which is usually applied to setup processes on machines, but in this case, as they are manual workstations, it represents a less conventional approach.

Thus, it is worth highlighting, in phase 1 of the SMED, which concerns the separation of external tasks, the solutions adopted mostly involved the transfer of tasks to the beginning of the shift and to the responsibility of logistics workers. In phase 3, the proposal to organize the production order and to simplify the line sides audit, resulted in a reduction of about 53% and 68% in the average audit times for BL1 (assembly line side) and BL2 (packing line side), respectively.

The use of a heuristic method of operation scheduling, made it possible to solve the issue of tasks that can be performed in parallel, reducing the total changeover time and balancing the workload between the two workers.

The 5S methodology, together with the *Kamishibai* cards, created a robust system for maintaining the necessary tools for the cells, which will contribute to maintain both cells organized and cleaned in the long term.

Globally, the execution of these actions led to an 18% decrease in the average duration of the production code change process. Furthermore, there was a favorable outcome regarding process standardization and the upkeep of tools and equipment.

Future work could include improving the ergonomic conditions of both workstations, particularly considering that the products are heavy and difficult to handle. Improving those conditions would reduce the effort required of the workers, improve motivation, simplify tasks (be it manufacturing tasks or setup tasks), and thus reduce their time, which could further reduce setup times.
The main contribution of this study, both from an academic and an organizational standpoints, is the development and application of an approach that successfully integrates quality tools within the SMED process, which helps the identification of improvement actions and fosters worker engagement.

AKNOWLEDGEMENTS

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Integration of Machine Learning Tools with Lean Six Sigma Activities in Forensic Engineering: A Literature Review

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STRUCTURED ABSTRACT

Purpose – This paper addresses challenges in forensic engineering, particularly in the detection and analysis of material failures. It explores the integration of Machine Learning (ML) techniques, specifically Convolutional Neural Networks (CNN), within the Lean Six Sigma (LSS) DMAIC methodology to streamline and automate the process of material failure detection. It aims to contribute towards leaner, more efficient, and cost-effective methods for forensic engineering investigations.

Methodology - The methodology employed in this study entailed a thorough literature search, involving the selection of relevant articles based on predefined criteria, their subsequent categorization into distinct sections, a careful analysis of key insights, and the identification of significant research gaps. Utilizing the VOSviewer software®, bibliometric analysis was conducted to examine the collected data. This paper offers a comprehensive review of the existing literature, conducts a rigorous analysis, outlines research gaps, and proposes future avenues for exploration in this interdisciplinary domain.

Findings – The paper identified various difficulties within forensic engineering, including challenges such as expert time loss and complex processes, alongside emphasizing ML's promise in detecting material failures and proving for its combination with LSS to enhance operational efficiency.

Practical implications- Forensic engineers can leverage the identified synergy to enhance efficiency in their practices, while lean experts may optimize processes by integrating ML technology for automation and process improvement.

Originality/value - The originality lies in the interdisciplinary fusion of forensic engineering, ML, and LSS, offering fresh insights to improve material failure detection processes.

Keywords: Forensic engineering, Lean Six Sigma, Convolutional Neural Networks, image recognition.

Paper type: Literature review.

INTRODUCTION

Forensic engineering involves the application of engineering science and art in the legal system, which requires the assistance of qualified engineers. The duties of forensic engineers include investigating accidents, preparing engineering reports, providing testimony in administrative or judicial proceedings, and drafting advisory opinions when life or property is threatened (Cobb and Carper, 2000). Deformations and failures of materials are inherent to nearly every aspect of human activity (Meakin, 1991). As stated by Voight (1989), it is difficult to predict the deformation and failure of materials based on factors such as crystalline structure, dislocation structure, and microcracks. Even manual detection of microscopic images is labor-intensive, time-consuming, tedious, requires experts, and costly (Wu et al., 2019; Kubera et al., 2022; Alqahtani et al., 2021; Golomingi et al., 2022; Bordas et al., 2022). As per Machaka and Balan (2022), conventional forensic techniques are becoming outdated. By enhancing incident detection capabilities, analysts can focus more on forensic investigation functions (Machaka and Balan, 2022). The latest technologies would also simplify this process, such as automatically scanning microscopic images and analyzing them afterwards (Golomingi et al., 2022).

Lately, Machine Learning (ML), a subset of Artificial Intelligence (AI), has gained widespread adoption for automating various tasks. As ML continues to advance, Deep Learning (DL), particularly through Convolutional Neural Networks (CNN) (Pak and Kim, 2017), has emerged as a dominant force. CNNs exhibit exceptional image recognition capabilities, with a track record of success in competitive settings (Pak and Kim, 2017). Notably, CNN achieved victory in the ImageNet challenge in both 2012 and 2015 (Russakovsky et al., 2015), due to its ability to perform feature extraction automatically, rendering manual feature extraction unnecessary.

Simultaneously, Lean Six Sigma (LSS) is increasingly recognized as a vital tool for organizations seeking to achieve business objectives and maintain competitiveness (Papic et al., 2017). When utilized with innovative strategies, LSS facilitates the development of high-quality products and streamlined processes (Alblooshi and Shamsuzzaman, 2020). The prevalent LSS approach, DMAIC (Define, Measure, Analyze, Improve, and Control), offers a standardized, versatile methodology applicable across diverse sectors (Psychogios and Tsironis, 2012; Panayiotou and Stergiou, 2020). DMAIC employs a toolkit to enhance processes, reduce waste, minimize variation, and determine root causes (Sordan et al., 2020; Bhat et al., 2020).

A comprehensive literature review is crucial since it systematically maps the existing knowledge and methodologies within forensic engineering, particularly the application of ML and LSS. This review is instrumental in establishing a baseline from which the novel integration of CNN with the LSS DMAIC methodology can be assessed for its innovation and practical relevance. Consequently, this paper extensively investigates this integration to tackle material failure challenges. It outlines research objectives, conducts a literature analysis, identifies research gaps, and concludes with recommendations for future research.

OBJECTIVES

This research aims to conduct a literature review focusing on ML applications within the LSS DMAIC methodology for expediting the lead time of manual detection of microscopic images. The study explores the potential integration of LSS and ML to enhance and automate material failure analysis in forensic engineering while addressing identified research gaps.

RESEARCH METODOLOGHY

A literature search was conducted, identifying five main sections:

1. Challenges in Forensic Engineering
2. Practical Implications of Automated Image Recognition
3. Machine Learning Tools for Image Recognition
4. Lean Six Sigma Practices for Reducing the Lead Time in the Processes
5. Integrated use of Lean Six Sigma and Machine Learning tools

Relevant keywords were identified for each section as shown in Table 1. The results were obtained by employing Scopus, Google Scholar and ProQuest, as seen in Figure 1.

Table 1 – The corresponding keywords for each section of the literature.

Section number	Selected keywords
1	“forensic engineering” AND “challenges” AND “material failure”
2	“image” AND “detection” AND “recognition” AND automated” OR “automatic”
3	“image classification” AND “cnn” OR “convolutional neural networks” AND “material detection” AND "image recognition" AND “deep neural network”
4	"lean six sigma" AND "machine learning" AND "lead time" OR "lead-time”
5	"lean six sigma" AND "machine learning" AND "process improvement"

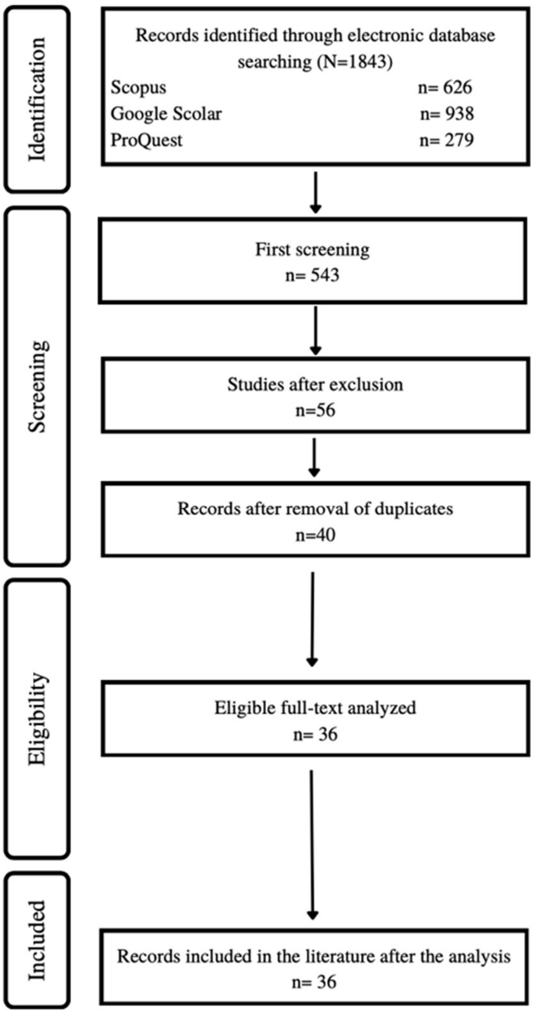

Figure 1 – Flowchart of the research methodology.

The publication year range was specifically chosen from 2015 to February 2024 to focus on the most recent research developments. This study was limited to papers published in English to ensure consistency in language comprehension and analysis. The capital “N” denotes the total number of papers sourced from the three search engines, while the lowercase “n” indicates the number of papers identified by each individual engine. Utilizing the keywords listed in Table 1, an initial selection yielded 1,843 articles, a considerable volume reflecting the breadth of existing research.

The keyword selection criteria were derived from a literature review which indicated a rising interest in LSS and ML over recent years. However, there was a noticeable gap in their application within the field of forensic engineering. This research was initiated to highlight developments in LSS and ML specifically within this underexplored area. Subsequently, 543 relevant studies were selected through a careful process of screening titles and abstracts, prioritizing the most recent and pertinent papers. The inclusion criteria focused on the relevance to the predefined research themes, while exclusion criteria were based on redundancy and irrelevance to the scope of this review. In the exclusion phase, a detailed content analysis led to the identification of 40 unique articles after removing duplicates. Finally, in the eligibility phase, thorough accessibility checks were performed, and 36 papers with full access were selected for in-depth review.

RESEARCH METODOLOGHY ANALYSIS AND RESULTS OF THE SELECTED LITERATURE

A total of 36 articles were selected to be studied in depth by segmenting them into five sections. A detailed explanation of the five main sections is provided in this part. In addition, a summary of research gaps will be presented in the final part.

Challenges in Forensic Engineering

Forensic engineering, as highlighted by Rizvi et al. (2022), confronts a multitude of challenges, including root cause analysis, reverse engineering, and network traffic analysis. Tackling these issues demands substantial investments in training, time, and effort. Network traffic analysis, in particular, often involves sifting through a high frequency of false positives, making it a time-consuming and complex task (Rizvi et al., 2022). Moreover, recognizing failure patterns in images becomes notably challenging with large and intricate images (El-Din, 2022).

Understanding the root causes of material failures, such as loading conditions, is paramount, but acquiring this critical data remains a challenge for forensic engineers (Ren et al., 2018). Material failures' unpredictability in the face of impact loads further complicates matters. A study by Chen et al. (2021) revealed the demanding process of examining individual simulations to identify these influences, underscoring the need for swift and efficient pre-crash detection facilitated by Artificial Neural Networks (ANN).

Concrete quality evaluation, a prerequisite for building and civil engineering projects, was traditionally a costly and labor-intensive process, requiring specialized equipment and time to analyze properties beyond compressive strength (Kasperkiewicz, 2003). In summary, Table 2 captures a range of forensic engineering challenges, proposed solutions, and existing research gaps.

Table 2 – Challenges Faced by Forensic Engineers, Solution and Gaps.

Author(s)	Challenge	Solution	Gap/future work
Rizvi et al. (2022)	Expert time loss/lengthy and complex process	ML models	Make use of different algorithms, hybrid techniques, and approaches
El-Din (2022)	Image pattern identification	ML pattern recognition techniques	Forensic AI requires operational and real-world data application
Ren et al. (2018), Chen et al. (2021)	Identifying the loading condition/Time-consuming simulation analyzation	DNN technique namely ANN	3D structures with complex geometries can be analyzed using ML
Kasperkiewicz (2003)	Labor-intensive, expensive, special tools and great deal of time	ML specifically ANN	Increased characterization of material quality attributes such as emissions and ultrasonics

Legend: AI-Artificial Intelligence, ANN-Artificial Neural Network, DNN-Deep Neural Network, ML-Machine Learning

Practical Implications of Automated Image Recognition

As the shift from Industry 3.0 to Industry 4.0 (I4.0) continues, it is necessary to intensify efforts to convert traditional systems into more efficient and automated ones. This will give both the agricultural and industrial sectors a competitive advantage (Akhtar et al., 2020). The application of image recognition varies, but it has a common objective in all sectors, i.e., it identifies images quickly, reliably, and for a large set of data. Five different methods were explored for image recognition as follows:

1. HSV, CIELAB and YCbCr (Akhtar et al., 2020)
2. COCO-API RCNN & K-NEAREST NEIGHBOR (Maheswari et al., 2020)
3. Divisive Single Linkage and Divisive Average Linkage methods (Saputra et al., 2020)
4. Image processing (Attachie and Owusu, 2020)
5. Active contour method and SVM classification method (Shariaty et al., 2019)

All achieved the intended outcome. Due to all techniques having the same future gap, finding another technique that is more accurate and reliable than the original is crucial. Especially with Attachie and Owusu (2020), the image processing technique used in this paper involves several manual steps. However, a further technique could be developed to avoid the time loss associated with all the manual steps.

Machine Learning Tools for Image Recognition

CNNs are essential in DL, enabling the direct extraction of discriminative features from raw input data through a hierarchical structure. CNNs are commonly assembled using convolution, activation, and pooling modules (Ieracitano et al., 2020). These networks find diverse applications across fields, including tool wear (Wu et al., 2019), medicine (Kubera et al., 2022), forensic science (Golomingi et al., 2022), grain size analysis (Bordas et al., 2022), nanomaterials (Ieracitano et al., 2020), material failure detection (Alqahtani et al., 2021 and Strohmann et al., 2021), 2D materials (Shin et al., 2021), solid waste management (Ziouzios et al., 2022), and urban pollution (Tasnim et al., 2023).

Most studies employ precision as an evaluation metric and propose multiple models to address their core issues. Data augmentation, encompassing translation, rotation, stretching, zooming, and color adjustments, is frequently used to increase training data, enhance accuracy, and prevent overfitting.

CNNs prove valuable for reducing processing times (Golomingi et al., 2022), minimizing execution errors, cutting labor costs, reducing manual input, and enhancing efficiency. They outperform traditional methods in terms of processing time, human involvement (Wu et al., 2019; Bordas et al., 2022), and error rates.

Challenges in this domain include grain similarity, object overlap, and mutual object appearance (Kubera et al., 2022). Future research opportunities involve applying CNN-based algorithms to a broader range of materials, such as reinforced concrete that is used in civil structures (Alqahtani et al., 2021). CNNs present a promising avenue for tackling diverse material-related challenges.

Lean Six Sigma Practices for Reducing the Lead Time in the Processes

In the challenging field of forensic engineering, LSS offers a promising solution. Forensic engineers frequently confront intricate challenges such as root cause analysis, material failures, and data analysis. Daniyan et al. (2022) emphasize that LSS, when combined with automation and skill development, proves particularly effective. LSS provides a toolkit encompassing tools, namely, Value Stream Mapping, Total Productive Maintenance, Design of Experiments, Statistical Process Control, 5S, and Quality Function Deployment (Albliwi et al., 2015). These tools effectively streamline operations, reduce lead times, and uncover concealed inefficiencies. Furthermore, Nedra et al. (2019) illustrate that LSS can harmonize with the Plan, Do, Check and Act (PDCA) methodology.

Despite its effectiveness, the broader utilization of the LSS DMAIC methodology remains an opportunity. An analysis of eleven LSS studies highlights various tools within the DMAIC methodology as illustrated in Figure 2. Process Cycle Efficiency, as used in four studies, facilitates the reduction of lead times, while Value Stream Mapping reveals hidden inefficiencies (Keyte & Locher, 2017). Kaizen and 5S further optimize production processes, enhance product quality, and increase production speed (Adeodu et al., 2021). To maximize efficiency, comprehensive integration of 5S is recommended (Ishak et al., 2020). In essence, LSS offers a promising approach to elevate forensic engineering operations and minimize lead times, effectively addressing the specific challenges encountered in forensic engineering field.

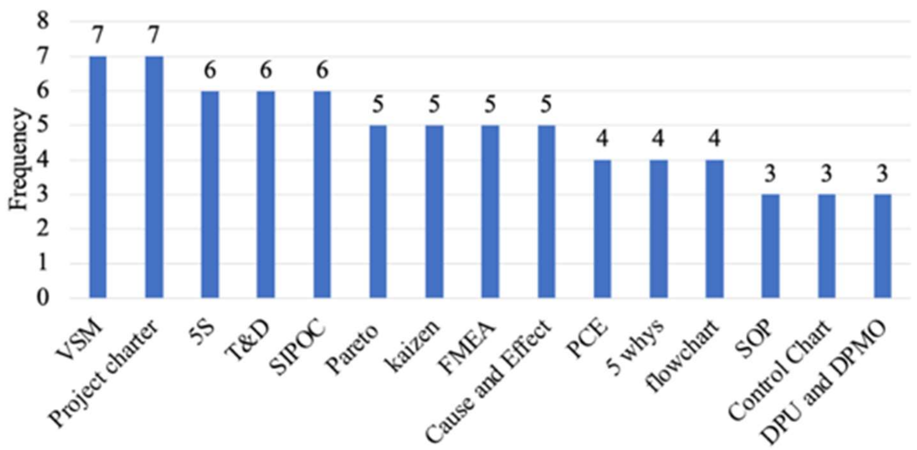

Figure 2 – Lean Six Sigma tools applied in the DMAIC phases of the selected studies.

Integrated Use of Lean Six Sigma and Machine Learning Tools

The integration of Industry 4.0 (I4.0) in manufacturing organizations establishes a virtual network connecting manufacturers and suppliers, facilitating the exchange of intangible (data, knowledge, information) and tangible assets (machines, equipment, personnel) (Kamble et al., 2020). Combining Lean principles with I4.0 and ensuring effective LSS and ML implementation offers valuable benefits (Ilangakoon et al., 2021). Panayiotou and Stergiou (2020) suggest numerous possibilities, including leveraging technological advancements such as the Internet of Things (IoT) and I4.0 to enhance processes following LSS principles.

Scopus conducted an analysis tracking the evolution of LSS and ML, along with ML subfields. The query incorporated key terms such as "lean six sigma", "artificial intelligence", "machine learning", "deep learning" and "convolutional neural networks." The results are visually represented in Figure 3, illustrating the concurrent exploration of LSS and ML. Notably, the fusion of LSS and ML emerged in 2018, marking its inception. This data highlights the increasing significance of both LSS and ML in research, with a publication increase from 2019 to 2021, a slight decrease in 2022, and peak citations in 2020, followed by 2021 and 2022. These citation patterns emphasize the pivotal roles of LSS and ML in contemporary research.

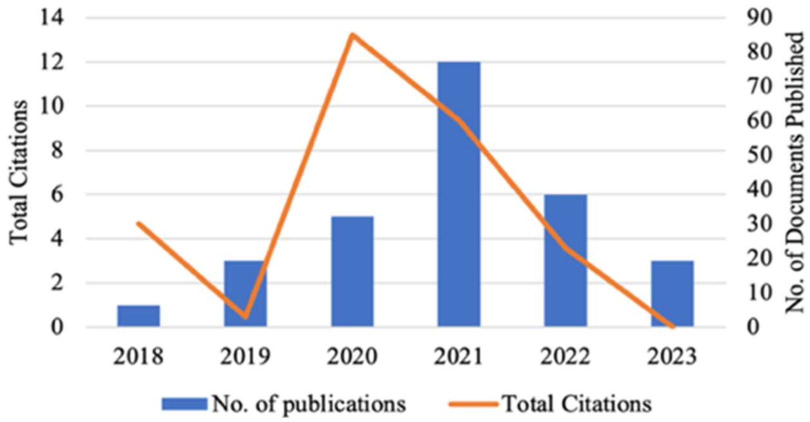

Figure 3 – An analysis of the trend in the integrated use of both LSS and AI.

In three of the five studies, ML and ANN effectively reduced process times, including selection and lead times, as presented in Table 3. ML had various applications, spanning classification, prediction, and optimization.

Table 3 – Advanced analytics associated with each technology integrated in LSS practices.

Author(s)	Technology used	DMAIC phase	Purpose
Wilantara et al. (2022)	BDA+ANN	Improve	Prediction
Gomathi Prabha and Yuvaraja (2022)	IoT+ AR	Improve and Control	IoT: monitoring the system, AR: simulating the process
Improta et al. (2022)	ML	Improve	Classification
Zgodavova et al. (2020)	ML+ANN	Control	Prediction
Nader (2022)	RSM	-	Optimization

Legend: ANN-Artificial Neural Network, AR- Augmented Reality, BDA-Big Data Analytics, IoT-Internet of Things, ML- Machine Learning, RSM- Response Surface Methodology

Gomathi Prabha and Yuvaraja (2022) merged LSS with the IoT. The IoT-LSS combination, seen in Gomathi Prabha and Yuvaraja's study (2022), notably enhanced productivity and quality. The latter employed Value Stream Mapping and line-balancing with IoT for in-house testing process monitoring. Furthermore, Zgodavova et al. (2020) confirmed the effectiveness of intelligent systems in minimizing variability and boosting process capability. Remarkably, one study excelled in automatically classifying patients into distinct groups using ML models (Improta et al., 2022).

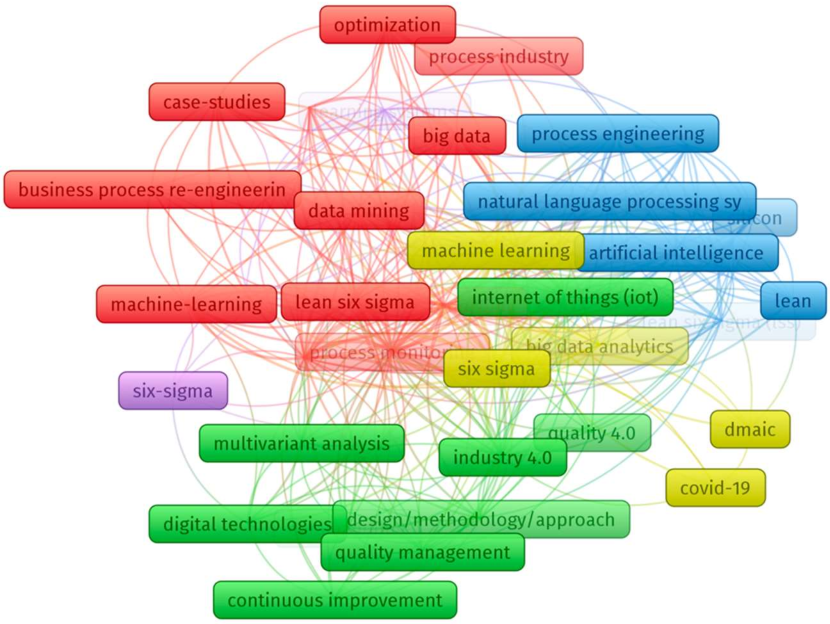

Figure 4 – The Relationship Between Lean Six Sigma and Machine Learning through VOSviewer Software®.

After analyzing both LSS and ML state-of-art literature, a VOSviewer software® was employed to explore the connection between the two approaches by analyzing all the keywords from the examined papers in Table 1 except for the first section. The result of the relationship is shown in Figure 4. It demonstrates the investigation of all keywords that appeared frequently. Ali et al (2023) indicated that there are several ways to describe the relationships between the keywords, including using color, square size, text size, and the thickness of the connecting lines. Furthermore, groupings are apparent when keywords share the same description.

The red cluster indicated that LSS is utilized alongside AI, Big data, data mining and natural language processing. Furthermore, in the green cluster, the new advanced technologies such as quality 4.0, industry 4.0, IoT and digital technologies were sharing the same features. In conclusion, VOSviewer software demonstrates a significant correlation in research between LSS and advanced technologies such as AI and ML. It was also investigated through the bibliometric analysis what are the ML tools that are primarily used for image recognition and classification as illustrated in Figure 5.

Figure 5 – Primary ML tools for image recognition and classification.

Alsadi et al. (2023) reviewed the integrated use of Lean methodologies and Industry 4.0 technologies, employing bibliometric analysis to identify future research opportunities. The paper confirmed benefits similar to those noted in this study, such as enhanced operational efficiency, real-time decision-making, increased production flexibility, and cost reductions, achieved through techniques, namely, value stream mapping and smart control systems. Alsadi et al. (2023) paper highlights the need for further research in underexplored areas. Accordingly, this paper identifies specific gaps within the relatively new domain of forensic engineering. Pongboonchai-Empl et al. (2023) conducted a systematic review on the integration of 14.0 technologies into the LSS DMAIC methodology, observing a frequent focus on ANN and ML, with ANN featured in 387 studies compared to 50 studies in ML. Despite the difference, both technologies are gaining attention in research combined with LSS. Their findings primarily relate to the manufacturing sector, with additional interests in healthcare and higher education, though forensic engineering remains unexplored. The study identified nine gaps in the literature, notably the enhancement of LSS and DMAIC phases in details which was addressed in this paper by introducing CNN, an ML tool, for image pattern recognition.

Research Gaps

Several research gaps have been identified as a result of reviewing and analyzing the literature on the integrated use of LSS with ML tools in the domain of image recognition within the field of forensic engineering. Firstly, enhancing material analysis by incorporating additional characteristics could refine ML's precision. Moreover, future strategies might include diverse algorithms and hybrid methods for detecting and classifying material failures. There is a considerable deficiency in real data integration within forensic ML applications. While LSS remains pertinent, integrating I4.0 technologies such as cloud computing, robotics, and ML is crucial. Current discussions on LSS and AI integration focus mainly on Big Data and the IoT, highlighting the need to explore other technologies such as ML. Additionally, the literature lacks comprehensive ML strategies for classifying various material failures, though CNNs have been suggested, as evidenced in the past four years from the literature by their widespread use in image classification, object detection and handwriting recognition, particularly noted in red cluster in Figure 5. The cluster also demonstrates the strong relationship between ML, CNN and image classification. Despite the proven efficacy of CNNs in handling image data, their application has mostly been confined to specific material types or failure modes. This indicates a need to extend their applications to a wider range of material types and failure modes. Furthermore, a thorough review of current literature indicates that while ML techniques are increasingly explored across various engineering disciplines, their integration within the LSS approach for forensic engineering, especially in material failure analysis, is still limited. This marks a significant area for potential advancements in automating and enhancing detection processes.

CONCLUSION AND FUTURE WORK RECOMMENDATION

This study successfully developed a robust methodology for the analysis of 36 articles, categorizing them into five sections. The exploration of the correlation between LSS and ML across various domains confirms the significance of conducting forensic engineering case studies for validation. Furthermore, this research has identified several critical research gaps, providing the areas where further investigation and study are necessary.

The study discussed challenges faced by forensic engineers, automatic image recognition, and the advantages of CNNs for image detection. Additionally, it outlined the benefits of combining LSS with ML. While there is a growing attention on LSS and ML, their intersection remains underexplored. Although a connection has been identified, further investigation is necessary. Forensic engineers encounter ongoing challenges in material failure detection, highlighting several research gaps. First, there is a need for the development of ML models incorporating additional material features to enhance the precision of forensic material detection. Second, research should diversify to involve more than two types of material failure. Lastly, integration of ML with other engineering concepts, particularly hybrid approaches that combine LSS with ML technologies, is crucial. This includes recognizing the relevance of LSS within the context of Industry 4.0 technologies for achieving operational excellence.

The literature suggests that ML, a subset of AI, holds great potential for enhancing material failure detection in forensic engineering. There is a promising opportunity for forensic engineers to be assisted in distinguishing between multiple material failure types by automatically classifying material failure features using CNNs and significantly improving the material detection process by applying the LSS DMAIC methodology.

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Sustainable Management in the hotel sector: Practices and Challenges

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STRUCTURED ABSTRACT

In the hotel sector, sustainability has emerged as a crucial imperative as awareness of the environmental, social, and economic impacts of hotel operations has increased. Hotels, traditionally seen as significant consumers of natural resources and generators of waste, are now being called upon to adopt more sustainable practices to reduce their environmental impact, support local communities, and promote social equity. Sustainability in the hotel sector encompasses a variety of areas, from efficient management of energy and water to the use of eco-friendly materials, promoting responsible tourism, and implementing corporate social responsibility policies. This approach not only meets the growing expectations of environmentally conscious consumers but can also result in long-term economic benefits such as reduced operational costs and improved brand reputation. However, challenges such as high initial costs, resistance to change, and lack of awareness may still pose obstacles to successful implementation of sustainability in the hotel sector.

Purpose - The purpose of this research is to present appropriate practices for sustainable management in the hotel sector, recognizing the increasing importance of sustainability due to current economic, social, and environmental challenges such as resource scarcity, climate change, and social inequalities.

Design/methodology/approach – The basis for developing the research method consisted of constructing an interview script applied to sector experts, with questions resulting from the analysis of the state of the art of the topic under study. From the interview results, a proposal for diagnosing sustainable management of the sector was developed in the form of a questionnaire, which was sent to hotel units.

Findings - After collecting, analysing, and processing the collected data, the results highlight widely addressed sustainable practices, including plastic elimination, use of LED lighting, waste reduction, implementation of presence sensors, material donation, promotion of local products to support the community, HR practices for work-life balance, professional qualification, selection of local suppliers, contribution to the local economy and employment, and gender equality and compensation.

Practical implications – The identified practices can be directly applied by hotel units aiming to improve their sustainable management. This includes tangible measures such as plastic reduction and the use of LED lights, as well as internal policies such as work-life balance and gender equality in compensation.

Value - The study emphasizes the importance of the hotel sector in promoting sustainability, recognizing its fundamental role in contributing to a sustainable future. Additionally, it highlights both the progress observed in sustainable management and the need for a shift in mindset in hotel units that have not yet considered sustainability, emphasizing the benefit for future generations and the planet as a whole.

Keywords: Management systems; hotel sustainability; hotel enterprises; sustainable practices

Paper type: Research paper (e.g.)

INTRODUTION

The tourism and hotel sector, being the fastest growing industry in the world, and especially in developing countries and regions, has not remained indifferent to the issue of sustainability, even with the emphasis on being seen as a means of economic development.

The main global entity involved in the issue of sustainability is the UN - United Nations, which through the 2030 SDG Agenda presented the 17 Sustainable Development Goals (SDGs) to be achieved by the year 2030. Last year, the Secretary-General of the United Nations stated "We are at a moment's notice. But together, we can make this a moment of hope. I urge all Member States to make 2023 the moment when we jump-start progress on the SDGs, to create a more peaceful and prosperous future for all" (Carvalho et al., 2022).

This issue was of interest to the International Organization for Standardizations (ISO), which developed and updated management systems, to align with the SDGs.

Sustainability is more than a 21st century trend. In reality, the facts reveal that the world is facing a worrying crisis, with its resources being depleted with each passing day. Given this scenario, sustainability emerges as a vital response to protect remaining resources and ensure that future generations have access to them. In this context, there is a need to explore this topic, therefore, the fundamental purpose of this study is to highlight appropriate practices to promote sustainability in the hotel sector, recognizing its growing relevance in the face of current economic, social, and environmental challenges, such as the scarcity of resources, climate change, and social disparities.

LITERATURE REVIEW

Sustainability

From 2000 to 2015, the UN developed the 8 Millennium Goals and later, the 17 Sustainable Development Goals. Efforts are currently being invested to achieve these objectives and the goals defined in the 2030 agenda, which seeks to improve social, economic, and environmental aspects, that is, it seeks to develop the world in a sustainable way (United Nations, 2024)[1] .

[1] https://unric.org/pt/objetivos-de-desenvolvimento-sustentavel/

Through the efforts of people and organizations, it may be possible to achieve the desired objectives of sustainable development, to enable the delivery of a better world to the next generations, through practices that can meet organizational objectives and where everyone can take advantage biggest party.

The concept of sustainability, according to the BCSD (Business Council for Sustainable Development), describes sustainability as the ability to satisfy our needs in the present without compromising the ability of future generations to satisfy their own needs, that is, In a way, sustainability aims to bring together efforts at an environmental, economic and social level to provide the future generation with the opportunities and quality of life that the current generation is offered (BCSD Portugal, 2024)[2] .

Sustainability covers three pillars, with the environmental dimension being the most recognized worldwide, with the idea that sustainability is only based on the environmental dimension. However, sustainability also seeks to combat social inequalities, that is, the social dimension and finally, the economic dimension where resources can be managed ethically and sustainably.

As there is an increasing concern for the world to be sustainable, organizations and people in their singularity end up inserting this theme into the business world. Therefore, some concepts were developed to incorporate sustainability in organizations, as stated by the authors Nunnally, JC, & Bernstein, IH (1994), "corporate social responsibility, which is a "company's contribution to sustainable development" (OECD, 2001, p.13)" and also adds the TBL (Triple Bottom Line) model as a "business-based concept" and "a variation of the sustainability agenda for corporate companies" (Mihalič, Žabkar, &Cvelbar, 2012).

The Triple Bottom Line model is defined by the expressions "Profits, Planet and People", which translate into the dimensions of sustainability, which we all know (Santos et al., 2018). This is a model used to expand the knowledge of organizations' stakeholders, as it goes beyond financial aspects and is transparent in terms of revealing the impacts it has (Arowoshegbe, 2016).

At the level of the social pillar, there are two ways to read this issue, internally and externally. It is necessary to implement practices and responsibilities with employees, related to aspects such as flexibility, fair remuneration, benefits, inclusion, and diversity, among others, and with the surrounding community.

[2] https://bcsdportugal.org/sustainability/

The environmental pillar seeks to ensure the establishment of more appropriate production practices, such as reducing pollutant emissions, the responsible search for natural resources, and the mitigation of mass waste.

The economic pillar encompasses more sustainable and financially responsible management, in a manner aligned with profit and promoting the ability to support future generations (Triple bottom line or tripod of sustainability – REVERSA LOGÍSTICA, 2015).

Management and sustainability systems in the hotel sector

From an early age, the hotel sector had to worry about issues related to good organizational management, to guarantee the maximum quality of its service, contributing to its good image and competitiveness, being considered a crucial factor for the quality of a hotel service (Bridiet al., 2019).

The concept of "service" by the definition of ISO 9000:2015, refers to the "Output of an organization in which at least one activity is necessarily performed between the organization and the customer" (IPQ, 2015), that is, the service requires the involvement of activities between the customer and the organization, with the aim of meeting the needs and expectations desired by the customer.

There are many models for analysing service quality that the hotel sector can implement. ISO standardizations, together with the objectives outlined by the 2030 Agenda, can serve as a method to guarantee sustainable organizational management, resulting in the sustainable quality of a service provided.

Due to the constant variations in change that the sector faces daily, the development of sustainable hotel management is a relevant step.

This leads to a need to contribute to sustainable development objectives so that dependence on the outside and the exposure of new disruptions to value chains can be reduced. (Ministério dos Negócios Estrangeiros, 2024)[3]. However, it is worth noting that it was through international tourism and business travel that Sars-Cov-19 spread at a drastic speed throughout the world (Lew et al., 2020).

Focusing on sustainability in the hotel sector, it is known that it is a sector in continuous growth and that since the 1960s it has sought to generate responses to the environmental and social impacts of its activity (Mousavi et al., 2017).

[3] https://ue.missaoportugal.mne.gov.pt/pt/portugal/sobre-portugal/economia

This confirms that this is a sector with a great impact on the three pillars of sustainability due to its consumption of natural resources, its effect on the environment, and its economic and social impact on the communities where such establishments are located (Boronat-Navarro & Pérez-Aranda, 2020).

It is often sought that the implementation of sustainability has an effect on the development of competitive advantages, which leads many hotel units to rethink the entire environment of sustainability implementation, and that ultimately can translate into revenue for the hotel (Mousavi et al., 2017).

With the aim of obtaining competitive advantages, there are hotel units that are involved in sustainability initiatives, which often neglect environmental and social issues, often acting solely on initiatives to reduce the use and waste of energy and water (Pamfilie et al., 2018).

However, obstacles are often identified in the implementation of sustainable actions, since according to some studies, there is concern about the costs of a hotel being sustainable, in the sense that making a hotel sustainable "requires small actions, as well as large investments to adapt processes and infrastructure" (Boronat-Navarro & Pérez-Aranda, 2020).

These investments can subsequently be reflected in the issue of increasing prices, which often translates into rethinking the action of implementing appropriate sustainability practices, as it influences the increase in prices for the final consumer (Boronat-Navarro & Pérez-Aranda, 2020).

Studies show that customers who have a sustainable routine are willing to pay more for the sustainable service that the sector makes available to consumers (Aznar et al., 2016). Influences that exist on the issue of selecting a sustainable hotel fall on the habits, customs, cultures, and traditions of consumers. In other words, guests' concerns regarding sustainability may be reflected in guests' preferences when selecting a hotel (Mousavi et al., 2017).

RESEARCH METODOLOGHY

This article is classified as an applied investigation, as it seeks to solve practical problems, with objectives set out to be exploratory in nature. To support this research, a literature review was carried out to identify the main aspects related to management and sustainability systems in the hotel sector, as well as sustainable practices to create a guide to good practices. The preferred databases for scientific research were Web of Science, Scopus, and ResearchGate. To expand the number of scientific studies, other reliable digital platforms were used. To start the search, the following search keywords were used: "Management systems in the hospitality industry"; "sustainability in hospitality"; "Sustainability practices in the hotel sector"; "sustainable hotels". Based on the information collected, the research instrument was prepared, and presented in the form of a questionnaire, (Table 1) submitted to an initial assessment by experts in the hotel industry, via interviews, based on Delphi, which is a methodology that intends to study a certain subject, which helps to develop and/or generate new qualified information, with the support of a base of experts, through interviews (Linstone et al., 2002). The respective result will be through a qualitative methodology, which allows the understanding and interpretation of the phenomena in question.

The choice of specialists (10 elements) sought to cover all areas of activity related to the hotel sector, namely tourism associations (1 element), higher hotel schools (5 elements), and hotel management (4 elements). All with higher academic training, 50% with a PhD, and 50% with more than 5 years of experience associated with the area of hospitality, sustainability, and management systems/excellence.

Based on the interviews, a questionnaire was prepared to survey the hotel sector market to understand the trends, taking into account the questions asked by the experts.

In this way, the analysis of the hotel market to which the questionnaire would be directed was provided. The selection was on the hotel projects of the Portuguese hotel association, and around 721 invitations to participate in the study were sent, with a total of 79 responses being obtained, however, due to the existence of incomplete questionnaires, the removal was carried out. of 8 questionnaires, totalling a total of 71 respondents. The region with the highest number of respondents is the Lisbon Metropolitan Area region, with 28%, followed by the Centre region, with 24%, the regions with a lower contribution, with a response rate <10%, found in the Autonomous Region of the Azores, Algarve and Alentejo. In terms of sociodemographic characteristics of the classification of hotel establishments, the majority of respondents are allocated to 4-star hotel units, with a rate of 61% of respondents. Regarding the functions that respondents perform, 46% are related to management.

Table1- Table of questions formulated for specialists and hoteliers vs. the theoretical framework

Section	Interview Questions	Questions from the questionnaire applied to the hotel sector	Theoretical Reference

Hotel Sustainability	Do you consider sustainability (economic, social, and environmental) relevant in the hotel sector? It's because?	How important is your hotel sector to sustainability issues and publicity?	(Bohdanowicz&Zientara, 2009; Mousavi et al., 2017)
	What value does the hotel sector or the hotel unit to which it belongs have for the issue of sustainability?	Is sustainability valued by the hotel industry where you work?	(Mihalič, Žabkar, &Cvelbar, 2012; Mishra, 2016; Mousavi et al., 2017)
	What issues (social, environmental, and economic) affect the hotel sector? Describe the problem.	Which of the following issues negatively affect your hotel business where you work?	(Mousavi et al., 2017)
	Do you believe that the concept of a "sustainable hotel" can increase market growth? And in what sense?	Does the hotel where you work have a sustainable hotel concept?	(Boronat-Navarro & Pérez-Aranda, 2020; Fuentes-Moraleda et al., 2019; Kang et al., 2012)
Sustainable practices in the hotel sector	You can list three sustainability practices (economic, social, and environmental) implemented or that could be implemented by the organization and that have been successful in relation to the recommendations of the European community.	– Which of the following sustainability practices - environmental dimension, are implemented in the hotel where you work? – Which of the following sustainability practices - Social Dimension, are implemented in the hotel where you work? – On the following scale, select which of the following sustainability practices - Economic Dimension, are implemented in the hotel where you work?	(Alameeri et al., 2018; Ayuso, 2006; Bacari et al., 2020; Shanti, 2016)

Source: Produced by the authors

After analysis and discussion of results, a guide to good sustainability practices to be used by the sector was formalized. This guide includes practices described by experts in the interviews, practices resulting from the literature, and, finally, practices described by hotel units.

RESULTS

The presentation of results will be carried out in two modules, the first module relating to interviews carried out with experts and the second module relating to the results obtained from questionnaires sent to hotel units.

Hotel Sustainability - Interview

- *Relevance of the theme*

When it comes to the importance that the hotel sector gives to sustainability issues, experts consider the importance to be high. Since it is a competitive sector with great management complexity, it can be a differentiating step. Furthermore, publicizing concerns and actions for sustainability improves its image.

In relation to the various levels of sustainability, it is relevant at the economic level so that the viability and sustainability of business and economic activity can be guaranteed. At a social level, concern for the surrounding environment and all stakeholders should be increased, starting with involving local work/employment. And at an environmental level, concern increases, considering it a duty to contribute to reducing negative effects and preserving what we have.

- *Valuing sustainability*

Regarding appreciation, experts say that the hotel industry, in general, values sustainability, as it is something that brings a competitive advantage, in addition to the awareness that assets are finite.

However, the appreciation is reflected mainly at an economic level, to find efficient solutions for the business. The environmental and social issue is also valued, however, mainly by consumers and employees.

- *Problems affecting the sector*

Regarding the problems identified by the experts, the main problems were the issue of lack of qualified labour, inflated costs, and the increase in the cost of living.

In terms of problems less mentioned by experts, they came from the group of experts related to hotel units and the association, such as the low occupancy rate, the difficulty of generating good profitability rates, lack of training, and cost assistance.

- *Sustainable Hotel Concept*

The revelation of the recent sustainable hotel concept to experts revealed that this concept can bring with it a competitive advantage, resulting in growth in the market, with some guests looking for sustainable hotels because they implement many sustainable behaviours in their daily lives.

However, experts in the hotel sector highlight a concern, in the sense that, if the added value is not visible or proven, customer adherence may be reduced, that is, there will not only be a disclosure of the sustainability issue but be possible to visualize in practice. Furthermore, educational experts state that not all guests/clients are concerned about sustainability in their daily lives.

Sustainable Practices in the Hotel Sector - Interview

- *Environmental Practices*

As environmental practices, experts highlighted the following practices, in order of relevance: elimination of plastic, use of LED lights, placement of presence sensors, reducers on taps, rainwater retention system, controlled irrigation system, and reducing waste.

- *Social Practices*

Specialists in social practices highlighted the following, in order of most applied practices, the promotion of purchasing local products to support the local community, donation of materials, donation of food, professional qualification, and HR practices aimed at work/life balance guys.

- *Economic Practices*

The last, economic dimension practices, also follows, listed in order of greatest emphasis by experts, the professional qualification of young people, access to employment and salary in gender and remuneration parity, contribution to the local economy, and tax incentives for companies that aim for sustainable development.

Hotel Sustainability – Questionnaire

Table 2- Relevance of sustainability

Relevance of sustainability	Yes	No	AT
At an environmental level	80%	8%	11%
At an economic level	80%	7%	13%
On a social level	69%	11%	20%

According to the questionnaire data, as shown in table 2, the hotel sector is notable and publicizes the importance it gives to this issue, prioritizing mainly the environmental and economic level.

Table1- Valuing sustainability

Valuing sustainability	**Valuation level**
Yes, mainly due to the surrounding society	24%
Yes, mainly by top management/management	59%
Yes, mainly by employees	54%
Yes, mainly by consumers (client)	48%
No	10%

According to table 3, the hotel sector reveals that top management/management are those who value sustainability the most, followed by employees and customers.

Table 2- Problems affecting the sector

	Average	**Median**	**Variance**	**Standard deviation**
Lack of qualified labour	4.25	4.00	0.763	0.874
Lack of Training	3.55	4.00	1,108	1,053
Inflated costs	4.13	4.00	0.741	0.861
Increase in the cost of living and activity	4.28	4.00	0.520	0.721
Low occupancy rate	2.48	2.00	1,339	1,157
Investments in technology	2.97	3.00	1,142	1,069
Difficulties in generating good profitability rates	3.01	3.00	1,243	1.115
Lack of financial aid	3.21	3.00	1,026	1,013
*Legend: 1- Totally Disagree; 2- I disagree; 3- I neither agree nor disagree; 4 – I agree; 5 – Totally Agree				

The hotel sector identified the following problems, table 4, which could negatively affect the hotel sector, the lack of qualified labour, the increase in the cost of living and activity, inflated costs, and lack of training. It is confirmed that on average, both problems listed have an average and median on the agreed scale (4), excluding the lack of training with an average of neither agree nor disagree (3). In terms of variance and standard deviation, the problems that present the greatest dispersion are the low occupancy rate, difficulties in generating good profitability rates, and investments in technology, which translates into a slightly high variation, the deviation that has the lowest error, It is associated with problems, increased cost of living and activity, inflated costs and lack of qualified labour.

Table3- Sustainable Hotel Concept

Sustainable Hotel Concept	**Valuation level**
Yes, and I don't recognize the advantages	6%
No, and I don't recognize the advantages	4%
No, but I consider it to have competitive advantages	34%
Yes, and it results in a competitive advantage	56%

For the hotel sector, we tried to understand whether they knew the concept of a sustainable hotel and whether it translated into competitive advantages. As can be seen, from table 5, they have implemented this concept in their units, and it results in a competitive advantage, even hoteliers who do not implement this concept believe they bring with them competitive advantages.

Sustainable Practices in the Hotel Sector - Questionnaire

Table 6- Environmental Practices

Environmental Practices	Implemented with results	Implemented without results	To implement	Not applicable
Use of 100% cotton textiles	45%	0%	32%	23%
Waste reduction	80%	1%	8%	10%
Eliminating plastic	63%	3%	20%	14%
Free parking and charging for electric vehicles	44%	3%	17%	37%
Controlled irrigation system	49%	0%	11%	39%
Using LED lights	86%	1%	6%	7%
Solar Panels	48%	1%	21%	30%
Biological Gardens	25%	4%	23%	48%
Reuse of bathwater	21%	0%	37%	42%
Rainwater retention system	30%	3%	27%	41%
Reducers on taps	65%	0%	24%	11%
Presence sensors	83%	1%	6%	10%
Recycling in all zones	80%	4%	13%	3%

Of the practices mentioned by the experts, the aim was to identify within the hotel sector which practices have the highest level of implementation by the sector. Therefore, in table 6, the practices implemented and with results are presented: the use of LED lights, presence sensors, waste reduction, and recycling in all areas.

Table4- Social Practices

Social Practices	Implemented with results	Implemented without results	To implement	Not applicable
Promotion of education, culture, and internal social responsibility	51%	4%	20%	25%
Support for families in need through food recovery	30%	1%	30%	39%
HR practices aimed at work/life balance	56%	4%	27%	13%
Professional qualification	51%	4%	30%	15%
Cleaning forests and beaches	31%	0%	24%	45%
Food donation	46%	0%	24%	30%
Promotion of purchasing local products to support the local community	68%	3%	8%	21%
Sponsorship of local events	65%	6%	11%	18%
Donation of materials (mattresses, unused clothing, etc.)	66%	1%	14%	18%
Support from local and national associations (e.g. customer comments revert to monetary value).	44%	0%	25%	31%

The practices that were implemented and achieved successful results by the hotel units, as shown in table 7, include promoting the purchase of local products to support the local community, donating materials, and sponsoring local events. The practice identified as being in the implementation phase is essentially support for families in need through the use of food and professional training.

Table 8- Economic Practices

Economic Practices	Implemented with results	Implemented without results	To implement	Not applicable
Entrepreneurship and recovery and preservation projects of classified heritage	44%	1%	23%	32%
Employment and salary in gender and remuneration parity	70%	6%	11%	13%
Professional qualifications of young people	59%	4%	15%	21%
Tax incentives for companies that aim for sustainable development	32%	1%	31%	35%
Selection of local suppliers	89%	1%	3%	7%
Buying recycled goods	51%	3%	27%	20%
Contribution to the local economy	79%	1%	10%	10%
Cautious investments	82%	1%	7%	10%

In terms of the economic practices most implemented with results, by the hotel sector, table 8 shows the selection of local suppliers, cautious investments, contribution to the local economy, and employment and salary in parity with gender and remuneration. The practices that are currently in the implementation phase mainly include tax incentives for companies that aim for sustainable development and the purchase of recycled goods to be implemented.

In all dimensions, the percentage of practices implemented without results is very insignificant, as the maximum number of hotel units selecting this option does not exceed 6%. However, something that should be the subject of study, is to understand the reasons that may lead to these implementations not being effective.

DISCUSSION OF RESULTS

Hotel sustainability is an extremely important topic, as it is a sector that mobilises thousands of people. According to the experts and hotel units, this importance is passed on, corroborating Mousavi et al. (2017), who state that the hotel sector seeks to generate responses to environmental and social impacts. However, there are still hotel units that do not give due significance to the issue of sustainability. The appreciation of sustainability in the hotel sector is seen by experts as being more aligned with economic aspects. However, in surveys of hotel units, they emphasise both environmental and economic aspects, which are valued mainly by top management and employees. This partly contradicts Girard and Nocca (2017), who claim that top management views sustainability primarily as an economic strategy.

Regarding concerns, experts and hotel units agree that the lack of qualified labour, inflated costs, and the rising cost of living are the main obstacles to the development of the sector. These last two aspects are mentioned in the literature review (Boronat-Navarro & Pérez-Aranda, 2020).

Concerning the concept of a sustainable hotel, both studies state that stakeholders increasingly demand the implementation of sustainable practices. These translate into competitive advantages, which reduce the problems affecting the sector, corroborating various authors such as Mousavi et al. (2017), who mention that the implementation of sustainability leads to the development of competitive advantages and that brand exposure is a tool capable of attracting customers.

According to the results obtained, what can influence the demand for a hotel unit is the effective dissemination of its sustainable practices. Marketing is the best tool any sector has to advertise its brand and present its image, promoting the expectation that the image seen by the customer is met during their stay (Li et al., 2015). However, if this is not effective, customer adherence may be reduced and not have the desired impact. Nevertheless, not all guests/customers have this concern with sustainability in their daily lives, and in this sense, their demand when selecting a hotel unit will not be a factor to consider or eliminate.

Sustainable practices in the hotel sector are crucial for mitigating environmental impact and promoting social responsibility, ultimately contributing to the long-term viability and competitiveness of the industry. Throughout the literature review, various sustainable practices were identified (Stylos & Vassiliadis, 2015; Abdou et al., 2020) which are listed in Table 9. This table represents the practical outcome of this work, summarising the sustainable practices recommended by experts and the hotel units that participated in this study, covering the three dimensions of sustainability: environmental, social, and economic.

Table 9- Suggestions for sustainable management practices for hotel units

Practices Environmental Dimension
1. Good thermal insulation, on windows, walls, and ceilings.; 2. Turn off certain equipment by default; 3. Use of refillable water and/or hygiene product dispensers; 4. Towel and sheet reuse program; 5. Place rubbish bins in strategic locations to encourage the recycling process; 6. Swap plastic cups for durable, multipurpose cups; 7. Give preference to energy-efficient products, such as the use of LED lights; 8. Use of renewable energy sources, such as solar panels; 9. Preservation and revitalization of water, through a rainwater retention system, reducers in taps, and controlled irrigation systems. 10. Reuse organic waste (for natural land fertilizers); 11. Select equipment with certificates that contain reduced noise or gas emissions; 12. Implementation of the environmental management system and/or sustainability management system for accommodation establishments.
Practices Social Dimension
1. Promotion of the purchase of local products to support the local community, as well as support from local and national associations and sponsorship of local events; 2. Encourage and raise awareness of all interested parties towards conscious behaviour in the environment; 3. Publicize, through the website, to customers, the sustainable actions that the unit practices; 4. Employee involvement, through the promotion of education, culture, and internal social responsibility; cleaning forests and beaches; 5. Propose voluntary cooperation from guests and ask them to turn off temperature control systems or opt for shorter showers. 6. Support for families in need through the use of food and the donation of materials; 7. Human resources practices oriented towards work/life balance and professional qualification; 8. Basic information about the region (gastronomy, culture, history, among others) and what attitudes to have in local communities, taking into account awareness of the surrounding environment. 9. Implementation of the occupational health and safety management system.

Practices Economic Dimension
1. Professional qualification of young people; 2. In-house production of daily cleaning products; 3. Employment and salary in gender and remuneration parity; 4. Contribution to the local economy, through the purchase and promotion of local markets; 5. Partnership with the local authority, to contribute to conducting an ecological energy audit and offering subsidies. 6. Tax incentives for companies that aim for sustainable development; 7. Entrepreneurship projects and recovery and preservation of classified heritage. 8. Selection of local suppliers and purchase of recycled goods; 9. Cautious investments. 10. Implementation of the quality management system.

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CONCLUSIONS

This work aims to present the results of research on the impact of sustainability in the hotel sector, identifying both current and potential practices. It was conducted through the analysis of data collected from interviews guided by the Delphi methodology and a questionnaire sent to hotel units.

Some hotel units prioritize economic concerns over sustainability, although they acknowledge its importance. The concept of sustainable hotels is relatively new but recognized by the sector, with growing demand from stakeholders. This presents a compelling reason to start implementing and promoting sustainable practices, aiming to attract all stakeholders and potentially raise awareness among those less attentive to sustainability issues. In this regard, a list of sustainable management practices for Portuguese hotels was developed, suggested by experts and hotel units, aligned with the literature review and the ISO 21401:2018 standard - Tourism and related services — Sustainability management system for accommodation establishments — Requirements.

Sustainability is of utmost importance and a critical topic. Hotel units can be significant contributors to sustainability, as the sector is highly competitive and involves complex management. Many hotel units are already taking steps in this direction, however, many other hotel units do not have the issue of sustainability in mind, and their vision needs to be changed.

Limitations

Due to the lack of responses from associations related to tourism and hospitality, and also due to the small number of respondents, the sample is only satisfactory, it could be robust to result in a more sustained evaluation of the data.

Future work proposals

For future work, the results obtained could also be analysed considering the different characteristics of the hotels, such as quality indicators, location, target clientele, and other factors. It is also suggested to carry out a comparison with other areas of the tourism sector and extend the research to other types of accommodation units to analyse which ones incorporate more sustainable management practices.

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Discrete-Event Simulation Tools Applied to the Healthcare Context

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STRUCTURED ABSTRACT

Purpose - Healthcare is a field of activity in which decisions have very complex characteristics and require various types of knowledge to be made in the most assertive way possible. Searching for tools to support decision-making has been recurrent and inevitable in this complex scenario, such as optimization methods and simulation techniques.

Design/methodology/approach - Optimization methods aim to find the optimal solutions to the problems under investigation, and simulation techniques allow these solutions to be tested before they are implemented, guaranteeing the quality of the results, and minimizing the consequences of wrong decisions, inefficient physical interventions, and unnecessary costs. This paper identifies the most widely used Discrete-Event Simulation tools reported in the literature over the last ten years, outlining their applications and identifying possible gaps for future research.

Findings - The main technical characteristics have been pointed out, such as the most common software, the factors that determine their choice and the most suitable software for the problem situations presented. Specific simulation characteristics are also presented, such as the number of replications, the type of simulation adopted, the methods used to validate the models and integration with optimization tools.

Originality/value - The results of this work can contribute to the development of specific tools with a focus on healthcare, to other research aimed at filling the gaps found, to an attempt to standardize actions for recurring problems, and to the construction of a framework for choosing the most appropriate computational tools for each problem situation.

Keywords: Healthcare, Optimization, Discrete-Event Simulation, Decision Support Tools.

Paper type: Literature review.

INTRODUCTION

Over the years, the decisions surrounding the management of Healthcare (HC) resources have grown exponentially, in line with the increase in the population, their life expectancy, and their need for health services. Healthcare management is a critical activity, as it has to deal with significantly limited human and material resources, and decisions must be agile, precise, and objective. The impact of these decisions can directly affect a significant number of people, including irreversibly.

The complexity of these decisions has required managers to use scientific resources to support decision-making to mitigate mistakes, reduce costs, and improve the quality of the decisions made. Among these scientific resources is Operations Research (OR), which describes various mathematical methodologies for modeling real problems, such as optimization methods, as well as forecasting techniques to identify possible impacts of decisions before they are implemented, such as simulation models. In terms of optimization, problems are transformed into mathematical models and solved using proposed or existing solution algorithms; in terms of simulation, problems can be modeled using Discrete-Event Simulation (DES), Agent-Based Modeling and Simulation (ABMS) and System Dynamics (SD) approaches, which, according to Taboada et al. (2013), are the main techniques applied to HC systems.

Wang and Demeulemeester (2023) presented a literature review on the problem of optimization and simulation applied to HC resource planning. This study highlights the use of these techniques in hospital environments, such as operating rooms, outpatient clinics, and clinics, and in-home healthcare environments. Due to the breadth of the research carried out, they were able to organize a total of 84 papers, many of which presented more than one aspect of the defined scope, such as the strategic, tactical, or operational level of the decision, objectives, optimization, and simulation methods and/or techniques adopted, algorithms implemented, validation, among others.

As Singh et al. (2022) point out, over the years, DES has been applied in HC to evaluate emergency departments and outpatient clinics (Viana et al., 2014); determine work teams (DeRienzo et al., 2017); reduce delays in patient care (Baril et al., 2016); reduce response times to patients (Pan et al., 2015); and improve quality (Rutberg et al., 2015).

Therefore, considering that decisions on managing resources (human or material) for healthcare are highly critical and complex, studies aimed at applying scientific methodologies such as optimization techniques, combined with forecasting tools such as simulation models, are justified and extremely important. This paper presents a Systematic Literature Review, focusing on Discrete-Event

Simulation applied to the HC context, in which the most recurrent computational tools in the literature are identified, as well as the types of applications, the technical characteristics, and the selection criteria, among other aspects.

DISCRETE-EVENT SIMULATION IN THE HEALTHCARE CONTEXT

Simulation is imitating a real-world problem through a model constructed with computational tools, in which time is an important variable. It is an Operations Research methodology for modeling and analyzing systems, which allows users to evaluate the behavior and efficiency of existing systems or design new ones (Jacobson et al., 2013). Its use in organizations has grown considerably in recent years, with applications in various areas such as manufacturing, services, supply chain, and risk analysis, among others (Dehghanimohammadabadi and Keyser, 2017).

In the healthcare context, Nawawi et al. (2021) and OH et al. (2016) reveal that various studies have been carried out that relate simulation techniques (static, agent-based, discrete-event, or dynamic) to a wide range of areas, such as scheduling, staff optimization, physical layout changes, improvements in triage methods, reduction of waiting times, logistics services, queue management, management of demand and supply, analysis and management of risks, among others.

OH et al. (2016) proposed a decision support tool based on Discrete-Event Simulation to improve patient flow in the emergency department, using a framework for developing the simulation model. This framework, which can be extended to other systems, consists of eleven basic stages: 1) Problem Identification and Defining Goals; 2) Data Collection; 3) Data Analysis; 4) Process Modeling; 5) Simulation Model Construction; 6) Model Verification and Validation; 7) Experimentation; 8) Optimization; 9) Decision Making; 10) Implementation; 11) Results Evaluation and Performance Monitoring.

Figure 1 schematically presents the simulation process, from observing a "real-world problem", through abstraction to a symbolic model, verification and validation of conceptual and computational models, evaluation of obtained results, decision-making, and back to the real world, implementing the decision and monitoring results for continuous improvement.

As can be seen in Fig. 1, the simulation process can be divided into three dimensions:

a) Real-World – Real-world management /or operational problems for which decisions must be made quickly and accurately. This dimension groups together stages 1, 2, and 3, which will serve as the basis for creating the simulation, and the final stages 10 and 11, where decisions will be effectively implemented and continuously monitored.

b) Modeling – In this dimension, the necessary models for the simulation process are created: i) The conceptual model: documents the actions that the simulation should perform, under a mathematical, logical, or graphical representation; ii) the computational model: translates the conceptual model generated into a programming language or specialist software (Sargent, 2013). This dimension corresponds to stages 4 to 9.

c) Verification/Validation – Both the conceptual model and the computational model must be verified (a phase in which it is assessed whether the model does not contain coding errors) and validated (a phase in which it is assessed whether the model truly constitutes a representation of the problem being investigated) (Sargent, 2013).

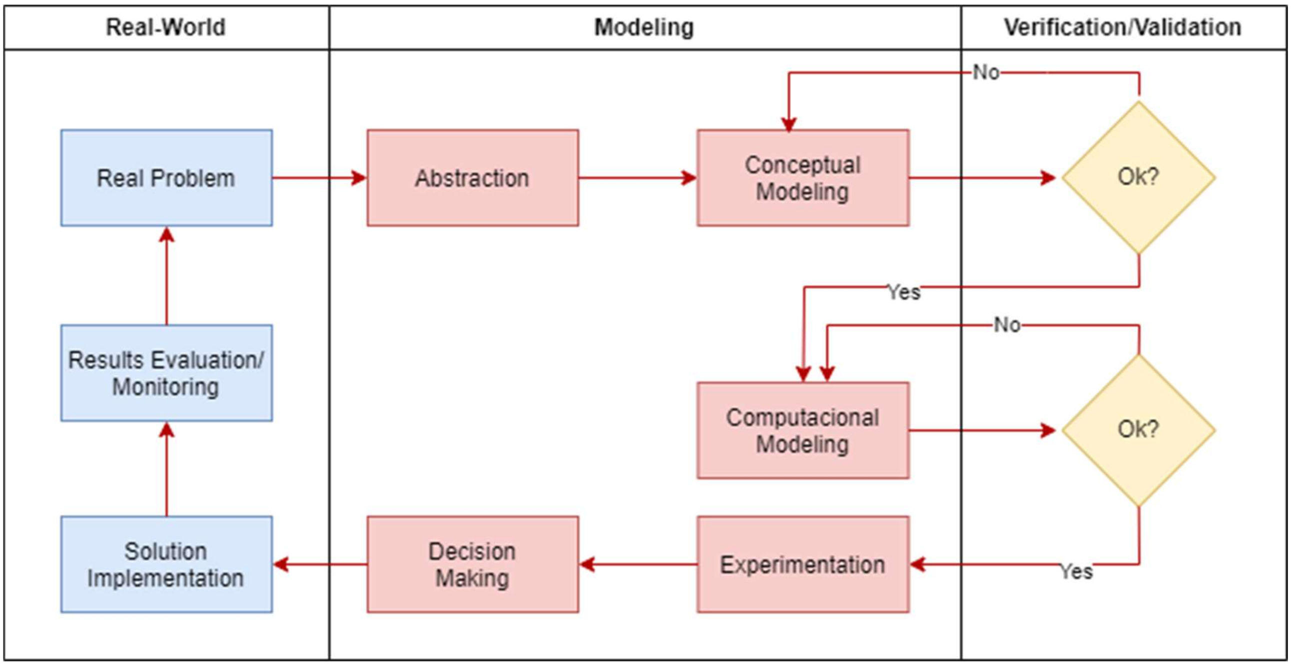

Figure 1 – Diagram of the Generic Simulation Process

It is important to note that in Fig.1, "Experimentation" corresponds to the execution of the experimental design, that is, the execution of simulation runs, with all desired replications, evaluation of the obtained responses of interest, optimization of these responses, and analysis of the validity of the results.

SYSTEMATIC LITERATURE REVIEW

Applying simulation to make decisions in healthcare has increased in recent years (Azadeh et al., 2016) and academic studies using computer simulation as a research method in healthcare have recently increased in popularity (Oh et al., 2016; Jacobson et al., 2013).

This growth trend in applications and research confirms the relevance of simulation with a focus on healthcare. It justifies research initiatives aimed at Systematic Literature Review (SLR), as a way to provide syntheses of the state of knowledge in this field, or to gather important data like the types of simulation adopted and their applications, forms of integration between different platforms, optimization algorithms used, simulation and optimization software chosen, etc.

Different research methodologies and protocols are available to conduct studies focusing on systematic reviews. Among them, the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) methodology stands out as a guide for constructing systematic review reports, based on a checklist of 27 items divided into eight sections (Page et al., 2021).

This work is based on the PRISMA methodology to identify the papers considered for analysis, whose main characteristics were described in the section Research Methodology.

The complexity of the analyses may require the use of several computational tools. In an attempt to bring together such tools into a single software package, Aria and Cuccurullo (2017) developed a tool based on the open-source statistical package "R," called *Bibliometrix R-package*. It provides a set of tools for bibliometric research for data collection, analysis, and visualization.

Bibliometrix allows for the collection and analysis of data from two popular bibliographic databases: *Clarivate Analytics Web of Science* and *Scopus*. It has a user-friendly interface with all functions available, generating various tables and charts, and allowing data export to Microsoft Excel spreadsheets, which can further enhance the power of the results obtained. In graphical terms, it can easily generate conceptual maps and keyword clusters, co-occurrence networks, collaboration networks, and historiography, among others.

RESEARCH METHODOLOGY

In this study, the SLR is based on the PRISMA methodology, and data analysis is performed using Bibliometrix tools. For this reason, two databases were chosen, *Scopus* and *Web of Science*, and the period between 2014 and 2023 was selected so that the analysis would cover the last decade.

Three search criteria were adopted, each representing a specific domain for the research: a) "discrete-event simulation" or "discrete event simulation"; b) "simulation software"; and c) "health*", spelled like this to make it easier to find possible variations of the term "Health Care".

The preliminary search was conducted by locating the keywords concatenated with logical conjunctions in the search string, present in the titles, abstracts, or in the list of keywords of the articles. Table 1 presents the search strings for both bibliographic databases and the number of papers found.

Table 1 – Results of preliminary search

Databases	**Search Strings**	**Number of papers**
Scopus	(TITLE-ABS-KEY ("discrete-event simulation") OR TITLE-ABS-KEY ("discrete event simulation") AND TITLE-ABS-KEY ("simulation software") AND TITLE-ABS-KEY (health*))	44
Web of Science	"discrete-event simulation" (All Fields) OR "discrete event simulation" (All Fields) AND "simulation software" (All Fields) AND health* (All Fields)	9654

In addition to the search strings, and as a way of reducing the volume of papers found, inclusion and exclusion criteria were also defined following the PRISMA model. Table 2 summarizes these criteria and, as a result, a total of 80 papers were located, 15 from Scopus and 65 from Web of Science. The term "Health Professions" was excluded because it could have generated a biased analysis that was not in line with the scope of the research.

Table 2 – Inclusion and exclusion criteria

Criteria	**Inclusion**	**Exclusion**
Period	between 2014 and 2023	
Language	English	
Type	Articles, conference papers or reviews and proceedings papers	
Subject area		Medicine, Social Sciences, Health Professions, Physics and Astronomy, Materials Science, Energy, Chemistry, Economics, Telecommunications, Transports, Electronic

After applying the inclusion and exclusion criteria to both databases, their results were combined, no duplicate works were identified between the two bibliographic bases, and a total of 80 papers from

52 different sources were selected. These papers were then analyzed using the Bibliometrix tool in the R statistical package. Considering the specified period, the volume of papers published per year can be seen in Fig. 2. Figure 3 shows the most relevant sources in terms of the volume of publications.

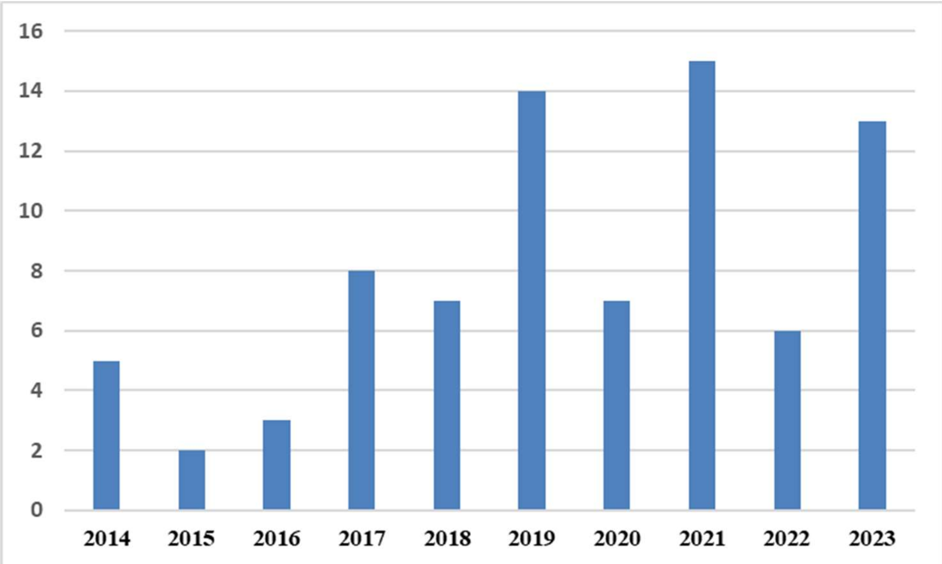

Figure 2 – Annual Scientific Production

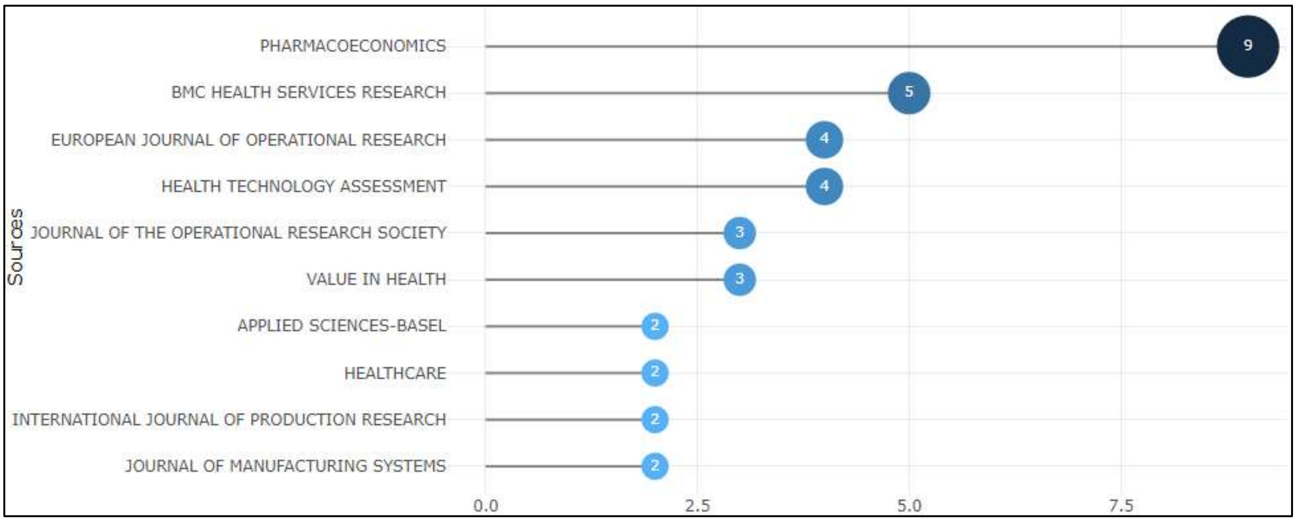

Figure 3 – Most Relevant Sources
Fonte: Bibliometrix.

Among the selected papers, a total of 266 keywords were referenced by the authors. Figure 4 presents the Word Cloud Diagram, which describes the volume of keywords cited by the size of the fonts used: the larger the font, the more citations in the papers found.

Figure 4 – Word Cloud Diagram
Fonte: Bibliometrix.

Figure 4 shows that the most relevant keywords are "Discrete-Event Simulation", "Health-Care", "Computer Simulation Software", and their variations, corresponding to 16.5%, 5.6%, and 5.3%, respectively. Also noteworthy in this diagram are the keywords "management", "cost-effectiveness", "optimization", and their variations, highlighting the nature of management combined with technology in decision-making in healthcare problems.

In order to analyze the results of the SLR, additional exclusion criteria were evaluated: relevance of the papers found (Out of Scope, n=49 or 61%), given the scope of the research (Scope Deviation, n=4 or 5%), and the non-existence of a DOI (Digital Object Identifier) (No DOI, n=4 or 5%), among others, which further reduced the number of selected articles. In the composition of the total list of selected articles, some were added because it was considered that, although they did not meet the selection criteria adopted, they would be relevant to the research analysis (Papers Add, n=4 or 5%). Considering these new inclusion and exclusion criteria, a total of 28 articles were selected, 16 of which were literature reviews. Figure 5 shows the percentage of papers, after the additional inclusion and exclusion criteria.

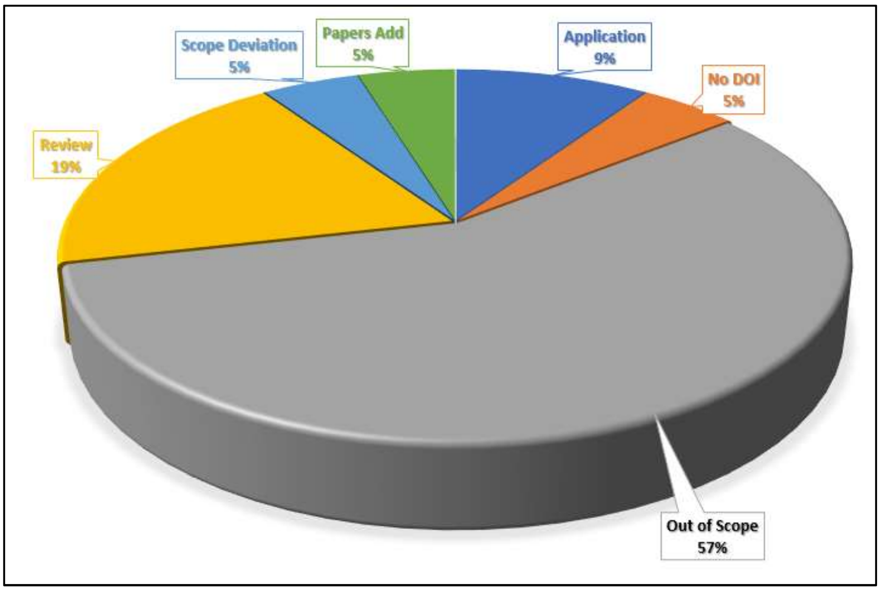

Figure 5 – Classification according to additional inclusion and exclusion criteria

RESULTS

Among all the papers selected, only twelve referred to applications of specialized simulation software for analyzing and optimizing healthcare problems.

The most recurrent problem among these works, 42% or 5 papers, is patients' waiting time in different departments of clinics or hospitals. Two papers focused on patient flow and the remaining 42%, or 5 papers, had a variety of focuses, such as managing the department's capacity, developing layouts, and resource deployments, among others.

Three articles focused on finding solutions to problems related to the COVID-19 pandemic, such as vaccination logistics, management of testing units, and allocation of special structures for treatment; the others divided the attention of different departments, such as the emergency, radiology, or admissions departments, outpatient clinics, pharmacies, or laboratories. One paper presented a system to support health education in the simulation and management of patient flow, providing practical experience.

Table 3 lists these papers, identifying the simulation methods and software utilized.

Table 3 – Papers on simulation software applications

		Method			Simulation Software					Simulation Process						Optimization Method (if exists)
Year	Authors	DES	ABS	SD	AnyLogic	Arena	FlexSim	Simul8	Others	Conceptual Modelling	Verification	Validation	Warm-up	Replication	Experimentation	
2014	Kadri et al.	✓				✓				✓		✓	✓	✓	✓	
2014	Viana et al.	✓		✓				✓	✓	✓		✓	✓	✓	✓	
2015	Alhaag et al.	✓				✓				✓	✓	✓		✓	✓	
2017	Shakoor et al.	✓				✓					✓	✓	✓	✓		
2018	Romano and Iuliano	✓				✓								✓	✓	GA
2018	Criddle and Holt	✓							✓	✓				✓		
2019	Bean et al.	✓							✓	✓						
2021	Gowda et al.	✓					✓									
2021	Asgary et al.	✓	✓		✓					✓	✓	✓				SMO
2022	Singh et al.	✓					✓				✓	✓				
2023	Abid et al.	✓				✓								✓	✓	
2023	Hossain et al.	✓					✓			✓	✓	✓			✓	

Notes: **DES** – Discrete-Event Simulation; **ABS** – Agent-Based Simulation; **SD** – System Dynamic; **GA** – Genetic Algorithm; **SMO** – Simulation-Based Multi-Objective Optimization.

It is important to highlight some aspects of the information shown in Table 3. Firstly, in the "Method" column, there is no preference for applying DES over the other simulation methods. DES, ABS, and SD are simulation methods that have different specific applications. Each of these methods has some advantages over the others, and there may be hybrid implementations between two or more of them (Brailsford et al., 2019; Abdelghany and Eltawil, 2017, 2014). Few papers describe the simulation process for investigating real or non-real problem situations. This small number of papers also shows, without any reasonable justification, a preference for using Arena software as a computational modeling tool and the absence from the list of well-known software in various engineering areas, such as C++, ProModel, or NetLogo. Few studies describe the combined application of different simulation methods and the simulation-optimization approach.

Considering the main aspects of the Simulation Process, it can be seen that the majority of studies do not present the Conceptual Model, nor describe the criteria adopted for verification and validation, which are considered of fundamental importance for understanding the process, developing the computer model, and guarantee the model's accuracy, according to classic authors such as Robinson

(2014). Few authors consider the need to introduce a warm-up period in their models, in addition to setting up an adequate number of replications, as a way of increasing the statistical reliability of the results. The experimental design adopted was not considered in most of the papers and, finally, none of the papers covered all the aspects considered relevant in a simulation process. Although not the focus of this literature review, the only optimization methods mentioned were also listed in Table 3: GA and SMO.

All the other papers found in the search procedure carried out in the bibliographic databases were literature reviews, focusing on different aspects of simulation applied to the healthcare problem. Table 4 summarizes these papers, identifying their objectives and main conclusions.

Table 4 – Reviews on simulation applied to healthcare

		Databases						Search Period	No. Documents Found	Methods	
Year	Authors	WoS	Scopus	PubMed	EBSCO	Google Scholar	Others			DSS	Simulation
2014	Abdelghany and Eltawil						✓	2007-2014	NA		✓
2017	Salleh et al.		✓	✓		✓	✓	1996-2017	10		✓
2017	Bradley et al.	✓	✓				✓	2000-2014	44	✓	✓
2017	Abdelghany and Eltawil						✓	2007-2014	19		✓
2017	Salleh et al.		✓	✓			✓	1990-2017	37		✓
2018	Salmon et al.						✓	2000-2016	254		✓
2018	Zhang	✓		✓	✓	✓		1997-2016	211		✓
2020	Kunc et al.		✓					NA	130	✓	✓
2020	Zhang et al.						✓	NA	211	✓	✓
2020	Liu et al.		✓	✓		✓	✓	1980-2014	483		✓
2021	Zabel et al.	✓	✓				✓	2000-2019	27		✓
2022	Ala and Chen	✓					✓	2000-2021	150	✓	✓
2022	Forbus and Berleant			✓	✓			2017-2021	311		✓
2023	Ouda et al.	✓	✓		✓			2004-2022	62		✓
2023	Philip et al.	✓	✓					2006-2020	161		✓
2023	Zhang et al.	✓	✓	✓	✓		✓	2019-2021	372		✓

Note: **NA** – Not Available.

In Table 4, the "No. Documents Found" column refers to works, cited as journal publications, conference proceedings, thesis, and others. The "Methods" column refers to the main focus of the literature review: DSS (Decision Support Systems) or Simulation (discrete-event simulation, agent-based simulation, or system dynamics).

Table 5 presents the specific objectives for each review paper listed in Table 4.

Table 5 – Objectives of Reviews on simulation applied to healthcare

Year	Authors	Objectives
2014	Abdelghany and Eltawil	Comparison between the individual approaches to simulation in its three main methods (discrete event simulation, agent-based simulation, dynamic systems) and the hybrid approach of these methods.
2017	Salleh et al.	Discrete-event simulation (DES) for resource modeling (RM) in health technology assessment (HTA) context.
2017	Bradley et al.	A scoping review of the use of OR to analyze global health issues, emphasizing health equity and research impact.
2017	Abdelghany and Eltawil	It presents the different ways of integrating the three simulation approaches, the simulation methods available and how they are used in the healthcare context.
2017	Salleh et al.	It presents a repository of works focusing on the use of simulation models for decision-making in healthcare.
2018	Salmon et al.	The analysis with the aim of applying the simulation to the Emergency Department environment.
2018	Zhang	Literature review on Discrete Event Simulation applied to the Healthcare problem.
2020	Kunc et al.	Application of Operations Research in healthcare, considering human behavioral aspects.
2020	Zhang et al.	Formulate a generic reporting checklist for healthcare-related DES studies and critically appraise the existing studies.
2020	Liu et al.	It describes the evolution of DES in the context of healthcare services and healthcare management in the period 1980-2014.
2021	Zabel et al.	To identify processes to engage stakeholders in healthcare Simulation Modeling, and the impacts of this engagement on model design, model implementation, and stakeholder participants.
2022	Ala and Chen	Minimizing waiting times and increasing patient satisfaction by applying simulation-based modeling, mathematical optimization, Markov chains and artificial intelligence, among others.
2022	Forbus and Berleant	Define the current state of the art with respect to the use and application of DES to healthcare context, analysis of what and how it is being done, and potential areas for expansion.

2023	Ouda et al.	Literature review presented focusing on discrete event simulation and agent-based simulation in the context of Emergency Departments.
2023	Philip et al.	Identify the major and emerging research issues in general and specialized outpatient departments (OPD); find the commonly used performance measures in OPD; and identify the commonly used simulation methods for OPD modeling.
2023	Zhang et al.	Literature review of works dedicated to the application of simulation with a focus on predicting and assessing the impacts of COVID-19.

Some of the papers identified by the inclusion criteria of this research did not adhere to its scope and others, such as Petropoulos et al. (2023), Wang et al. (2021), Lamé and Simmons (2020), and Defraeye and Van Nieuwenhuyse (2016) dealt with aspects related only to the definition of simulation techniques (and Operations Research) applied to decision-making in healthcare problems. Petropoulos et al. (2023) is a compilation of all the theories surrounding Operations Research, including principles, practice, mathematical programming and optimization, modeling, simulation, and decision-making. The work by Wang et al. (2021) presented a robust systematic literature review on operating room planning and scheduling for outpatients e inpatients. However, simulation was considered only an Operations Research technique for decision-making and was not related to any practical application. The work by Lamé and Simmons (2020) only contextualized the main types of simulation and discussed how they could be applied to the health problem. Finally, Defraeye and Van Nieuwenhuyse (2016) presented a generic literature review involving staffing and scheduling under non-stationary service demands, with a focus on Queue Theory, which is understood to be closely related to the subject of this research.

Finally, it should be noted that in the work of Ouda et al. (2023), states that Healthcare administrators are becoming more aware of the benefits of using DES to manage resources and improve processes. In their paper, a broad literature review was presented focusing on discrete event simulation and agent-based simulation in the context of Emergency Departments. The various applicable methods were discussed, such as mathematical modeling, "what-if" analysis, Design of Experiments, and a systematic framework for generating scenarios, as well as presenting the main techniques for generating operational scenarios from DES models. In addition to the aforementioned processes for verifying and validating simulation models, the authors also discuss the importance of calibrating these models as an essential tool in simulation.

CONCLUSIONS

This study aimed to investigate the application of the main simulation methods - discrete event simulation, agent-based simulation, or dynamic systems - in the healthcare context, by systematically reviewing the literature in academic and scientific databases.

A total of 80 papers were located using the specified search criteria, but of this total, only 28 were considered to be truly adherent to the research proposal, 12 of which related to the application of simulation to healthcare problems and 16 were literature reviews.

The few studies found make it clear that there is a favorable environment for simulation research applied to healthcare. Several gaps can be observed in scheduling appointments and optimizing the time allocated to them, evaluating the layout of offices or clinical procedures, scheduling care teams (doctors, nurses, and assistants), optimizing the scheduling of procedures, etc.

However, despite the small sample size, the importance of applying Operations Research methodology to support decision-making is clear, with simulation as the main Operations Research technique available. In addition, most authors considered Discrete Event Simulation the main and most effective tool for modeling healthcare problems at different levels of complexity. The results presented from the modeling and simulation demonstrated its effectiveness, both in finding the optimal outcome of the problems reported, and in predicting the impacts of the decisions implemented and evaluating the possible scenarios derived from them.

As far as the application of simulation tools is concerned, this is easy to notice:

- Arena software is the most recurrent computational tool among the selected papers. However, there is no information on the criteria used to choose this tool to justify this preference.
- Discrete Event Simulation is the methodology adopted in all the studies, even those that adopted a hybrid approach with the other methods, ABS or SD.
- The number of studies related to the application of computer simulation tools, specifically in the healthcare context, is still small, considering that there is a certain consensus about their applicability, understanding of the problems, agility in building and implementing the models, and accuracy of the results.
- Considering that this is an emerging topic among managers in the area, there is a lack of papers on how to conduct the simulation process that demonstrate the appropriate techniques for collecting and processing input data, identifying the appropriate statistical distributions for each

situation, building conceptual models, building the computer model and, above all, the most appropriate techniques for verifying, calibrating, and validating simulation models.

In terms of literature reviews, it can be seen that there is a considerable body of publications on the subject, but with very different and specific approaches to different areas of knowledge, such as scheduling problems, emergency department investigations, operating room scheduling, ambulance routing, balancing and formatting the workforce, decisions considering aspects of human behavior, minimizing waiting times and increasing patient satisfaction, among many others.

For future work, a systematic review of the literature with broader criteria is suggested, to identify other papers on the application of computational tools in related areas of knowledge whose models and results can be replicated in the healthcare context.

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Contribution of the Energy Management System (ISO 50001) to ESG

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STRUCTURED ABSTRACT

Purpose - Given the importance of efficient energy management and sustainability, this article seeks to identify relationship of the ISO 50001 with sustainability, using the Environmental, Social and Governance (ESG) criteria for this purpose.

Design/methodology/approach - The methodological procedure adopted has been qualitative and consisted in document analysis and the creation of a relationship matrix. Based on that, it was possible to assess at which level each of the sub-clauses of ISO 50001 contributes to achieving ESG elements, considering the Morgan Stanley Capital International (MSCI) criteria. A team of five academics analyzed individually the standard and classified all sub-clauses according to the criteria. Then, based on the individual means and ranges, a second analysis was conducted to assess the points where there was the greatest difference of opinion between the evaluations.

Findings - Among all aspects evaluated, those regarding "Product liability," a part of the Social aspect of ESG, sparked the most disparity among researchers. In essence, experts found ambiguity in ISO 50001 concerning its contribution to "Product liability"; some perceived a significant contribution, while others saw none directly, suggesting only indirect influence even after reassessment. Conversely, "Social opportunities" within the Social aspect provoked the least uncertainty. Consensus swiftly emerged that ISO 50001 requirements offer limited direct contribution to ESG elements.

Originality/value – This study assesses the ISO 50001 standard's contribution to ESG, considering that both are relevant subjects and usually treated separately.

Keywords: ISO 50001, Environmental, Social, Governance.

Paper type: Research paper

INTRODUCTION AND BRIEF THEORETICAL REVIEW

Global warming is largely driven by the current energy system, accounting for approximately 75% of total greenhouse gas emissions. Therefore, it is crucial to make changes both in how energy is produced and consumed (IEA, 2024). With this aim, financial incentives can assist in investing in energy efficiency, aiding companies through significant changes in the technologies used. In Germany, for example, government incentives through financial measures contribute to companies making voluntary commitments to energy efficiency measures. Moreover, this country stands out in the number of ISO 50001 certifications – Energy Management System (Oki and Salamanca; 2021).

ISO 50001 is among the management systems (MSs) developed by the International Organization for Standardization (ISO) with the highest number of certifications, with 28,164 certificates issued worldwide for this MS (ISO, 2023). This standard is a strategic tool that involves implementing an energy policy, setting energy usage goals, developing action plans to achieve them, as well as measuring progress, which may include adopting more efficient technologies, improving processes, and reducing energy waste (ISO, 2024). With the advent of Industry 4.0 and Industry 5.0, many opportunities for adopting new technologies have emerged, contributing to the improvement of the Energy Management System (EnMS) (Introna et al., 2024). According to a survey of 83 companies that implemented ISO 50001, it was observed that, on average, these companies achieve annual rates of 4.1% in terms of energy performance improvement in the first year of implementation. Through these results, it can be concluded that the implementation of an EnMS like ISO 50001 can be considered a very important lever in combating climate change (Fitzgerald et al., 2023).

However concerning and noticeable the climate issue may be (heavy rains and/or droughts, extreme heat, etc.), climate change is not the sole point to be observed when considering sustainability. Companies, just as they have been seeking to adopt certifiable management systems to enhance their processes, are also focusing on achieving better performance in terms of Environment – Social – Governance, known as ESG.

The term ESG originated in 2004 through a challenge from the UN Secretary-General to 50 large financial institutions to incorporate social, environmental, and governance factors into the capital market. Large companies are closely monitored by their stakeholders, and ESG provides solidity, reduced costs, and contributes to reputation enhancement and greater resilience to uncertainties and vulnerabilities (Global Compact, 2023). The discourse around ESG practices intensified with the onset of the Covid-19 pandemic, underscoring the urgency and significance of initiatives with greater resilience in addressing sustainability issues. Moreover, the financial market is a cornerstone for fostering sustainable economic growth (CMV, 2022). Notably, there has been a significant increase in the volume of sustainable investments globally in recent years. In 2016, the five primary markets covered by the report (United States, Canada, Japan, Australia, and Europe), had $22.8 billion in global assets under management for sustainable investments, which rose to $35.3 billion by 2020 (GSIA, 2020).

Given the above, this article aims to identify the relationship between ISO 50001 and sustainability from the perspective of ESG. Companies may want to use ISO 50001 to achieve external goals and sustainability objectives (Fuchs et al., 2020). It is expected that ISO 50001 will contribute to aspects related to climate change; however, this article seeks to identify whether it can contribute to other elements of ESG, considering that research on the relationship between ISO 50001 and ESG themes is still missing in searches conducted in Scopus and Web of Science databases. To do this, 5 experts evaluated each of the sub-clauses of ISO 50001 related to ESG elements through a relationship matrix to identify whether the standard contributes to ESG. For ESG categorization, the MSCI criteria (2022) were used, which are divided into 4 categories for the environmental pillar (climate change, natural capital, pollution/waste, environmental opportunities) and social (human capital, product responsibility, stakeholder engagement, social opportunities), as well as 2 categories for governance (corporate governance, corporate behavior). Therefore, the question sought to be answered by the article is: Can ISO 50001 support other elements of ESG besides climate change?

RESEARCH METODOLOGHY

This article is based on a qualitative method, named Document Analysis. According to Jupp (2006), documents can change or reinforce a belief, attitude or behavior. In this article, a relationship matrix was constructed where the sub-clauses of the ISO 50001 standard were presented on the y-axis and the elements of ESG according to the MSCI were presented on the x-axis (Table 1). For each of the intercession points in the matrix, a scale from 0 to 10 was used, where 0 represented that there was no direct contribution from that ISO 50001 sub-clause to the ESG elements; 1 to 3 represented that there was a direct but weak contribution of the standard to ESG elements; 4 to 6 that there was a direct and average contribution of the standard to the ESG elements; while from 7 to 10 there was a construction of the direct and strong standard for ESG elements. This scale was designed to provide more options for evaluators and to facilitate joint data analysis.

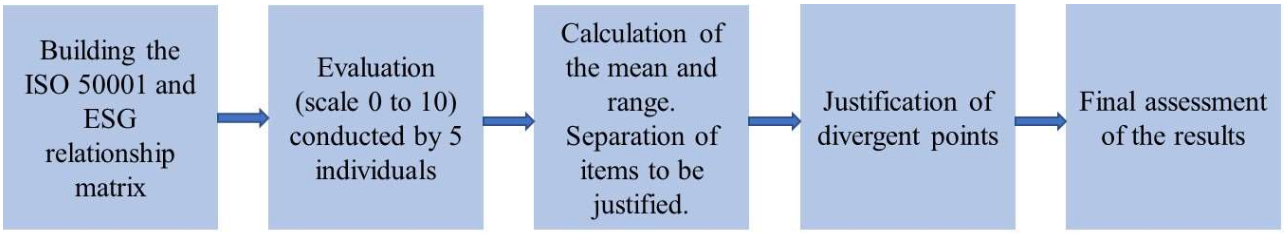
Table 1 - Partial example of the matrix filled in by each of the assessors

7 a 10	Strong	Contributes directly and strongly to ESG elements
4 a 6	Media	Contributes directly and averagely to ESG elements
1 a 3	Weak	Contributes directly and weakly to ESG elements
0	Null	Does not contribute

		Environment				Social				Governance	
		Climate Change	Natural Capital	Pollution and Waste	Environment opportunitie s	Human Capital	Product liability	Stakeholder opposition	Social opportunitie s	Corporate governance	Corporate behavior
4.1	Organization context	9	9	9	9	7	5	3	0	6	10
4.2	Stakeholder needs and expectations										
4.3	Scope										
4.4	Energy Management System										

For this classification, five out of the six authors of this article participated in the evaluation. These individuals work in the field of management systems, sustainability, and/or ESG. Each of these five individuals conducted the assessment individually, without interference from one another. After completing this process, the average and range were calculated for each of the evaluated points. Figure 1 presents the research flowchart.

Figure 1 - Research Flowchart



Based on the range, for the points that showed a range greater than 5, the evaluators were asked to justify the reasons for giving that score. In some cases, only one of the evaluators significantly diverged from the others, in which case only that evaluator was requested to justify. However, in cases where there was a discrepancy between evaluations involving more than one evaluator, all were asked to justify that point.

Another point to highlight is that for cases where this discrepancy was more significant than 5 but tending towards the maximum score, for example, where the range was 6 but the maximum score was 10, and the minimum was 4, in this case, the need for justification was excluded. It was understood that regardless of whether this contribution was considered direct and moderate or direct and strong, there was still a significant contribution in some way. However, in cases where this same discrepancy of 6 occurred at the lower extreme, for example, with at least one member giving the minimum score of 0 and the maximum of 6, justification was requested. This meant that for at least one evaluator, that point did not contribute to the ESG elements, while for the other evaluator, that point contributed directly and moderately to the ESG.

In this way, it was not only considered the range itself but an evaluation was made for each of the points where the discrepancy was greater than 5. After obtaining all justifications, an assessment was made, which is presented in the results section.

RESULTS

The main results are presented visually in Table 2 below. As it can be seen, the average value calculated based on the evaluations made by the five assessors is presented. Upon analyzing this Table, it is noted that ISO 50001 contributes directly to all elements of ESG (different colors are assigned based on the intensity of the relationship: 0 pink, 1-3 yellow, 4-6 purple, 7-10 green), as there were no points where the score was null (pink color = zero) according to the average. Regarding the intensity of this contribution, it is predominantly direct and weak (yellow color) in terms of the social aspect, especially regarding product liability, stakeholder opposition, and social opportunities. For the environmental aspect, as anticipated, the standard contributes directly and moderately to strongly to climate change. Besides climate change, the standard also contributes to natural capital, pollution and waste, and environmental opportunities, with predominant direct and moderate to strong contributions in all these cases. In the social aspect, concerning human capital, similar to the environmental aspect, the contribution was direct and moderate to strong. It is noteworthy that in the governance aspect, both in corporate governance and corporate behavior, there were assessments showing a direct and moderate contribution, but most assessments showed a direct and strong contribution. Thus, in the overall assessment of corporate governance and corporate behavior, the contribution of ISO 50001 was stronger than that of climate change, which was already expected to have a contribution.

Table 2 - Average among the evaluations made

		Environment				Social				Governance	
		Climate Change	Natural Capital	Pollution and Waste	Environment	Human Capital	Product liability	Stakeholder	Social opportuni	Corporate governan	Corporate behavior
4.1	Organization context	7	7	6	7	7	4	6	2	6	6
4.2	Stakeholder needs and expectations	6	6	6	7	7	3	8	1	6	6
4.3	Scope	7	7	7	7	6	4	7	1	6	6
4.4	Energy Management System	7	7	7	8	8	4	7	1	8	8
5.1	Leadership and commitment	7	7	6	7	7	3	4	1	9	8
5.2	Politics	7	7	7	7	8	4	5	2	8	7
5.3	Roles, responsibilities and authorities	5	5	5	6	8	3	1	1	8	6
6.1	Actions to address risks and opportunities	7	7	7	8	6	4	7	3	7	7
6.2	Objectives, energy targets and planning	7	7	7	7	7	4	6	3	8	7
6.3	Energy review	7	7	7	9	7	4	4	1	7	8
6.4	Performance indicator	6	5	6	7	3	3	1	1	7	6
6.5	Energy baseline	5	5	5	6	6	3	1	1	7	6
6.6	Planning for energy data collection	5	4	4	8	4	4	2	1	8	7
7.1	Resources	4	4	4	8	7	3	2	1	8	5
7.2	Competence	4	4	4	5	9	3	1	1	5	5
7.3	Awareness	4	4	4	5	8	3	1	1	6	6
7.4	Communication	3	3	3	4	8	3	6	3	6	5
7.5	Documented	4	4	4	4	5	2	1	1	7	6
8.1	Operational planning and control	6	6	6	7	7	4	6	1	8	7
8.2	Project	7	7	7	9	6	4	5	2	7	8
8.3	Acquisitions	7	6	6	7	3	3	8	1	7	7
9.1	Monitoring, measurement, analysis	5	5	5	6	4	3	1	1	6	7
9.2	Internal audit	4	4	4	5	8	3	4	1	7	7
9.3	Critical analysis by management	6	6	6	7	7	3	5	1	9	7
10.1	Non-conformity and Corrective Actions	5	5	5	5	6	3	2	1	7	7
10.2	Continuous	5	5	5	6	6	3	2	1	7	7

7 a 10	Strong	Contributes directly and strongly to ESG elements
4 a 6	Media	Contributes directly and averagely to ESG elements
1 a 3	Weak	Contributes directly and weakly to ESG elements
0	Null	Does not contribute

In Table 3 shows the range between assessments. Blank cells represent an amplitude less than or equal to 5. However, as stated in the Research Methodology section, an individual assessment was made for cases where the amplitude was more significant than 5. The grey cells represent cases where the amplitude tended towards the upper extreme of the evaluation; that is, all evaluators considered that there was some contribution, although this contribution may have varied from weak to medium, from weak to strong, or from medium to strong. The green cells show the points where more than one evaluator differed from the others. For example, in sub-clause 6.6, when evaluating climate change, the scores given by the five evaluators were, respectively: 9; 8; 6; 0; and 0. That is, for two evaluators, this sub-clause contributes directly and strongly to mitigating climate change, for one of the evaluators, this contribution exists, although it is in a direct and average way, while for two other evaluators, this contribution is null. In this case, everyone was asked to justify. The blue cells show a significant discrepancy between just one of the evaluators compared to the others. For example, in sub-clause 5.3, when evaluating the contribution to the stakeholder opposition, it is noted that one of the evaluators gave a score of 6, which represents that for him, there is a direct and average contribution to this ESG element. However, the other evaluators scored respectively: 0; 1; 0; and 0. In other words, the contribution is null or very close to null for these four evaluators. In this case, only the evaluator who scored 6 was asked to justify his opinion. Of the total of 260 points evaluated in the matrix, 131 showed divergence (50% approximately), but of these 131, a total of 59 needed to be justified for the reasons presented above, which represents around 23% of the total points evaluated.

Therefore, through Tables 2 and 3, it can be concluded that the ISO 50001 standard contributes in some way to the elements of ESG; however, in 28% of its sub-clauses, there may be divergences in interpretation regarding its contribution to the elements of ESG. The ESG element that generated the greatest divergence was product liability, while those related to Governance, as well as the human capital element related to the Social aspect, showed the greatest convergence. From these points (28%) that showed divergence and based on the justifications provided, the main points and interpretations of these justifications will be analyzed next.

Table 3 - Range and points for critical evaluation

		Environment				Social				Governance	
		Climate Change	Natural Capital	Pollution and Waste	Environment	Human Capital	Product liability	Stakeholder	Social opportuni	Corporate governan	Corporate behavior
4.1	Organization context	5	5	4	4	3	8	5	5	4	7
4.2	Stakeholder needs and expectations	6	6	6	7	3	5	5	6	4	7
4.3	Scope	5	5	5	5	4	7	5	5	4	7
4.4	Energy Management System	5	5	5	5	5	7	5	5	3	5
5.1	Leadership and commitment	7	7	9	6	6	6	6	5	2	4
5.2	Politics	5	5	5	5	5	7	7	5	6	4
5.3	Roles, responsibilities and authorities	9	9	9	6	5	5	6	5	3	6
6.1	Actions to address risks and opportunities	5	5	5	4	3	7	5	6	6	3
6.2	Objectives, energy targets and planning	5	5	5	5	5	9	4	7	4	7
6.3	Energy review	5	5	5	2	4	9	3	5	6	3
6.4	Performance indicator	8	8	8	7	5	6	6	5	6	5
6.5	Energy baseline	7	7	7	5	4	6	5	4	6	5
6.6	Planning for energy data collection	9	9	9	3	7	8	6	5	4	7
7.1	Resources	10	10	10	6	5	5	6	5	2	4
7.2	Competence	9	9	9	10	4	5	5	5	7	3
7.3	Awareness	9	9	9	10	6	5	5	5	6	6
7.4	Communication	6	6	6	7	5	5	2	10	3	5
7.5	Documented	9	9	9	9	7	7	5	4	6	6
8.1	Operational planning and control	7	7	7	9	5	10	1	5	7	8
8.2	Project	5	5	5	5	2	8	2	5	2	4
8.3	Acquisitions	6	6	6	4	7	6	4	4	5	3
9.1	Monitoring, measurement, analysis	9	9	9	9	4	7	6	5	10	9
9.2	Internal audit	8	8	8	8	5	5	5	5	9	6
9.3	Critical analysis by management	7	7	7	6	5	6	4	5	3	3
10.1	Non-conformity and Corrective Actions	9	9	9	10	6	5	7	5	10	10
10.2	Continuous	8	8	8	7	7	6	6	5	3	5

The difference was not enough to justify
More than one evaluator disagreed
Only one evaluator disagreed

Starting with the environmental aspect, upon analyzing the "climate change" element, it is noted that although with some divergences, as can be observed in Table 3, ISO 50001 contributes directly and from (predominantly) moderately to strongly to this element as observed in Table 2. However, some elements within "climate change" showed divergences, such as planning for energy data collection, resources, competence, awareness, communication, documented information, and non-conformity. According to MSCI, when evaluating "climate change," carbon emissions, product carbon footprint, financing environmental impact, and climate change vulnerability are considered. Therefore, it was under this perspective of "climate change" that ISO 50001 was evaluated. The reasons that led the evaluators to consider whether there was a contribution or not are shown in Table 4 below. One of the evaluators even considered that depending on the item, as in the case of sub-clause 7.5 referring to documentation. In this case, the evaluator justified: "Documentation will increase the likelihood of addressing this item, but not necessarily it will lead to improvement, so the direct link is moderate." In Table 4, the most similar justifications are highlighted. However, it is important to highlight that not in all cases, the contribution was direct and strong, for example, as in the case specified in the previous sentence. That is, there are cases such as in sub-clauses 7.1, 7.2, 7.3, 7.4, 7.5, and 10.1 where one of the evaluators considered that the contribution will depend on the situation.

Table 4 - Climate Change

Section	Contributes directly	Null
6.6	The systematic collection of energy data is vital for identifying trends and opportunities to improve energy efficiency, which can have a significant impact on reducing greenhouse gas emissions	Data collection is indirectly related to improvements that would affect this concern. It's necessary, but collecting data will not improve climate change.
7.1	Providing adequate resources for energy management is essential for implementing initiatives that contribute to climate change mitigation. For example, a company that lacks financial resources to invest in equipment to control carbon emissions will have its performance in terms of ESG affected.	These are items more directly related to organizational aspects, in terms of preparing internal questions for the EnMS. From this perspective, climate change is not related to them.
7.2	Ensuring that staff are competent in energy management contributes to more effective and efficient actions that support the reduction of climate impact.	
7.3	Raising awareness of the importance of energy efficiency promotes a corporate culture that supports initiatives to combat climate change.	
7.4	Communicating effectively about energy use and efficiency can encourage behaviours supporting reducing climate impact.	
7.5	Maintaining detailed documentation on performance and energy efficiency initiatives supports transparency and commitment to climate goals.	

Section	Contributes directly	Null
10.1	Identifying and correcting non-conformities related to energy management is crucial to maintaining the organization's commitment to reducing climate impact.	Non-conformities and corrective actions related to the EnMS do not impact environmental aspects, because they refer to internal aspects

Also regarding the environmental aspect, when analyzing the "natural capital" element, the evaluations resemble those of the "climate change" element. That is, it is noted that although there are some divergences, ISO 50001 contributes directly and from (predominantly) moderately to strongly to this element, as observed in Table 2. However, some elements within "natural capital" showed divergences, coincidentally the same ones presented in "climate change". According to MSCI, when evaluating "natural capital," water stress, raw material sourcing, biodiversity and land use are considered. Therefore, it was under this perspective that ISO 50001 was evaluated. The reasons that led the evaluators to consider whether there was a contribution or not are shown in Table 5 below. Table 4, sought to consolidate the most similar justifications, but not all cases showed a direct and strong contribution. There are cases such as in sub-clauses 7.1, 7.2, 7.3, 7.4, 7.5, and 10.1 where one of the evaluators considered that the contribution would depend on the situation, the same as what happened with "Climate Change".

Table 5 - Natural Capital

Section	Contributes directly	Null
6.6	The planning for energy data collection includes points that encompass the use of raw materials and water stress, with the latter affects the energy source coming from hydroelectric power plants.	Data collection is indirectly related to improvements that would affect this concern. It is necessary, but collecting data will not lead to improved climate change.
7.1	Resources earmarked for energy management can contribute to preserving natural capital by reducing energy consumption and switching to renewable sources.	These are items more directly related to organizational aspects, in terms of preparing internal questions for the EnMS. From this perspective, natural capital is not related to them.
7.2	Developing energy management skills can lead to more efficient use of natural resources and lower environmental impact.	
7.3	Promoting awareness of the impact of energy use on natural capital encourages sustainable behaviour among employees.	
7.4	Effective communication about energy management practices can lead to greater protection of natural capital by highlighting the importance of sustainability.	
7.5	Keeping documented information about the EnMS helps ensure the sustainability of energy management practices and the preservation of natural capital.	
10.1	The assessment of non-conformities is an important ally in natural capital, because when carrying out this assessment aiming at the EnMS,	Non-conformities and corrective actions related to the EnMS do not impact environmental aspects, because they refer to internal aspects

Section	Contributes directly	Null
	many aspects that will be impacting natural capital will be considered and actions taken	

The same evaluations were made for "pollution and waste" and "environmental opportunities", both belonging to the environmental aspect of ESG. The data is consolidated in Table 6 for "pollution and waste" and Table 7 for "environmental opportunities". As observed in the two previous aspects evaluated, the evaluations resemble the previous ones. Although there are some divergences, ISO 50001 contributes directly and from (predominantly) moderately to strongly to these elements, as observed in Table 2. However, some elements within "pollution and waste" and "environmental opportunities" showed divergences, coincidentally the same ones presented in "climate change" and "natural capital". According to MSCI, when evaluating "pollution and waste", toxic emissions & waste, electronic waste, and packaging material & waste are assessed. When evaluating "environmental opportunities", MSCI considers opportunities in clean tech, opportunities in renewable energy, and opportunities in green building.

Table 6- Pollution and Waste

Section	Contributes directly	Null
6.6	Collecting and analyzing energy data can help identify and reduce inefficiencies that result in pollution and energy waste, leading to cleaner and more sustainable operations.	Data collection is indirectly related to improvements that would affect this concern. It is necessary, but collecting data will not improve climate change.
7.1	Allocating resources to improve energy efficiency contributes directly to reducing polluting emissions and minimizing waste through efficient energy use. For example, besides being less efficient, old equipment consumes more energy and resources and generates more emissions.	These are items more directly related to organizational aspects in preparing internal questions for the EnMS. From this perspective, pollution and waste are not related to them.
7.2	Ensuring that employees are competent in efficient energy management practices helps to decrease pollution and waste, as they will be better equipped to identify and implement more efficient energy use practices.	
7.3	Making employees aware of the impacts of energy use and consumption on pollution and waste can motivate them to adopt more sustainable practices that reduce these impacts.	
7.4	Effective communication about energy management policies and practices can raise awareness of pollution and waste issues, promoting actions that help reduce these impacts.	
7.5	Maintaining documentation on energy consumption and use allows energy practices to be continuously monitored and improved, potentially reducing the pollution and waste associated with energy use.	

Section	Contributes directly	Null
10.1	The recording and evaluation of non-conformities assist in the analysis of pollution and waste, considering that the use of energy, especially depending on the source of that energy, has a significant pollution potential, and all waste should be combated.	Non-conformities and corrective actions related to the EnMS do not impact environmental aspects because they refer to internal aspects

Table 7 - Environmental Opportunities

Section	Contributes directly	Null
7.2	Developing energy management competence among employees can drive innovation that benefits the environment.	These are items more directly related to organizational aspects in preparing internal questions for the EnMS. From this perspective, environmental opportunities are not related to them.
7.3	Promoting awareness of energy efficiency can lead to greater participation in environmental programs and sustainability initiatives.	
7.4	Communication failures can lead to issues within the EnMS, which may result in people overlooking the environmental opportunities present before them.	
7.5	Documented information contributes to the assessment and analysis of environmental opportunities because energy consumption is closely linked to environmental concerns, especially when there is much discussion about green and more energy-efficient buildings, as well as renewable energy. Documented information becomes a valuable ally in this regard.	
10.1	Non-conformities are what lead to identification of the biggest opportunities. Responding to non-conformities with corrective action can improve environmental performance and capitalize on energy efficiency opportunities.	Non-conformities and corrective actions related to the EnMS do not impact environmental aspects, because they refer to internal aspects

Another element that showed several points with divergences among the evaluators was "product liability". In this element, out of the 26 points evaluated in the standard, there was a convergence of opinions among the evaluators in only 8 of them. This demonstrates that for this element of ESG, ISO 50001 does not clearly specify its contribution to the ESG elements, depending greatly on the interpretation of those who read and use the standard. Furthermore, in the overall assessment, when examining the average of the evaluations, it is noted that for this element of ESG, ISO 50001 predominantly contributes directly and weakly to the ESG elements. The justifications are shown in Table 8 below.

Table 8 – Product Liability

Section	Contributes directly	Null
4.1	Understanding the context in which the organization operates, including energy efficiency aspects, can influence product responsibility, ensuring that products are created and manufactured according to sustainable practices. Furthermore, according to MSCI, when assessing "product liability," one of the evaluated points is a responsible investment, whereby "companies are evaluated on their integration of environmental, social and governance considerations in the management of their own assets or the assets they manage on behalf of others". Therefore, when evaluated from this perspective, it is noted that there is a contribution.	Point 0.1 of ISO 50001 states that it is not applicable for products but rather for the "This document does apply to the design and acquisition of facilities, equipment, systems or processes that use energy within the scope and limits of the MS". Therefore, I interpret that all the benefits in terms of product liability will be indirect rather than direct
4.3	Determining the scope of the EnMS helps the organization to identify areas that impact product responsibility, especially those related to energy use in production.	
4.4	Establishing an effective EnMS contributes to manufacturing products more efficiently and sustainably, which can reduce product liability related to energy issues.	
5.1	The requirement refers to leadership and commitment along with the whole organization, namely workers, products and processes involved in the EnMS	
5.2	The energy policy can impact the company's energy decisions, affecting the safety of employees and third parties	
6.1	Planning to address risks and opportunities related to EnMS ends up impacting responsible investment, that is, safety in your operations, bringing greater security to your employees and the environment	
6.2	Setting clear energy objectives and targets can minimize product liability by continuously improving energy efficiency during product production	
6.3	It contributes because conducting an energy review may lead to decisions that impact the safety of employees and the surrounding environment	
6.4	Energy performance indicators are important for monitoring the energy efficiency of processes that can affect product liability	
6.5	Establishing an energy baseline helps the organization measure energy performance over time, influencing efficiency and product liability	
6.6	The planning and data collection process can potentially impact safety during the data collection itself	
7.5	Documented information can contribute to safety and protect both the company and employees from potential accusations in case any issues involving energized equipment occur, thereby putting people at risk.	
8.1	Operational planning and control contribute to ESG as they can impact safety and the company's ability to engage in responsible investment.	
8.2	For the organization to conduct an analysis of energy performance improvement and operational control in projects, it is necessary to be attentive to issues involving	

Section	Contributes directly	Null
	risks to safety, health, as well as engage in responsible investment	
8.3	Purchasing energy-efficient products and services can impact product liability by ensuring that energy use during the production and operation of products meets energy performance criteria.	
9.1	Monitoring, measurement, and analysis are related to ESG since the way these monitoring and analysis are conducted can jeopardize the safety of individuals	
9.3	Critical analysis by management can impact the safety of individuals	
10.2	Continuous improvement can impact ESG as these changes may result in alterations that are beneficial from an energy perspective but may lead to safety issues	

The other elements of ESG showed fewer divergences, as can be seen in Table 9 and Table 10. Table 9 presents the justifications for the elements where more than one evaluator diverged, whereas for the ESG elements where there were fewer divergences (see Table 3 - green color), while Table 10 presents the justification where only one of the evaluators diverged from the others (see Table 3 - blue color).

Table 9 - Divergences among multiple evaluators related to other ESG elements

Section	ESG	Contributes directly	Null
8.3	Human Capital	Purchasing energy-efficient equipment and services can reduce operational risks and improve working conditions, benefiting human capital.	The main relationship with human capital goes through governance-related activities.
6.6	Stakeholder opposition	Systematically collecting energy data can help the company be more transparent about its energy performance, reducing potential conflicts with stakeholders concerned about sustainable practices.	Data collection does not involve direct stakeholders. Maybe it uses their feedback as an input, but this point does not address directly stakeholders' concerns
7.1	Stakeholder opposition	Adequately allocating resources to energy efficiency demonstrates commitment to sustainable practices, which can reduce stakeholder opposition.	There is no relationship between resources and stakeholder opposition given that the provision of resources takes place within the organization
10.2	Stakeholder opposition	Commitment to continuous improvement and adaptation to emerging stakeholder needs can help minimize opposition, promoting a positive image of corporate responsibility.	Continuous improvement might require stakeholder involvement, but the standard does not ask for this explicetly
4.2	Social opportunities	Understanding stakeholders' needs and expectations can help the organization identify and seize opportunities to improve social welfare through energy efficiency practices	Point c of the ISO 50001 addresses opportunities, but they are more environmental as this is an energy MS, not social. There is no relationship.
6.1	Social opportunities	Identifying risks and opportunities in the context of the EnMS can reveal ways the organization can contribute positively to society, such as energy efficiency projects that benefit local communities.	Point d addresses opportunities, but they are more environmental as this is an energy MS, not social. There is no relationship.

Section	ESG	Contributes directly	Null
6.2	Social opportunities	Setting energy objectives and targets aligned with social responsibility can lead to initiatives that offer social benefits, such as energy efficiency education and community partnerships	Point d of the ISO 50001 addresses opportunities, but they are more environmental as this is an energy MS, not social. There is no relationship
7.4	Social opportunities	Effective communications about energy management can engage stakeholders and the wider community in social activities related to energy sustainability and the environment.	The main benefits of communication are linked the environmental issues due to the nature of the EnMS. There is no direct relatioship
9.1	Corporate governance	Corporate governance is strengthened by rigorous monitoring and evaluation of energy performance, which demonstrates compliance and accountability.	Null relation because, for me it is a more operational question.

In Table 10, regarding the "Stakeholder Opposition" element, most evaluators considered there is no contribution, while one evaluator considered there is a contribution, ranging from medium to strong. Therefore, the justifications in Table 10 are from this evaluator who considered there is a contribution. For the "Corporate Governance" and "Corporate Behavior" elements, the justifications were provided by the evaluator, who considered that there was no contribution.

Table 10 – Divergences presented by only one evaluator

Section	ESG	Justificativa
5.3	Stakeholder opposition	Clearly defining roles, responsibilities and authorities can help align internal expectations and reduce potential conflicts or opposition from internal stakeholders, such as employees. This can indirectly contribute to managing opposition from external stakeholders by ensuring that the organization operates cohesively and efficiently.
6.4	Stakeholder opposition	Establishing clear and measurable energy performance indicators allows the organization to monitor and communicate tangible progress in terms of energy efficiency. This transparency and demonstration of commitment to continuous improvement can help mitigate stakeholder opposition by showing accountability and concrete results.
9.1	Stakeholder opposition	Monitoring, measuring, analyzing and evaluating energy performance provides fundamental data for internal and external decision-making and communication. The ability to demonstrate improvements and effectively manage energy performance can reduce stakeholder opposition by demonstrating the organization’s commitment to responsible and efficient energy practices.
10.1	Stakeholder opposition	A proactive approach to identifying and correcting non-conformities in the energy management system demonstrates to stakeholders the organization’s commitment to continuous improvement and compliance. The ability to respond quickly and effectively to problems can build trust among stakeholders and minimize opposition, showing that the organization is responsible and capable of self-correction.
10.1	Corporate governance	Non-conformity and corrective action are operational questions.
10.1	Corporate behavior	Non-conformity and corrective action are operational questions.

Through these analyses, it is possible to observe which elements of ESG receive contributions from ISO 50001 and which do not. For companies aiming to excel in ESG and already having ISO 50001 or intending to implement this standard, it is possible to observe which elements they will have to make an effort to implement if they want to excel in ESG.

CONCLUSIONS

The association between ISO 50001 and ESG is not widely found in the literature and this research seeks to evaluate how can ISO 5001 contribute to enhance ESG performance. Initially, it was assumed that in the Environmental aspect, the climate change element would benefit. However, through this article, it is possible to observe that, on average, all sub-clauses of the standard make some contribution to all ESG elements, although this contribution ranges from weak to medium or strong.

It is also observed that the elements of ESG that would have a predominantly weak contribution are product liability, stakeholder opposition, and especially social opportunities. For the other elements, the contribution would tend from moderate to strong. Additionally, when observing the divergences in the evaluators' responses, it is noted that 23% of the evaluated points may raise doubts about this contribution, meaning that ISO 50001 may or may not contribute to the elements of ESG depending on the evaluator's interpretation. The justifications were presented in the results section, where both the viewpoints of those who believe there is a contribution and those who believe there is no contribution are presented.

For companies seeking to excel in ESG and already have ISO 50001 implemented or are in the process of implementing it, this article helps identify the weaker aspects the company will need to overcome if it wants to excel in ESG. For companies that do not yet have ISO 50001 or do not intend to implement it, this article demonstrates that implementing this standard can contribute to ESG, providing one of the options for the company to excel in ESG. For academia, the contribution lies in providing a study that combines two topics of great interest both in the academic and business spheres. For future research, it is suggested that the same study be conducted for other management systems

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Suitability of ISO 9001:2015 standard in the digital transformation context: literature review

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STRUCTURED ABSTRACT

Purpose - The last revision of the ISO 9001 standard (quality management systems) was carried out in 2015 when Industry 4.0 was still in its infancy, and the concept of Quality 4.0 was only introduced after that revision. This study aims to review the literature focusing on the suitability of ISO 9001 considering the current context of Digital Transformation (DT). The literature review intended to identify articles that discuss gaps, or outdated features of ISO 9001, or misalignments with current needs, or contributions to the debate on updating ISO 9001, or mentions of the need to update ISO 9001, or proposals for revising its requirements, or references to a future research agenda. **Design/methodology/approach** - A systematic literature review was accomplished using the PRISMA methodology to summarise the literature published between 2011 and 2023, available on Web of Science and Scopus. The search query was "ISO 9001" or "quality management system" and terms related to DT or synonyms. The list was imported into Rayyan software to analyse the data from the relevant literature.

Findings - After using a set of predetermined inclusion and exclusion criteria, the literature review revealed few articles investigating changes or future approaches to ISO 9001 because of DT. Only less than 1% of the articles were selected with data relevant to the study. The literature has provided some insights in approximately a quarter of the articles included, but more details are needed to identify possible changes to ISO 9001. Approximately 50% of the articles identified refer to integrating ISO 9001 and Industry 4.0 as a future research agenda.

Originality/value - The main topics of the articles that identified gaps, obsolescence, misalignments of ISO 9001 with current needs, contributions to discussions on updating ISO 9001, references to the necessity of its revision, and proposals for revising its requirements were sustainability, innovation, risks (especially with analytics, predictive software and artificial intelligence (AI)), Stakeholder

identification accompanied by objectives, measures and monitoring, dynamic inter-organisational relationships, cyber-security (data protection and security aspects), validation of quality control equipment based on AI and decision-making and problem-solving processes, including a more simplified language and writing style of ISO 9001:2015 requirements.

Keywords: ISO 9001:2015, Digital Transformation, Quality 4.0, Industry 4.0

INTRODUCTION

The first iteration of ISO 9001 was published in 1987 and, since then, with the revisions made to account for the developments of organisations and markets, it has become the best-selling standard in the world (Anttila and Jussila, 2017). This first iteration was comprised of three standards and was first revised in 1994 to emphasize preventive actions. The 9001:2000 revision encompassed a complete rewrite, compiling the previous three standards into one. This revision focused on making the standard usable by organisations of all sizes and across different sectors while prioritising stakeholder needs and the integration of quality management systems into the business processes. The ISO 9001 standard was once again revised in 2008 and 2015, the latter constituting the version that is "in use" today (American Society for Quality - ASQ, no date a). The American Society for Quality - ASQ, defined Quality Management Systems (QMS) as formalized systems for documenting processes, procedures, and responsibilities for achieving quality policies and objectives. The ISO 9001 standard certification is probably the most common and widely spread approach worldwide, providing the criteria for a QMS supported by the PDCA (Plan-Do-Check-Act) cycle, a process-based approach, and a continuous improvement mindset to achieve quality outcomes and customer satisfaction (Minglana, Tobias and Roxas, 2021). These systems are implemented by organisations to increase the quality of their products, services, and processes, decrease process variations and costs, increase efficiency and, consequently, correspond to and exceed customer expectations.

The ISO 9001:2015 standard introduced risk-based thinking instead of preventive action and streamlined some of the required documentation considering the digitisation already happening at the time of the revision. It also introduced seven quality management principles that aim to promote continuous organizational improvement (American Society for Quality - ASQ, no date a): Customer focus, Leadership, Engagement of people, Process approach, Improvement, Evidence-based decision making, and Relationship management.

There have been numerous articles on the potential benefits for organisations of obtaining the ISO 9001:2015 certification or implementing its principles (Camango and Cândido, 2023). Nevertheless, despite the number of certified organisations still surpassing 1,000,000, this number has stagnated and the number of organisations that lost that certification has been increasing rapidly (Clougherty & Grajek, 2023; Mastrogiacomo et al., 2021).

Rapid and disruptive technological advancements have led to the emergence of Industry 4.0 (I4.0), prompting businesses to adapt their models, processes, products, and services to keep pace with rapidly evolving contexts and paradigms. With the focus now on the connection between the digital and physical systems, supported by connected and intelligent ecosystems at both intra and inter-organizational levels, organisations have increased automation, augmentation, and the integration of people, devices and processes leading to the appearance of increasingly complex and sophisticated processes and products which, in turn, require more complex quality management systems encompassing quality control and assurance and more accurate measurement and correction tools (Cots, 2018; Herceg *et al.*, 2020; Sader, Husti and Daroczi, 2022).

Moreover, some authors question the alignment of the ISO 9001:2015 standard with I4.0 and argue that the current version needs to be revised to be integrated with the new operating trends of organisations worldwide that encompass the vital role of technology and how it can be used to augment people's capabilities and achieve organizational performance and quality goals (Asif, 2020; Chiarini and Cherrafi, 2023). I4.0 and Digital Transformation have led to more cyber-physical organisations that have access to a greatly increased volume of data inputs providing feedback, a greater capacity for adaptability and automation, and vertical, horizontal and end-to-end connectivity, not only within organisations but across the entire value network resulting in more intelligent and efficient processes and organizations. These developments are now shaping modern business and have outpaced the current Quality Management Systems, including the ISO 9001:2015 standard (Asif, 2020; Minglana, Tobias and Roxas, 2021). I4.0 processes have non-linear and more concurrent information flows to support efficient demand and supply where quality is defined by flexibility, agility, responsiveness and product usage experience in addition to compliance with product and service specifications (Asif, 2020).

By adapting the traditional quality methods and models, Quality 4.0 (Q4.0) shifts quality to a holistic strategy across the entire organization, embracing new technology and its users and processes to maximize value (Armani *et al.*, 2021; Antony and Sony, 2023). The synergy between quality management practice and technological tools allows organizations to take advantage of Big Data collected in real-time, implement innovative processes and products whose adaptive capacity ensures superior quality and performance and, consequently, customer satisfaction and stakeholder interest across the value network (Salimova *et al.*, 2020; Carvalho *et al.*, 2021).

This paper aims to address the research question, "Is ISO 9001:2015 suitable in the context of digital transformation (DT)?" by focusing on an analysis of the existing literature. The objective was to identify articles that discuss gaps, or outdated features of ISO 9001, or misalignments with current needs, or contributions to the debate on updating ISO 9001, or mentions of the need to update ISO 9001, or proposals for revising its requirements, or references to a future research agenda.

RESEARCH METHODOLOGY

A systematic literature review was accomplished using the PRISMA methodology. The search query was "ISO 9001" or "quality management system*" and terms related to DT or synonyms. The following query was defined, as shown in table 1:

Table 1- Search conducted in Scopus and Web Science

		terms related to DT and synonyms
"quality management system*" OR "ISO 9001" OR "ISO9001"	**AND**	quality 4.0" OR "quality4.0" OR "industry 4.0" OR "industry4.0" OR "service 4.0" OR "service4.0" OR "digital*" OR "virtual" OR "digital* transformation" OR "digital* technology")) OR (("digital quality management system*") OR ("quality management system* 4.0") OR ("autonomous quality management system*") OR ("TQM 4.0") OR ("DQMS") OR ("total quality management 4.0"

To validate the inclusion and exclusion criteria during the screening and eligibility phases, a training phase was conducted. On December 5, 2022, the query was applied to Scopus and Web of Science databases, for the period from 2011 to December 5, 2022, focusing solely on review articles (252 articles in Scopus and 8 articles in Web of Science). The titles, abstracts and keywords of the articles were analysed, refining the exclusion criteria for subsequent phases.

Inclusion and exclusion criteria

The research was conducted using the Scopus and Web of Science databases, and the study was carried out in two phases to synthesize the literature published between 2011 and 2023. Initially, a search was performed on January 28, 2023, followed by a data update on January 1, 2024. The research timeframe for the first phase was confined to the period from 2011 to January 28, 2023. The year 2011 was chosen due to the emergence of the concept of I4.0. Exclusions from Scopus encompassed Book Chapters, Books, Notes, Editorials, Short Surveys, and Data Papers, while Early

Access and Editorial Material were excluded from Web of Science. In total, 3809 documents were reviewed, consisting of 3630 documents from Scopus and 179 from Web of Science, in languages including English, Portuguese, Spanish, Italian, and French. Figure 1 depicts the PRISMA methodology employed during the period.

Rayyan (https://rayyan.ai/) was utilized to identify duplicate articles, facilitate the selection process, and ensure blinded decision-making. This process, which included reviewing titles, abstracts, and full texts, was undertaken by a researcher with more than twenty-five years of experience in implementing ISO 9001 standards. Articles excluded during the full-text review phase were reassessed by another researcher, a specialist in the quality field, who was blinded to the initial decisions. Complete concordance between the two researchers was achieved in all instances, eliminating the need for a third-party consultation.

A total of 3809 articles were initially identified, with 145 identified as duplicates. Consequently, 3664 articles underwent title, abstract, and keyword screening. During this phase, records were excluded (3454 articles) for not addressing Quality Management Systems or ISO 9001 within the context of digital transformation. From these, 210 articles were selected for full-text review. The articles assessed for eligibility were excluded for the following reasons: reason 1 - lack of access to full texts, reason 2 - irrelevance to the research questions, and reason 3 - focus on Quality Management Systems without reference to ISO 9001 standards. Ultimately, 17 articles were included in the review for this period.

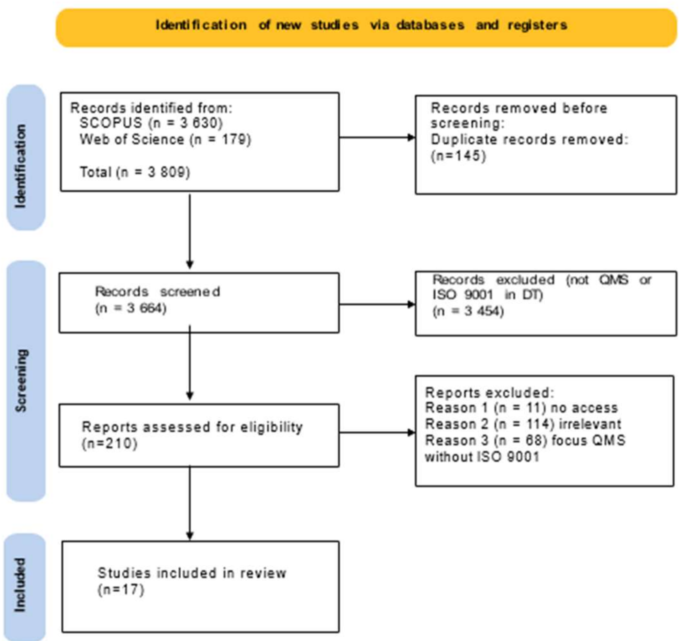

Figure 1 – PRISMA flow diagram (period from 2011 to January 28, 2023)

The research timeframe for the second phase was confined to the year 2023, during which 1005 documents were sourced from Scopus and 18 documents from Web of Science, with the same inclusion and exclusion criteria applied as in the first phase. In total, 5 articles were included in the review for this second period. Figure 2 illustrates the PRISMA methodology employed during this phase.

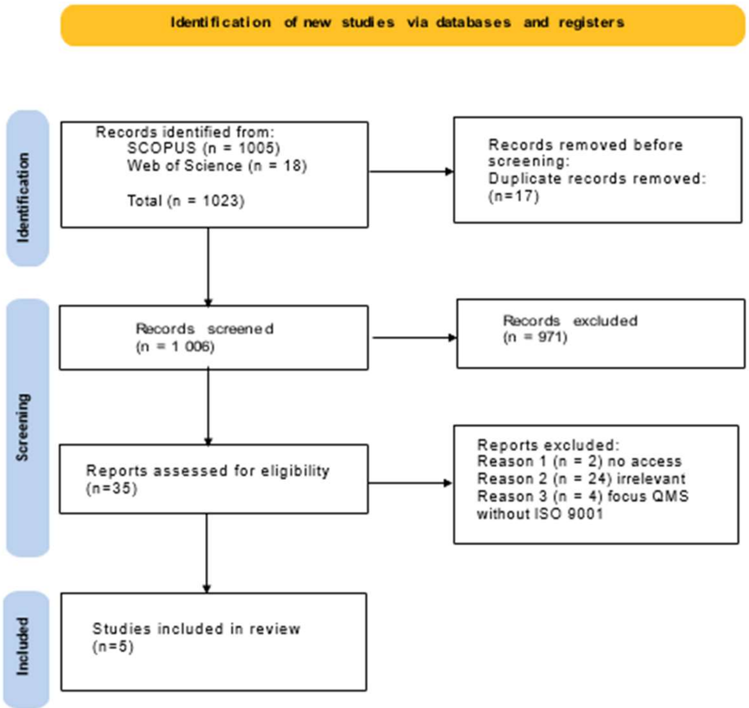

Figure 2 - PRISMA flow diagram (period from 2023 to January 1, 2024)

The 17 articles included from the period 2011 to January 28, 2023, were combined with the 5 articles from 2023 to January 1, 2024. After removing 1 duplicate, a total of 21 articles were available for analysis in this review.

Data Extraction

The Rayyan software was used to read the titles, abstracts, and keywords of the articles, as well as to mark the articles as excluded or included based on whether they addressed Quality Management Systems or ISO 9001 within the context of digital transformation. Following this categorization, the data were exported to an Excel spreadsheet where categories such as "No access," "irrelevant to the research questions," and "focus on Quality Management Systems without reference to ISO 9001 standards" were marked. Finally, only the articles included (n=21) were marked in the Excel spreadsheet with the following categories: gaps or outdated features of ISO 9001, misalignments with current needs, contributions to the debate on updating ISO 9001, mentions of the need to update ISO 9001, proposals for revising its requirements, or references to a future research agenda.

RESULTS

The 21 selected articles were categorized into three groups as outlined in Table 1. The three groups were constituted by:

Group 1 - Articles identifying gaps, outdated features of ISO 9001, misalignments, or contributing to discussions on updating ISO 9001.

Group 2 - Articles that mention the need to update ISO 9001 or present proposals for revising its requirements.

Group 3 - Articles referring to a future research agenda.

Table 1 – Distribution of the 21 articles by group

Authors	1	2	3
(Rönnbäck and Eriksson, 2012)	x	x	
(Barata *et al.*, 2013)	x		
(Sitek *et al.*, 2016)	x		
(Aleksandrova, Vasiliev and Alexandrov, 2019)	x		
(Asif, 2020)	x	x	x
(Lepistö, Saunila and Ukko, 2022)	x		
(Canbay and Akman, 2023)	x		
(Muruganandham *et al.*, 2023)	x		
(Siougle, Dimelis and Malevris, 2023)	x		
(Vykydal and Nenadál, 2022)	x		
(Chiarini and Cherrafi, 2023)		x	
(Fonseca, Carvalho and Santos, 2023)		x	
(Fonseca *et al.*, 2023)		x	x
(Foidl *et al.*, 2016)			x
(Sader, Husti and Daróczi, 2019)			x
(Chiarini, 2020)			x
(Saihi, Awad and Ben-Daya, 2021)			x
(Fonseca *et al.*, 2021)			x
(Chiarini and Kumar, 2022)			x
(Sader, Husti and Daroczi, 2022)			x
(Thekkoote, 2022)			x

Table 2 outlines the distribution of the 21 articles across the three groups as follows: Group 1 comprises 10 articles, representing approximately 48% of the total; Group 2 includes 5 articles, accounting for about 19%; and Group 3 includes 10 articles, also representing approximately 48% of the total. Notably, one study is included in all three groups, while two studies appear in two groups.

Table 2 – Distribution of Articles Across Groups

Group description	Number of articles
Group 1. Gaps, outdated features, or misalignments in ISO 9001; contributions to updating discussions	48%
Group 2. Mention of the need for updates or proposals for revising ISO 9001 requirements	24%
Group 3. References to a future research agenda	48%

Table 3 summarizes the articles that refer to: gaps, outdated features of ISO 9001, misalignments, or contributing to discussions on updating ISO 9001. In Tables 3, 4 and 5 the topics considered most relevant within the group are highlighted in bold.

Table 3 – Summary of articles - group 1

Authors	Group 1
(Rönnbäck & Eriksson, 2012)	"… there are principles that were not considered in ISO 9000 and in this study. The ISO standard has not incorporated concepts such as '**innovation', 'sustainability' or 'network'**, which both current practitioners and researchers put a great deal of emphasis on."
(Barata et al., 2013)	This article contributes to the discussion on how **Information Systems** will be addressed in the 2015 version.
(Sitek et al., 2016)	"…the ISO standard does not explicit mention and formulates requirements for the **handling with dynamic inter-organisational relationships**." Existing approaches to manage quality contain specifications and guidelines that are in line with improvements of long-term processes or stable processes with repeating characters.
(Aleksandrova, Vasiliev and Alexandrov, 2019)	"Quality management system based only on ISO 9001 does not guarantee the success of the enterprise and the fulfilment of all customer requirements. In this case, it is necessary to further focus on other approaches, including those offered by **modern digital technologies and system engineering**." "The use of modern systems makes it possible to use this approach, which allows to **build information models** and solve a wide range of interrelated tasks of digital production, including those related to quality."
(Asif, 2020)	"…shows that **QM models are not aligned with Industry 4.0 and need to be updated."** "…neither ISO 9001 nor ISO 9004 were developed to respond to Industry 4.0 developments. Consequently, many developments which underpin Industry 4.0 remain unaddressed in both standards."

(Lepistö et al., 2022)	"At a general level, ISO 9001 requires identifying system-relevant stakeholders and their requirements. In addition, the organization must monitor and review information about its stakeholders and their essential requirements." "Based on the evidence from this study, the mere **identification of stakeholders will not improve performance unless it is accompanied by objectives, measures and monitoring**, even if the ISO Quality Standard does not directly require them."
(Vykydal & Nenadál, 2022)	"… lot of certified quality management systems, mainly against ISO 9001:2015 requirements are **rigid, static and they do not comply with current demands on new era of digitalisation.**" "But traditional approaches to the **quality management and structures of current quality management systems will have to be transformed in order to meet dramatic technological development**, presented by Industry 4.0 concept."
(Canbay & Akman, 2023)	Study of **ISO 9001:2015 TQM Principles** to determine the changes in TQM principles in the I4.0 environment. "As a result, evidence-based decision making, continuous improvement and process management principles are applied much more easily with I4.0, the principles of leadership and employee participation continue to develop. While some principles become easier to implement, some TQM principles and practices **may need to be repositioned in terms of business management**." "…but also a new understanding of stakeholder relationships and duties, role of employees, transformation of fundamental business concepts, and more."
Muruganandham *et al.*, 2023)	"Despite this kind of tight coupling of continuous quality improvement approaches, the implementation of QMS based on ISO 9001:2015 standard has been slow. This is due to the reason that the **traceability of activities and immutability of the information** have not been addressed in fool-proof manner in ISO 9001:2015 standard."
(Siougle et al., 2023)	"The inherent upgrades of the successive ISO 9001 versions which incorporate data protection into quality management practices can consistently and significantly impact on firm performance in the long run." "A common objective shared between quality management models and Industry 4.0 is the improvement of firm performance. Our findings indicate that a "strong" **data protection** level can contribute significantly towards this direction". " Our study explored the effect of data protection on the relationship between ISO 9001 and firm performance." "The findings also reveal a positive and statistically significant impact of ISO 9001 on **data security**. Certified firms are more likely to uphold data security relative to the non-certified, indicating that the benefits deriving from quality implementation can enable more effective organization and management of data protection.

Although the article (Barata et al., 2013) predates the 2015 revision of ISO 9001, it remains relevant and contributes to the discussion on how information systems will be addressed. The 2016 article by Sitek et al. remains pertinent despite referencing the ISO 9001:2008 standard. It underscores that the ISO standard does not explicitly articulate or formulate requirements for managing dynamic inter-organizational relationships. The article by Rönnbäck & Eriksson (2012) remains relevant despite referencing the ISO 9001:2000 standard. It highlights that the ISO standard has not incorporated concepts such as 'innovation', 'sustainability' or 'network'.

The literature review provided insights from approximately 50% of the articles included and associated with **Group 1**, which is focused on identifying gaps and outdated features in the ISO 9001 standard to better align with modern technological advancements and organizational needs. Discussions were focused on the need for digital integration, emphasizing how the incorporation of modern digital technologies and systems engineering could bridge existing gaps in quality management systems. There's an emphasis on the standard's current misalignment with I4.0, highlighting the urgent need for updates to accommodate new technological paradigms. Additionally, this group addresses the lack of modern principles such as innovation, sustainability, and effective networking within the standard, suggesting that these elements are beneficial for aligning with recent research advancements. The group also considers data protection and security, recognizing their growing importance in organizational performance. Further discussions include the better integration of information systems into the quality management framework, adapting quality management principles, and the importance of managing stakeholder requirements more effectively to enhance system performance. There are also concerns about the slow adoption of the standards due to challenges in traceability and information immutability.

Table 4 details the articles mentioning the need to update ISO 9001 or presenting proposals for revising its requirements.

Table 4 – Summary of articles - group 2

Authors	Group 2
(Rönnbäck & Eriksson, 2012)	The ISO standard has not incorporated concepts such as '**innovation', 'sustainability' or 'network'**, which both current practitioners and researchers put a great deal of emphasis on. Hence, quality management and ISO could benefit from reviewing the principles in order to keep up with recent research".
(Asif, 2020)	"Calls for updating quality models with more relevant features - **mindfulness, intellectual capital management, enabling quality predictions from big data**, lean organizational structures**, and managing networked firms**".
(Chiarini & Cherrafi, 2023)	"Some issues emerged relating to … **validation of quality control equipment based on artificial intelligence, and decision-making and problem-solving processes**". "...even if data are automatically collected, there are several situations where opportunities for improvement and problem solving should be managed not only through analytics and AI, but also through a human decision-making process." "…it is fundamental to analyse not just the opportunities introduced by i4.0 technologies but also the potential introduced **risks, especially with analytics, predictive software and AI**"

(Fonseca, Carvalho, et al., 2023)	"By integrating **sustainability within management systems standards** and subsequently implementing and disclosing sustainable development goals and results, the proposed framework can align and integrate sustainability with organizations' strategy, processes and key performance indicators and results."
(Fonseca, Domingues, et al., 2023)	"… ISO 9001:2015 attained its main objectives." "Nevertheless, it is suggested in the next ISO 9001 review cycle to use a **more simplified language and writing styles** to improve the easiness of understanding and consistency of interpretations of ISO 9001:2015 requirements making clauses easier to implement and improving its auditability (e.g. 4.1., 6.1, 4.2). Consequently, these requirements should be considered for possible enhancements in future ISO 9001 editions." "…**views Clauses 4, 5, 6 and 7 as top priorities to be considered in the forthcoming ISO 9001 review cycle."** "… major global trends such **as sustainability**, the fight against climate change and resource scarcity, the growing call for a more inclusive and social responsiveness society and the digital transformation, have deeply influenced the global institutional organisational and societal contexts." "…the monitoring and assessment of the need to revise ISO 9001:2015 is following both ISO rules and the dynamic of global change and transformation."

The literature review yielded insights from approximately a quarter of the articles related to **Group 2**, which focuses on proposing revisions and updates to the ISO 9001 standard to make it more relevant and effective. This includes advocating for the integration of sustainability within management systems, aligning organizational strategies with global sustainability goals and enhancing performance indicators. The group also tackles the challenges and opportunities presented by Industry 4.0 technologies, particularly artificial intelligence, and predictive analytics, emphasizing the need for effective risk management strategies. A suggestion from this group is the simplification of the language used in ISO 9001 to improve understanding and ease of implementation. Furthermore, it advocates for updates that enhance organizational adaptability, emphasizing the modernization of quality models with features such as mindfulness, intellectual capital management, the capacity to make quality predictions from big data, and the effective management of networked firms. It also highlights the importance of validating quality control equipment based on artificial intelligence, and decision-making and problem-solving processes.

Table 5 highlights the articles referring to a future research agenda.

Table 5 – Summary of articles - group 3

Authors	Group 3
(Asif, 2020)	"What will be the underlying **structure and core values of future quality models**? and should the new model be prescriptive or descriptive? These questions present an opportunity for future research."

(Chiarini, 2020)	"…we also need research dedicated to the integration of **I4.0, CPS and ISO 9001**." "What about integration between ISO 9001 requirements and the CPS introduced by I4.0?"
(Chiarini & Kumar, 2022)	"…the relationship between **ISO 9001** certification and **I4.0**, digital leadership characteristics and management involvement, AI and quality management…."
(Foidl et al., 2016)	"…provide a general understanding about the upcoming challenges and opportunities for the quality management domain through the advent of **Industry 4.0**. and to provide a solid basis for further research by formulating research challenges". Namely: How can the huge volume of data and information, evolving through Industry 4.0, be used; Which quality related measures must be taken, do define and regulate the limits of the **rules, in which the machines and products can act and decide on their own**, to be compliant with existing quality policies and objectives?
(Fonseca et al., 2021)	"The investigation of **ISO 9001 within Industry 4.0** and digital processes are suggested for future research."
(Fonseca, Domingues, et al., 2023)	"Another proposed line of research would be to investigate the role of ISO 9001:2015 within digital transformation and sustainability and the mutual interactions and synergies between ISO 9001:2015. Namely, how can **ISO 9001:2015 supports digital transformation and sustainability** and how the standard needs to evolve to ensure synergies with the new paradigms."
(Sader et al., 2019)	"…suggests future research works to discuss the impact and the role of Industry 4.0 on TQM practices and results. An industrial partnership is highly recommended to ensure good implementation of TQM principles through obtaining **ISO 9001:2015 and jointly developing Industry 4.0**-based quality management system at the organization."
(Sader et al., 2022)	How to integrate models (**ISO 9000 family**, EFQM and other TQM tools or techniques) with the recent development of **Quality 4.0**.
(Saihi et al., 2021)	"…there is a need for including more articles about the mapping and integration of **ISO 9001 requirements and Industry 4.0 features**. "A detailed integration between ISO 9001 requirements and the I4.0 features warrants further research. "…The same discussion and findings applied to predictive quality where full potential of I4.0 is still to be explored further."
(Thekkoote, 2022)	Further research needs to integrate **ISO 9001, CPS and I4.0**

Although the study by Foidl et al. (2016) references the ISO 9000:2005 standard, the article is significant because it addresses the emerging challenges and opportunities within the quality management domain through the advent of I4.0. It provides a solid basis for future research by formulating specific research questions. Namely: How can the huge volume of data and information, evolving through Industry 4.0, be used? Which quality related measures must be taken, to define and regulate the limits of the rules, in which the machines and products can act and decide on their own, to be compliant with existing quality policies and objectives?

Approximately 50% of the articles within **Group 3**, which is dedicated to outlining future research directions, emphasize the necessity of integrating ISO 9001 with I4.0. Group 3 outlines a research agenda to explore and address future challenges in quality management as influenced by I4.0. Moreover, there's an interest in understanding the synergies between ISO 9001, digital transformation, and sustainability, looking at how the standard can evolve with these broad trends.

CONCLUSIONS

After applying a set of predetermined inclusion and exclusion criteria, the literature review identified a limited number of articles addressing changes or guidance to ISO 9001 considering digital transformation (DT). Notably, fewer than 1% of the screened articles provided insights directly relevant to the research question.

An evaluation of the existing literature on this topic yields an ambiguous answer to the research question: "Is ISO 9001:2015 suitable in the context of digital transformation (DT)?" ISO 9001:2015 offers partial suitability for contexts involving digital transformation; it should address more requirements for managing the complex, interconnected, and dynamic challenges inherent to such transformations. Modifications to the standard are essential to synchronize with the specific needs and rapid advancements associated with digital transformation. To remain relevant, ISO 9001:2015 must undergo an evolution to address the emerging challenges presented by a digitally transformed business environment.

The objective was to identify articles addressing gaps, or outdated features of ISO 9001, misalignments with current needs, contributions to the debate on updating ISO 9001, mentions of the need to update ISO 9001, proposals for revising its requirements, or references to a future research agenda and it was accomplished.

The main topics of the articles identified were sustainability, innovation, risks (especially with analytics, predictive software, and AI), stakeholder identification accompanied by objectives, measures and monitoring, dynamic inter-organisational relationships, cyber-security (data protection and security aspects), validation of quality control equipment based on AI and decision-making and problem-solving processes, including a more simplified language and writing style of ISO 9001:2015 requirements. Figure 3 illustrates the main topics.

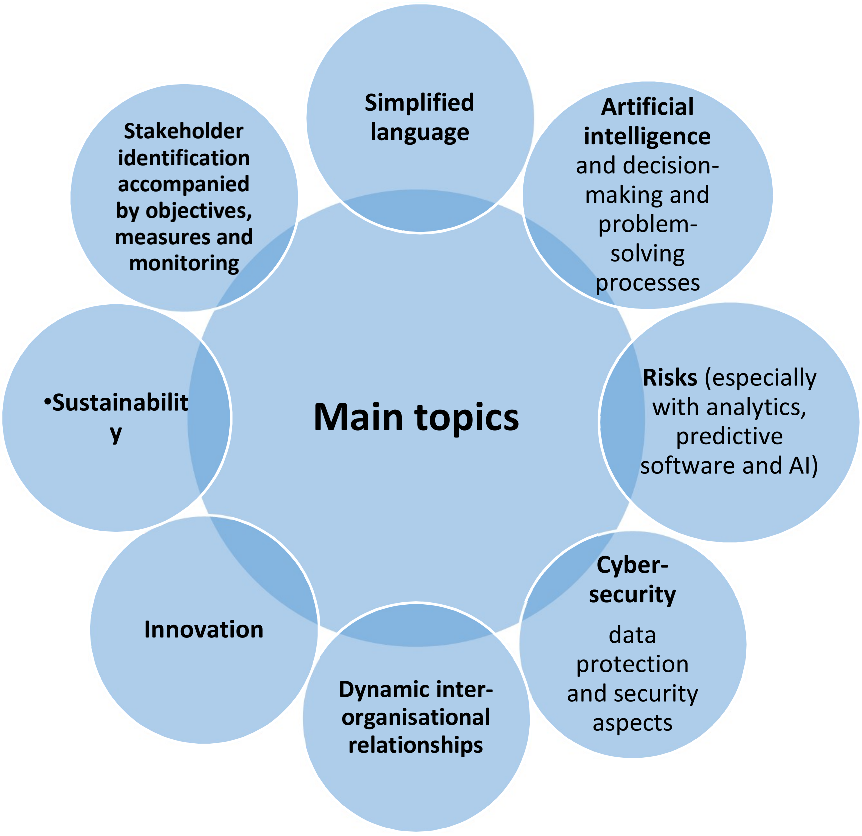

Figure 3 – Main topics involved in the three groups

The analysed future research directions emphasize the necessity of integrating ISO 9001 with Industry 4.0. While the focus is predominantly on the industrial sector, these considerations must be extended to both industrial and service sectors.

In conclusion, additional details are essential to identify and outline the potential modifications required for ISO 9001 to better address the challenges.

Future work

Based on this review, future work will involve evaluating the suitability of ISO 9001 in the context of Digital Transformation and formulating hypotheses for potential alterations or new requirements within the ISO 9001 framework. These hypotheses will be validated through interviews with auditors, certification bodies' representatives, or other relevant institutions. This future work aims to contribute to the ongoing understanding and adaptation of quality management standards to the constantly evolving landscape of Digital Transformation. These modifications must be addressed across both industrial and service sectors to ensure the standard's broad applicability and effectiveness across a diverse range of organizations and domains.

Limitations

The review process, primarily executed by a single researcher, entailed the assessment of titles, abstracts, and full texts. To increase the robustness of the exclusion process, a secondary researcher re-evaluated the excluded articles to validate the decisions made by the initial researcher. However, despite this measure, the inherent subjectivity of the review process could potentially influence the final selection of articles.

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Data Science Application on Six Sigma: Global Survey Findings

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STRUCTURED ABSTRACT

Purpose - The Six Sigma (SS) program is a successful improvement initiative adopted by organizations worldwide. The digitalization of companies has led to a significant increase in data generation, which requires processing and analysis. Adapting to this data variety and complexity represents a challenge for SS, as its techniques developed in an era of data scarcity prove inadequate in the current context. Several studies suggest re-examining SS and incorporating new knowledge, especially techniques from Data Science (DS). This study aims to identify the most promising DS analytical techniques for SS projects and determine the most suitable ones for inclusion in SS training programs.

Design/methodology/approach – An online survey collected responses from 348 SS experts from 49 countries evaluating the applicability of DS techniques in SS. The analysis of the collected data included exploratory techniques and hypothesis testing.

Findings – The sector in which the experts work significantly influenced their assessments. Service, sales, and marketing professionals shared similar evaluations, distinct from those in industrial and cross-functional sectors. As a result, it is recommended to design two distinct training programs covering different analytical techniques suitable for each audience.

Originality/value - This study is the first to empirically assess the application of DS techniques in SS through a global survey. Moreover, it delineates the optimal training for SS specialists based on their activity sector, ensuring they gain essential skills to extract valuable insights from data-rich Industry 4.0 environments.

Keywords: Six Sigma, Data Science, Industry 4.0, Digital age,

Paper type: Research paper

INTRODUCTION

Since its inception in Motorola in the 1980s, SS has emerged as one of the most widely embraced and successful improvement programs in various sectors (Kregel et al., 2021; Zwetsloot et al., 2018; Park et al., 2020). This methodology uses performance statistics, employing a structured approach known as DMAIC (Define, Measure, Analyze, Improve, and Control), and various statistical techniques. Additionally, it entails comprehensive training programs for specialists, called green belts, black belts, and masters, who analyze and improve the performance of their processes to achieve strategic objectives (Kregel et al., 2021; Ismyrlis and Moschidis, 2018; Zwetsloot et al., 2018).

With the advent of Industry 4.0 (I4.0), a technological revolution has begun, marked by the interconnectedness of machinery and equipment through cloud computing. This integration has rendered processes more intricate and autonomous, resulting in a significant surge in the volume and complexity of data commonly referred to as Big Data. These datasets are often abundant, unstructured, self-correlated, and characterized by a low signal-to-noise ratio (Palací-López et al., 2020). Consequently, analyzing such data is inherently complex and requires specialized skills. Traditional Six Sigma tools, developed in an era of data scarcity, have proven inefficient for the demands of the present context (Kregel et al., 2021; Palací-López et al., 2020; Saidi and Soulhi, 2018).

Conversely, the analysis of this vast amount of data has sparked numerous innovations in statistics and simulation, giving rise to a burgeoning field known as Data Science (DS) (Sodhi, 2020; Zwetsloot et al., 2018). DS represents a multidisciplinary domain integrating statistics, computer science, and specialized technical knowledge pertinent to the studied domain (Carmichael & Marron, 2018). It encompasses data collection and preprocessing, statistical analysis, predictive modeling, machine learning, and the interpretation of results. It uses scientific methods and algorithms to extract information and insights from the data (Tay & Loh, 2021). It has become a comprehensive discipline for transforming data into knowledge for decision making. It is evolving with the advancement of technology and is increasingly required by organizations worldwide (Ferrer, 2021),

To effectively address the challenges and capitalize on the opportunities of the data-rich Industry 4.0 environment, the SS program needs a reformulation, incorporating new knowledge and skills to its experts (Ferrer, 2021; Anvari et al., 2021; Maia et al., 2024). Several studies have underscored the necessity of incorporating advanced analytical techniques, such as those utilized in DS, into the SS toolkit. Studies conducted by Maia et al. (2024), Gupta et al. (2020), Zwetsloot et al. (2018), Palací-López et al. (2020), Arcidiacono and Pieroni (2018), Laux et al. (2017), Park et al. (2020), Tay and Loh (2021), Bhat et al. (2020), Gijo et al. (2021) and Chiarini and Kumar (2020) advocate for this integration. Such incorporation enables the handling of complex data, the exploration of previously unknown aspects, and the identification of new improvement opportunities. It is a valuable adjunct to SS, enhancing its efficacy as a methodology capable of propelling organizations to heighten levels of operational performance (Gupta et al., 2020).

According to Maia et al. (2024), there is a growing interest in the connection between Industry 4.0 and operational excellence methodologies. Although initial research has explored the integration of DS tools into SS, studies are scarce. An evolving field is observed, with limited research on the effective integration of these two domains .(Fogarty, 2015; Tissir et al., 2022; Kregel et al., 2021; Zwetsloot et al., 2018; Gupta et al., 2020).

The motivation of this study was to fill this knowledge gap in the literature. To achieve this, an empirical investigation is conducted through a survey to determine the most promising DS analysis techniques for SS projects, as perceived by DS and SS experts globally. Previous studies have suggested that the application of SS varies across sectors (Antony et al., 2022; Sony, 2020). Thus, the evaluation of technique applicability is conducted from the perspective of the area of activity of survey respondents in the companies where they work. The objective is to assist organizations in dealing with the challenges of the evolving digital landscape.

The following research questions were formulated:

- Does the relevance of SD techniques in SS vary depending on the different sectors of specialist activity?
- Which DS analysis techniques are most promising for SS projects (which are most suitable for each sector)?

The remainder of this paper is organized as follows. Section II describes the research methodology, including details of the research instrument and analytical tools employed in this study. Section III provides a comprehensive data analysis and discusses the key research findings. Finally, Section IV presents conclusions, academic and business implications, study limitations, and directions for future research.

RESEARCH METHODOLOGY

A cross-sectional study was conducted using an online survey to address the research questions mentioned above. The target audience included data scientists, statisticians, SS specialists, company quality managers, and the academic community.

The research instrument developed for data collection was a structured questionnaire. This was elaborated using Microsoft Forms software, an online tool designed for this purpose and made available in both English and Portuguese. The questionnaire was divided into two sections, one for collecting the profile of survey participants and the organizations they work for, and another dedicated to assessing the applicability of a list of Data Science (DS) tools in SS projects.

The first section included multiple-choice and open-ended questions related to the participants' specialties, country of operation, years of experience, area of operation, role they perform, company's field of activity, and company size.

The second section used a five-point Likert scale (1: not applicable to 5: very applicable) to assess the degree of applicability of the 14 SD analytical tools in SS projects, as presented in Figure 1. These tools were chosen by are the most frequently addressed in DS courses, based on the evaluation of the curricula of 42 undergraduate and postgraduate courses (specialization and MBA) from different countries. To help participants understand the tools, a brief description of each tool was presented on the survey form.

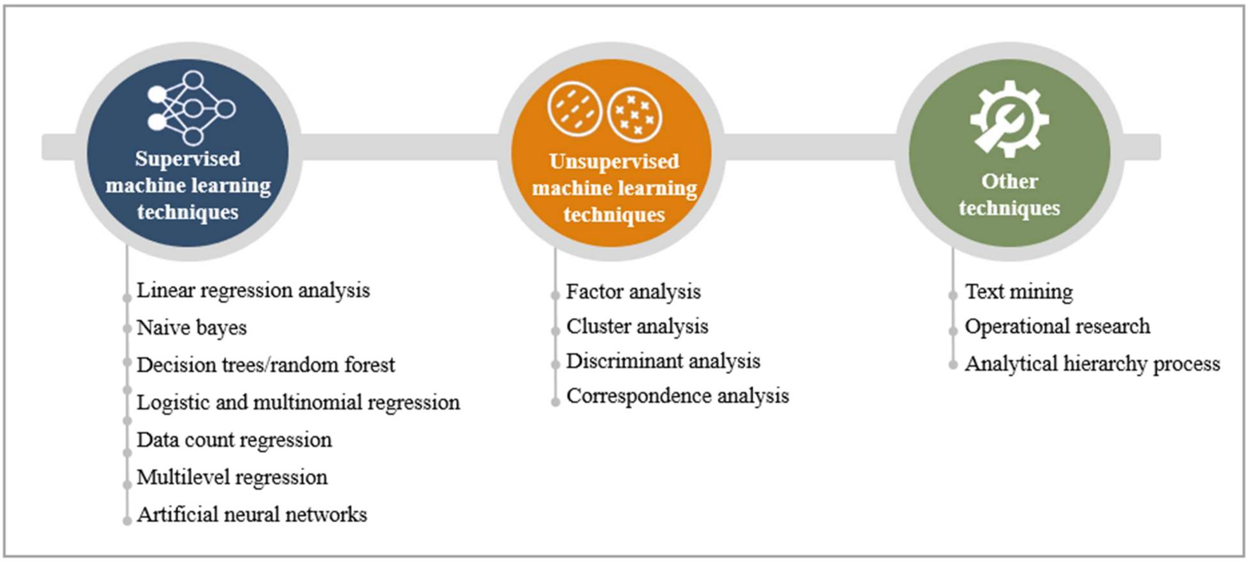

Figure1 – Data Science tools selected for the survey

A comprehensive data science course should include programming languages, such as Python, R, and SQL, as well as data visualization, cloud computing, and Big Data processing tools. These tools will make it easier to apply the analytical techniques used in this study. However, these topics are not the focus of this study because they are not analysis techniques themselves. Additionally, the specific selection of tools may vary depending on business preferences and industry demands.

The survey questionnaire was initially tested by ten experts. This group included five Six Sigma professionals, three data scientists, and two individuals proficient in both Six Sigma and Data Sciences. The pilot test aimed to identify potential improvements that could enhance the comprehensibility of the questionnaire and ensure its alignment with the research questions defined by the researchers. Comments and feedback from the pilot study were subsequently used to review the questionnaire items, making them more readable and relevant to the investigation.

After testing, the questionnaire was distributed via email and the LinkedIn platform between January and May 2023. Sampling was carried out using the "snowball technique," which involves collecting data under the influence of research participants. These participants were encouraged to pass it on to their contacts, leading to a cumulative effect on the respondents (Neuman, 2006).

The collected data were analyzed using exploratory techniques, descriptive analyses, and hypothesis testing using Minitab and R software. After analyzing the data, the most relevant techniques in SS projects were identified, and training programs for specialists were mapped by the application area.

RESULTS

Sample Description

A total of 348 respondents from 49 countries contributed to the research conducted. The countries with the highest participation were the United States (74), Brazil (57), and India (32), as shown in Figure 2.

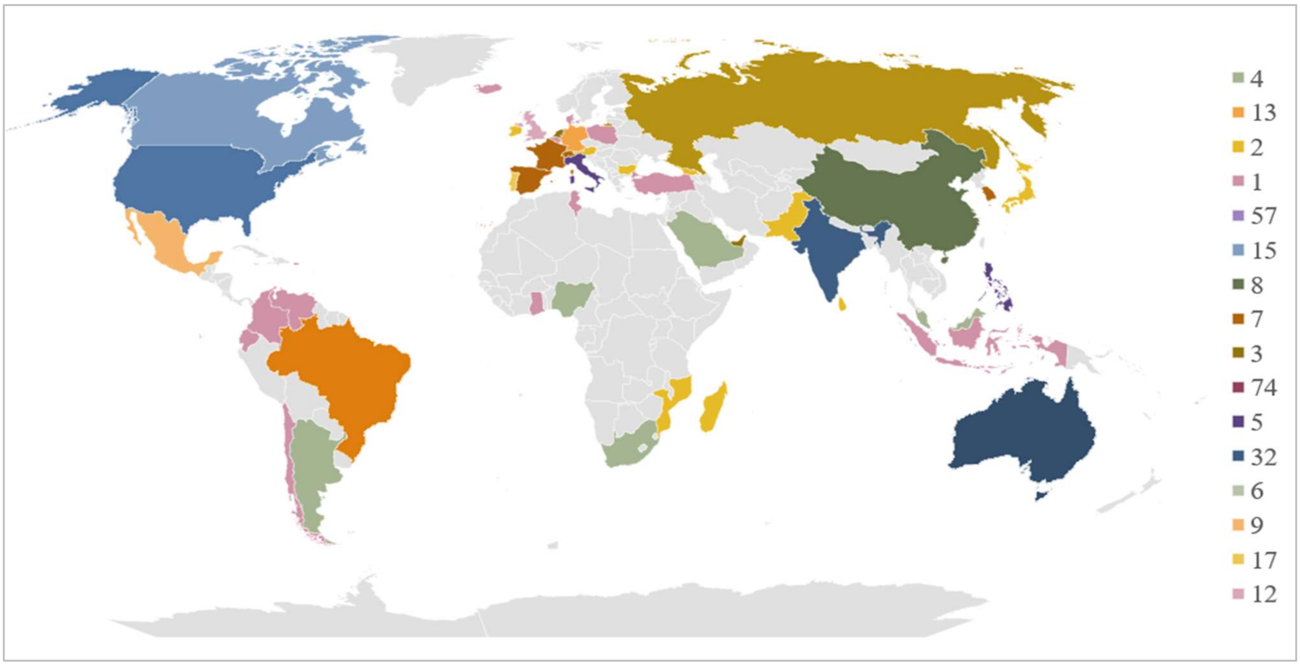

Figure 2 - Geographic distribution of survey participants (country of operation)
Source: primary survey data

According to the primary survey data, approximately 90% of the respondents specialize in the pure SS methodology or associate it with another approach. Among these respondents, 54% are Lean Six Sigma (LSS) experts, 18% are SS specialists, and 18% are involved in SS and DS. The survey also notes that 36% work in the industrial sector, 34% in services, 19% have multifunctional role across different areas, and 11% are engaged in sales and marketing. Additionally, 67% of the respondents are employed by large companies, and 74% have more than 10 years of experience, with 53% having over 15 years of experience, as indicated in Figure 3.

Among the respondents, 25% hold positions as analysts, specialists, or managers in companies' quality or continuous improvement (CI) areas. Additionally, 23% serve as Green Belts (GB), Black Belts (BB), Master Black Belts (MBB), or Six Sigma specialists, and 18% work as consultants in management or Lean Six Sigma (LSS). Together, these groups represent 66% of the sample and are characterized by their practical experience in company improvement projects.

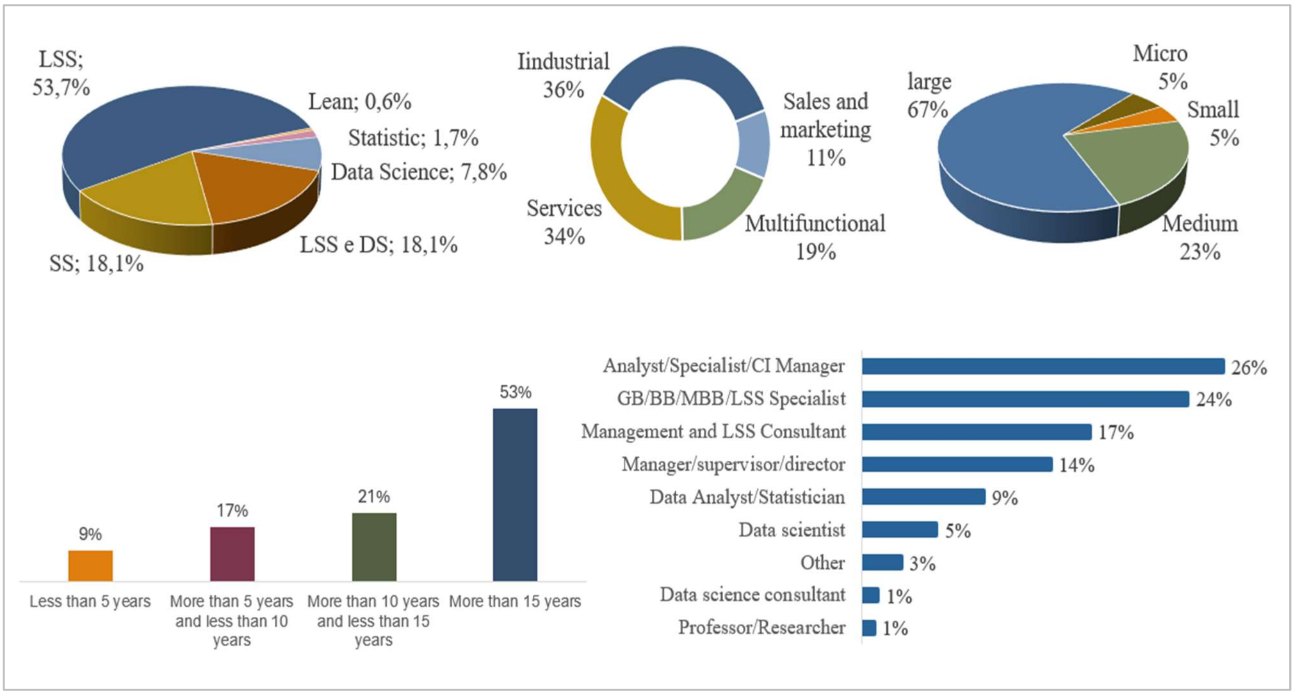

Figure 3 – Specialty, area of activity, size of companies, length of experience and function by survey respondents
Source: primary survey data

The distribution of the sectors of the companies where the respondents work is presented in Figure 4. It can be observed that a wide range of sectors is represented in the sample, with notable representation in the manufacturing industry, particularly chemicals and pharmaceuticals, as well as consultancy services.

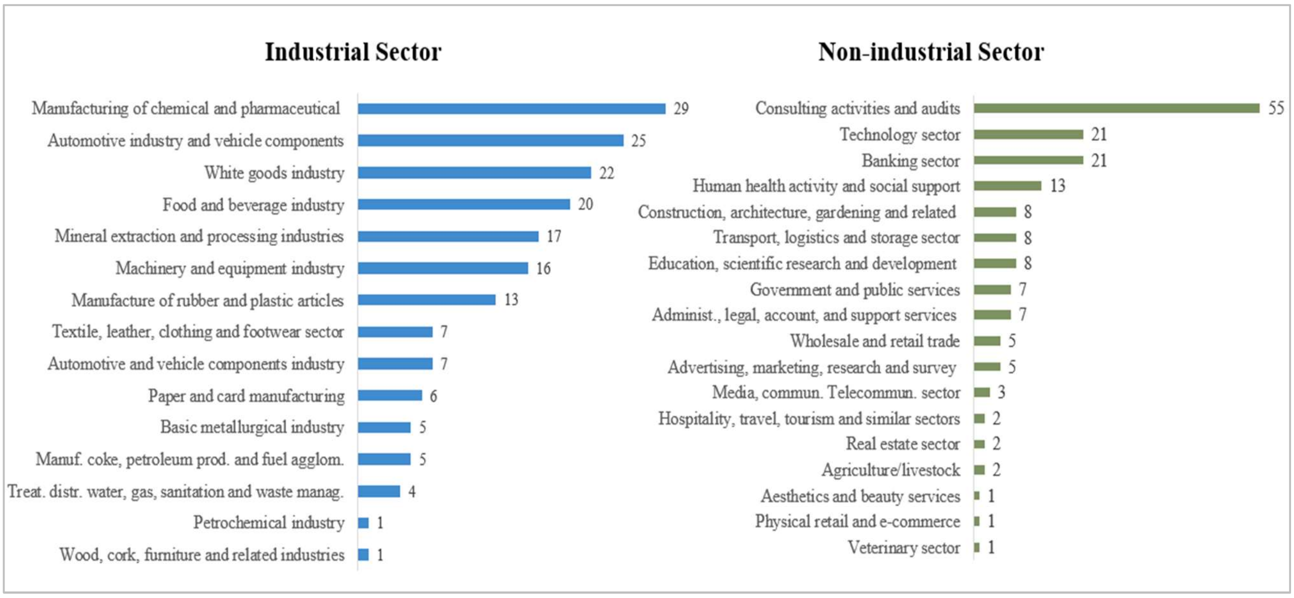

Figure 4 - Sector of the company where the interviewees work
Source: primary survey data

Influence of the specialist's sector of activity

The first research question explores whether the applicability of SD techniques in SS varies across different sectors of activity. To address this question, the frequency responses regarding the applicability of each technique in SS was calculated using a scale of "1- not applicable", "2- slightly applicable", "3- moderately applicable", "4- applicable" and "5- highly applicable" within each sector ("Industrial", "Services", "Sales and Marketing" and "Multifunctional"). Subsequently, for each technique, the association between these variables ("applicability in SS" and "activity sector") was evaluated using Pearson's chi-square test. The chi-square test was chosen for its ability to determine associations between categorical variables (Buckalew & Pearson, 1982).

As the variable "applicability in SS" is ordinal, the Kruskal-Wallis test was also applied. The Kruskal-Wallis test is appropriate for testing the hypothesis of significant differences between three or more independent groups concerning a continuous or ordinal variable. It tests the null hypothesis that all populations have equal distribution functions against the alternative hypothesis that at least two populations have different distribution functions (Vargha & Delaney, 1998).

Table 1 displays each technique's statistics, degrees of freedom, and p-values from the Chi-square and Kruskal-Wallis tests. Regarding the Chi-square test, significant associations (p-value ≤ 0.05) were observed between the specialist's sector of activity and the applicability of all techniques, except for "logistic and multinomial regression" and "data count regression". This indicates that, for most techniques, there is an association between the specialist's sector of activity, that is, the assessment of the technique depends on the specialist's sector, with varying according to the sector in which the specialist works.

Similarly, the Kruskal-Wallis test revealed significant differences between sectors of activity concerning the assessment of applicability in SS for all techniques (p-value ≤ 0.05), except for "logistic and multinomial regression" and "Analytical hierarchy process". This suggests rejection of the null hypothesis that all populations have equal distribution functions against the alternative hypothesis that at least two populations have different distribution functions, indicating that at least two groups have different opinions on the applicability of techniques.

These findings suggest that the relevance of Data Science techniques in Six Sigma varies depending on the specialist's sector of activity.

Table 1- Statistics, degrees of freedom and p-values of Chi-square tests and Kruskal-Wallis Tests

Data science techniques	**Chi-square tests**			**Kruskal-Wallis Tests**		
	X^2	*d.f.*	***p*-values**	**H**	*d.f.*	***p*-values**
Factor analysis	55,808	12	0,000*	40,99	3	0,000*
Cluster analysis	112,698	12	0,000*	94,26	3	0,000*
Discrimination analysis	92,380	12	0,000*	73,01	3	0,000*
Naive bayes	73,747	12	0,000*	48,59	3	0,000*
Correspondence analysis	44,981	12	0,000*	34,15	3	0,000*
Decision trees and random forest	52,896	12	0,000*	35,50	3	0,000*
Linear regression analysis	40,100	12	0,000*	28,49	3	0,000*
Logistic and multinom. regression	14,329	12	0,280	2,53	3	0,470
Data count regression	16,710	12	0,161	10,23	3	0,017*
Multilevel regression	23,627	12	0,023*	26,96	3	0,000*
Artificial neural networks	51,830	12	0,000*	24,89	3	0,000*
Text mining	91,187	12	0,000*	68,12	3	0,000*
Operational research	38,265	12	0,000*	22,02	3	0,000*
Analytical hierarchy process	21,136	12	0,048*	3,31	3	0,346

Source: primary survey data
Note: * Significant at the 0.05 significance level

Applicability of DS techniques in SS projects

To assess the effectiveness of DS techniques in Six Sigma projects, we stratified the database based on the specialists' areas of activity. This approach aims to obtain more accurate and relevant results for each specific area, allowing for more targeted analysis and the identification of useful trends and patterns for each sector.

The mean and median of the assessment scores were calculated to quantify the level of applicability of the techniques. Additionally, stacked bar graphs were generated to illustrate the distribution of responses across each applicability category for each technique. Figure 5 presents the visual representation of this data.

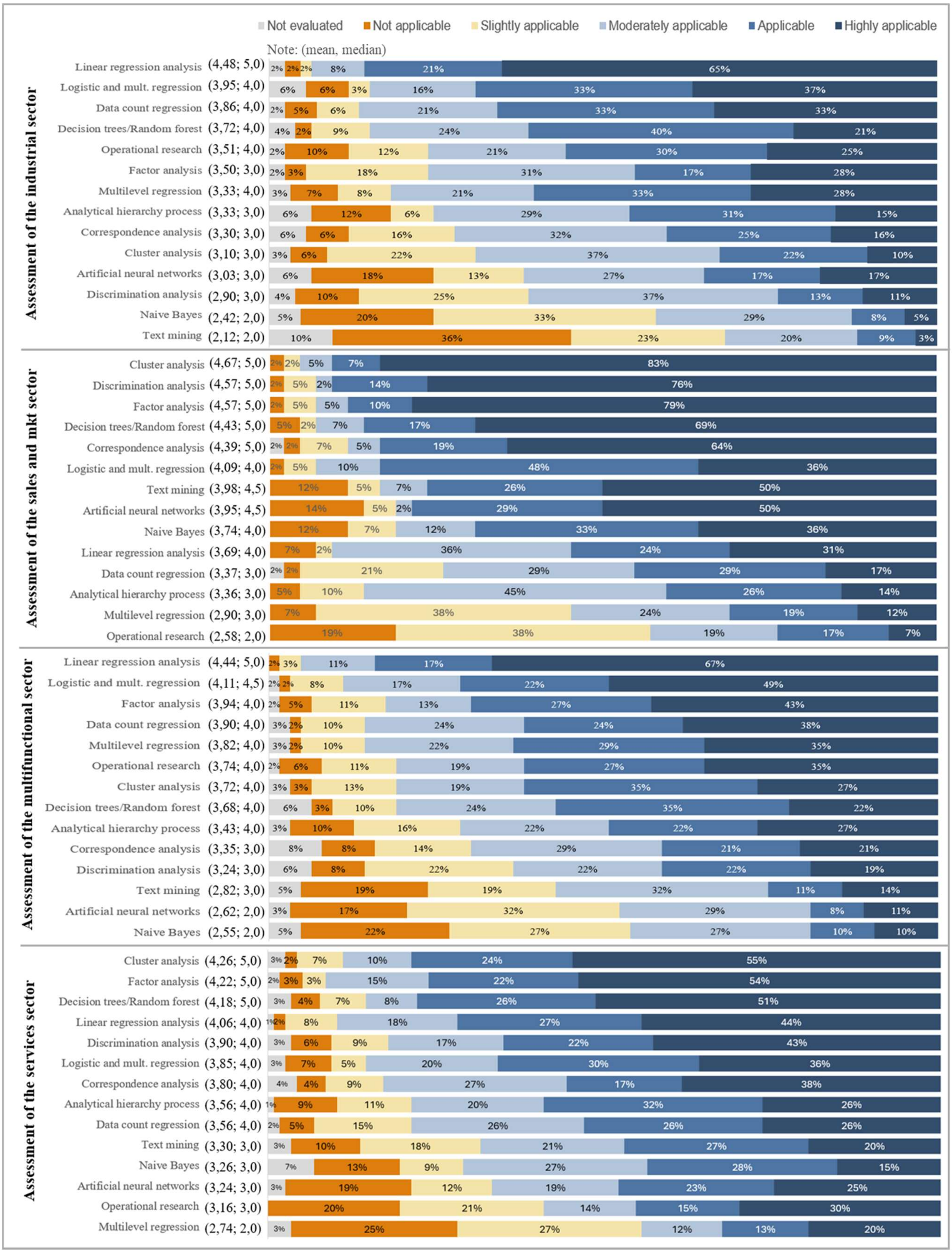

Figure 5 – Assessment of the suitability of each DS technique in SS by sector
Source: primary survey data

According to the survey, respondents within the industrial sector prefer supervised machine learning techniques. In particular, techniques such as linear regression analysis ($\bar{x}$ = 4,48; $\tilde{x}$ = 5,0), logistic and multinomial regression ($\bar{x}$ = 3,95; $\tilde{x}$ = 4,0), regression for count data ($\bar{x}$ = 3,86; $\tilde{x}$ = 4,0), and decision trees and random forests ($\bar{x}$ = 3,72; $\tilde{x}$ = 4,0) emerged as the most applicable in SS. Conversely, naive Bayes and text mining techniques received more unfavorable responses ("not applicable" and "slightly applicable") with 53% and 59% respectively. Their mean scores were notably lower, at 2,42 and 2,12 respectively, indicating a lower perceived applicability compared to other techniques.

In the sales and marketing sector, unsupervised machine learning methods like cluster analysis, discriminant analysis, and factor analysis are highly recommended, with 90% of the respondents finding them "highly applicable" or "applicable." These techniques garnered mean scores of 4,67, 4,57, and 4,57, respectively. Conversely, operations research and multilevel regression received less favorable responses, with mean scores of 2,90 and 2,58, respectively, suggesting a lower level of applicability.

For specialists working in the multifunctional sector, techniques such as linear regression analysis ($\bar{x}$ = 4,44; $\tilde{x}$ = 5,0), logistic and multinomial regression ($\bar{x}$ = 4,11; $\tilde{x}$ = 4,5), and factor analysis ($\bar{x}$ = 3,94; $\tilde{x}$ = 4,0) have emerged as the most applicable in SS, with over 70% of respondents giving favorable responses. However, naive Bayes ($\bar{x}$ = 2,55; $\tilde{x}$ = 2,0) and artificial neural networks ($\bar{x}$ = 2,62; $\tilde{x}$ = 2,0) garnered nearly 50% of unfavorable responses regarding their application in SS ("not applicable" and "slightly applicable").

More than 70% of respondents in the services sector consider cluster analysis ($\bar{x}$ = 4,26; $\tilde{x}$ = 5,0), factor analysis ($\bar{x}$ = 4,22; $\tilde{x}$ = 5,0), decision trees and random forests ($\bar{x}$ = 4,18; $\tilde{x}$ = 5,0), and linear regression analysis ($\bar{x}$ = 4,06; $\tilde{x}$ = 4,0) to be "highly applicable" or "applicable". Conversely, only multilevel regression ($\bar{x}$ = 2,77; $\tilde{x}$ = 2,0) received more than 50% unfavorable responses regarding its application in the sector, indicating that few techniques have a low level of applicability.

For a more objective analysis, Wilcoxon signed-rank tests were conducted for each technique in each sector. These tests are appropriate for ordinal data, such as Likert scale ratings (Chen & Liu, 2020), Based on survey responses, the applicability of each technique was assessed by testing whether the median score was significantly higher than the moderate level (3 on the rating scale). If the median score is significantly higher than 3, it can be concluded that the perception of the technique's applicability is greater than moderately applicable. Table 2 shows the Wilcoxon statistic (W) and p-values for each test.

Table 2- Statistics, and p-values of Wilcoxon signed-rank tests

Data Science techniques	**Industrial**		**Multifunctional**		**Services**		**Sales and Mkt**	
	W	***p*-values**	***W***	***p*-values**	***W***	***p*-values**	***W***	***p*-values**
Factor analysis	2781,0	0,000*	1279,0	0,000*	4435,0	0,000*	789,5	0,000*
Cluster analysis	1662,5	0,151	1021,0	0,000*	4966,0	0,000*	795,0	0,000*
Discrimination analysis	1253,0	0,766	647,0	0,073	3731,0	0,000*	827,0	0,000*
Naive bayes	673,0	1,000	273,0	0,992	1840,5	0,043*	538,5	0,002*
Correspondence analysis	2116,0	0,004*	559,0	0,023*	2807,5	0,000*	736,5	0,000*
Decision trees rand. forest	3615,5	0,000*	830,0	0,000*	4940,0	0,000*	727,5	0,000*
Linear regression analysis	6199,0	0,000*	1547,0	0,000*	4234,0	0,000*	313,5	0,001*
Logistic and mult. regres.	4278,0	0,000*	1240,5	0,000*	3538,0	0,000*	687,5	0,000*
Data count regression	4112,0	0,000*	981,0	0,000*	2836,5	0,000*	310,5	0,023*
Multilevel regression	3628,5	0,000*	1017,0	0,000*	2050,5	0,931	242,5	0,660
Artificial neural networks	1804,0	0,467	306,5	0,978	2510,0	0,075	679,0	0,001*
Text mining	485,5	1,000	340,0	0,828	2497,0	0,013*	633,5	0,000*
Operational research	3442,0	0,000*	1037,5	0,000*	2933,5	0,113	171,0	0,985
Analytical hier. Process	2161,5	0,009*	787,0	0,009*	3235,5	0,000*	205,0	0,022*

Source: primary survey data
Note: * Significant at the 0.05 significance level

Based on the data presented in Table 2, it can be inferred that several techniques have a median score significantly higher than 3 (p-value of ≤ 0.05). This suggests that the applicability of these techniques in SS projects is considered relevant (more than moderately applicable) and they are strongly recommended for application in SS projects. These techniques were then selected as the most promising for SS projects in their respective areas of activity and are identified as new skills that should be developed by Six Sigma specialists. Figure 6 presents the selected techniques, categorized by the experts' sector of activity.

	Data Science techniques	Industrial	Multifunctional	Services	Sales and Mkt
Supervised machine learning techniques	Linear regression analysis	✓	✓	✓	✓
	Logistic and multinom. regression	✓	✓	✓	✓
	Data count regression	✓	✓	✓	✓
	Multilevel regression	✓	✓		
	Naive Bayes			✓	✓
	Decision trees and random forest	✓	✓	✓	✓
	Artificial neural networks				✓
Unsupervised machine learning techniques	Correspondence analysis	✓	✓	✓	✓
	Factor analysis	✓	✓	✓	✓
	Cluster analysis		✓	✓	✓
	Discrimination analysis			✓	✓
Other techniques	Analytical hierarchy process	✓	✓	✓	✓
	Operational research	✓	✓		
	Text mining			✓	✓

Figure 6 – Data Science techniques selected for each SS specialist's sector
Source: primary survey data

Based on Figure 6, it can be seen that the indicated techniques for the industrial area align with those suggested for the multifunctional area, except for cluster analysis, which is only recommended for the multifunctional area. Similarly, the tools recommended for services and sales/marketing overlap, except for the artificial neural network technique, which is only suitable for the sales and marketing area. Therefore, it is recommended to create two separate training programs: an industrial program for experts in the industrial and multifunctional sectors, and a non-industrial program for specialists in the services, sales, and marketing sectors.

Figure 7 shows the techniques mapped for the training programs. It is important to note that, for reasons of scope, the industrial program includes Cluster Analysis, although it is only indicated for the multifunctional area. This inclusion results from the evaluations of professionals in the industrial sector, with 37% of responses indicating the application of this technique (as shown in Figure 4).

Similarly, the inclusion of Artificial Neural Networks in the non-industrial program is justified by the fact that 43% of professionals in the service sector expressed a favorable opinion on the application of this technique (as shown in Figure 4), despite it being significant only for the sales and marketing sector.

	Industrial Program	Non-industrial Program
Supervised machine learning techniques	Linear regression analysis Logistic and multinomial regression Data count regression Multilevel regression Decision trees random Forest	Linear regression analysis Logistic and multinom. regression Data count regression Naive Bayes Decision trees random Forest Artificial neural networks
Unsupervised machine learning techniques	Correspondence analysis Factor analysis Cluster analysis	Correspondence analysis Factor analysis Cluster analysis Discrimination analysis
Other techniques	Analytical hierarchy process Operational research	Analytical hierarchy process Text mining

Figure 7 – Techniques mapped to training programs
Source: primary survey data

The first program is designed for professionals working in industrial sectors who perform multifunctional roles. It focuses on data science techniques beneficial in environments characterized by manufacturing processes, supply chain management, and quality control. The program involves predictive and pattern analysis, techniques for quantifying relationships of cause and effect, and methods for process optimization. These techniques enable professionals to address various questions related to waste reduction, efficiency improvement, quality control, and process stabilization.

The second program is developed for non-industrial sectors, targeting specialists in service, sales, and marketing. Data Science techniques applied in this particular program emphasize dynamism sector and customer-centricity. As key techniques involve customer segmentation, sentiment analysis, and sales forecasting. These will enable professionals to have deeper customer insights into behavior for more effective and optimized marketing strategies. The program allows professionals of non-industrial domains to contribute to business growth and raise customer satisfaction via a focus on these approaches.

This segmentation is important for several reasons:

- Relevance: the customization of the need-based training programs for professionals from the various sectors, will form professionals receive education that is applicable to their work context, increasing the successful implementation of DS techniques in Six Sigma projects
- Effectiveness: Specialized programs afford professionals the most relevant tools and methodologies. For example, machine-learning models to predict equipment failure would be much more useful for someone in the industrial profession, while data visualization techniques revealing customer trends would be more useful for someone in the marketing profession.
- Adaptable Context: Each sector presents unique challenges and opportunities, which ensure that such training programs do not just transfer knowledge but indeed support the ability of application and adaptability of techniques of data science in ways that would address the sector-specific challenges.

In addition to the techniques mentioned above, it is necessary to include in training programs languages to implement them, such as Python or R programming languages, tools for Big Data processing, database query languages (SQL and NoSQL), and applications in Hadoop and Spark. Cloud computing platforms that include AWS, GCP, and Microsoft Azure should also be considered. There are a variety of toolsets, based on user interests, resources, and preferences, that may apply to the industry as a whole.

CONCLUSIONS

Discussion

This study evaluated the most promising Data Science techniques for application to Six Sigma projects. A survey involving 348 experts from 49 countries was employed as the methodological approach, making the study both global and diverse based on the perceptions and experiences of professionals across diverse industries. The survey allowed for a broad understanding of the professional's perception regarding the techniques applied by a data scientist and identified those most adapted to be applied in Six Sigma projects.

The analysis of the collected data highlights the importance of the differences and particularities of professionals from different sectors. One of the main results of the research was the mapping of two different programs for training professionals in Six Sigma, each with indications of specific DS techniques that meet the needs of each audience.

The analysis of the data collected pointed out the importance of the differences and particularities of professionals from different sectors. One of the main results of the research was the mapping of two different programs for training professionals in Six Sigma, each with indications of specific DS techniques that met the needs of each audience. One program aimed at the industrial context, focusing on those who work in industrial sectors and in a multifunctional way; the other program is oriented to non-industrial sectors, dealing with specialists from the services, sales, and marketing sectors. This strategic segmentation aims to ensure that the training programs serve their objective most efficiently and to serve the needs of each sector in the training of professionals in the Data Science techniques that are most useful to its work context. Such an understanding makes more effective and contextually relevant projects, thereby increasing the relevance and impact of Six Sigma. This differentiation ensures that not only is knowledge imparted through training programs, but also that adaptability does not apply to the techniques in such a manner that challenges within a given sector are addressed.

By mapping these two programs with distinct techniques, organizations can better equip themselves to face the challenges of the evolving digital era. Professionals developed from these programs will have improved analytical skills to study and investigate the circumstances of traditional techniques. As such, such professionals will be better prepared and well-equipped

This study makes a significant contribution to the existing literature in that it provides a valuable empirical basis for a comprehensive global analysis, enabling deeper theoretical and practical understanding in this interdisciplinary field. The sectoral analysis found in the study contains many recommendations on customizations that should be considered.

The practical implications of this study are as follows. By mapping the most appropriate DS techniques, organizations can improve their training programs and develop specialized programs that equip SS professionals with DS skills most relevant to their sector. Thus, these techniques can be used to obtain more precise knowledge for good decision-making and to improve project results. Integrating advanced DS analytical techniques with SS will ultimately foster a culture of innovation and continuous improvement.

his study adds, therefore, academic depth and practical advice for those organizations willing to integrate DS and SS. Based on empirical insights, industry-specific recommendations may be envisaged for providing valuable roadmaps to increase the effectiveness of SS projects with advanced data science techniques to both researchers and practitioners.

Limitations and future research

This study included a sample of 348 professionals from 49 countries. this may not adequately reflect the distribution of participants across sectors, experiences and regions of the world, subsequently affecting the generalizability of results. Future research can be conducted under different cultural and organizational contexts.

The study considered the 14 most used Data Science tools, which does not encompass the entire range of techniques and tools available in the field. This limitation may affect the applicability of the results, as other relevant and emerging tools were not evaluated. Future studies could expand the set of tools analyzed to include a broader variety of Data Science techniques. Moreover, with Data Science technologies evolving rapidly, the most effective techniques and tools can change quickly. Therefore, the results and recommendations may need periodic updates to remain relevant in an ever-changing technological landscape.

Some future enhancements of this approach could be assessed: longitudinal studies on the effectiveness of the proposed training programs. These studies should monitor the performance of the professional being trained and the implementation of Data Science techniques in Six Sigma projects, with the evaluation of long-term impact and the evolution of practices.

Since knowledge of the issue right here is still in its infancy, further research is required on a practical and theoretical level, especially on the subject of applying these techniques in real project development environments. Future research can be of enormous importance in order to identify the barriers, advantages, difficulties, and facilitators in implementing Data Science techniques in Six Sigma. They could also show the need for adaptation of the Six Sigma methodology or DS techniques to increase its applicability in projects for a broad and efficient adoption. These could chime in on the elaboration of strategies and platforms to facilitate the integration of techniques, contributing then to the continuous growth of this interdisciplinary field.Additionally, exploring how Data Science techniques can be integrated with other continuous improvement methodologies, such as Lean and Agile, could further enhance results.

By presenting limitations and proposals for future research, the article not only presents its boundaries, but exposes the challenges to be faced and indicates paths for subsequent studies and practical applications in this vast, expanding field of research.

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ONA-Accredited Primary Health Care Quality through Google Review Analysis

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STRUCTURED ABSTRACT

Purpose – The quality of healthcare services is crucial, given the increasing demands of users and competition among institutions. This study analyzes user perception of primary healthcare services based on Google Reviews comments, using natural language processing.

Design/methodology/approach – This exploratory-descriptive study analyzed comments from 101 healthcare units in São Paulo, Brazil, certified by the Brazilian Accreditation Organization until February 2024. Python (googletrans, pandas) collected data, while matplotlib, nltk, WordCloud, and networkx were used for visualization and analysis.

Findings – A total of 7,689 comments were analyzed, showing users rated services more positively (51.4%) than negatively (40.7%), with 7.8% expressing neutral sentiments. Noteworthy for public services, indicating satisfaction. Eastern and Southern regions had the highest evaluations. The Northern region received more “strongly positive” comments. Negative aspects included personnel, time, and communication issues. Positive aspects highlighted service as “professional” and “attentive”.

Research limitations/implications – Limited to accredited primary healthcare units in São Paulo, Brazil, this study suggests opportunities for replication in various countries, healthcare institutions, and accreditation programs, offering insights into service quality assessment and improvement.

Practical implications – This study helps identify shortcomings and highlight positive aspects in primary healthcare services, contributing to continuous improvement in the quality of care.

Originality/value – This study stands out from others because it focuses on evaluating users' perceptions of services offered by primary healthcare units in São Paulo, Brazil. It utilizes data mining techniques to analyze sentiments expressed in Google review comments.

Keywords: Healthcare, Service Quality, Sentiment Analysis, Brazil.

Paper type - Research paper

INTRODUCTION

While healthcare quality has historically been assessed against professional practice standards, there has been a discernible shift in recent years towards prioritizing patients' perceptions as a central factor in determining healthcare quality. Today, individuals are becoming more informed and seeking innovative avenues to access healthcare services, leading to a heightened awareness of the quality of services offered by healthcare facilities (Batbaatar et al., 2017; Swathi et al., 2023). Besides that, the quality of service provided in healthcare facilities is intrinsically linked to various essential aspects, such as favorable clinical outcomes, high levels of patient satisfaction, and ensuring patient safety (Hammanjoda and Singh, 2024). Therefore, understanding the elements that influence the quality of healthcare services becomes fundamental to promoting effective, safe, and excellent care.

In an era dominated by digital communication and consumer-driven feedback, many individuals regularly leave comments across various platforms expressing both satisfaction and dissatisfaction with the service they have experienced at specific establishments. Consequently, the importance of online reviews cannot be overstated (Nandwani and Verma, 2021; Vashishtha et al., 2023). These reviews serve as valuable indicators of the quality of service provided, reflecting the culmination of various essential aspects influencing healthcare service delivery. A strategy used by healthcare providers to enhance quality of services is accreditation programs; institutions that adopt these programs are committed to the ongoing pursuit of excellence in healthcare delivery and provision of care (Gupta et al., 2023).

In this context, the increasing amount of user-generated content on online platforms like Google Reviews presents an intriguing opportunity to complement traditional methods of assessing healthcare quality. These reviews frequently provide insights into patient experiences, offer a unique window into the strengths, weaknesses, and overall performance of healthcare institutions. By leveraging natural language processing (NLP) techniques and sentiment analysis, this study aims to extract meaningful patterns and insights from Google Reviews pertaining to primary healthcare facilities accredited by the National Accreditation Organization (NAO) of Brazil. Through a systematic analysis of user comments, this research seeks to answer the following research questions:

a) How do patients perceive the quality of care provided by NAO accredited primary healthcare facilities?

b) What are the predominant themes and sentiments expressed in Google Reviews related to these facilities?

This study stands out for adopting a distinctive approach compared to most research on user satisfaction and service quality in healthcare. While most studies traditionally rely on questionnaires or interviews to capture user perceptions, this work innovates by using social media as a platform for users to share their experiences and opinions freely and publicly (Serrano-Guerrero et al., 2024). Furthermore, the scope of the study focuses exclusively on primary care institutions that have achieved quality system certification from an accreditation body. This careful selection of participating institutions underscores a commitment to excellence and continuous improvement in healthcare services.

Additionally, recognizing patients' perspectives on various healthcare aspects is pivotal for evaluating care quality within healthcare systems. Nevertheless, there remains a notable gap in research exploring the correlation between accreditation and patient-reported experiences (Van Doorn-Klomberg et al., 2014). Then, this study seeks to address this gap by examining how accreditation impacts user experiences with healthcare services provided by basic healthcare units.

This work is structured into five sections. Firstly, the introduction presents the topic that will be explored and outlines the objectives to be achieved. Secondly, it provides definitions of themes that guide this study: sentiment analysis and Vader. Thirdly, the approach followed to gather data, analyze it, and structure the findings are discussed. Fourthly, the findings and discussions are presented. Lastly, the fifth section comprises the conclusion, including the limitations of the studies and avenues for future research.

SENTIMENT ANALYSIS

Sentiment analysis or opinion mining is a natural language processing (NLP) technique aimed at identifying, extracting, and quantifying the emotional polarity expressed in people's opinions, emotions, sentiments. This polarity is typically classified as positive, negative, or neutral, depending on the context and the words used in the text (Hutto and Gilbert, 2014). Organizations can benefit from these analyses by extracting and detecting consumer or user sentiments regarding their services or products, thereby deriving valuable insights (Arief and Samsudin, 2023).

The goal of sentiment analysis is to understand the opinions, attitudes, and emotions expressed by users regarding certain topics, products, services, or events. Applications of sentiment analysis are diverse and include brand reputation monitoring, market trend identification, customer feedback and criticism detection, product, and service performance prediction, among others. In summary, sentiment analysis plays a fundamental role in understanding the emotions and opinions of users regarding various aspects of everyday life and the business world such as security, travel, finance and corporate, medical, entertainment, education (Mäntylä et al., 2018).

VALENCE AWARE DICTIONARY FOR SENTIMENT REASONER (VADER)

The Valence Aware Dictionary for Sentiment Reasoning, commonly known as VADER, is a lexicon-based approach and tool used for sentiment analysis in text data and developed by Hutto and Gilbert (Hutto and Gilbert, 2014) The lexicon-based approach according to Nandwani and Verma (2021) "maintains a word dictionary in which each positive and negative word is assigned a sentiment value". It is specifically designed to understand and interpret the sentiment expressed in social media texts, online reviews, and other forms of online communication, and performance well in social media domain. VADER is particularly valuable due to its ability to handle both sentiment intensity and polarity, providing a nuanced understanding of emotions expressed in text (Hutto and Gilbert, 2014). The challenge with microblog texts compared to traditional texts is that, predominantly, social media texts are brief and riddled with noise, thereby complicating interpretation (Mardjo and Choksuchat, 2022).

VADER assigns a polarity score to each word in a text, indicating whether it conveys positive, negative, or neutral sentiment. It also considers the intensity of sentiment, capturing variations such as strong positivity or mild negativity. By analyzing the overall sentiment of a piece of text based on these scores, VADER enables automated systems to understand the emotional tone and context of online content. The algorithm assigns a sentiment score (−1 to +1), which represents a polarity (negative or positive), for each word. Scores less than or equal to −0.05 are considered negative, scores greater than or equal to +0.05 are considered positive, and scores between these values are considered neutral (Arief and Samsudin, 2023).

The significance of VADER lies in its practical applications across diverse domains. Researchers utilize VADER to analyze public opinion and sentiment trends, including emotional responses in healthcare, such as evaluating tweets about COVID-19 (Arya et al., 2022; Serrano-Guerrero et al., 2023; Vashishtha et al., 2023). In finance, it offered insights into the behavior of cryptocurrency investors through sentiment analysis of tweets (Mardjo and Choksuchat, 2022). Additionally, in politics, VADER was employed to investigate voter intentions during events like the 2020 US election (Endsuy and Banjarnegara, 2021).

METHODOLOGY

To achieve the objectives of this study, a descriptive-exploratory approach was employed. The following sections detail the sampling process utilized in this research, the characteristics of the basic healthcare units considered, the database and its extraction process, as well as the techniques applied to organize, treat, and analyze the data. The Figure 1 illustrates each step followed in this research to achieve the stated objectives.

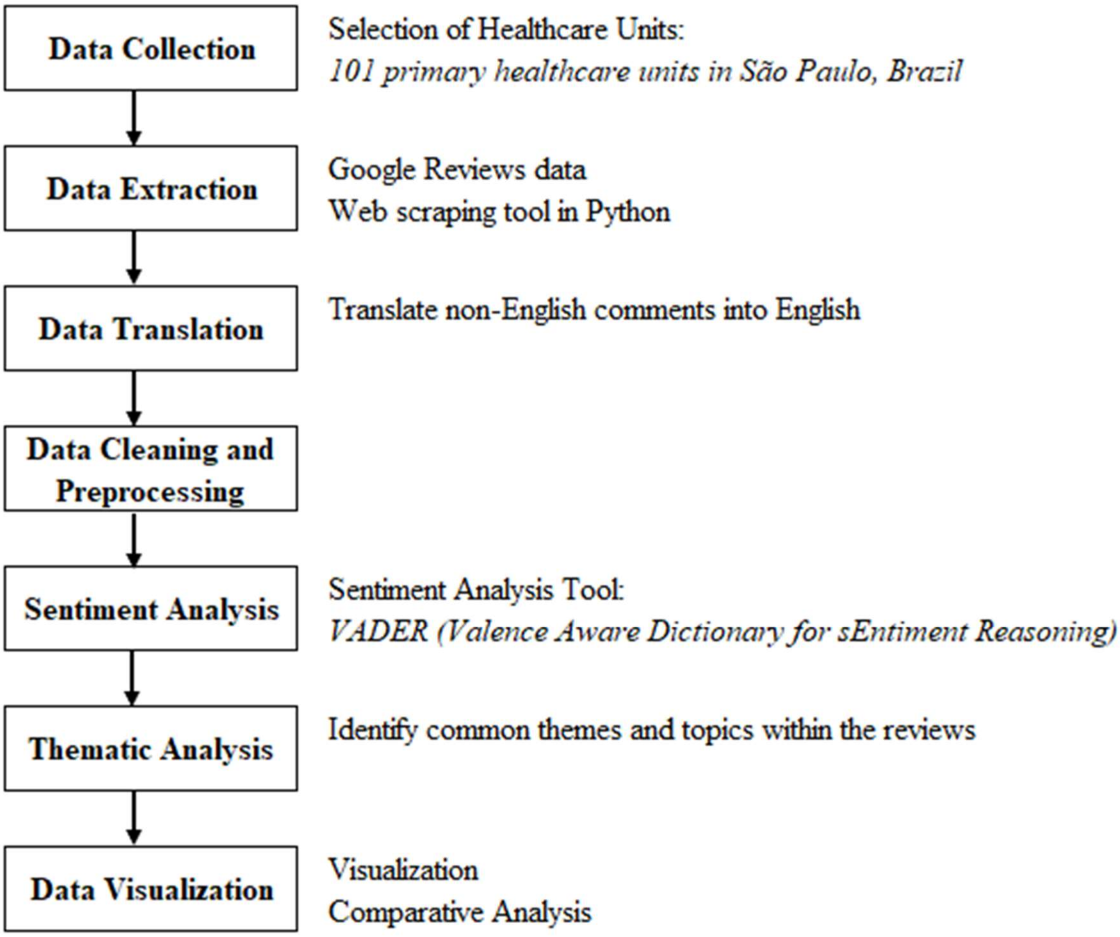

Figure 1 – Flowchart of methodology.

SAMPLING

According to the 2022 census, Sao Paulo municipality is home to 11.45 million residents. By 2023, approximately 8 million individuals were utilizing the municipal healthcare network. Basic Health Units (BHUs) play a crucial role in meeting the healthcare needs of the population, with BHUs spread across five regional districts: downtown, east, north, west, southeast, and south. The quantitative distribution of BHUs by health region is depicted in Figure 2.

For this study, only Health Units providing primary healthcare services in São Paulo, State of Sao Paulo, Brazil, and recently accredited by the National Accreditation Organization of Brazil (NAO), were considered. In total, 101 out of 469 Basic Health Units were included in the sample until February 2024. The South region had the highest number of BHU analyzed, comprising 29.7% of the sample.

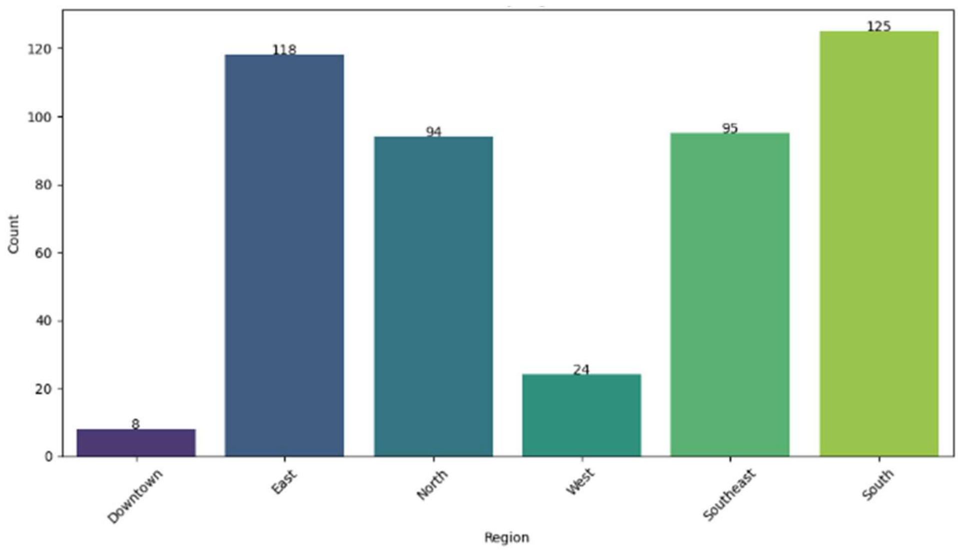

Figure 2 – Graph of total BHUs per districts.

DATA EXTRACTING

The data analyzed in this study are derived from user comments on Google Reviews regarding the services provided at basic health units. Reviews up to February 2024 were included in the analysis. Python programming was utilized for data extraction, organization, and translation. Table 1 displays the code used for automating the extraction of comments. There was no time restriction for data collection. The data were tabulated based on four characteristics: comment timestamp, comment content, user's code, and rating stars. Subsequently, the data were translated from Portuguese to English using the Googletrans Python library.

Table 1 - Comment Extraction Code.

```
for index, value in df['Search Link'].items():
    url = value

   driver = webdriver.Firefox()
   driver.get(url)
   sleep(2.5)

   # Find the review button and click, enter the review page
    review = 
driver.find_element(By.XPATH,'//*[@id="QA0Szd"]/div/div/div[1]/div[2]/div/div[1]/div/div/div[3]/div/div/button
[2]')
    review.click()
    sleep(2.5)

    timestamp = driver.find_elements(By.CLASS_NAME, 'rsqaWe')
    content = driver.find_elements(By.CLASS_NAME, 'MyEned span.wiI7pd')
    name = driver.find_elements(By.CLASS_NAME, 'd4r55')
    star = driver.find_elements(By.CLASS_NAME, 'kvMYJc')

    all_reviews = []
    l = 0

    for j in range(len(comments)):
        review_list = [l, name[j].text, time_frame[j].text, star[j].get_attribute('aria-label').strip(),
comments[j].text]
        all_reviews.append(review_list)
        l += 1

    columns = ["ID", "Name", "Timestamp", "Stars", "Content"]

   df1 = pd.DataFrame(all_reviews, columns=columns)
   driver.quit()

# close after the loop
driver.quit()
```

DATA ANALYSIS

The data analysis was structured into two stages. Firstly, a general overview of the data was conducted to characterize the sample of basic units and extracted comments. Python data visualization libraries such as seaborn and matplotlib were selected for this purpose due to their versatility and effectiveness in visualizing data. Secondly, a quantitative and qualitative evaluation of the comments' words was carried out to extract relevant information, identifying similarities and differences within the sample. Natural language processing libraries like NLTK were utilized for text processing, and qualitative analysis tools like WordCloud and network analysis tools such as NetworkX were employed to gain deeper insights into the textual data.

For sentiment analysis of the comments, a multi-step approach was adopted. Initially, the comments were cleaned by removing stop words, words with one or two letters, and a list of non-relevant words for the analysis (e.g. “look”, “went”, “one”, “said”). Subsequently, the Vader algorithm was applied to classify the sentiments of the comments. Table 2 presents the code used for performing this analysis. To ensure transparency and reproducibility, all steps of the data analysis process were documented, and the code used for analysis was provided in Table 2.

Table 2 - Vocabulary Analysis Code

```
import nltk
from nltk.corpus import stopwords
nltk.download('stopwords')
nltk.download('vader_lexicon')


custom_list_stop = []
for v in list(vocabulary):
  if len(v) == 1 or len(v) == 2:
    custom_list_stop.append(v)
custom_list_stop = custom_list_stop
print(custom_list_stop)


others = ['post','one', 'went', 'get', 'say', 'come', 'would', 'said', 'want', 'told', 'look', 'put', 'give', 'take', 'make', 'take ']
stop_words = set(stopwords.words('english') + custom_list_stop + others )


df_lim['Clean'] = df_lim['Clean'].apply(lambda x: " ".join(word for word in str(x).split() if word.lower() not in stop_words))

# Apply the polarity_scores function to the 'text' column
from nltk.sentiment import SentimentIntensityAnalyzer
from tqdm.notebook import tqdm
sia = SentimentIntensityAnalyzer()
df_analisado['sentiment_scores'] = df_analisado['Clean'].apply(lambda text: sia.polarity_scores(text))
```

RESULTS

DESCRIPTION OF BASIC HEALTHCARE UNITS

The comments from 101 basic health units in the municipality of São Paulo, Brazil, accredited between October and February 2024, were evaluated. These units are dispersed across five regions of the municipality as shown in Figure 3. Notably, the South region contributed the largest share of BHUs, comprising 29.7% of the sample.

A total of 7,864 comments were extracted from the Google review platform up until February 2024, and the Figure 4 displays the average number of comments per region. It is noteworthy that the North, East, and Southeast regions exhibited a higher average number of comments. This suggests a discrepancy between the number of BHUs in each region and the number of comments received, indicating that the region with the most BHUs does not necessarily correspond to the region with the most comments. Additionally, it is important to clarify that BHUs in the Central region were not included in this analysis because due to the absence of accredited BHUs in that area at the time of the study.

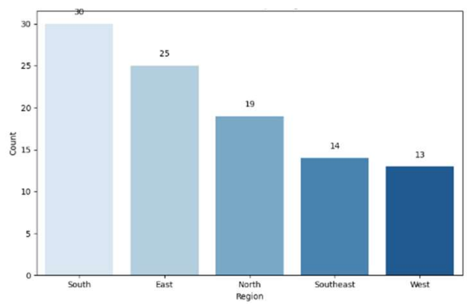

Figure 3 – Number of basic units per region sampled.

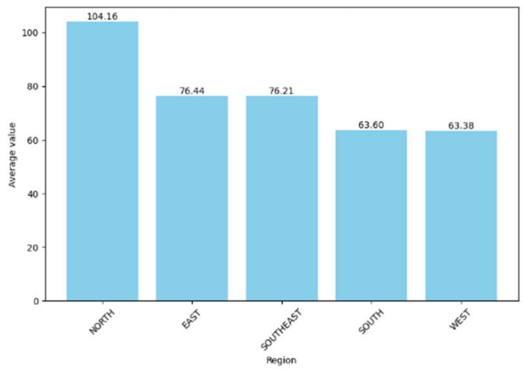

Figure 4 – Average number of comments per region.

In the analysis of unit sizes, most units evaluated (89.11%) fell into the medium scale category, employing 50 to 150 individuals. Following this, small-scale units (5.94%) with fewer than 50 employees, and large-scale units (4.95%) with more than 150 employees were observed. It is noteworthy that units in the West region were exclusively of medium size, whereas in the East region, units of all three sizes were evaluated.

CHARACTERIZATION OF COMMENTS

The analysis examined the distribution of comments across time intervals. Figure 5 depicts the progression of comment numbers over time. Two distinct periods emerge: from 0 to 365 days, showcasing a notable surge in the final 30 days (0 to 30), and from 731 to 3650 days, where a higher volume of comments was observed compared to the previous interval. This marked increase in the last year aligns with the accreditation process of Basic Health Units, while the second period matches with the COVID-19 pandemic scenario.

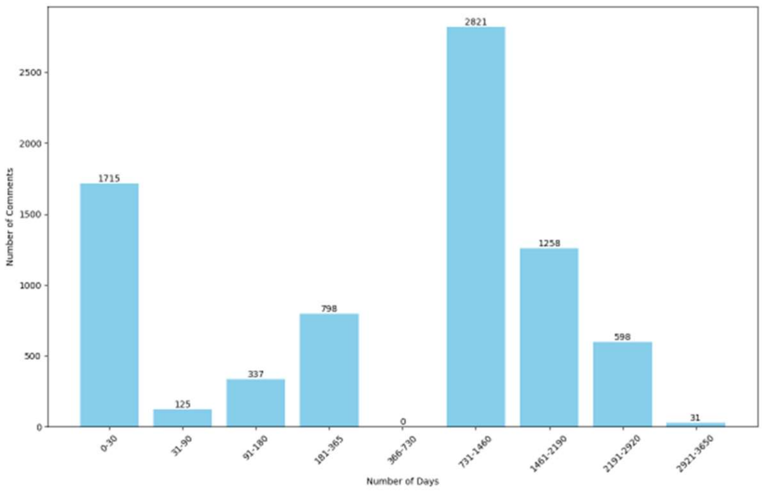

Figure 5 – Total commentaries per period in days.

The comments were categorized into "strongly negative", "negative", "neutral", "positive", and "strongly positive" based on the star ratings provided by evaluators. The graph illustrated in Figure 6 shows the distribution of comment based on these classifications. It was evident that comments classified as "strongly negative" and "strongly positive" constituted the majority in terms of sheer quantity.

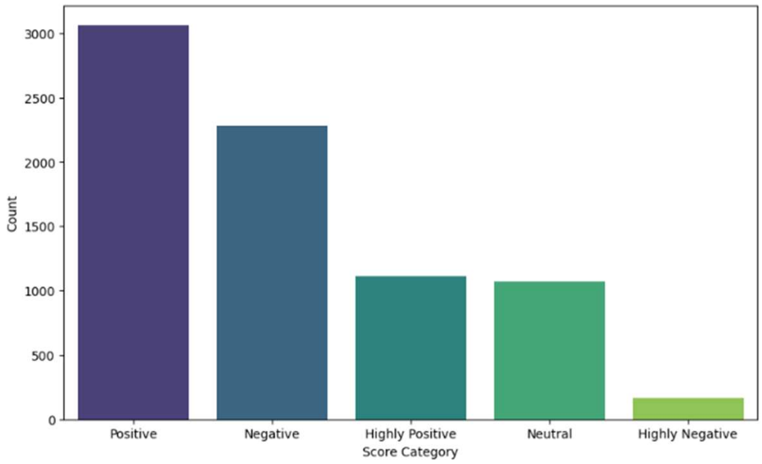

Figure 6 – Distribution of comments by stars.

Additionally, Figure 7 showcases the regional distribution of comments based on these classifications. It is worth noting that North region garnered the highest number of "strongly positive" comments, closely followed by the East region. Moreover, in general, reviewers tended to express more positive sentiments (51.4%) than negative ones (40.7%). Only a marginal percentage, 7.8%, of comments were deemed neutral.

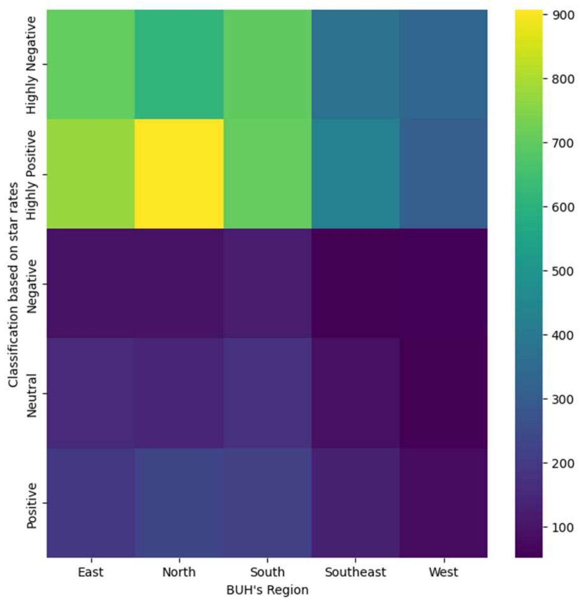

Figure 7 – Relationship matrix of comments categorized by star and region.

When specifically examining comments from the past year, it became apparent that the East region, followed closely by the South region, received the highest number of evaluations. However, in contrast, despite the North region amassing a substantial number of comments, there were slightly more "strongly negative" remarks than "strongly positive" ones. This trend indicates a slight depreciation in the perceived quality of service within this region. This scenario diverges from the general analysis of comments without temporal restrictions. Therefore, this study will focus solely on comments from the past year, as this period aligns closely with the accreditation timeframe.

SENTIMENT ANALYSIS OF SAMPLE

During the sentiment analysis of the comments, it was noted that the expressed sentiments largely align with the star ratings, although they do not exhibit the same polarization between "strongly positive" and "strongly negative" as observed in the star ratings. Furthermore, in the sentiment analysis, a predominance of "positive" evaluations was evidenced, followed by "negative" evaluations, as illustrated in Figure 8.

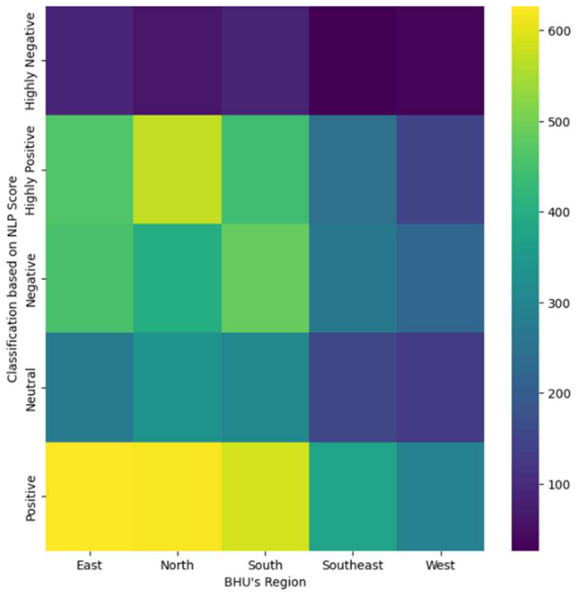

Figure 8 – Relationship matrix of comments categorized by sentiment analysis and region.

Additionally, two-time frames of comments were compared: from 0 to 365 days (covering the accreditation process until accreditation was achieved) and from 731 to 3650 days (prior to the accreditation period or the pandemic period). Figures 9 illustrate this comparison between the two periods.

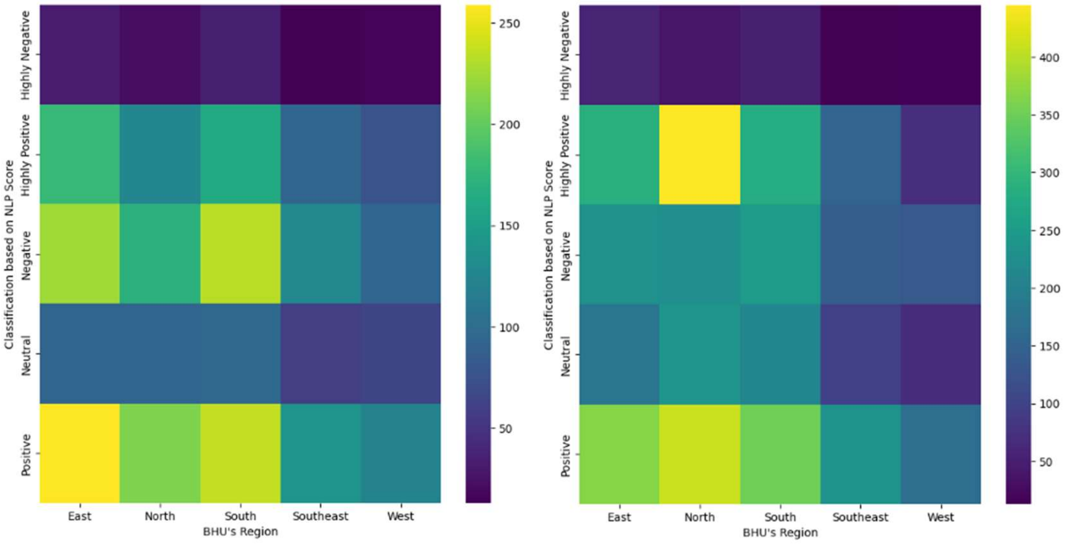

Figure 9 – Comparative between two periods of timestamp – left (0 to 365) and right (731 to 3650).

Upon analyzing the sentiments conveyed in the comments throughout these time spans, it became apparent that there was a higher frequency of positive sentiments in the last year. This trend was particularly pronounced in the Eastern and Southern regions, although a significant number of negative comments were also observed subsequently.

Conversely, compared to the second period, it was noted that the quantity of positive comments decreased in relation to the preceding period. However, there was a noticeable increase in the frequency of "strongly positive' comments, indicating that users reported more gratifying experiences with the services received, particularly in the Northern region.

Furthermore, it is noteworthy that "negative" comments were more prominently featured during the first period than in the second. This suggests a slight deterioration in the experiences of users and their families or caregivers over the past year, despite the continued prevalence of positive comments. Additionally, there was a higher frequency of neutral sentiments expressed during the initial period compared to the second. This indicates that users felt more inclined to freely express their opinions during this time frame.

POSITIVE SENTIMENT ANALYSIS

Upon examining topics related to the classification of positive sentiments, a prevalent theme emerged: users consistently conveyed satisfaction, particularly towards the individuals providing the service ("employees", "doctors", "people"). Adjectives that positively described the service received, focusing on the demeanor of individuals such as "professional" and "attentive" were more commonly observed than references to tangible aspects of healthcare facilities. Notably, the term "reception" also featured prominently, suggesting users' positive sentiments towards the initial service encounter. Furthermore, primary care units emerged as crucial vaccination hubs, with the word "vaccine" prominently represented in the word network, indicating users' positive attitudes towards this aspect of healthcare. This word network is depicted in Figure 10.

A comparison was made between the word networks for the two analyzed time periods, and it revealed no significant differences. In other words, no confirmed changes were detected in how users perceive the services provided by primary care units before and after the accreditation process. Another analysis conducted was by region. It was observed that the word "doctor" was only present in the word network of the Southeast region. On the other hand, a new word, "team" emerged in the word networks of the East and South regions, reinforcing satisfaction with the involvement of all individuals responsible for providing health services in primary health care units. Additionally, the word "organized" gained prominence in the word networks of the West and North regions to characterize the service. It is worth adding that satisfaction with the "time" was significant in the East and West regions.

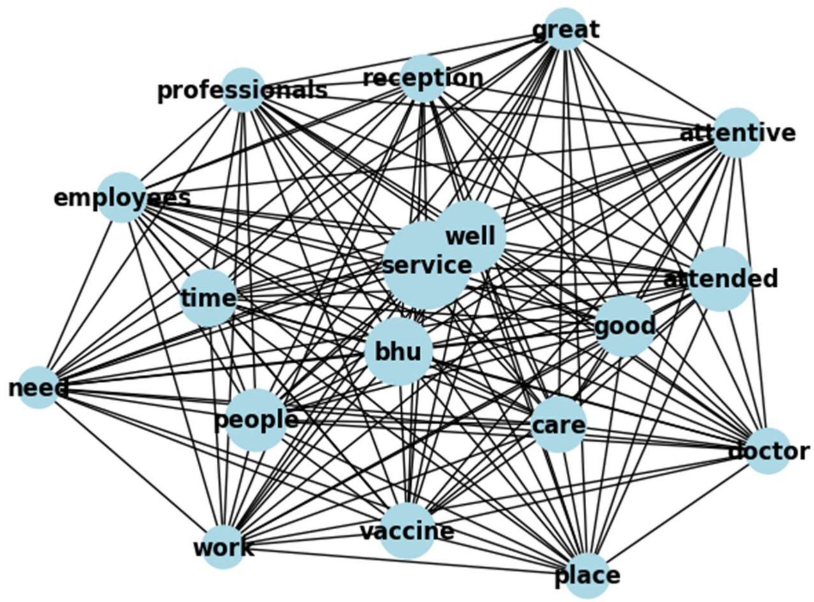

Figure 10 – Word network of positive feelings.

NEGATIVE SENTIMENT ANALYSIS

Regarding the words expressing negative sentiments (Figure 11), it was observed that the main drivers for user dissatisfaction were primarily related to service time, communication, and interactions with personnel in primary care. Service time was associated with words like “waiting”, “hours”, and “time”; communication was linked to “phone” and “know”; and interactions with people were associated with words like “employees”, “doctor”, and “people”. Particularly noteworthy is the word “know”, which is related to the service’s ability to provide pertinent information to users when requested. “Place” was also mentioned in a general sense, without specific characteristics being presented. When analyzing the differences between the two time periods (before and after the accreditation process), no significant differences were confirmed regarding the main satisfaction elements. And comparing word networks by region, although they present different configurations, the words comprising each of these networks do not differ, meaning that user-expressed feelings of dissatisfaction are associated with the same topics regardless of the region.

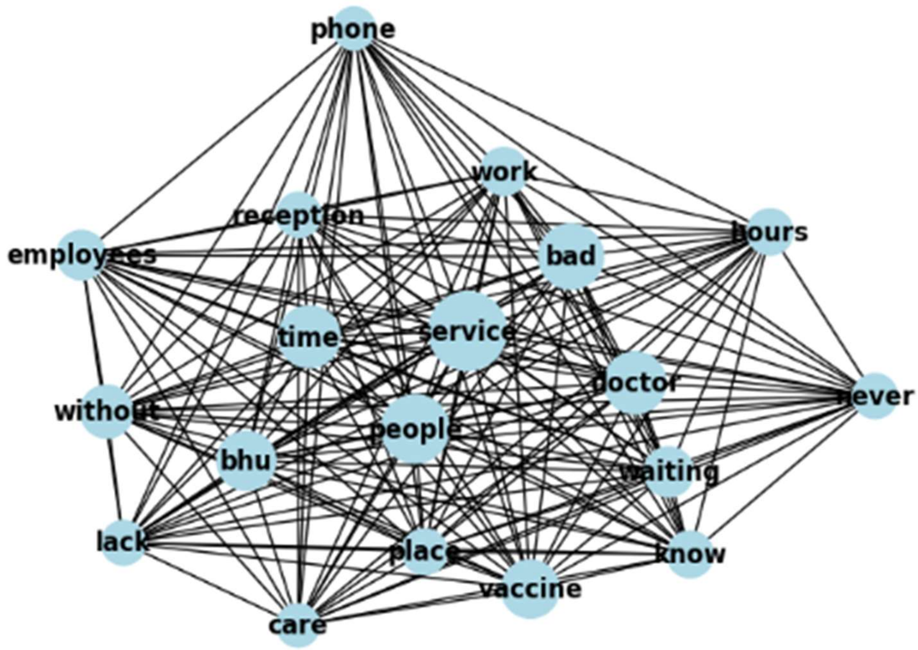

Figure 11 –Word network of negative feelings.

DISCUSSION

The use of NLP has emerged as a common method for understanding the experiences of patients, users, and families within healthcare provision. An analysis of sentiment from comments by users of primary care providers in Brazil, known as basic healthcare units (BHUs), shows that despite the public nature of these services – being provided by the government – many users express positive sentiments regarding the service they receive. This suggests that there is a satisfactory level of service for those involved in the process.

The assessment of primary healthcare services varies across regions, particularly concerning positive aspects. Protasio et al. (2017) supported this finding in their study on primary care in Brazil, confirming that user satisfaction varies by region due to differences in accessibility qualifications, approaches to meeting user needs, and work processes. Notably, the analysis of comments sample showed that the northern region stood out in terms of positive sentiment comments, reflecting a relatively high to very high Human Development Index (HDI) in this region.

It was discovered that the factors exerting the greatest influence on both positive and negative feelings regarding the received service are closely tied to the individuals delivering the care, particularly medical or support staff (reception). Interestingly, terms associated with the nursing team did not stand out prominently in the word networks. This could be attributed to the fact that individuals tend to have more interaction with doctors, despite the presence of contact with the nursing team within these facilities, primarily for routine exams. Furthermore, it is evident that professionals in these services face negative evaluations, highlighting the urgent need for ongoing professional development. This includes not only comprehensive training but also establishing a supportive work environment that enables efficient and satisfying performance of their duties. Providing the necessary resources and tools for effective task performance, coupled with emotional support and recognition for their contributions, is essential. Cultivating such a supportive environment encourages professionals to feel motivated and committed to delivering high-quality service. Ultimately, this enhances user satisfaction and reinforces the organization's positive reputation.

Additionally, it was observed that words related to people were associated with a caring and attentive approach in service delivery. This observation is supported by the findings of Hammanjoda and Singh (2023), who evaluated the effects of service quality dimensions on individual satisfaction in primary care institutions and found that the dimension of empathy, which entail demonstrating compassion, respect for individuals' needs, and concern for well-being, had a significant impact effect during service delivery. Also, Protasio et al. (2017) emphasized the significance of listening to users in the primary care service delivery process, even if their needs aren't entirely met. This reinforces the importance of creating a welcoming environment, essential for patient, family, and caregiver satisfaction. This reinforces the importance of the service's ability to listen to and accommodate the needs of users within primary healthcare facilities.

Another intriguing discovery is that individuals did not convey either positive or negative sentiments regarding tangible aspects of the service, such as cleanliness, accessibility, and crowdedness. This observation highlights the emphasis placed on the individuals delivering the service. It suggests that people's perceptions and evaluations of the service experience are primarily influenced by interactions with the service providers rather than by tangible factors. This underscores the critical role of interpersonal interactions and the quality of care provided by healthcare professionals in shaping user satisfaction and overall experiences.

Furthermore, in the study by Javed and Ilyas (2018), which evaluated the quality of services in both public and private hospitals, it was observed that patients in public hospitals prioritize staff understanding their pain and being treated with courtesy, whereas patients in private hospitals prioritize prompt attention and adequate infrastructure. This indicates that personal aspects are more emphasized in public healthcare settings compared to private ones. Therefore, highlighting the importance of effective training for healthcare professionals and support staff is seen as essential in the care process within primary care providers.

Another aspect of the service highlighted by sentiment analysis was the timeliness of service delivery, echoing findings similar to those of Serrano-Guerrero et al. (2024). The perception of time consistently emerges as a critical factor in studies evaluating satisfaction within the healthcare context. Punctuality in service and treatment, coupled with the ability to allocate sufficient time to listen to patients, are deemed crucial aspects of healthcare service delivery, as highlighted by Serrano-Guerrero et al. (2024). This highlights the importance for managers aiming to enhance service provision in primary care units to implement practices geared towards continuous improvement in service delivery times. It is crucial to invest in solutions aimed at continuously enhancing service delivery, prioritizing the reduction of wait times for procedures and ensuring consistent service provision.

Upon comparing the time periods before and after accreditation, no significant differences were observed in either negative or positive sentiments. One plausible explanation for this lies in the fact that the units are still in their nascent stages. It is essential to recognize that the practices instituted by the new quality management model require time to yield tangible results, particularly in terms of fostering positive sentiments within the units. As such, it is reasonable to expect that over time, as the model becomes more entrenched, more pronounced improvements in both negative and positive sentiments will likely emerge.

A clearer understanding and further insight into this matter can be gained by considering the transitional nature of the accreditation process. It often takes time for the changes implemented through accreditation to manifest tangible improvements in service quality and user satisfaction. Additionally, the initial stages of implementing a new quality management model may involve challenges and adjustments as staff members adapt to new protocols and procedures. Therefore, while immediate differences may not be evident, it is important to maintain a long-term perspective and continue monitoring the performance of the units to assess the effectiveness of the accreditation process. Over time, as the units become more accustomed to the new model and refine their practices, it is expected that positive outcomes will emerge, leading to enhanced user satisfaction and overall service quality.

Indeed, individuals striving to enhance the perception of services in primary care within the Brazilian context should prioritize addressing the negative aspects of the service. Interestingly, these negative aspects do not display significant differences between regions, unlike the positive aspects, which exhibit variations across different regions.

CONCLUSION

By comprehensively analyzing the factors influencing service quality in healthcare through a data-driven approach, this research significantly aids decision-making within the healthcare sector. It empowers policymakers, healthcare administrators, and stakeholders to optimize resource allocation, effectively addressing the diverse needs of patients and users. Consequently, this endeavor not only enhances service quality but also ensures the satisfaction of all stakeholders involved in the healthcare process. Moreover, it promotes the delivery of patient-centered care and fosters a culture of continuous quality improvement within the healthcare system.

As the next steps for this project, the comparison of user perceptions one year after the implementation of the accreditation program is pivotal to validate its impact on service users' perceptions. This comparison is essential as the current findings of this study are intricately linked to the implementation process. Consequently, it will enable a thorough assessment of the program's effectiveness in enhancing service quality and meeting user expectations. Additionally, there are plans to explore the association between perceptions about service quality and various social and healthcare indicators of each region. This analysis will provide valuable insights into the broader context surrounding service delivery and help identify potential factors influencing user perceptions.

Moreover, exploring comments separately for each topic can provide more detailed insights into their characteristics. This approach allows for a deeper understanding of users' perceptions and experiences regarding specific aspects of the service. Since discussions in this study were primarily focused on macro-level topics, delving into comments related to each individual topic can uncover valuable insights that might have been overlooked.

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Enablers and Barriers in Hospital Accreditation: A Integrated Review

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STRUCTURED ABSTRACT

Purpose - This study investigates factors influencing successful implementation, performance, and sustainability of hospital accreditation programs, addressing the research question: "What contributes to or impedes accreditation program effectiveness in healthcare institutions?".

Design/methodology/approach - This paper presents an integrated literature review conducted until December 2023, using Scopus and Web of Science databases. Relevant articles were identified using keywords such "hospital", "healthcare service", "healthcare organization", "healthcare institution", and "healthcare provider". The screening process involved dual-screening based on title and abstract, followed by dual full-text review. Thirty-three articles were eligible for content analysis. Findings were categorized based on a consensus set of factors derived from the sample studies.

Findings - The study identified 25 classes of factors influencing hospital accreditation program success, categorized into seven groups: workforce, organizational, facilities/equipment, operational, evaluation process, accreditation program, and external factors. Operational factors, workforce, and evaluation process emerged as commonly cited barriers, while operational factors, workforce, and organizational factors were frequently mentioned as facilitators.

Originality/value - This study synthesizes literature to illuminate the factors influencing hospital accreditation program success, aiding healthcare organizations in optimizing implementation and evaluation processes for accreditation.

Keywords: Challenges, moderators, external quality assessment, healthcare.

Paper type: Literature Review

INTRODUCTION

Healthcare institutions grapple with the intricate task of maintaining a delicate equilibrium between delivering top-notch services and managing costs effectively. Accreditation programs play a pivotal role in this balancing act, serving as the bedrock of quality management. They not only bolster process efficiency but also uphold service excellence and adherence to global standards (Gualandi et al., 2020; Ritchie et al., 2019). Hospital accreditation entails systematic external evaluations across healthcare service dimensions: structure, process, and outcome, promoting quality improvement initiatives (Falstie-Jensen et al., 2021; Karamali et al., 2020).

However, alongside their undeniable benefits of accreditation programs, healthcare organizations confront a multitude of challenges (Ng et al., 2013). Tashayoei et al. (2020) underscored the need to identify and address these challenges to enhance program success and neglecting them may lead to nonconformities during assessment (Al Kuwaiti and Al Muhanna, 2019). Similarly, Melo's (2016) qualitative research elucidated factors influencing accreditation implementation, shedding light on varied organizational outcomes.

This study identifies challenges and facilitators in accreditation program implementation, aiding hospital organizations. Through integrated literature review and systematic selection, it examines factors influencing implementation, performance, and sustainability. The research question is "what contributes to or impedes accreditation program effectiveness in healthcare institutions?".

The article is structured into five sections: introduction, outlining research objectives; methodology details the research approach; results, showing an overview of sampled articles, followed by quantitative analysis of identified challenges and facilitators; discussion, analyzing these factors; conclusion, suggesting future research directions.

RESEARCH METODOLOGHY

Initial searches were conducted using Scopus and Web of Science databases known for their high-quality content and rigorous selection process. Papers considered until December 2023 were included. The search logic, outlined in Figure 1, encompassed articles in Portuguese, English, and Spanish without a specific time frame. Filtering for articles and literature reviews in journals yielded 1,811 articles.

After removing 300 duplicate documents, 1,511 unique documents remained. Excluding articles without abstracts left 762 documents for analysis. These underwent dual screening of title and abstract to ensure validity. Forty-eight articles were selected for full reading, assessing objectives, methodology, and results. Fifteen articles were excluded due to unclear methodology or misalignment with the research scope, resulting in a sample of 33 eligible articles for content analysis. Reference lists were also examined, but no additional papers were included. From this final sample of articles, factors identified as facilitators and barriers for accreditation program were listed, categorized, and coded for analysis.

#1 TITLE-ABS-KEY (hospital OR "healthcare service" OR "healthcare organization" OR "healthcare institution" OR "healthcare provider")

#2 TITLE ("accreditation" OR "external quality assessment")

#3 TITLE-ABS-KEY("dental" OR "dentistry") OR TITLE-ABS-KEY("accreditation council for graduate medical education" OR "acgme") OR TITLE-ABS-KEY("magnet accreditation" OR "Magnet® Accreditation" OR "Magnet Recognition") OR TITLE-ABS-KEY(laboratory OR laboratories OR "ISO-15189" OR "iso 15189" OR "iso15189") OR TITLE-ABS-KEY("mental service" or "psychiatry" OR "mental health") OR TITLE-ABS-KEY("image services" or "radiology") OR TITLE-ABS-KEY("imaging service*" OR "radiology" OR "nuclear medicine") OR TITLE-ABS-KEY("american society for metabolic and bariatric surgery" OR "MBSAQIP" OR "bariatric accreditation" OR "Bariatric Surgery accreditation" OR "bariatric surgery" OR "accreditation in bariatric surgery") OR TITLE-ABS-KEY("public health accreditation board" OR "public health department accreditation" OR "PHAB") OR TITLE-ABS-KEY("primary care provider*" OR "primary healthcare accreditation") OR TITLE-ABS-KEY("national pathology accreditation advisory council" OR "accredited pathology laboratory" OR "Accredited Pathology Laboratories" OR "accreditation for pathology" OR "Accreditation of Pathology Laboratories" OR "national pathology accreditation" OR "NPAAC") OR TITLE-ABS-KEY("NURSING HOME" OR "Home Care" or "residential care of elderly" OR "geriatric nursing" OR "Home Health Care Service*") OR TITLE-ABS-KEY("chemotherapy certification" OR "commision on cancer" OR "accreditation council of oncology" OR "cancer care commission" OR "american society for radiation oncology" OR "cancer accreditation") OR TITLE-ABS-KEY("hemodialysis unit accreditation" OR "National Dialysis Accreditation Commission" OR "NDAC") OR TITLE-ABS-KEY("Baby Friendly accreditation" OR "Baby-friendly hospital accreditation" OR "Baby Friendly Hospital Initiative" OR "BFHI")

#4 #1 AND #2 AND NOT #3

Figure 1 – Search strategy.

RESULTS

CHARACTERIZATION OF STUDIES

Most articles focused on accreditation programs in Iran (12 articles), followed by Brazil (4 articles), Saudi Arabia (3 articles) and Australia (2 articles). Qualitative research, particularly semi-structured interviews, was the predominant methodology. Studies mostly occurred in public institutions, with many evaluating national accreditation programs.

QUANTITATIVE ANALYSIS

Twenty-five classes of barriers were categorized into seven categories: workforce, organizational, facilities and equipment, operational, accreditation program, evaluation process, and external factors. Figure 2 offers a summary, with bubble size indicating the percentage of mentions among analyzed articles.

Most barriers fell into five categories: operational factors (27.34%), workforce (28.07%), evaluation process (13.60%), and accreditation program (11.99%) and organizational factors (11.99%). Conversely, the least mentioned were external factors (2.19%), facilities and equipment (4.82%). The categories of operational factors, workforce and accreditation program have the highest number of items discussed in the sample. Among these categories, the most frequently cited factors were “people” (22.2%) in the workforce category, followed by management (13.6%) in the operational factors category, and indicators (6.7%) in the accreditation program category. Effects of the pandemic (0.15%) and accreditation manuals (0.29%) were less discussed.

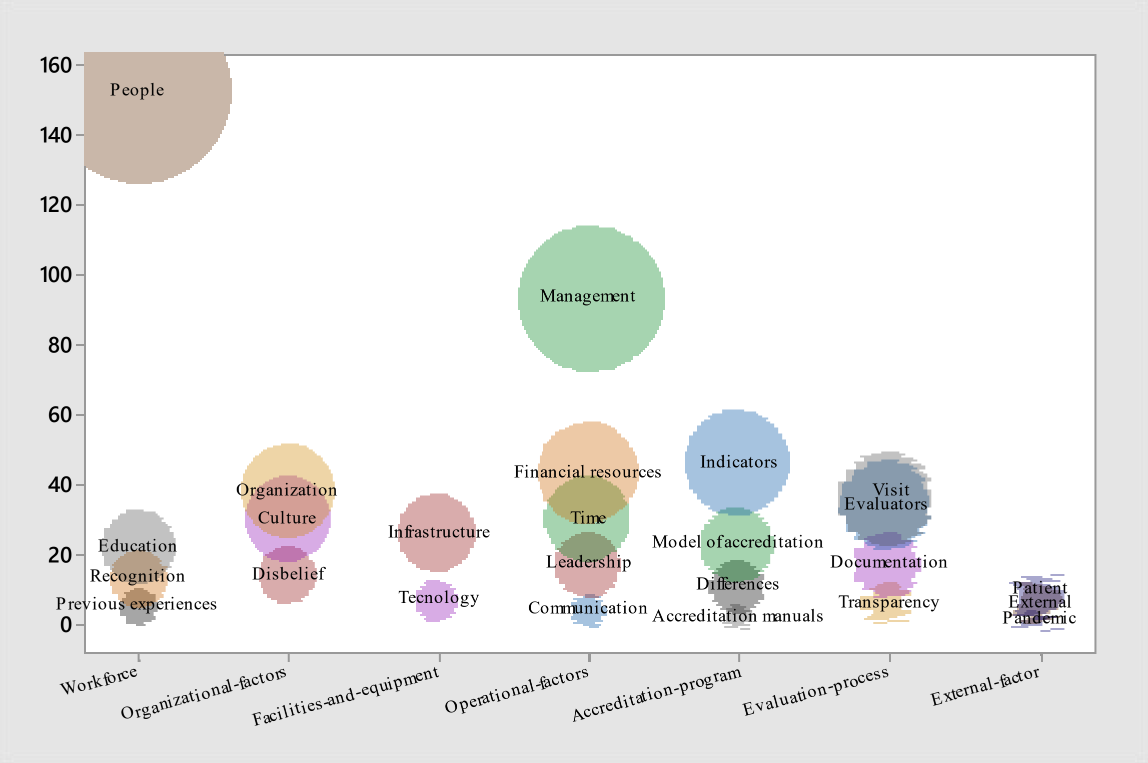

Figure 2 – Graph of categorized barriers.

Among enabling factors, twenty-five were identified and categorized similarly to the barriers. Workforce emerged as the most influential (30.75%), followed by operational factors (30.75%) and organizational factors (14.13%). External factors, and facilities and equipment were less represented, accounting for only 3.60% and 3.88%, respectively. Additionally, operational factors, workforce, and evaluation process had the highest number of item classes. Figure 3 below illustrates the main classes of enablers classified into their respective categories.

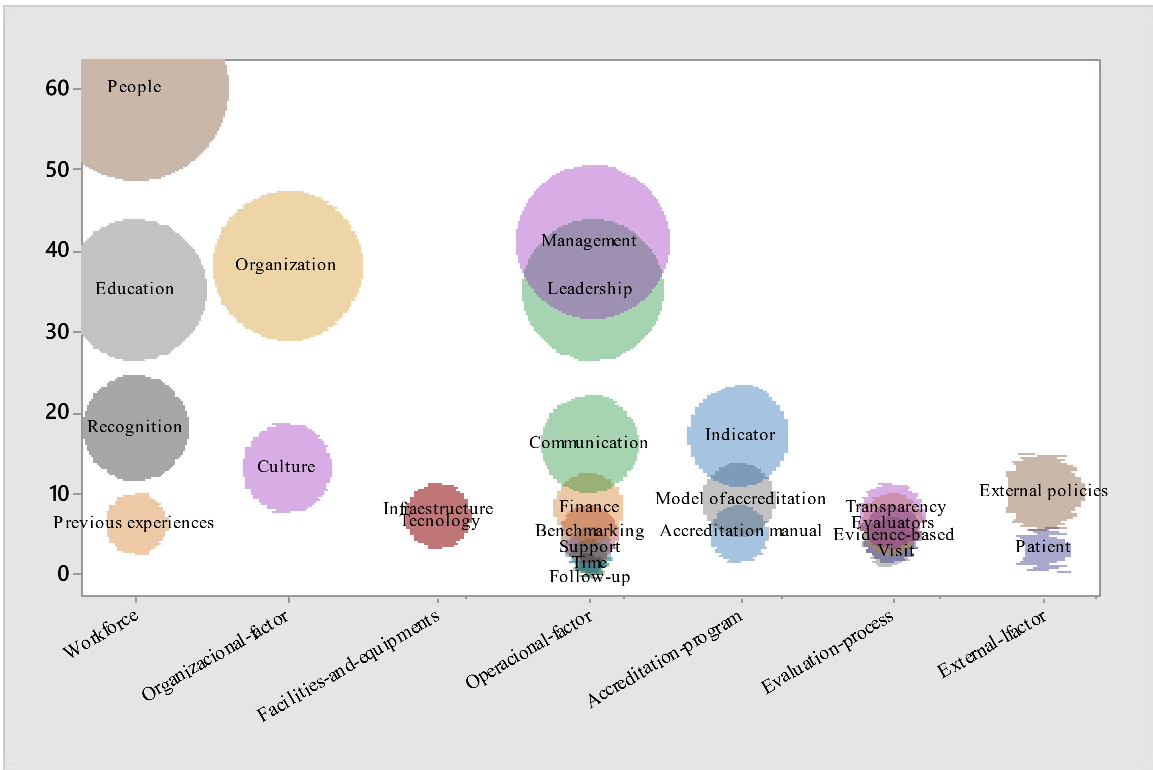

Figure 3 – Graph of categorized facilitators.

DISCUSSION

Subsequent sections will explore each category of factors hindering or enabling hospital program implementation in detail.

CATEGORIZATION OF BARRIERS

WORKFORCE

The factor most frequently cited in this category is "people". Resistance to change is a common theme, as highlighted by several studies (Bord et al., 2021; Al Mansour et al., 2022a), especially among medical professionals (Ebrahimipour et al., 2021). The implementation of accreditation practices often requires the adoption of new work routines, involving adherence to protocols and procedures to meet required standards. This place demands on healthcare professionals involved in the accreditation process, necessitating their time, effort, and willingness. Additionally, discussions within this category include a shortage of qualified personnel and a high turnover of professionals, which contribute to increased workload, stress, and diminished motivation among staff (Mansour et al., 2021a).

Other factors within this category hinder the successful implementation of accreditation programs. These include a lack of engagement, motivation, skills, and capabilities among healthcare professionals involved in the accreditation process (Reisi et al., 2019). Also, the demanding nature of accreditation can exacerbate stress behaviors, leading to anxiety, fatigue, and feelings of fear and guilt among professionals (Greenfield et al., 2011a). Additionally, the pressure to perform well and adhere to accreditation standards can impose significant psychological strain on individuals (Vali et al., 2020).

Continuous education of workers, like training and qualification, poses barriers within the workforce category. The lack of tailored training programs, not aligned with accreditation needs, and provided in limited timeframes, is concerning (Sharifi et al., 2017; Nekoei-Moghadam et al., 2018). Ebrahimipour et al. (2021) noted that many professionals lack specific accreditation training during university education, resulting in inadequate preparation to effectively manage accreditation programs.

Moreover, the study revealed that insufficient recognition, inadequate incentives, and limited financial rewards pose significant challenges to achieving positive outcomes from healthcare accreditation programs (Sharifi et al., 2017; Robbins et al., 2021).

The absence of previous experience with accreditation programs in hospitals is reported as a barrier (Mosadeghrad and Ghazanfari, 2021). This lack of experience can lead to challenges in comprehending program objectives and standards, resulting in organizational indifference towards the program and its outcomes (Agrizzi et al., 2016). Additionally, Hussein et al. (2022a) argued that when employees are unfamiliar with the accreditation process, they may perceive it as disruptive rather than value-adding, hindering engagement and cooperation and making it more challenging to achieve desired outcomes.

OPERATIONAL FACTORS

In the operational factors category, barriers related to “management” were predominant. Accreditation programs place substantial demands on managers, necessitating intensive planning activities with last-minute changes and additional working hours for both managers and staff

(Mansour et al., 2021b). Poor hospital management and lack of a structured quality management system were also identified as challenges (Alástico and De Toledo, 2013a).

Katoue et al. (2021) emphasized the lack of collaboration among hospital departments, hindering their understanding of accreditation roles and contributions. This leads to inefficiencies and inconsistencies in meeting requirements (Bord et al., 2021). Moreover, key stakeholders are often excluded or involved late in accreditation activities (Bastani et al., 2021a). Restricted information access further hampers transparency and data flow essential for the accreditation process (Robbins et al., 2021).

Limited participation and engagement of the human resources department during accreditation activities is a recurring challenge, indicating weaknesses in personnel recruitment and development (Bahadori et al., 2018). Hospitals also face substantial time-related constraints, including limited time for understanding and preparing for the program (Al Mansour et al., 2022a) and during implementation (Mirandola and Mendes, 2014; de Grande and de Mendes, 2015a), as well as delays in obtaining necessary resources for the accreditation process (Bord et al., 2021).

The authors spotlighted significant challenges in financial investments for hospital accreditation, including expenses for hiring consultancies, recruiting new employees (Bastani et al., 2021a), and conducting training programs (Mansour et al., 2021b). Additionally, organizations' reluctance to invest in accreditation programs is influenced by a perceived lack of positive cost-benefit ratio (Sharifi et al., 2017; Al-Alawy et al., 2021).

The absence of strong, involved, and engaged leadership significantly hampers the successful implementation of hospital accreditation programs (Sax and Marx, 2014). Additional barriers include high turnover of managers (Shakibaei, 2019) and a shortage of trained managers to support the program (Ebrahimipour et al., 2021). Lastly, weak and/or inadequate communication between departments further compromises accreditation processes (Ebrahimipour et al., 2021; Yousefinezhadi et al., 2020a).

ORGANIZATIONAL FACTORS

The organizational structure, strategy, objectives, and culture have been identified as barriers for hospitals in implementing accreditation programs. Issues related to culture, disbelief, and organization, which encompass policies, strategies, and governance, were classified under the organizational factors category.

Perceiving accreditation programs solely as a means of financial gain limits understanding of their broader benefits (Shakibaei, 2019). Additionally, barriers include the absence of an organizational strategy aligned with accreditation (Mansour et al., 2021b), ambiguity in objectives (Reisi et al., 2019), constant changes in vision and strategic plans (Mansour et al., 2021b; Reisi et al., 2019), lack of alignment with organizational goals (Al-Alawy et al., 2021), and top-down decision-making processes (Agrizzi et al., 2016).

Additional barriers in this category include the lack of alignment between accreditation programs and other organizational initiatives (Sax and Marx, 2014; Yousefinezhadi et al., 2017), and the absence of a solid foundation for implementing such programs within hospitals (Sharifi et al., 2017). This result in accreditation programs not being prioritized as effective tools for enhancing healthcare quality and safety, leading to a failure in their deep institutionalization within the organizational culture (Ebrahimipour et al., 2021).

Organizational culture presents a significant barrier, with authors highlighting the lack of promotion of a culture of quality and safety within healthcare organizations. This leads to limited worker involvement in hospital accreditation programs (Agrizzi et al., 2016; Hinchcliff et al., 2013a). Stakeholders often perceive quality as confined to specific departments rather than an overarching organizational culture (Hinchcliff et al., 2013b). Additionally, accreditation is often viewed merely as a formal activity, lacking comprehensive focus on promoting quality and continuous improvement (Agrizzi et al., 2016).

Another prevalent barriers were the culture of fear, blame, and punishment within healthcare institutions, discouraging full engagement in the accreditation process (Bahadori et al., 2018; Shakibaei, 2019), lack of confidence among professionals and skepticism towards accreditation results further impede successful implementation (Greenfield et al., 2011b; Hinchcliff et al., 2013b) and failure to observe tangible changes or noticeable improvements resulting from accreditation, limiting perceived opportunities for learning and growth throughout and after the process (Bord et al., 2021).

STRUCTURE OF PROGRAM

This topic encompasses various factors associated with the nature of accreditation programs. One prominent issue highlighted by authors is the mandatory nature of most accreditation programs, which can create resistance within organizations. Individuals within healthcare institutions may display reluctance or pushback towards the accreditation process (Bastani et al., 2021a; Hussein et al., 2022b).

The accreditation process is often criticized as bureaucratic and difficult to implement (Yousefinezhadi et al., 2020b; Robbins et al., 2021). Some hospitals perceive it as an externally driven idealistic quality program, lacking internal initiative. Hospital institutions may feel compelled to meet criteria that may not be necessary for their specific context (Agrizzi et al., 2016). The discontinuity of the accreditation process, with visits occurring every two years, hinders sustained engagement and reduces worker participation (Ebrahimipour et al., 2021). Frequent changes to the accreditation manual and unclear requirements, as noted by de Grande and de Mendes (2015a) and Ebrahimipour et al. (2021), respectively, add to the complexity.

The set of standards evaluated in accreditation programs is acknowledged as another category of barriers. There are numerous measures, some of which are unclear or irrelevant to specific departments within hospital (Ghazanfari et al., 2019). Reisi et al. (2019) and Nekoei-Moghadam et al. (2018) added the challenge posed by the lack of customization of measures, as the standards are not tailored to the specific characteristics of healthcare organizations.

EVALUATION PROCESS

This category focuses on elements pertaining to visitation, evaluators, transparency, and documentation in accreditation. The evaluation process is perceived as rigid (Ghazanfari et al., 2021), with contradictory judgments within the same organization (Bastani et al., 2021b), and there is often emphasis on documentation and checklists, neglecting to consider the valuable lessons learned and challenges encountered by workers involved in the accreditation process (Sharifi et al., 2017; Vali et al., 2020; Al-Alawy et al., 2021).

Several challenges were identified regarding evaluators participating in accreditation visits. These challenges encompass limited knowledge about the area being evaluated (Bastani et al., 2021a), a lack of enthusiasm in gathering information from hospital staff, decreased attentiveness and increased fatigue during the evaluation process, and judgmental mindset (Bastani et al., 2021c; Greenfield et al., 2011a), conflicts among surveyors (Sharifi et al., 2017), and inadequate training on the core concepts (Yousefinezhadi et al., 2020b). Process transparency concern include the evaluation checklist (Agrizzi et al., 2016), unclear assessment requirements (Bastani et al., 2021a), and the data collection methods employed by evaluators (Ebrahimipour et al., 2021). Additionally, the excessive emphasis on documentation, stemming from the substantial number of documents that need to be completed, diverts attention away from patient care and from all individuals involved in the process (Greenfield et al., 2011a; Mansour et al., 2021b).

INFRAESTRUCTURE AND EQUIPMENT

The state of infrastructure and equipment in healthcare facilities presents a notable but less frequently discussed challenge to accreditation programs. Issues such as inadequate facilities, equipment scarcity, and limited access to information technology hinder program execution. Aged and poorly maintained structures, insufficient resources for installation, and limited care service resources compromise accreditation processes (De Sousa Mendes and De Sousa Mirandola, 2015; Reisi et al., 2019; Yousefinezhadi et al., 2020b). Mansour et al. (2021b) also emphasized inadequate facility maintenance as a critical challenge. Moreover, limited technological advancement, including unreliable information systems failing to meet professionals' needs, and interoperability issues exacerbate challenges (Ebrahimipour et al., 2021; Mansour et al., 2021b). These factors lead to difficulties in efficiently performing work and pressure to overcome technological obstacles quickly.

EXTERNAL FACTORS

External factors influencing accreditation include patients' lack of understanding and discomfort with new procedures (Ebrahimipour et al., 2021; Katoue et al., 2021). High patient demand strains healthcare teams, hindering their ability to prioritize accreditation tasks (Reisi et al., 2019).

Finally, environmental factors such as instability, political climates, and government pressure can impede program success (Greenfield et al., 2021; Al Mansour et al., 2022a; Mansour et al., 2021b). Furthermore, the covid-19 pandemic diverted efforts toward addressing the healthcare crisis, significantly impacting the effective implementation of accreditation programs (Hussein et al., 2022a).

CATEGORIZATION OF FACILITATORS

WORKFORCE

The workforce category stands out as the most extensively discussed set of facilitators among authors. It encompasses discussions that underscore the pivotal role of engaged and participatory individuals as facilitators during the implementation and development of accreditation programs in hospitals (Alástico and De Toledo, 2013b; Bord et al., 2021; Ehlers et al., 2017; de Grande and de Mendes, 2015a).

Teamwork and the multidisciplinary nature of teams are essential components closely associated with successful accreditation processes. The diverse expertise of team members, as emphasized by studies (Alástico and De Toledo, 2013b; Hussein et al., 2022b; Saadati et al., 2018), plays a collaborative role in driving accreditation success. Moreover, fostering a culture of collaboration among employees, as highlighted in research (Ebrahimipour et al., 2021; Katoue et al., 2021).

It is crucial to ensure individuals possess or develop skills aligning with accreditation requirements (Al Mansour et al., 2022a). Sustaining motivation, collaboration, and commitment to the accreditation challenge proposed by the healthcare institution are vital (Algunmeeyn et al., 2020a). Establishing a recognition program in advance to acknowledge and reward the efforts of those involved is recommended.

Past experiences in accreditation or quality programs are also pivotal, as individuals bring valuable insights and knowledge gained from previous situations (Alástico and De Toledo, 2013b; Hinchcliff et al., 2013b). Accumulated experience makes navigating the accreditation process less challenging and more effective. Therefore, hiring professionals with prior experience in implementing quality programs and accreditation in healthcare institutions is advisable. These individuals act as knowledge multipliers, supporting colleagues unfamiliar with accreditation's benefits and challenges.

OPERATIONAL FACTORS

Resource management is consistently emphasized throughout the accreditation process. Firstly, clear definition and mapping of organizational processes are vital to ensure all stakeholders have a comprehensive understanding of operational procedures, promoting efficient resource allocation and utilization (Shakibaei, 2019). Secondly, reviewing job function scopes and creating new positions are imperative to meet evolving accreditation demands, ensuring the organization possesses the necessary resources and expertise to support the process (de Grande and de Mendes, 2015a; Mirandola and Mendes, 2014). Additionally, awareness campaigns are crucial in elucidating the importance and benefits of accreditation, fostering a culture of engagement and commitment that enhances resource management (Alástico and De Toledo, 2013b; Hussein et al., 2022b).

The standardization of procedures and utilization of appropriate tools contribute to efficient resource management by streamlining processes and reducing duplication of efforts (Saadati et al., 2018). Vali et al. (2020) suggested that different sectors within the organization should collaborate to achieve better results. In addition, Alástico and De Toledo (2013b) emphasized the importance of clearly defining performance indicators and basing continuous improvement initiatives on the results obtained from these indicators.

The management of requirements is a crucial aspect of quality management for organizations, particularly when considering the requirements necessary to achieve the objectives of hospital accreditations. It reinforces the importance of individuals having a mutual understanding of these standards, not only to comprehend them but also to ensure transparency in the evaluation process (Reisi et al., 2019; Hussein et al., 2022b, 2022a).

The authors stressed the crucial role of participative and committed leadership in facilitating the accreditation process for healthcare organizations (Katoue et al., 2021; Al Mansour et al., 2022a). Effective leaders actively engage, demonstrate dedication, support the team, facilitate improvement, and encourage individuals involved in the accreditation program (de Grande and de Mendes, 2015a; Shakibaei, 2019). Strong leadership necessitates the possession of relevant qualifications and expertise (Algunmeeyn and Mrayyan, 2022). Thus, investing in the development of capable leaders is essential for hospitals embarking on their accreditation journey.

Regular and effective communication among departments and stakeholders is crucial for successful accreditation programs. Clear channels ensure seamless information flow throughout the process (Alástico and De Toledo, 2013b; Al Mansour et al., 2022a; Mirandola and Mendes, 2014). Additionally, periodic meetings monitor actions, track progress, and address challenges (Alástico and De Toledo, 2013b; Mirandola and Mendes, 2014). Lastly, Ghazanfari et al. (2021) introduced benchmarking as a practice for hospitals to identify superior practices and solutions from other healthcare institutions.

ORGANIZATIONAL FACTORS

This category includes a clear organizational structure, encompassing well-defined division of labor and roles (Hussein et al., 2022b; Al Mansour et al., 2022a) and ensuring that there is a clear chain of command and coordination (Bahadori et al., 2018).

Establishing committees such as quality and safety committees proves beneficial, as they promote quality management and safe practices (Alástico and De Toledo, 2013b). Moreover, having a dedicated quality department with stable management and qualified professionals is crucial for accreditation programs. This dedicated team ensures ongoing monitoring, evaluation, and improvement of processes and practices (de Grande and de Mendes, 2015a; Al Mansour et al., 2022a).

In addition to the aforementioned factors, healthcare organizations must comprehend the benefits of accreditation programs, serving as a driving force to persevere in the accreditation process and actively pursue desired outcomes (Mirandola and Mendes, 2014; Hussein et al., 2022b). Furthermore, having a clear strategic plan that aligns with other organizational programs is essential for ensuring cohesive efforts and maximizing effectiveness (Hussein et al., 2022b, 2022a).

Ultimately, an organizational culture stands as a critical determinant of accreditation program success. Fostering a culture that values and prioritizes these programs is essential (Algunmeeyn et al., 2020b; Al Mansour et al., 2022b). Additionally, cultivating a participatory approach that encourages individuals to contribute ideas and opinions freely, without fear of judgment, is crucial. This approach not only empowers individuals but also enhances engagement throughout the accreditation journey (Ehlers et al., 2017).

STRUCTURE OF PROGRAM

The characteristics of accreditation programs can indeed yield positive effects throughout the accreditation process. One such characteristic is the voluntary nature of accreditation, serving as an incentive for institutions to establish hospital accreditation programs. With accreditation being voluntary, healthcare organizations have the autonomy to decide whether to undergo the process. This autonomy can motivate institutions to actively participate in accreditation programs, acknowledging the potential benefits associated with accreditation (Sharifi et al., 2017).

Another characteristic is the systematic approach that allows organizations to progress and improve gradually. Accreditation programs often have multiple levels or stages, and organizations can advance through these levels by meeting specific criteria and demonstrating continuous improvement (Robbins et al., 2021; Sax and Marx, 2014).

Hinchcliff et al. (2013b) emphasized the importance of flexibility in accreditation programs, particularly in terms of language and format, to ensure they align with the culture of the organization and are more accessible and understandable for health institutions. By adopting a flexible approach, accreditation programs can be tailored to accommodate the unique characteristics, needs, and cultural aspects of different healthcare organizations.

EVALUATION PROCESS

The evaluation process, a significant topic discussed, covers factors related to evaluators that conduct the visitation, methodology used during the evaluation, transparency of evaluation process, and evidence-based approaches. Concerning evaluators, it is advisable to prioritize continuous training efforts aimed at enhancing their skills and knowledge. This ensures they remain updated on current accreditation standards, methodologies, and best practices (Bord et al., 2021; Ghazanfari et al., 2019).

Greenfield et al. (2011a) stated the need for evaluators to acting collaboratively and avoid imposing a confrontational stance during accreditation. This approach fosters a friendly and constructive environment between the hospital and the evaluator agency. By promoting collaboration, open communication, and respect, both parties can effectively work together towards achieving accreditation. Additionally, it is suggested that a team of multidisciplinary recruiters, with previous experience in accreditation, should be considered for the evaluation process. This ensures evaluators have a diverse range of expertise and knowledge to comprehensively assess the institution's compliance with accreditation standards (Greenfield et al., 2011a, 2015).

This author also highlighted the importance of enhanced interaction between the organization seeking accreditation and the evaluator agency. This fosters greater engagement, collaboration, and effectiveness during the assessment process. By promoting open lines of communication, active participation, and a sense of partnership, institution and evaluator agency can work together more effectively during the assessment process (Greenfield et al., 2011a).

Transparency in the evaluation process is understood as an area for improvement. (Robbins et al., 2021) suggested the use of scientific and objective methods to score the evaluation, while Hinchcliff et al. translating accreditation criteria for professionals to achieve greater uniformity in understanding the requirements evaluated by all parties and ensure consistency in evaluations. Ghazanfari et al. (2021) also discussed the necessity for a shared understanding of the assessed standards among all parties. To address this, they proposed implementing a continuous education program and actively involving evaluators in translating requirements to hospitals during their journey for accreditation.

Lastly, as mentioned by Shakibaei (2019), it is crucial to promote evidence-based performance during the accreditation process. This means that the presentation of fulfillment of the requirements should be supported by factual evidence and data, rather than relying solely on the assessors' personal interpretations. By adopting an evidence-based approach, organizations can ensure objectivity and transparency in demonstrating their compliance with accreditation standards.

FACITILIES AND EQUIPMENTS

Hussein et al. (2022b, 2022a) stressed the importance of maintaining infrastructure for accreditation. Similarly, de Grande and de Mendes (2015b) supported this notion, indicating that new facilities played a role in facilitating the implementation of accreditation programs.

Implementation of electronic information systems aids accreditation; these systems enable the recording, storage, and easy retrieval of documentation and reports (de Grande and de Mendes, 2015a; Katoue et al., 2021). Crucially, chosen systems must align with existing infrastructure to avoid disruptions; it means that compatibility and integration with the organization's current systems are essential to avoid any disruptions or compatibility issues.

EXTERNAL FACTORS

External factors in hospital organizations, divided into external and patient factors, are vital for accreditation success. Authors concurred that a national strategy is crucial to encourage continuous improvement within healthcare organizations (Hussein et al., 2022b); some authors suggested the Ministry of Health should support accreditation initiatives (Robbins et al., 2021).

Authors underscored the significance of collaboration between the organization and external stakeholders. Sharifi et al. (2017) emphasized the increased public involvement in regions with accreditation processes, while Ghazanfari et al. (2021) mentioned a scientific committee's role in setting standards. Furthermore, Mansour et al. (2021b) highlighted the value the value of consultancy support; and Bord et al. (2021) advocated the need for collaboration among Ministry of Health, the Medical Association and the JCI to achieve a mutually beneficial outcome in accreditation processes.

The involvement of healthcare users is crucial for hospital accreditation. Algunmeeyn and Mrayyan (2022) noted that users play a significant role in enhancing service quality and, subsequently, assisting organizations in achieving accreditation success. They recommended regularly distributing surveys to users, enabling them to evaluate healthcare services and provide suggestions for improvements. By doing so, users can actively contribute to enhancing service quality and helping organizations meet accreditation standards. Furthermore, Greenfield et al. (2021a) urged organizations to promote public understanding of accreditation for desired outcomes.

CONCLUSIONS

Understanding the barriers and facilitators of accreditation is crucial for hospitals striving for improved outcomes. This study analyzed 33 articles focusing on hospital accreditation processes. Most barriers identified were linked to facilitators, suggesting addressing facilitators could overcome challenges. People were highlighted as crucial in accreditation success, emphasizing the importance of individuals in the process. However, limitations include potential missed articles due to search logic and exclusion of other medical-assistance services. Future research could explore how these factors change over time and whether institutional nature affects them.

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Exploring Project Management in Brazilian Healthcare Amid Global Health Crisis

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STRUCTURED ABSTRACT

Purpose - The global health crisis has brought about a spectrum of effects on project management practices within diverse institutions. This article aims to delve into the ramifications on project management within healthcare organizations, particularly focusing on the challenges and opportunities encountered by project professionals amidst the outbreak in Brazilian healthcare institutions, encompassing hospitals, health operators, and consultancies.

Design/methodology/approach - The study employed a qualitative approach, gathering data through semi-structured interviews with fourteen project professionals. Analysis of the collected data was carried out using NVivo software.

Findings - The global crisis has reshaped project management, yielding positive and negative outcomes. Human resources management emerged as one of the hardest-hit areas, grappling with unprecedented challenges in workforce organization and adaptation. Conversely, communication management experienced a notable positive shift, fueled by the widespread embrace of remote work practices. This transition underscored the resilience and adaptability of project teams, highlighting the value of agile methodologies in navigating uncertain and dynamic environments.

Practical implications - Healthcare organizations recognize the importance of fortifying their human resources management and communication capabilities, particularly in the wake of unexpected challenges. This entails crafting adaptable policies and procedures, conducting training programs to refine communication skills, and embracing technologies that streamline remote work and foster collaboration among teams.

Originality/value - This research aims to advance discussions on healthcare project management, particularly within the context of a developing nation such as Brazil.

Keywords: Global health crisis, Project Management, Healthcare, Brazil.

Paper type: Research paper

INTRODUCTION

The Covid-19 pandemic has prompted reevaluation of project development approaches, revealed deficiencies while fostered innovation opportunities (Cheshmehzangi, 2021; Piyathanavong *et al.*, 2024). Hygiene rules and remote work adoption have accelerated digital tool usage, transforming sectors like education, events, services, and civil construction (Bonifati *et al.*, 2020; Buschuyev *et al.*, 2021; Li *et al.*, 2023; Thalmeiner *et al.*, 2021). Organizations adapt to these changes, recognizing crises as catalysts for innovation and highlighting the necessity of adaptation (Keenoy *et al.*, 2021).

Organizations' response to the pandemic, pivotal for long-term development (Wang *et al.*, 2021), notably included swift adoption of remote work amid restrictions. This led to heightened use of remote collaboration tools, crucial for monitoring projects, overcoming social distancing challenges, supervising workspaces remotely, and facilitating project progression (Kokot, 2023; Kordova and Hirschprung, 2023).

The healthcare sector underwent profound changes during the pandemic, embracing innovative work solutions, new collaborations, and advancements in infrastructure management (Bednarz *et al.*, 2021). Despite the pandemic's adverse effects, including financial strain and social disruption, it also catalyzed opportunities for growth and learning valuable lessons amid adversity.

Therefore, this study aims to explore the correlation between the Covid-19 pandemic and its influence on project management within healthcare institutions in Brazil, addressing a research gap identified by Bednarz et al. (2021). They stress the necessity for inquiries into how the pandemic has impacted project management practices within healthcare organizations. The research objective is twofold: to evaluate the adverse effects of the pandemic on hospital projects and to extract lessons learned, guiding decision-making and offering insights for future planning. Through this investigation, the study seeks to enrich project management literature in the healthcare sector, particularly within hospitals. Data was gathered via semi-structured interviews with project professionals in healthcare institutions.

The primary research questions that this study seeks to address are as follows:

- What are the positive and negative impacts of the Covid-19 pandemic on project management in health institutions?
- What are the key skill adaptations necessitated by the pandemic in project management within health institutions?

By exploring these questions, the study aims to provide insights into the effects of the pandemic on project management in healthcare organizations and shed light on the necessary skill adaptations in this context.

The article is structured into five sections. The first section contextualizes the problem under investigation: project management in healthcare institutions during the Covid-19 pandemic. The second section outlines the methodology, detailing the sample survey and data collection methods. In the third section, the main results are presented. Following this, the fourth section engages in discussions, comparing findings with existing literature. Finally, the fifth section provides general considerations, acknowledges limitations, and proposes avenues for future research.

METHODOLOGY

This study adopts a qualitative research approach, utilizing semi-structured interviews with professionals engaged in project management within healthcare organizations in Brazil. The semi-structured interviews were designed to include open-ended questions, supplemented by "how" and "why" queries, aiming to gain comprehensive insights and understand different perspectives on the discussed topic. This approach allowed for flexibility and encouraged participants to provide detailed information.

Fourteen project experts who were involved in managing projects within healthcare institutions (such as hospitals, health operators, and service providers) during the pandemic were selected for interviews. The data obtained from the interviews were transcribed manually, and content analysis using NVIVO software was employed for data analysis. The following key issues were discussed with the participants, drawing on the research protocol used in the study by Bednarz et al., (2021) as a reference for developing the research questions:

1) Description of the projects the participants were involved in and the project management methodology.
2) Project knowledge area most impacted by the Covid-19 pandemic.
3) The opportunities that the Covid-19 pandemic has provided for the projects.
4) Technical and behavioral skills required to project professionals.

Participants were sourced from LinkedIn, focusing on professionals in Brazil's healthcare sector. Selection criteria targeted roles like "project manager", "project coordinator", "project specialists" or "project analysts" in hospitals. Seventy-four individuals were contacted, but fifty-two declined or did not respond. Eight were ineligible, as they did not work in project management or were not involved in projects during the pandemic period. Ultimately, fourteen accepted the invitation to participate in the research.

The interviews were arranged individually and conducted using video conferencing platforms like Google Meet or Microsoft Teams in January 2022. Participants were guaranteed the confidentiality of shared information, and their consent to record the interviews was secured. On average, interviews lasted between 25 to 40 minutes. Table 1 provides an overview of the respondents' profiles.

Table 1 – Characteristics of respondents.

ID	Occupation	Type of Organization	Organization size	Project Type
1	Project Coordinator	Private Hospital	Large	Technology
2	Functional Project Coordinator	Technology company	Small	Technology
3	Project Manager	Private Hospital	Large	General
4	Project Manager	Technology company	Small	Technology
5	Project Coordinator	Private Hospital	Large	Technology
6	Project Specialist	Private Hospital	Large	General
7	Project Manager	Private Hospital	Large	General
8	Project Director	Public hospital	Large	Infrastructure
9	Project Consultant	Health Operator	Large	General
10	Project Consultant	Health Operator	Large	General
11	Project Specialist	Private Hospital	Large	General
12	Project Coordinator	Public hospital	Medium	Infrastructure
13	Project Analyst	Private Hospital	Large	New business
14	Project Consultant	Consultancy	Small	General

RESULTS

This section provides an in-depth exploration of the key negative and positive aspects of the Covid-19 outbreak that project professionals had to confront. It also highlights the essential skills required to navigate and adapt to this crisis context.

ASSESSING THE NEGATIVE IMPACTS

The respondents unanimously expressed that the Covid-19 pandemic posed numerous challenges to the projects they were involved in. As an unforeseen event, the healthcare institutions they worked with were not adequately prepared in advance to manage their projects in this crisis context. One participant emphasized: "*the pandemic period was an extremely delicate and complex time in terms of project management*", emphasizing that the primary focus of institutions during the initial stages of the pandemic was on saving lives rather than managing ongoing projects. Building on this, the following discussion will outline the key negative aspects highlighted by the respondents regarding the Covid-19 pandemic in relation to various areas of project management knowledge.

One of the field most profoundly impacted by the pandemic was project portfolio management, as numerous projects had to be interrupted to accommodate the demands of the current context. Respondents indicated that the scarcity of personnel, movement restrictions imposed by Covid-19, and decisions made by institutional boards were the primary reasons why certain projects could not progress. Conversely, other projects were prioritized to address the needs of the new normal and took advantage of regulatory flexibility, such as the implementation of telemedicine. A participant shared their experience, stating: "*initially, we had telemedicine as a research project, and there were already ongoing projects at the national level. Due to the pandemic, we shifted our focus to a teleconsultation project between doctors. In 2020, we were granted permission by the technical ordinance of the Public Health Emergency of National Importance (ESPIN) to provide consultation services to patients, so we started conducting doctor-patient consultations via telemedicine. It became a new project, a project for a new product...providing care via telemedicine to those patients in greatest need*". This example illustrates how the criteria for prioritizing projects within the organization shifted because of the Covid-19 scenario.

The procurement area emerged as another focal point among the participants' discussions. The challenge lies in negotiating contract clauses with suppliers in a manner that would minimize losses to the projects. One participant highlighted the significance of these negotiations, stating, "*at the beginning of the pandemic, our team negotiated extensively for shorter delivery times, better pricing, and solutions that would meet our immediate needs. As time went on, we took the opposite approach and renegotiated these contracts. It was a substantial project with significant returns. Without going into specifics, it involved numerous contracts and companies, and the outcomes were highly positive*".

Furthermore, another participant underscored the importance of exclusive contracts with certain medical suppliers. These contracts provided assurance regarding the availability of medications or medical supplies, offering preferential treatment over other buyers. However, as the Covid-19 situation became more manageable and resources became more readily available in the market, the feasibility of these exclusive contracts started to be questioned by healthcare institutions. One interviewee mentioned the dilemma faced, stating, "*I have an exclusive contract, and breaking it* *would result in financial loss due to penalties. There is an opportunity cost to consider: what is more advantageous for me? Breaking the contract would incur a fine and financial loss, but it would enable procurement at a cheaper market rate. Alternatively, I could maintain the contract, avoid the penalty, but pay more than the market value*".

Interestingly, the participants did not specifically highlight cost management as a significant area impacted by the pandemic. However, it is important to note that cost management is inherently intertwined with the various challenges and disruptions caused by the pandemic, such as increased expenses for safety measures and adjustments to project plans. While not explicitly mentioned, cost management likely played a role in the decision-making processes and resource allocation during the crisis.

In terms of human resource management, the lack of qualified resources was indeed a notable challenge for projects in healthcare institutions, particularly those involving the implementation of technology. One project coordinator emphasized this issue, stating, "*we faced a constant struggle to secure qualified resources to advance the project*". This highlights the competition for skilled professionals and the difficulties in ensuring the availability of the right expertise to support project activities, especially in the context of technology-driven initiatives.

Despite the availability of online communication tools during the pandemic, respondents emphasized that communication and project team integration posed challenges for project managers. The difficulty arose from the lack of mutual understanding between different parties involved in the project, particularly when technical aspects were involved. For instance, one manager shared their experience, stating, "*I brought together members from the medical team and the IT staff, but they struggled to communicate effectively. The medical team had a more nuanced and complex approach, while the IT team tended to be more binary in their thinking. There was a disconnect in understanding, with each group expressing different perspectives and priorities. On one hand, the IT team focused on processes and the direction of the project, while the medical team approached it from a more abstract standpoint*".

This lack of alignment in expectations within the project team resulted in fragmented execution, with everyone focusing on their assigned tasks without fully comprehending the impact of their work on others. Consequently, the manager concluded that effective communication was crucial to ensure everyone's engagement and understanding of the project's goals and objectives. By fostering clear and open communication, project members could better grasp the context, purpose, and interdependencies of their work, promoting better collaboration and alignment.

The Covid-19 pandemic significantly impacted the well-being and quality of life of individuals working on projects, leading to a direct negative effect on their productivity. The respondents extensively discussed these aspects, highlighting various challenges faced by project teams. For instance, individuals falling ill with Covid-19 needed to take time off from work, resulting in smaller or even canceled team meetings. One respondent shared a specific example, stating, "*We would arrive at meetings, and there would be hardly anyone there. They wanted to help, but there simply weren't enough people available. At Hospital X, the director, who was over 60 and in the high-risk group, was intubating a patient. In such situations, it became nearly impossible to make progress on certain projects*".

Furthermore, respondents addressed the issue of team overload, with individuals assuming additional responsibilities to prevent delays in critical tasks. One participant mentioned, "*Often, you find yourself playing the role of someone you would have liked to hire, just to avoid further delays in specific situations*".

The lack of motivation within the teams was another significant concern highlighted by participants. They emphasized the importance of an "emotional salary" which encompassed a healthy work environment, effective communication with leadership and peers, and recognition for their work. The absence of these elements compromised team engagement and motivation throughout the project lifecycle within the health sector.

Additionally, participants noted that the institutions they worked for provided psychological support to both care and non-care professionals to ensure their well-being and enable them to perform their activities effectively. It is worth mentioning that while most respondents highlighted the negative impact of the pandemic on productivity and well-being, one participant noted a strong sense of engagement within the health sector, leading to increased productivity.

Scope management is indeed a crucial knowledge area in project management, and one of the respondents emphasized that it posed significant challenges for their institution, particularly due to the evolving nature of the pandemic and the limited understanding of the disease's context. The respondent highlighted that "*scope management was severely affected because the scope was initially well-defined, but with the changes brought about by the pandemic, it had to be continuously modified.*

The lack of knowledge about the disease meant that what was within the scope one day could be completely changed within a week".

On the other hand, respondents working on technology projects mentioned that they had to accommodate additional requirements within the project scope, but this did not pose major problems. However, one participant, a project analyst, raised a specific situation they encountered during the pandemic. In the context of network infrastructure, they faced challenges related to equipment and connectivity. For instance, they mentioned a scenario where additional computer workstations were needed but lacked available network ports. The participant expressed the need for physical on-site assessments to determine the appropriate solution, which was hindered by the remote work situation. They resorted to requesting pictures and specifications remotely to gather the necessary information.

Remote work emerged as a key strategy for project continuity within healthcare organizations during the pandemic. Video conference calls and online management tools were utilized to facilitate meetings and project monitoring and control. While this new way of working provided certain advantages, managers also acknowledged the challenges it presented.

One notable challenge was the slower flow of information, leading to longer decision-making processes. Communication became more complex, as one participant explained, "*the biggest barrier compared to face-to-face interactions was the difficulty of contacting people. Previously, if I had a question or needed to speak with someone, I could simply pick up the phone or walk over to their desk. Now, I had to message them in a chat, ask if they were available, wait for their response, and then schedule a conversation for a later time*".

Security concerns related to remote work were also highlighted, particularly for projects that required strict confidentiality due to the sensitivity of medical data. In such cases, on-site meetings were deemed more suitable for ensuring data privacy and security.

ASSESSING THE POSITIVE IMPACTS

The pandemic brought about a positive aspect for health institutions, which was a greater awareness and improved use of resources. People within organizations became more conscious of the limitations and scarcity of essential materials such as personal protective items (e.g., masks, goggles, gloves, aprons), medications, and equipment. This shift in mindset was seen as an evolution and a response to the crisis. As one participant stated, "*I believe we have evolved a lot due to this necessity, this crisis that compelled us to utilize resources more effectively. Sometimes it's not about spending less, but* *rather about achieving more with less and spending responsibly. This has been an ongoing evolution that the pandemic has accelerated*".

Another participant shared an initiative implemented in one of their projects to promote conscious consumption of supplies. They explained, "*We raised awareness about consumption by distributing masks not in full boxes, but in smaller packets, so that our internal clients would realize the scarcity and value of each mask. It aimed to make them mindful that masks were not easily replaceable*".

The Covid-19 outbreak also had a positive impact on healthcare institutions by strengthening their internal supply chain. Organizations implemented strategies to reduce their reliance on external suppliers, thus protecting themselves from potential shortages of medical materials. This required various departments within the hospital to work collaboratively to achieve desired outcomes and meet institutional needs. For example, one participant highlighted a project to internal production of masks and aprons as a response to the scarcity of surgical masks. They described the strategy, stating, "*At the beginning of the pandemic, surgical masks were not available at all. So, we devised a strategy... We followed the guidelines set by Anvisa (National Health Surveillance Agency) and decided to manufacture our own masks. We procured the raw materials, hired a company to manufacture the masks, aprons, and other necessary items*".

Remote work was a recurring topic discussed by the participants, and they highlighted it as a new way of working that emerged during the pandemic. They emphasized the benefits and opportunities it presented. One project analyst mentioned that virtual meetings allowed for efficient schedule and cost control. Except for one manager, all participants had experience conducting projects remotely during the pandemic. They regarded this approach as an opportunity to increase productivity in project execution while also reducing administrative costs for the institution, such as travel expenses and visits to customers and suppliers.

Moreover, another manager stated that "*remote work enabled professionals to engage in consulting activities online, utilizing platforms like Zoom. This included tasks such as establishing crisis management offices and working on continuous process improvement*".

According to the respondents, remote work enabled individuals to be more focused, organized, and productive. They were able to handle more responsibilities without the need for physical presence, leading to increased efficiency. Additionally, remote work fostered greater integration and collaboration among different departments. One participant shared their experience of working on a project to expand medical centers. Prior to the pandemic, they could only manage five projects simultaneously due to the requirement of physical presence at hospitals. However, during the pandemic, with the shift to remote work, they were able to handle fifteen projects in parallel. This significant increase in productivity was attributed to the ability to conduct meetings involving multiple departments, such as IT, Clinical Engineering, Property Security, sustainability, operation, maintenance, and hospitality. The remote work setup facilitated effective communication and collaboration across these various areas, enabling smoother project coordination and progress.

All the interviewees unanimously shared the view that the Covid-19 pandemic has had a positive impact on project management in health institutions by promoting a shift towards a more agile approach. They observed that the management process became more iterative, allowing for faster and more adaptive responses to the constant changes in the pandemic scenarios. However, it was noted that none of the projects managed by the professionals interviewed followed a completely agile approach.

Instead, the pandemic accelerated a movement towards incorporating agile tools and practices within the traditional project management approach. Tools such as daily stand-up meetings, Kanban boards, and the formation of cross-functional teams (referred to as "squads") were adopted to enhance collaboration, increase flexibility, and improve the project's responsiveness to changing circumstances.

Respondents emphasized the significant role of project management in supporting health institutions during the pandemic, enabling them to navigate through the challenges and uncertainties that arose. This underscores the strategic importance of project management for organizations during times of crisis, enabling them to differentiate themselves from competitors and achieve more efficient outcomes. One participant stated: "*Today, it is fortunate to witness institutions that recognize the direct relationship between projects and strategies. Companies and individuals alike are realizing the significant value that project managers bring to the table. The establishment of Project Management Offices (PMOs) is becoming more prevalent, indicating a growing trend. The alignment of strategic needs with project management practices is experiencing exponential growth*".

ESSENTIAL SKILLS FOR PROFESSIONALS ENGAGED IN HEALTHCARE PROJECT MANAGEMENT

Another point discussed with the participants was whether there has been a demand for specific competence for those people who are assuming positions in projects in health institutions.

The participants emphasized the importance of soft skills when assuming positions in projects within health institutions. They noted that technical skills could be developed through the course of project activities. However, given the chaotic and psychologically challenging nature of the pandemic, the ability to empathize became particularly valuable. One manager mentioned that they adopted a more empathetic approach, prioritizing people's well-being and creating a calmer environment, and he/she stated "*I have changed my approach in selecting team members. Now, I prioritize individuals who demonstrate empathy and possess a calm demeanor. It was unintentional, but it seems that we naturally started prioritizing these qualities. If technical training is lacking, we are committed to providing the necessary training and support. In some cases, we have hired individuals from the market who may not be fully ready yet. We understand that we need to take this approach to attract individuals who may require additional development, as otherwise, they may leave the organization quickly. It is essential for individuals to be dedicated to continuous learning and studying. We are looking for individuals who are committed to personal growth too*".

Several participants emphasized the importance of having comprehensive project management skills, including proficiency in project management tools, planning, control, and project execution. They believed that these skills were essential for professionals seeking positions in projects within health institutions. One participant mentioned the growing demand for project management expertise and the need for individuals who can effectively manage projects, employ methodologies, generate indicators, and navigate challenges successfully, as she/he said: "*I think everyone will have to have this skill a little bit, you know? To manage projects. [...] Everyone is talking a little more about this today; you see that people are looking for more people to manage projects, who have a methodology, who can generate indicators, who effectively manage to... yeah... not get hit, right?*".

However, only two participants specifically highlighted the importance of certification and technical qualifications in processes and projects. They acknowledged that in the midst of daily demands and pressures, it can be challenging to apply techniques effectively without proper training and certification. They added that during hectic periods, the focus on technique can sometimes be overshadowed, making it even more crucial to have the necessary qualifications.

Furthermore, participants emphasized the significance of having a holistic perspective on projects and processes, as well as impartiality, to achieve better results. This means having a comprehensive understanding of the overall objectives and intricacies of projects and processes and making impartial decisions to drive success. These qualities were seen as critical for professionals in project management roles within healthcare institutions.

In addition to the skills mentioned earlier, project managers in the pandemic period valued flexibility as a crucial attribute. They emphasized the importance of individuals who can adapt to the constant changes in the project's environment. One participant stated that "*workers should be receptive to new demands, initiatives, and interests that may arise unexpectedly. And the ability to work effectively in an adaptive manner, beyond the planned scope, was seen as essential*".

Leadership and teamwork skills were also highly valued. Project managers recognized the significance of strong leadership to guide the team through uncertain times and keep them motivated. They emphasized the need for clear and objective communication to ensure everyone involved in the project is well-informed and aligned with the project's objectives and progress. Additionally, the ability to work and manage conflicts with remote teams was highlighted.

DISCUSSION

This study examined the primary effects of the Covid-19 pandemic on project management in healthcare institutions in Brazil. It involved the perspectives of fourteen project professionals who provided insights into the positive and negative aspects of managing their projects during the initial waves of the disease. The findings of this research are aligned with the results discussed by Bednarz et al. (2021) in their evaluation of project management in healthcare institutions in Poland. Similar to their findings, this study highlights the significance of remote work as a lasting form of work, not just a temporary solution.

The ability to adapt and be flexible in the face of uncertainty and changing circumstances was identified as crucial in the exploration of healthcare project management during the pandemic in the province of Saudi Arabia by Al Moslih et al. (2021). This further supports the notion that adaptability and flexibility are important competencies for project professionals in the healthcare sector during the Covid-19 crisis. Furthermore Kadenic and Tambo (2023a, 2023b) emphasized the importance of agile project management methods in responding to and maintaining resilience in the face of change.

Additionally, the conditions of stress, fear, and overload experienced by professionals working in healthcare institutions during the pandemic, as highlighted by Shaukat et al. (2020) were also identified in this research. These challenges underscore the importance of addressing the well-being and mental health of project professionals and providing support to help them navigate the unique demands of the pandemic.

Regarding the negative impacts, several key points emerged. Firstly, portfolio management underwent substantial disruption, prompting a reassessment of project priorities to address the urgent demands of the pandemic. This entailed either advancing certain projects or discontinuing others. Secondly, contract management posed challenges as hospitals navigated renegotiations to address financial and relational implications arising from the crisis, echoing findings by Al-Mhdawi et al. (2023). Thirdly, people management emerged as a major concern, with human resources facing heightened pressures and demands during the health crisis. Abujraiban and Assaf (2022) emphasized importance of strategic planning in human resources to proactively identify necessary skills and expertise for a well-prepared workforce. Fourthly, scope management and requirements gathering were impacted by the pandemic's unpredictable nature, necessitating continual adaptations to project scopes.

Lastly, communication management had to adapt to the remote work format, posing challenges in maintaining effective communication channels and collaboration among project teams. Waheeb et al. (2023) highlighted challenges associated with new communication methods during the pandemic, suggesting that the transition to remote work might result in a loss of informal communications. They also noted potential delays in achieving consensus on project issues due to the absence of face-to-face interactions and spontaneous discussions, hindering timely problem resolution. Moreover, effective stakeholder engagement was emphasized as vital for disseminating information, establishing clear communication lines, fostering trust, and facilitating collaboration among various stakeholders involved in healthcare projects (Najib et al., 2022).

On the positive side, several notable aspects emerged from the discussions. Firstly, the scarcity of health materials in the market during the initial waves of the pandemic prompted healthcare institutions to optimize their resources efficiently. This included maximizing the use of materials and workforce to cope with supply constraints. Waheeb et al. (2023) added about the importance of creativity in problem solving as well as finding for alternative solutions. Secondly, there was a focus on developing internal suppliers as a strategic measure to reduce dependence on external suppliers. This approach aimed to mitigate uncertainties surrounding the delivery and quality of critical supplies, ensuring a more reliable and streamlined supply chain within healthcare institutions.

Thirdly, remote work was highlighted as an opportunity to enhance staff productivity. Through the utilization of technology such as virtual meetings and collaboration tools, project professionals could optimize their time, improve connectivity between different hospital areas, and facilitate communication and coordination among dispersed teams. Lastly, improvements in cost management were highlighted. The pandemic mandated a more vigilant approach to financial resources, resulting in a heightened emphasis on cost control and efficiency in project management.

In the post-pandemic scenario, project professionals are expected to possess key attributes such as empathy, effective communication, flexibility, and agility. These skills are deemed essential for navigating the complexities and uncertainties of project management in a rapidly changing environment. These competencies identified in the research align with existing literature, which underscores the importance of developing specific competencies amidst the pandemic. Strategic thinking, integral thinking, leadership, communication, and coordination have been recognized as critical skills for professionals navigating through challenging situations such as the Covid-19 pandemic (Buschuyev *et al.*, 2021; Koch and Schermuly, 2021).

CONCLUSION

This research enriches project management literature by offering insights amidst the Covid-19 pandemic's influence. Its unique aspect lies in its broad perspective, extending beyond health care to encompass project management overall. Conducted in Brazil, a developing nation with notable healthcare challenges during the pandemic, the study provides valuable insights into the pandemic's impacts on project management. By examining the impacts of the pandemic on project management in this specific context, the study offers valuable insights that can inform future research and practice in project management.

This work acknowledges certain limitations that should be considered. Firstly, the sample size of fourteen participants, limited to healthcare institutions in Brazil, restricts the generalizability of the findings. However, it is important to note that the objective of the research was not to generalize the results, but rather to gain a deeper understanding of project management in healthcare institutions during the Covid-19 pandemic.

Additionally, this research did not employ quantitative techniques to analyze the relationships among the respondents. Future research could consider incorporating quantitative methods to explore and quantify these relationships more effectively. Furthermore, focusing on a specific knowledge area of project management could enhance the depth of the study and provide more detailed insights into the subject matter. Exploring specific areas, such as risk management or stakeholder management, could yield valuable findings and practical implications for project professionals in the healthcare sector. Lastly, it is suggested that future studies replicate this research at different time periods to understand how the perception and management of projects in the context of the pandemic evolve over time. This would provide a more comprehensive understanding of the long-term effects and strategies employed in project management during crises. Overall, while this study has limitations, it serves as a foundation for further research and opens opportunities for exploring different aspects of project management in healthcare institutions during challenging times like the Covid-19 pandemic.

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Improvement of patient flow in healthcare: systematic review and bibliometric analysis

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STRUCTURED ABSTRACT

Purpose – Addressing healthcare access challenges necessitates process improvements to alleviate waiting times, boost service quality, and cut costs. This study examines trends in continuous improvement and simulation methods in patient flow processes through bibliometric analysis of existing literature.

Design/methodology/approach - The review followed the PRISMA guidelines and utilized the Scopus and Web of Science databases. The review protocol was registered in Mendeley Data under DOI 10.17632/rmf2rmyrpf.1. It included 111 publications meeting the criteria of full-length articles with search terms appearing in the title, abstract, or author-supplied keywords, along with five other content-specific reasons. Additionally, bibliometric analysis was conducted based on publication year, keyword co-occurrence, care level, improvement method, intervention applied, metric measured, and the relationship between care level, improvement method, intervention applied, and metric measured.

Findings - The focus is on time metrics that reflect improvements in processes and general routines within health units. The present sample highlights specific improvement methods adopted by the authors (such as lean and simulation) along with a specific range of interventions. There was no correlation found between intervention complexity and the number of references. However, certain time metrics were more frequently discussed than specific isolated cases. Further research opportunities, particularly in quaternary and quinary care levels, are indicated.

Research limitations/implications - The subject is represented solely by the adopted English keywords.

Originality/value - This study bridges the gap between theoretical frameworks and practical implementation, facilitating healthcare professionals' comprehension of process improvement strategies in action.

Keywords: Healthcare, Patient flow, Improvement methods, Systematic Literature Review (SLR).

Paper type: Literature review

INTRODUCTION

Patient flow encompasses the movement of patients within a healthcare facility, typically from admission to discharge (Wang, 2023). It involves internal processes and the allocation of human and physical resources, all while ensuring appropriate care for each patient. Continuous improvement, a traditional approach, and simulation, a technological approach, can both identify and address various issues and bottlenecks within patient flow across different care levels, employing diverse strategies. In each improvement strategy, alongside typical metrics like waiting time and length of stay, it's crucial to also consider non-characteristic results such as service quality and patient satisfaction to comprehensively measure outcomes beyond mere process perceptions.

One of the most pressing challenges in healthcare today is the difficulty in accessing health services, primarily due to the burgeoning waiting lists, exacerbated by a low attendance rate and a lack of strategic planning (Sarmento Junior, Tomita and Kos, 2005; Santos *et al.*, 2019). Waiting lists or queues form when demand for specific treatments or services exceeds the facility's capacity, acting as bottlenecks hindering the patient flow process. In some countries such as Brazil, for example, public healthcare stands as complex systems, ranging from simple procedures like vaccinations to complex ones like organ transplantation (Ministério da Saúde, 2022). Thus, process improvement is indispensable not only to reduce waiting times within this intricate system but also to enhance service quality and reduce costs (Health Catalyst Editors, 2021), ultimately ensuring universal access to healthcare.

Healthcare for civilian patients is structured into four levels, contingent upon medical complexity and technological density (Torrey, 2022; Indeed Editorial Team, 2023; Secretaria de Estado de Saúde de Minas Gerais, 2023; NHS Providers, 2024):

1. Primary care: the initial point of contact for non-emergency situations, staffed by professionals like geriatricians, pediatricians, obstetricians, gynecologists, internal medicine physicians, nurses, and dentists.
2. Secondary care: offers specialized services of intermediate complexity referred from primary care, including specialties such as allergists, ophthalmologists, gastroenterologists, orthopedic surgeons, radiologists, diagnostic support, and urgent care.
3. Tertiary care: provides highly specialized and technologically advanced therapies and procedures, covering specialties like oncology, cardiology, transplants, neurosurgery, and intensive care units.

4. Quaternary care: an extension of tertiary care, offering even more specialized and rare treatments, including experimental procedures.

In contrast, military patients receive care across five levels (Nuhut and Sabuncuoglu, 2002)(Nuhut and Sabuncuoglu, 2002):

1. Primary or unit level: initial casualty care at platoon, company, and battalion medical aid stations.
2. Secondary or brigade level: hospitalization for emergency and surgical cases at brigade stations and surgical hospitals.
3. Tertiary or corps level: surgical and general treatment at corps stationary hospitals.
4. Quaternary or army level: surgical and general treatment at army hospitals and civilian facilities.
5. Quintenary or rehabilitation center: provides definitive treatment for patients.

Despite numerous studies addressing patient flow challenges and strategies (Manning and Islam, 2023) and hospital flow actions (Gualandi, Masella and Tartaglini, 2019), a comprehensive overview of optimizing patient flow in healthcare remains lacking. This study aims to fill this gap by analyzing research trends in continuous improvement and simulation methods related to patient flow processes through bibliometric analysis of a systematic literature review. The review, following PRISMA guidelines and conducted across Scopus and Web of Science databases, aims to identify gaps in the literature and provide a thorough review of publications focused on improving patient flow in healthcare, particularly through continuous improvement and simulation methodologies.

The paper's structure is as follows: Section 2 outlines the methodology, Section 3 presents the results with discussions on selected metrics and indicators, Section 4 analyzes the obtained results and research trends, and finally, Section 5 offers conclusions along with limitations and implications for future research.

RESEARCH METODOLOGHY

The present study utilized a systematic literature review to synthesize research trends related to process improvements in healthcare. The review was independently conducted by the first and last authors, with conflicts resolved by the second author. Result data were kept open and detailed to mitigate bias and enhance the evidence's certainty. Data collection adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Page, McKenzie, *et al.*, 2021; Page, Moher, *et al.*, 2021) for reproducibility. The search was performed on November 27th, 2023, across Scopus and Web of Science databases (Pranckutė, 2021), using the query strings outlined in Table 1. To avoid bias from missing results, no filters or additional keywords were applied. The number of returned references is also detailed in Table 1.

Table 1 – Query strings applied in Scopus and Web of Science databases.

Scopus
TITLE-ABS-KEY (("healthcare" OR "health care") AND ("patient flow") AND ("process*") AND ("improv*" OR "optimiz*") AND ("simulation*" OR "lean*")) Return: 274 items.
Web of Science
TS=(("healthcare" OR "health care") AND ("patient flow") AND ("process*") AND ("improv*" OR "optimiz*") AND ("simulation*" OR "lean*")) Return: 162 items.

From the amount of 436 references, as presented in Table 1, initially 118 duplicate records were removed from the sample, resulting in 318 records for screening. For these 318 records, two criteria were established for publications to be maintained in the review, ensuring quality and consistency across databases, leading to the elimination of 22 records and retaining 296 for screening:

- Only full-length papers were accepted, excluding notes, letters, comments, short surveys, meeting abstracts, and book reviews.
- Search terms from Table 1 had to appear in the title, abstract, and author-supplied keywords, excluding publications solely related to indexed keywords (e.g., Index Keywords in Scopus and Keywords Plus in the Web of Science database).

Subsequently, the remaining references were fully reviewed, if the title and abstract lacked sufficient information, elimination was based on the following criteria:

- Reason 1: Lack of reporting process improvements with the necessary phases to analyze the current process and implement interventions.
- Reason 2: Absence of a description of the care level.
- Reason 3: Failure to report results before and after the improvement.
- Reason 4: Lack of reporting the improvement interventions.

- Reason 5: Inaccessibility of the full publication, if required.

Criteria related to population, methods, design, and context were considered results in this step.

This analysis resulted in the elimination of 127 records due to reason 1, 17 records due to reason 2, 26 records due to reason 3, 10 records due to reason 4, and 5 records due to reason 5. Following this step, 111 references were retained for full reading and bibliometric analysis in this study to identify research trends and the current scientific development in the field. Table 2 outlines the selected metrics and indicators for discussion, and Figure 1 depicts the adapted PRISMA flow chart for the method (Page, McKenzie, *et al.*, 2021; Page, Moher, *et al.*, 2021). This review protocol was registered in Mendeley Data under DOI 10.17632/rmf2rmyrpf.1, which also contains a Microsoft Excel file used to record each step of this comprehensive review.

Table 2 – Indicators and metrics in the referred analysis.

Indicators and Metrics	Description
1- Publication by Year	Number of published papers by year in the sample.
2- Co-occurrence of keywords	Network of co-occurrence of keywords with more than ten occurrences in the sample. The map was generated in VOSViewer software.
3- Care Level	Care level discussed in the papers, considering that one work can discuss more than one care level. Categories: Primary, Secondary, Tertiary, Quaternary, Quinary (Nuhut and Sabuncuoglu, 2002; Torrey, 2022; Indeed Editorial Team, 2023; Secretaria de Estado de Saúde de Minas Gerais, 2023; NHS Providers, 2024).
4- Improvement Method	Improvement methods discussed in the papers. Categories: Lean, Simulation, Lean/Simulation.
5- Intervention Applied	Improvement process intervention applied in the papers, considering that one work can discuss more than one intervention. Categories: Staff Change, Process Redesign, Schedule Change, Task Standardization, Number/Type of Equipment, Layout Change, Queue Change, Visual Measures, Communication, Assignment/Role Change, Technology Introduction, Number of Rooms, Culture Change, Patient Transfer/Rejection, Staff Punctuality, Training, Holistic Care, Number of Vehicles, Tele-Consultation.
6- Metric Measured	Improvement process metric measured in the papers, considering that one work can discuss more than one metric. Categories: Acquired Infections, Blocking Rate, Cancellation Rate, Capacity Utilization, Closing Time, Cost, Cycle Time, Delay, Emergency Treatment Performance, Equipment Utilization, Health Care Worker Exposure, Leaving Without Being Seen Number, Leaving Without Payment Number, Length of Stay, National Emergency Access Target, Mortality Rate, No-Show Rate, Number of Patients In, Number of Patients Served, Number of Process Steps, Number of Trained Staff, Number of Unscheduled Return Visits, Overtime, Patient Boarding Time, Patient Satisfaction, Patient Throughput Rate, Patient Waiting Time, Queue Length, Readmission Rate, Room Utilization, Safety Incidents, Staff Satisfaction, Staff Utilization, Starting Time of Service, Traveling Distance/Time, Value-Added Time
7- Care Level vs. Improvement Method vs. Intervention Applied vs. Metric Measured	Once the care levels, improvement methods, interventions applied and metrics measured analysis were conducted, it was also presented an analysis crossing all parameters, indicating the number of papers discussing this metrics jointly. The categories for Care Level, Improvement Method, Intervention Applied and Metric Measured were also considered.

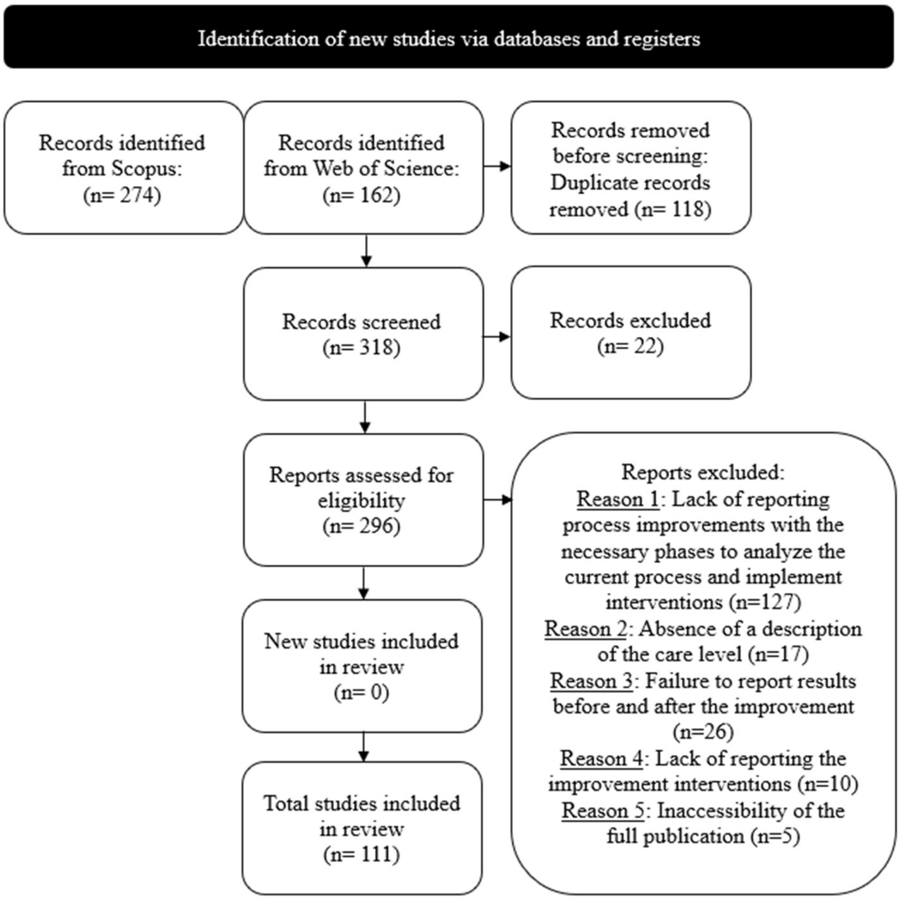

Figure 1 – PRISMA flow chart of the presented study (Page, McKenzie, *et al.*, 2021; Page, Moher, *et al.*, 2021).

For metrics “3- Care Level”, “5- Intervention Applied”, “6- Metric Measured”, and “7- Care Level vs. Improvement Method vs. Intervention Applied vs. Metric Measured”, a general classification of papers was conducted based on the mentioned categories (Table 2). Each paper could be included in one or more related categories, resulting in a total number of papers in each analysis higher than 111, as demonstrated in the subsequent subsections. These bibliometrics will be discussed.

RESULTS

Publication By Year

Figure 2 illustrates the evolution of studies concerning the improvement methods of patient flow in healthcare.

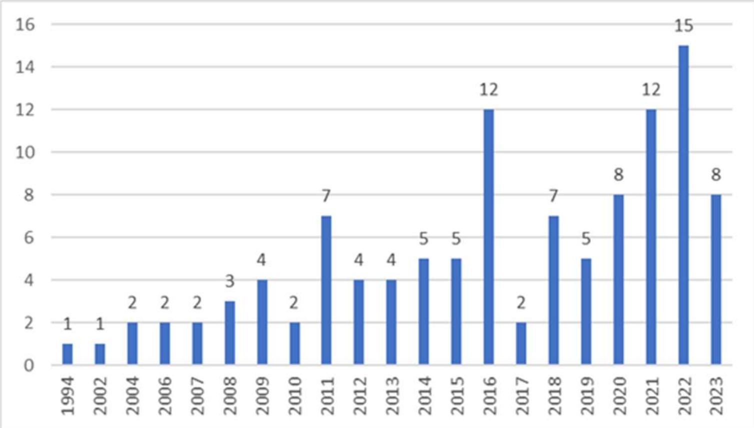

Figure 2 – Chart of publications years.

The graph indicates an initial effort documented in 1994 (Benson and Harp, 1994), followed by a period devoid of new publications until 2002, when another work was included in the sample (Nuhut and Sabuncuoglu, 2002). Although more productions per year were recorded after these years, the quantity remained relatively low, suggesting that while the subject had been identified, it was still minimally discussed. Works during this time primarily focused on foundational concepts rather than practical results.

However, from 2011 onwards, a more pronounced growth in the number of papers per year was observed, with seven references in 2011, reaching a peak of 12 papers in 2016 after a period of stability at lower values. High numbers of papers per year were found until 2023, indicating a clear upward trend from 2016 onwards.

The results indicate a recent surge in interest in the subject, accompanied by more technical and technological discussions in line with recent trends in research. As the quality of healthcare services continues to be a topic of increasing concern over the years, this issue becomes more pertinent, aligning with general perspectives within the health sector.

Co-Occurrence Of Keywords

Figure 3 illustrates the co-occurrence of keywords in the sample, focusing on those with more than ten occurrences.

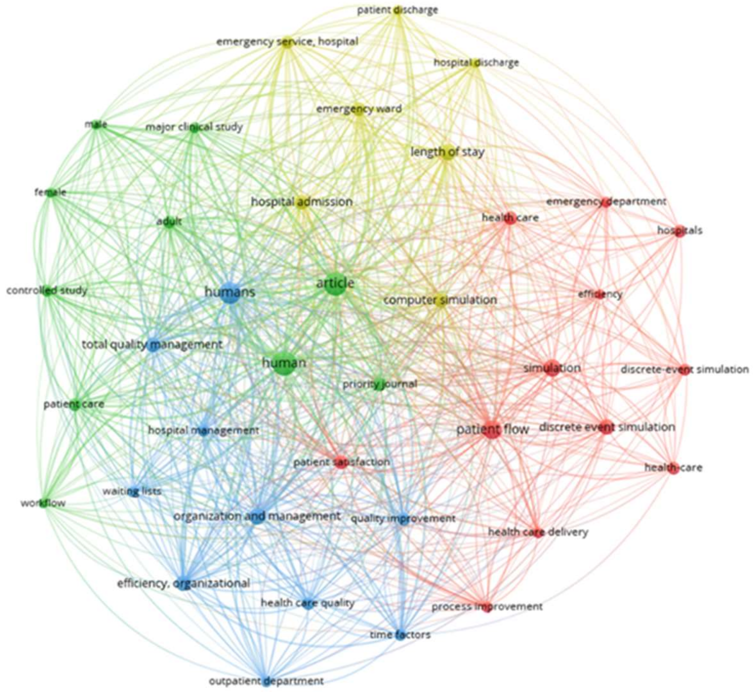

Figure 3 – Co-occurrence of all keywords with more than ten occurrences.

Four main clusters can be identified, each representing different perspectives related to the theme.

The first cluster (green) pertains to general discussions on the subject, emphasizing the importance of methods and controlled conditions for obtaining results. Methodological aspects such as gender parameters and study conditions are highlighted, indicating a predominant methodological perspective among these papers, within which the authors discuss the robustness of results and the level of impact they can cause on the systems analyzed. Although this technical perspective, closely linked to results' robustness, is present in the sample, some authors, such as Hydes, Hansi and Trebble (2012), and England et al. (2023), presented special attention to it in their methods and evidence.

The second cluster (yellow) delves into operations within the health sector, analyzing processes in hospitals and health units with different parameters. Specific scenarios and the application of technologies and techniques to achieve results in these processes are discussed. Jiang and Giachetti (2008), Huang, Hancock and Herrin (2012), and Robinson et al. (2019) brings some practical perspectives related to processes in health units that are illustrative of the mentioned cluster, for example.

The border between the second and third clusters (yellow-red) emphasizes technological applications, particularly in simulation-related cases. Results such as efficiency and patient satisfaction are the focus here, with discussions centering on process improvement. In the case of the red cluster, authors such as Deryahanoglu and Kocaoglu (2019), Maass et al. (2022), and Bera, Kumar and Bhattacharya (2023) presented discussions related to simulations and how these methods can assess the improvements in patient flow.

The fourth cluster (blue) focuses on improvement methods related to health units, emphasizing organizational aspects and management of operations and activities. Discussions revolve around strategic aspects leading to improvements in patient flow and other processes through the application of total quality management systems. This cluster is also represented by authors such as Dickson et al. (2009), Pellini et al. (2021) and Vidal-Carreras, Garcia-Sabater and Marin-Garcia (2022), with works directly related to quality tools and management systems in practical contexts.

Care Level

Table 3 presents the distribution of papers discussing improvements in patient flow across different care levels.

Table 3 – Clusters of papers by care level.

Categories	Publication Count	%
Primary	19	16%
Secondary	62	52%
Tertiary	35	29%
Quaternary	3	3%
Quinary	1	1%
Total	**120**	**100%**

The sample highlighted a greater focus on secondary care, followed by tertiary and primary levels. Few papers were identified at the quaternary level, and only one refers to the quinary level when discussing about military and civil care jointly (Nuhut and Sabuncuoglu, 2002), indicating a concentration of attention on initial care levels.

This focus on initial care is expected, given the higher demand for services at these levels within national health systems. Improvement methods primarily target these care levels, as most issues are encountered here, making them a priority for intervention.

It should be noted that this perspective is specific to the analyzed sample and that further research targeting quaternary and quinary care levels may provide additional insights.

Improvement Method

Table 4 presents groups of papers discussing improvement methods found in the literature.

Table 4 – Clusters of papers by care level.

Categories	Publication Count	%
Lean/Simulation	4	4%
Lean	43	39%
Simulation	64	58%
Total	**111**	**100%**

Two main methods, lean and simulation, were identified, with some works discussing both.

Lean, widely known in production and quality literature, allows for the optimization of patient flow in health units through process and routine simplification. Its concept and practical implications, so as the benefits of its consideration in the theme, are discussed by authors such as Dickson et al. (2009), Hydes, Hansi and Trebble (2012) and Pellini et al. (2021), which evidenced improvements in efficiency of health units and patient satisfaction, for example.

Simulation, on the other hand, predicts scenarios in healthcare environments, involving parameters such as waiting time and queue size to identify improvement opportunities specially in scheduling. Some examples of papers discussing the topic are Benson and Harp (1994), Maass et al. (2022) and Bera, Kumar and Bhattacharya (2023), which presents empirical and practical evidence of simulation effectiveness in improvement of the patient flow in health units.

Some papers combine elements of both methods, seeking to extract specific definitions and ideas from each to improve patient flow in health units.

Intervention Applied

Table 5 analyzes interventions applied in health units to improve patient flow and healthcare processes.

Table 5 – Clusters of papers by intervention applied.

Categories	Publication Count	%
Staff Change	43	16%
Process Redesign	33	13%
Schedule Change	30	11%
Number/Type of Equipments	26	10%
Task Standardization	26	10%
Layout Change	17	6%
Communication	14	5%
Queue Change	13	5%
Assignment/Role Change	12	5%
Technology Introduction	7	3%
Number of Rooms	5	2%
Culture Change	4	2%
Patient Transfer/Rejection	4	2%
Staff Punctuality	4	2%
Holistic Care	2	1%
Number of Vehicles	2	1%
Tele-Consultation	2	1%
Total	**111**	**100%**

Staff change emerged as the main action proposed and analyzed, reflecting the importance of human resources in driving improvements through staff replacements and reallocations. This perspective is considered by Gijo et al. (2013), Lima Rocha et al. (2022) and Bera, Kumar and Bhattacharya (2023), and it varies relatively to the nature of changes. For example, it can refer to movements of time, spaces related to human resources or even replacement of staff within the functional framework itself by other people.

Other interventions such as process redesign, schedule change, task standardization, number/type of equipments and layout change also garnered attention, focusing on analyzing processes to achieve more efficient routines and resource allocation.

There was no correlation between the complexity of the intervention and the number of papers discussing it. Complex actions such as staff change and process redesign and simple interventions such as schedule change received significant attention due to their potential impact on improving patient flow.

It is relevant to point that other actions such as communication and assignment/role change were also mentioned by more than ten works each, but the rest of the actions were only analyzed in a minor proportion. Among them, it is interesting to mention technology introduction, which could be expected to be discussed by a greater number of authors but is still not priority compared to interventions related to culture and general routines.

Metric Measured

Table 6 presents metrics measured in sample papers.

Table 6 – Clusters of papers by metric measured.

Categories	Publication Count	%
Patient Waiting Time	56	21%
Length of Stay	46	18%
Cycle Time	23	9%
Staff Utilization	20	8%
Number of Patients Served	14	5%
Patient Satisfaction	14	5%
Equipment Utilization	9	3%
Queue Length	8	3%
Capacity Utilization	7	3%
Room Utilization	6	2%
Leaving Without Being Seen Number	5	2%
Patient Boarding Time	5	2%
Value-Added Time	5	2%
Delay	4	2%
Traveling Distance/Time	4	2%
Cancellation Rate	3	1%
Closing Time	3	1%
Cost	3	1%
Mortality Rate	3	1%
Readmission Rate	3	1%
No-Show Rate	2	1%
Number of Patients In	2	1%
Patient Throughput Rate	2	1%
Staff Satisfaction	2	1%
Acquired Infections	1	0%
Blocking Rate	1	0%
Emergency Treatment Performance	1	0%
Health Care Worker Exposure	1	0%
Leaving Without Payment Number	1	0%
National Emergency Access Target	1	0%
Number of Process Steps	1	0%

Number of Trained Staff	1	0%
Number of Unscheduled Return Visits	1	0%
Overtime	1	0%
Safety Incidents	1	0%
Starting Time of Service	1	0%
Total	**111**	**100%**

As expected, time-related metrics such as patient waiting time, length of stay and cycle time are the most relevant, being mentioned by Nuhut and Sabuncuoglu (2002) and Vidal-Carreras, Garcia-Sabater and Marin-Garcia (2022), for example. Other metrics such as queue length and number of patients served received less attention, despite their importance in improving patient flow. Solving queues does not encompass the entire problem, being only a part of the patient flow and the number of patients served not bring the desired conclusion by itself.

Additional metrics included abandonment rates in queues without service, performance at different levels and stages and parameters associated with space, time, and resource availability in different health structures, highlighting the multifaceted nature of healthcare improvement.

Care Level vs. Improvement Method vs. Intervention Applied vs. Metric Measure

Table 7 consolidates indicators and metrics analyzed in the bibliometrics with three or more papers, revealing a variety of three care levels, two improvement methods, ten interventions applied, and nine metrics measured.

Table 7 – Clusters of papers by care level vs. improvement method vs. intervention applied vs. metric measured with three or more papers.

Care Level	Improv Method	Intervention	Metric	Publication Count	%
Secondary	Simulation	Staff Change	Patient Waiting Time	18	8%
Secondary	Simulation	Staff Change	Length of Stay	14	6%
Secondary	Simulation	Number/Type of Equipments	Patient Waiting Time	10	4%
Secondary	Simulation	Schedule Change	Patient Waiting Time	8	4%
Secondary	Simulation	Number/Type of Equipments	Length of Stay	7	3%
Secondary	Simulation	Process Redesign	Patient Waiting Time	7	3%
Secondary	Simulation	Staff Change	Staff Utilization	7	3%

Secondary	Simulation	Queue Change	Patient Waiting Time	6	3%
Secondary	Lean	Assignment/Role Change	Length of Stay	5	2%
Tertiary	Lean	Process Redesign	Length of Stay	5	2%
Secondary	Simulation	Schedule Change	Length of Stay	5	2%
Secondary	Simulation	Layout Change	Patient Waiting Time	5	2%
Tertiary	Lean	Process Redesign	Patient Waiting Time	5	2%
Tertiary	Lean	Schedule Change	Patient Waiting Time	5	2%
Tertiary	Simulation	Staff Change	Patient Waiting Time	5	2%
Tertiary	Lean	Process Redesign	Cycle Time	4	2%
Tertiary	Lean	Task Standardization	Cycle Time	4	2%
Secondary	Simulation	Layout Change	Length of Stay	4	2%
Secondary	Lean	Process Redesign	Length of Stay	4	2%
Primary	Simulation	Schedule Change	Length of Stay	4	2%
Secondary	Lean	Task Standardization	Patient Satisfaction	4	2%
Tertiary	Simulation	Number/Type of Equipments	Patient Waiting Time	4	2%
Secondary	Simulation	Number/Type of Equipments	Staff Utilization	4	2%
Secondary	Lean	Communication	Cycle Time	3	1%
Tertiary	Lean	Communication	Cycle Time	3	1%
Tertiary	Lean	Layout Change	Cycle Time	3	1%
Tertiary	Lean	Schedule Change	Cycle Time	3	1%
Primary	Lean	Task Standardization	Cycle Time	3	1%
Secondary	Lean	Task Standardization	Cycle Time	3	1%
Secondary	Simulation	Number/Type of Equipments	Equipment Utilization	3	1%
Secondary	Simulation	Staff Change	Equipment Utilization	3	1%
Secondary	Lean	Layout Change	Length of Stay	3	1%
Secondary	Simulation	Process Redesign	Length of Stay	3	1%
Secondary	Simulation	Queue Change	Length of Stay	3	1%
Secondary	Lean	Task Standardization	Length of Stay	3	1%
Secondary	Lean	Visual Measures	Length of Stay	3	1%
Secondary	Lean	Assignment/Role Change	Number of Patients Served	3	1%
Tertiary	Lean	Assignment/Role Change	Number of Patients Served	3	1%
Tertiary	Simulation	Number/Type of Equipments	Number of Patients Served	3	1%
Tertiary	Lean	Process Redesign	Number of Patients Served	3	1%
Secondary	Lean	Communication	Patient Satisfaction	3	1%

Secondary	Lean	Process Redesign	Patient Satisfaction	3	1%
Tertiary	Lean	Visual Measures	Patient Satisfaction	3	1%
Tertiary	Lean	Communication	Patient Waiting Time	3	1%
Primary	Simulation	Number/Type of Equipments	Patient Waiting Time	3	1%
Tertiary	Lean	Visual Measures	Patient Waiting Time	3	1%
Secondary	Simulation	Schedule Change	Staff Utilization	3	1%
Primary	Simulation	Staff Change	Staff Utilization	3	1%
Secondary	Lean	Task Standardization	Traveling Distance/Time	3	1%
Secondary	Lean	Process Redesign	Value-Added Time	3	1%
		Total		**225**	**100%**

The preferred care levels in the sample, as aforementioned, were primary, secondary, and tertiary, with the secondary being the most discussed, followed by tertiary and primary. When considering the most analyzed strategy in the sample, simulation as an improvement method (Benson and Harp, 1994; Maass *et al.*, 2022) involving staff change intervention (Gijo *et al.*, 2013; Lima Rocha *et al.*, 2022; Bera, Kumar and Bhattacharya, 2023) and analyzed using the patient waiting time metric (Nuhut and Sabuncuoglu, 2002; Vidal-Carreras, Garcia-Sabater and Marin-Garcia, 2022) was the most debated strategy. Furthermore, the second most relevant group in the list involved the same improvement method and intervention, but it was based on improving the length of stay metric (Deryahanoglu and Kocaoglu, 2019; England *et al.*, 2023). This points to an identified focus in the sample: simulation correlated with staff change promoted improvements in time metrics related to the processes and operation of health units, and this is also confirmed by the previous analysis of the present work (when considering each isolated parameter).

A third relevant strategy refers to the simulation method correlated with the number/type of equipment intervention and involving the patient waiting time metric (Corsini *et al.*, 2022; Maass *et al.*, 2022). This same metric was also correlated with studies involving schedule change, process redesign, queue change, and layout change, for example, which evidences that it is a widely applied metric that highlights improvements through different strategies, being the metric that came closest in the sample to the proposed objectives by the papers.

This comprehensive analysis provides insights into the literature's focus on improving patient flow in healthcare, highlighting areas of interest and potential avenues for future research.

DISCUSSION

The present bibliometric analysis highlights an increased interest in the subject matter within the literature, evident from a notable growth in the number of publications in recent years, likely influenced by expanded research in the healthcare domain. However, it's important to note that this trend cannot be definitively affirmed or deemed limiting based solely on the parameters analyzed.

When examining the co-occurrence of keywords, four distinct clusters emerge. These clusters are primarily related to methodological bias, practical operations and routines in the healthcare sector, technological applications in processes and structures, and organizational aspects, including management of operations and activities. Notably, these studies predominantly consider two improvement methods—lean and simulation—across three care levels: primary, secondary, or tertiary.

Taking a holistic perspective, certain focal points emerge in line with different strategies. Simulation stands out as a method receiving considerable attention from authors, given its capacity to analyze predicted scenarios and anticipated perspectives within the healthcare system. Consequently, discussions often revolve around interventions involving analysis and modifications in processes, structures, and human resources. Staff change, for instance, emerges as an intervention that demonstrates results and influences patient flows in units, leading to reductions in waiting and service times, alongside an increase in operational capacity.

Furthermore, actions such as Process Redesign, Communication, and Task Standardization also pertain to processes and general routines, operating at a strategic or managerial level, and have shown positive outcomes aligned with targeted objectives. Nevertheless, the overall contextual analysis of the papers predominantly emphasizes metrics related to time across different stages and activities in the healthcare system, along with attendance control and completion rates of healthcare cycles at various levels.

CONCLUSIONS

The present paper provides an overview of research trends in improvement methods related to patient flow across different healthcare levels through a systematic literature review utilizing the PRISMA statement. It reveals a recent surge in research interest, particularly focusing on time metrics that reflect enhancements in processes and general routines within health units. Specific improvement methods, notably lean and simulation, were identified in the sample, along with a specific range of interventions aimed at optimizing resources, layouts, and processes. Interestingly, there was no discernible correlation between intervention complexity and the number of references. However, certain time metrics were prioritized in discussions over specific cases such as patient satisfaction or costs, which are associated with parameters beyond processes, physical and human resources, and routines.

The purpose of this paper is to contribute by offering an analysis of the gap between theoretical frameworks and practical implementation in improving patient flow in healthcare. The goal is to promote a closer alignment between practical strategies and the realities of processes related to this topic. The purpose of this work was to contribute by offering an analysis of the scenario of works that study the gap between theoretical frameworks and practical implementation with regard to improving patient flow in healthcare, so that it is possible to promote an approximation between strategies in practice and the reality of the processes related to the topic. Considering research opportunities, the results suggest a myriad of possibilities based on different strategies, including those not prominently featured in the results, with only one or two papers related to them. Given the diverse range of interventions examined by authors and analyzed across various metrics, there is scope for new discussions focusing on perspectives that may not have been adequately explored, such as addressing issues at the quaternary and quinary levels, which were underrepresented in the sample.

However, certain limitations are evident in this paper. Firstly, the adopted keywords may have provided a broad perspective, potentially overlooking papers that could have made significant contributions to the discussion, even if they did not explicitly mention these keywords. Nonetheless, screening criteria were implemented to mitigate this issue. Secondly, the reliance on English keywords may have excluded relevant papers in other languages, as they were not captured by the search strings and consequently not considered in the analysis.

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Integrating Sustainable Development Goals (SDGs) into Quality Subjects for Higher Education Students

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STRUCTURED ABSTRACT

Purpose:

The purpose of this study is to explore how quality tools can be applied to develop sustainable education among higher education students, with a particular focus the analysis and understanding the challenges associated with the Sustainable Development Goals (SDGs).

Design/Methodology/Approach:

In a master's course in an Engineering School, focusing on quality tools, the SDGs were introduced as a subject of study for students to apply the aforementioned tools. Later, students' assignments were analyzed employing a mixed-methods approach to understand the impact of integrating SDGs into the curriculum.

Findings:

The assessment of the conducted exercise was well-received by students, demonstrating proficient use of the assigned tool. It has been proven that the introduction of basic quality tools to analyze problems related to the SDGs is effective, demonstrating that their use extends beyond the analysis of quality-related issues.

The gender analysis reveals differing perspectives on sustainable development among male and female students, providing valuable insights for inclusive educational interventions. Moreover, preliminary results show variations in students' preferences for specific SDGs, indicating potential areas for targeted educational campaigns and interventions.

Research Limitations/Implications:

The study's scope may be limited by sample size or specific institutional contexts. However, these findings contribute to sustainable development education by demonstrating the efficacy of quality tools in the integration of the SDGs, identifying gender-based differences in engagement, and highlighting variations in SDG popularity among higher education students. These insights are crucial for educators, curriculum developers and policy makers seeking to develop informed and committed individuals for the SDGs.

Keywords: Higher education, teaching quality, SDGs, quality tools

Paper type: Research paper

INTRODUCTION

In today's rapidly changing world, characterized by complex challenges such as climate change, inequality, poverty, and environmental degradation, the Sustainable Development Goals (SDGs) have emerged as a critical framework for achieving sustainable development. These goals, set by the United Nations (UN), encompass a comprehensive agenda aimed at addressing urgent global issues and ensuring a better future for all. The SDGs, a set of 17 interconnected global objectives, were adopted by the UN to address pressing social, economic, and environmental challenges by 2030. These goals encompass a wide range of critical issues including poverty eradication, quality education, gender equality, clean water and sanitation, affordable and clean energy, sustainable cities and communities, climate action, and more. So, the SDGs provide a comprehensive framework for governments, organizations, businesses, and individuals to work together towards a more equitable, sustainable, and prosperous world. The SDGs present a comprehensive and intricate agenda, posing significant implementation challenges for countries. Their success hinges largely on effective different implementation strategies (Redman, 2018). Achieving the SDGs demands collective action, innovative solutions, and partnerships across sectors and borders (Redman, 2018). This collective action requires the utilization of management tools to facilitate comprehension of the complexities associated with the implementation of the SDGs. By leveraging management tools, stakeholders can gain insights into the interconnected nature of SDGs, prioritize interventions, allocate resources efficiently, and track progress effectively.

According to Siva et. al (2016), quality tools have been employed to quantify and enhance the environmental impact of products and processes. However, the widespread adoption of these tools remains limited, and their adaptation to environmental management within companies is still lacking (Siva et al., 2016). In this sense, academic institutions have a great responsibility to integrate the use of management tools, and in particular quality tools, in addressing the challenge of achieving the SDGs. It is therefore important that management and improvement tools, such as the 7 basic quality tools, are applied in specific applications related to the SDGs.

Moreover, universities have the potential to significantly influence the shift in narratives towards sustainability, fostering new values, attitudes, and behaviors in future societies (Mohammadi et al., 2023). By integrating SDGs into educational curricula, educators play a pivotal role in inspiring and empowering students to understand, engage with, and take action on these pressing issues (Anand et al., 2015). With enhanced awareness and deeper knowledge of Sustainable Development Goals (SDGs), students can actively contribute to supporting, promoting, and achieving these development goals, utilizing their academic backgrounds effectively (Jati et al., 2019). By engaging with the SDGs across disciplines and through the application of practical exercises with quality tools, students can develop a holistic understanding of interconnected environmental, social and economic issues.

Therefore, it would be interesting to explore how programs in subjects for sustainable development education can be developed among higher education students. Considering previous studies on gender-linked differences in knowledge of the SDGs (Jati et al., 2019), it seems relevant to explore which SDGs are the most recognized or utilized among students and if there are differences between them. Related to these two issues, the following research questions are posed:

RQ1. Can Sustainable Development Goals (SDGs) be integrated into a curriculum to enhance students' quality tools knowledge?

RQ2. Are basic quality tools adequate for addressing the study of the SDGs?

RQ3. What specific differences exist in SDG’s perspectives between male and female students?

SDGs IN HIGHER EDUCATION

Utilizing real-world data in educational settings has proven instrumental in fostering a deeper comprehension of tool application among students (Heck, 2009). This is particularly relevant when considering the basic 7 QC tools, also known as the 7 traditional tools, which are widely acknowledged for their effectiveness in addressing various quality-related problems (Kumar et al., 2011). However, to maximize the learning potential of these tools, training shouldn't be limited to theoretical scenarios. By incorporating real-world data from diverse contexts into educational settings, students gain a richer understanding of how the 7 QC tools can be applied. This approach fosters a deeper comprehension of tool application beyond just learning. Equipping students with the ability to adapt these tools to various situations empowers them to become versatile problem-solvers across different disciplines.

Furthermore, employing a mixed methodology encompassing both quantitative and qualitative data collection techniques can significantly enhance the understanding of SDGs within the realm of education. This multifaceted approach enables students to not only grasp the numerical aspects of progress but also appreciate the nuanced socio-cultural contexts that underpin these goals (Albareda-Tiana et al., 2018).

That is the requirement postulated by the United Nations (2015) who stated in the goal target 4.7 (Education for sustainable development and global citizenship) that, "By 2030, ensure that all learners acquire the knowledge and skills needed to promote sustainable development, including, among others, through education for sustainable development and sustainable lifestyles, human rights, gender equality, promotion of a culture of peace and non-violence, global citizenship and appreciation of cultural diversity and of culture's contribution to sustainable development ." The role of education is a key in achieving the 17 SDGs. To create a more sustainable world, "individuals must become sustainability changemakers. They require knowledge, skills and attitude that empower them to contribute to sustainable development" (United Nations, 2015). Education, including education at higher education institutions, is a key for stimulating sustainable development. Thus, it is important to integrate sustainability values and knowledge in the curriculum of higher education institutions.

Despite the establishment of the SDGs in 2015, higher education institutions continue to face challenges in integrating these international goals within their campuses (Hansen et al., 2021).That's why it's necessary to include the SDGs in curricula, so that both faculty and students can understand and acquire the knowledge to apply it on campus. The literature reports on several universities that have integrated the SDGs into their learning programs, such as the University of South Africa's science campus in Johannesburg (Mawonde & Togo, 2019), the National University of Kaohsiung in Taiwan (Chang & Lien, 2020), or in Andalusian Universities in Spain (Poza-Vilches et al., 2022), incorporating the SDGs into teaching, research, community engagement, and campus operations. However, in the study reported by Alcántara-Rubio et al. (2022), the university faces challenges in engaging students due to various factors.

In the development, consideration and understanding of the Sustainable Development Goals (SDGs), the incorporation of a gender approach is paramount to ensure their effectiveness and inclusiveness. Gender is a fundamental aspect of social identity and intersects with various dimensions of human experience, such as access to education, health care, employment and political participation. By integrating a gender perspective into the formulation and evaluation of the SDGs, practitioners can address the specific needs and challenges faced by women, men and gender-diverse people. This approach not only promotes gender equality, but also enhances the overall impact and sustainability of development efforts (Manandhar et al., 2018).

The SDGs seem to suppose that poverty reduction and improved social and economic development will bring gender equality but that is not the case (Esquivel & Sweetman, 2016) . We have to develop more culturally nuanced and contextualized approaches when working with the underlying causes of deep-rooted and persistent gender inequality (Song & Kim, 2013).The SDGs will provide a ground to deal with the pervasive gender inequality around the world, but there is a need to dig deeper to expose the causes as well as work harder to erase gender gaps (Esquivel & Sweetman, 2016).

RESEARCH METHODOLOGY

In this section, we outline the methodology used with students to integrate knowledge of the Sustainable Development Goals (SDGs) into the application of quality tools. To facilitate the activity, students were first provided with comprehensive information on the seven key quality tools commonly used in problem-solving and process improvement. They were educated on how these tools can be effectively applied to address real-world challenges. Following this introduction, each student was randomly assigned one of the seven quality tools and instructed to apply it to an example directly related to one of the Sustainable Development Goals. In our quality improvement exercise, we utilized several of the seven basic tools of quality. Specifically, we applied the Pareto chart, cause-and-effect diagram, histogram, correlation diagram, flowchart, and data collection sheet. We did not include control charts in this exercise because they require ongoing data collection and are more suited for monitoring specific process characteristics over time. Therefore, we deemed it inappropriate for the scope of this particular exercise where the focus was on initial data collection and analysis rather than continuous monitoring. Students were required to gather and utilize real data to support their analysis and recommendations. Subsequently, student work was evaluated based on predetermined criteria.

Later, a graphical analysis was carried out to uncover patterns in gender preferences for various SDGs. This type of graphical representations can enhance comprehension of results when dealing with sparse data across multiple categories (Cleveland & McGill, 1985). By visualizing the data in this manner, complex patterns and trends can be readily identified and comprehended. Graphical tools offer a more intuitive and accessible means of exploring the dataset, enabling researchers to glean insights efficiently. This approach not only simplifies analysis but also serves to highlight significant findings in a compelling and accessible format for readers and researchers alike. Then we conducted a statistical analysis to examine the potential relationship between gender and the category of SDG chosen (environmental, economic, and social).

RESULTS

The aim of this study was to assess the viability of incorporating Sustainable Development Goals (SDGs) education into a course by employing the seven quality tools. The specific case examined the implementation of an operations management course within a postgraduate engineering program, involving 97 students divided into three distinct groups. As previously noted, students were tasked with choosing an SDG, locating real-world data pertinent to that goal, and applying the designated quality tool for analysis.

The majority of students demonstrated proficient use of the assigned tool and produced noteworthy conclusions or applications, as indicated by their achieved grades (averaging 8.8, with only three students failing the exercise). Additionally, the end-of-course survey yielded positive feedback for this aspect of the curriculum, receiving a rating of 4.4 on a scale from 1 to 5 (where 5 reflects the highest positive evaluation). In the comments section, several students expressed satisfaction with these sessions, particularly appreciating the integration of theoretical concepts with practical examples and the instruction of tools relevant to their prospective professional pursuits.

By employing these quality tools, individuals and organizations can gain valuable insights into complex issues related to the SDGs, enabling them to develop more effective strategies for achieving sustainable development.

In this case, different quality tools were effectively utilized to address to various exercises related to the SDGs. For instance, the Pareto Chart was utilized for analyzing SDG 14 (Life Below Water): identification of the primary types of waste polluting the oceans and SDG 3 (Good Health and Well-being): causes contributing to infant mortality. Data Sheets were used to study SDG 6 (Clean Water and sanitation): information on access to clean drinking water by country and SDG 14 (Life Below Water): characterization of the types of waste found on a particular beach, among others. Flowcharts were employed to examine processes linked to the increase in global meat consumption under SDG 2 (Zero Hunger) and the CO2 emission reduction process in a city for SDG 13 (Climate Action). Correlation diagrams was created to study the relationship between a country's GDP and life expectancy for SDG 1 (No Poverty) and to relate the GDP of different countries to their level of education, for SDG 4 (Quality Education). Additionally, a histogram was utilized to assess the proportion of parliamentary seats held by women across different countries for SDG 5 (Gender Equality) and this tool was also used to show the distribution of water quality indicators at a monitoring station in an American country, for SDG 6 (Clean Water and sanitation). In the same vein, the Ishikawa diagram was applied to the root causes associated with youth suicide, for SDG 3 (Good Health and Well-being) or the factors that can help eliminate world hunger (SDG 2: Zero Hunger).

These are some examples of how the students applied the different tools. To illustrate the results of the exercises, Figures 1 and 2 show some of the aforementioned examples.

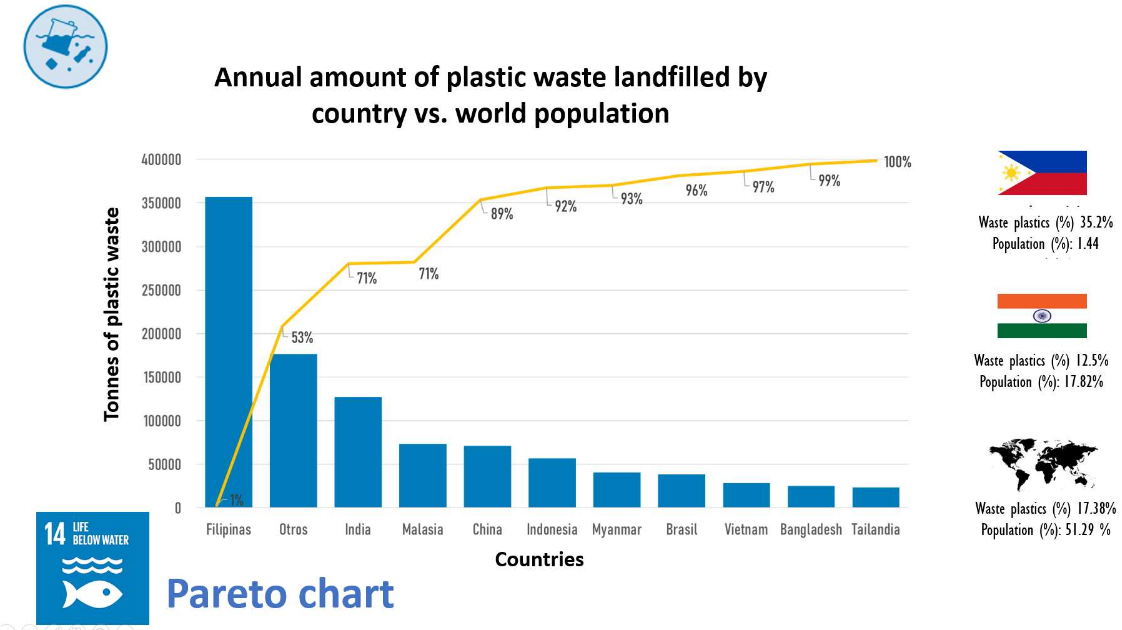

Figure 1 – Example of one of the exercises carried out by a student, applying the Pareto diagram to SDG 14 (Life below water)

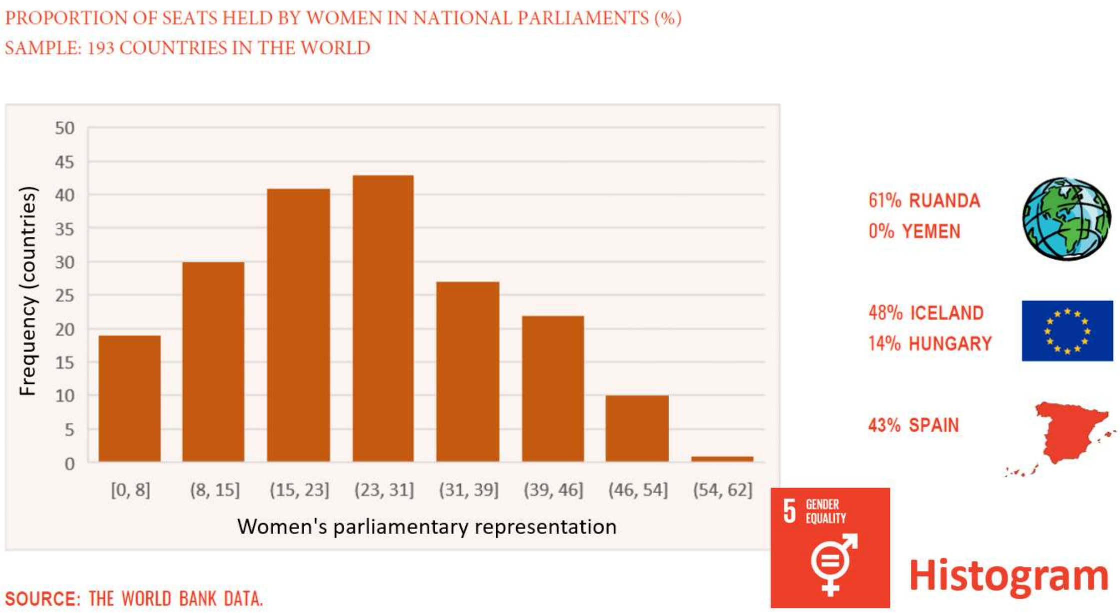

Figure 2 – Example of one of the exercises carried out by a student, applying the Histogram tool to SDG 5 (Gender Equality)

In addition to conducting individual exercises, a dedicated class session was organized to facilitate the sharing of results among participants. During this session, students were given the opportunity to present one or two applications of the assigned tools to the rest of the class. This interactive approach enabled students to learn from their peers' examples and engage in meaningful discussions focused on topics related to sustainable development goals.

This collaborative format aligns with research findings emphasizing the benefits of student presentations and peer interactions in educational settings. According to (Kågesten & Engelbrecht, 2007), students derive substantial benefits from presenting their work and participating in peer presentations, fostering an environment conducive to peer learning. Moreover, in graduate-level engineering courses, peer presentations have been shown to effectively engage students and enhance critical thinking and presentation skills (Macalpine, 1999). Thus, incorporating such interactive elements into the curriculum not only reinforces learning outcomes but also cultivates essential skills for future professional development.

Analysis of different perspectives on the SDGs

Upon receiving and evaluating the various student assignments, certain patterns in the selection of Sustainable Development Goals (SDGs) were identified. As depicted in the table below, certain SDGs emerged as more popular choices among students, while others, such as SDG 10 (reduced inequalities) and SDG 17 (partnerships for the goals), were not selected for the exercise by any student. This observation highlights a tendency towards specific SDGs over others, underscoring potential areas of interest and focus within the context of sustainable development initiatives.

As seen in the table, four of the Sustainable Development Goals - SDG 2, SDG 6, SDG 13, and SDG 14 - were chosen by 46 students (47% of the total). This selection highlights a significant focus among students on goals related to zero hunger (SDG 2), clean water and sanitation (SDG 6), climate action (SDG 13), and life below water (SDG 14).

Table 1 – Distribution of Sustainable Development Goal preferences among students

SDGs	Total (n. of Stds)
SDG 1 - No Poverty	4
SDG 2 - Zero Hunger	15
SDG 3 - Good Health and Well-being	9
SDG 4 - Quality Education	9
SDG 5 - Gender Equality	3
SDG 6 - Clean Water and sanitation	10
SDG 7 - Affordable and Clean Energy	9
SDG 8 - Decent Work and Economic Growth	2
SDG 9 - Industry, Innovation, and Infrastructure	2
SDG 10 - Reduced Inequality	-
SDG11- Sustainable Cities and Communities	2
SDG 12 - Responsible Consumption and Production	8
SDG 13 - Climate Action	11
SDG 14 - Life Below Water	10
SDG 15 - Life on Land	2
SDG 16 - Peace, Justice, and strong institutions	1
SDG 17 - Partnerships for the Goals	-
Total	97

Additionally, differences were observed in the SDGs chosen based on gender. Therefore, gender-based differences were analyzed to uncover any potential disparities or preferences related to SDG selection.

Table 2 – Gender-Based differences in Sustainable Development Goal Preferences

SDGs	**Female**	**Male**	**Total**
SDG1	-	4	4
SDG2	5	10	15
SDG3	4	5	9
SDG4	6	3	9
SDG5	2	1	3
SDG6	2	8	10
SDG7	1	8	9
SDG8	-	2	2
SDG9	-	2	2
SDG10	-	-	-
SDG11	-	2	2
SDG12	4	4	8
SDG13	3	8	11
SDG14	3	7	10
SDG15	1	1	2
SDG16	1	-	1
SDG17	-	-	-

Total	*32*	*65*	*97*

Based on the data presented in the previous table, it was hypothesized that gender-based preferences for certain SDGs might be influenced by a more pronounced social or environmental aspect. To explore this further, the SDGs were categorized into three groups based on one of three dimensions: social (related to living conditions and human development), environmental (related to biodiversity and natural resource conservation), and economic (related to the economy and its infrastructure). The classification is detailed in the following table. This approach aimed to identify potential underlying factors driving gender-specific preferences towards specific categories of Sustainable Development Goals.

Table 3 –Classification by dimension and choice of SDG type by dimension and gender, in number of students (and as a percentage of the total)

Dimension	SDGs	Female	Male	Total
Social: related to living conditions and human development	SDG 1 - No Poverty SDG 2 - Zero Hunger SDG 3 - Good Health and Well-being SDG 4 - Quality Education SDG 5 - Gender Equality SDG 16 - Peace, Justice, and strong institutions	18 (56%)	23 (35%)	41 (42%)
Environmental: related to biodiversity and natural resource conservation	SDG 6 - Clean Water and Sanitation SDG 7 - Affordable and Clean Energy SDG 13 - Climate Action SDG 14 - Life Below Water SDG 15 - Life on Land	10 (31%)	32 (49%)	42 (43%)
Economic: related to the economy and its infrastructure	SDG 8 - Decent Work and Economic Growth SDG 9 - Industry, Innovation, and Infrastructure SDG 10 - Reduced Inequality SDG 11- Sustainable Cities and Communities SDG 12 - Responsible Consumption and Production SDG 17 - Partnerships for the Goals	4 (13%)	10 (15%)	14 (14%)

Following the collection of data, graphical representation was employed to facilitate analysis. Considering the unequal number of males and females in the sample, the data was normalised to compare the percentage of each gender choosing specific SDGs. This led to the creation of a scatter plot. The plot's x-axis shows the percentage of females favouring each SDG, while the y-axis displays the percentage of males. Moreover, the bubble size on the plot indicates the total number of individuals endorsing each SDG, providing insight into the overall popularity of each goal. To aid in identifying gender preference trends at a glance, a line with a slope of 1 was included; deviation from this line suggests a gender preference. Additionally, SDGs were categorized by type and colour-coded within the bubbles—red for social, green for environmental, and blue for economic SDGs. This visual representation allows for an immediate understanding of gender inclinations towards different SDGs as well as the relative appeal of each goal.

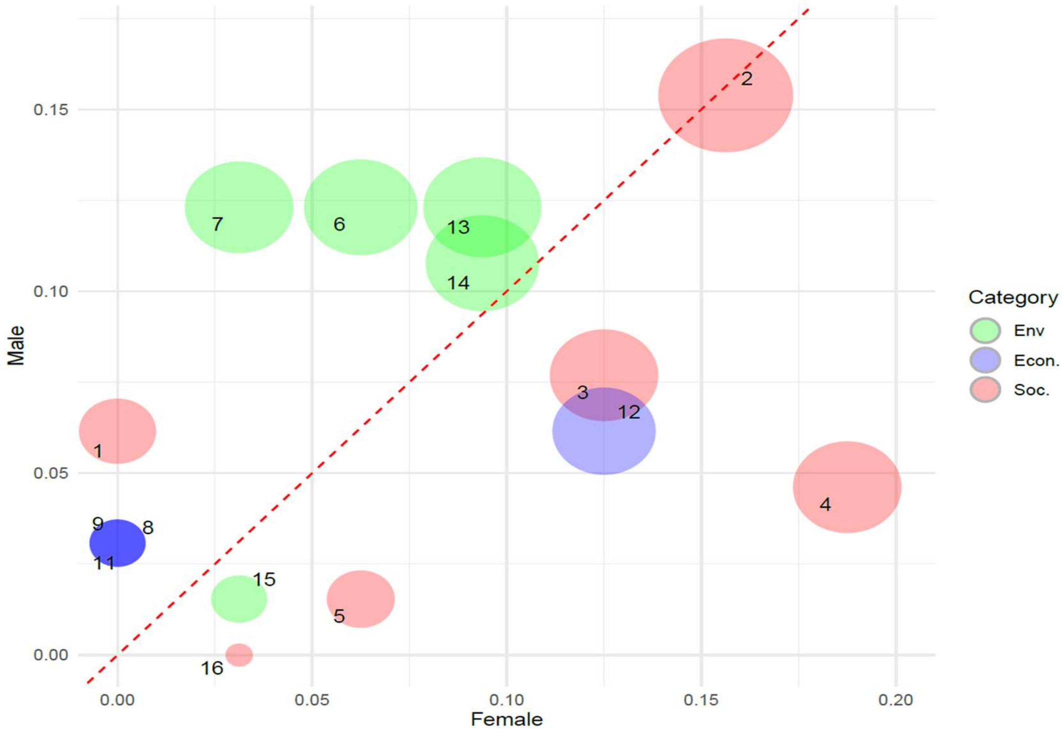

Figure 3 – Scatter Plot Analysis with normalized gender preferences for specific SDGs:

As seen in the Figure 3, there are differences between genders. It is noteworthy and interesting that most of the SDGs related to the environmental dimension were predominantly selected by males, whereas SDGs tied to social causes were favored by females. This pattern suggests a potential gendered perspective in goal-setting and prioritization within the context of sustainable development. The preference for environmental goals by males might reflect a focus on systemic and technological solutions, often associated with traditional male-dominated fields like engineering and policy. Conversely, the emphasis on social goals by females could highlight a tendency towards community-oriented and people-centered approaches, aligning with roles typically associated with caregiving and social work.

Regarding the economic SDGs, the majority of them (8,9 and 11) were selected by male students, except for SDG 12 (Responsible Consumption and Production), which was chosen by a higher proportion of women than men. This observation is interesting as SDG 12 primarily involves personal behaviors, contrasting with others that are more closely associated with infrastructure-related issues. Based on the data regarding students' selection of an SDG for their assignment, we conducted a statistical analysis to examine the potential relationship between gender and the category of SDG chosen (environmental, economic, and social). Initially, we tested whether the variables gender and SDG category are independent. The p-value obtained from this test was 0.1484, which does not provide sufficient evidence to reject the null hypothesis, indicating that we cannot confirm the independence of these variables.

Subsequently, we analyzed whether the choice of a specific SDG category is independent of gender. To achieve this, we reorganized the data into two groups for each category: those who chose the environmental SDG and those who did not, and similarly for the social and economic categories. The resulting p-values for the environmental (0.1273) and social (0.0795, which is closer to 0.05) categories were not low enough to reject the null hypothesis of independence. This suggests that there is no significant evidence to assert that the choice of these categories is dependent on gender. In contrast, for the economic category, the proportions of men and women were quite similar, further indicating that the selection of an economic SDG is not influenced by gender.

While the p-values obtained from our statistical tests do not provide strong evidence to reject the null hypothesis of independence between gender and the choice of SDG category, it is important to consider the potential impact of sample size on these results. The relatively high p-values, particularly for the environmental (0.1273) and social (0.0795) categories, suggest that our sample size may not be large enough to detect a statistically significant relationship, if one exists. This implies that with a larger dataset, we might achieve more conclusive results regarding the influence of gender on the choice of SDG category. Therefore, the lack of significant findings in this analysis could be partially attributed to the limited size of our sample.

In conclusion, while our statistical analysis did not establish significant relationships or clear preferences between gender and the choice of SDG categories, the data revealed some interesting trends. These trends suggest potential areas for further investigation and highlight the nuanced ways in which gender may influence the selection of SDGs. These observations, though not statistically conclusive, provide valuable insights into how diverse perspectives can shape and enrich the global agenda for sustainable development.

CONCLUSION AND DISCUSSION

As seen in this case, introducing the SDGs in a course focused on the application of quality tools is an effective way for students to incorporate the SDGs into their curriculum in a holistic way. Quality tools have long been integrated into engineering curricula, always with a practical approach aimed at bridging the gap between theory and real-world application (Pyo, 2005). In fact, several studies have extended the application of these tools beyond production processes to sectors such as tourism and healthcare (Grossu-Leibovica & Kalkis, 2023; Pyo, 2005). In addition, researchers have shown interest in linking quality management in companies with the implementation of the SDGs in their programmes, often through the analysis of sustainability reports (Fonseca & Carvalho, 2019). Therefore, integrating both topics into curricula in a related way seems very appropriate.

In terms of the differences observed in the selection of SDGs by the different genders, with women tending more towards social goals and men towards environmental goals, these differences raise considerations for the design of activities and curricula. This divergence is undoubtedly conditioned by different perspectives determined by social norms and experiences(Shang et al., 2021). Recognizing and addressing these differences is crucial to designing inclusive educational activities and curricula that resonate with all learners. Integrating discussion of the different SDGs and gender perspectives in the classroom can encourage critical reflection and understanding of diverse viewpoints. In this way, educators can create a more inclusive learning environment and relate it to the different social and environmental issues that concern us.

Despite having a sample size of 97 students, the study is constrained by the fact that the SDGs are 17. This relatively high number of groups means that the results can vary significantly with just a one-unit increase or decrease in any of the groups. For example, the SDGs in which only 1, 2 or 3 students have expressed interest are the most vulnerable, as the results could significantly change if even one student in that group had chosen differently, or if another student had opted for that group. This indicates that the findings in this study are less robust for small SDGs with smaller groups. Conversely, for SDG 2, Zero Hunger, with 15 students opting for this SDG a change involving one additional or one fewer student would not alter the conclusion that the choice of this group appears gender-neutral in this study.

In conclusion, this research contributes to the evolving field of education for sustainable development by suggesting a way to apply quality tools on the SDGs in the curriculum of higher education students. This case not only proposes an application to improve students' understanding of the SDGs, but also highlights the usefulness of applying quality tools to different areas, such as sustainability. Furthermore, it identifies gender differences in engagement and identifies variations in the popularity of particular SDGs among students. The findings of this study can be used to develop effective strategies for integrating the SDGs into higher education curricula, thereby promoting sustainable development practices and empowering students to become agents of change.

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Improvement methods in biobanking and biorepository processes: systematic review and research trends

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STRUCTURED ABSTRACT

Purpose – A quality management system that enhances processes is essential for every biobank and biorepository operation. This study aims to provide an overview of research development and trends in process improvement for biobanks and biorepositories through a bibliometric analysis of existing literature, emphasizing the correlation between these systems and operational improvements.

Design/methodology/approach - Following PRISMA guidelines, this review utilized the Scopus and Web of Science databases. The review protocol was registered in Mendeley Data under DOI 10.17632/8kx4fb3g6j.1. A total of 158 publications were included based on specific criteria, including full-length articles containing search terms in the title, abstract, or author-supplied keywords, alongside three other content-specific rationales. A bibliometric analysis focused on metrics such as publication year, journals, keyword co-occurrence, processes, and improvement methods.

Findings - Research trends primarily address the structural and technological aspects of biobanks and biorepositories, with greater attention to storage and processing protocols to enhance security, governance, and efficiency. A notable gap exists in the literature regarding “lean” and “guidelines/certification” improvement methods.

Research limitations/implications - The subject is delimited by the adopted English keywords and considers only the steps from regulation to distribution/disposal in biobanks and biorepositories. Future research should address this aspect.

Originality/value - This study offers a comprehensive perspective on improvements in biobanks and biorepositories, a viewpoint notably absents in the literature, which predominantly focuses on specific

cases. The correlation between improvements in biobanking and biorepositories and quality management systems addresses this gap by significantly enhancing the efficiency of these processes.

Keywords: Biobanking, Biorepository, Process implementation, Improvement methods, Systematic Literature Review (SLR).

Paper type: Literature review

INTRODUCTION

Nowadays, there is a growing trend in research and discussion surrounding biobanks and biorepositories, as they are essential structures for the scientific and technological advancement in human and veterinary health areas. A biobank can be defined as a legal entity, or a part thereof, that engages in the "collection, preparation, preservation, testing, analysis, and distribution" of specific biological materials, along with managing the related information and data (International Organization for Standardization, 2018). On the other hand, a biorepository is "a formally managed physical or virtual entity that may receive, process, store, and/or distribute biological specimens and/or samples", including their associated data (International Society for Biological and Environmental Repositories (ISBER), 2018). Biological materials, specimens, or samples are fundamental for research studies in disease pathogenesis, leading to accurate diagnoses, prognostics, and treatments (Uno, 2023). Despite the conceptual differences between these structures, they will be analyzed together since they are often discussed in conjunction and, in some cases, even confused and treated as a single entity. Joint treatment in this discussion does not interfere with the conducted analysis.

The world's first biobank was established in 1948 in Framingham, Massachusetts, U.S.A., by the National Heart, Lung, and Blood Institute (NHLBI) for the Framingham Heart Study (FHS), which focused on major coronary heart disease risk factors (Dawber and Kannel, 1966). Since then, biobanks and biorepositories must adhere to governmental and professional guidelines for standardized operating procedures in any territory (Troyer, 2008; Hallmans and Vaught, 2011; Sanderson-November *et al.*, 2022). For example, mentioning the Brazilian context, some guidelines are established by the Brazilian government in the theme (Conselho Nacional de Saúde, 2011; Ministério da Saúde, 2011), the National Cancer Institute (Instituto Nacional do Câncer – INCA) (National Cancer Institute (NCI), 2016), the International Society for Biological and Environmental Repositories (ISBER) (International Society for Biological and Environmental Repositories (ISBER), 2018), and the Organization for Economic Cooperation and Development (OECD) (Organisation for Economic Co-operation and Development (OECD), 2023) must be considered. Furthermore, standardization and accreditation programs are provided by organizations such as the International Organization for Standardization (ISO) (International Organization for Standardization, 2018), the Canadian Tissue Repository Network (CTRNet) (Canadian Tissue Repository Network, 2023), and the College of American Pathologists (CAP) (College of American Pathologists, 2023).

Additionally, a quality management system is required for every biobank and biorepository, which should identify and act upon opportunities for improvement through process review (International Organization for Standardization, 2018). Various methods can be utilized in this process (e.g., Kaizen, Lean, Six Sigma, or the Toyota Production System), with their basis being the continuous improvement model (Millard, 2022). This model reflects the notion of constantly implementing small-scale incremental improvements aligned with strategic goals and guided by several principles, such as defining standard operations. Moreover, it asserts that small-scale incremental improvements are typically inexpensive to implement, the impact of improvement must be measured and shared, management support is a prerequisite, and employees must be involved in improvement activities (Stelson *et al.*, 2017; Vasconcellos de Magalhaes Castro and De Camargo Junior, 2020; Millard, 2022).

Studies have been published covering process improvements in biobanks and biorepositories, such as procedures affecting biospecimen quality (Moore *et al.*, 2011), but an overall picture of these optimizations is still lacking. Considering this, the present work aims to provide an analysis of research trends in improvement methods related to biobanks and biorepositories' processes through bibliometric results of a systematic literature review. The review was based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement applied in Scopus and Web of Science databases, aiming to provide an overview of research development in the theme, identifying literature gaps, and offering a comprehensive review of publications related to the process improvement of biobanks and biorepositories.

The paper is organized as follows: Section 2 details the applied method. Section 3 presents the results, discussing the selected metrics and indicators. Section 4 discusses the results and research trends. Finally, Section 5 concludes the work with limitations and implications for future research and practice.

RESEARCH METODOLOGHY

A systematic literature review was conducted to synthesize research trends related to process improvements in biobanks and biorepositories, with each step recorded in Excel. Both authors independently conducted a comprehensive review following the protocol described above, ensuring that resulting data remained open and detailed to minimize bias and enhance the certainty of evidence. Any conflicts were resolved through discussions among researchers until a consensus was reached. Data collection adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses

(PRISMA) statement guideline for reproducibility, as previously demonstrated in literature(Page, McKenzie, *et al.*, 2021; Page, Moher, *et al.*, 2021).

Initially, the search strings outlined in Table 1 were applied to the Web of Science and Scopus databases (Pranckutė, 2021) to collect data, with the number of returned references also noted in the table. The search was conducted on October 30th, 2023, without applying filters to avoid bias due to missing results. The search strings were kept as simple as possible to minimize the risk of omitting relevant registers.

Table 1 – Query strings applied in Web of Science and Scopus databases.

Web of Science
TS=(("biobank*" OR "biorepositor*" OR "biological specimen bank*") AND ("improv*" OR "optimiz*")) Return: 2,431 items.
Scopus
TITLE-ABS-KEY (("biobank*" OR "biorepositor*" OR "biological specimen bank*") AND ("improv*" OR "optimiz*")) Return: 2,838 items.

From these 5,269 references, out of 2,164 duplicates, 3,105 registers remained for screening. Then, criteria were established to ensure the quality and consistency of papers across databases, accepting only full-length papers and excluding notes, letters, comments, short surveys, meeting abstracts, and book reviews. Additionally, publications were required to contain the search terms (Table 1) in the title, abstract, and author-supplied keywords, excluding those solely related to indexed keywords (e.g., Index Keywords in Scopus and Keywords Plus in Web of Science). This led to the elimination of 541 references, leaving 2,564 for screening.

Subsequently, titles, abstracts, and keywords of these references were screened based on three elimination criteria:

- Reason 1: Papers not prior to the distribution/disposal process and prior to the regulation process, excluding publications associating results/risk scores for diseases.
- Reason 2: Papers unrelated to improvements resulting from process implementation.
- Reason 3: Absence of reporting results before and after the improvement.

Criteria related to population, methods, design, and context were considered as results in this step.

This analysis resulted in the elimination of 1,541 references for reason 1, 813 references were eliminated for reason 2, and 52 for reason 3. From this step, 158 references were selected for full reading and bibliometric analysis to identify research trends and the current scenario of scientific development in the topic. Table 2 explains the selected metrics and indicators for discussions, and Figure 1 presents the adapted PRISMA flow chart for the method (Page, McKenzie, *et al.*, 2021; Page, Moher, *et al.*, 2021). This review protocol was also registered in Mendeley Data under DOI 10.17632/8kx4fb3g6j.1.

Table 2 – Metrics and indicators in the referred analysis.

Metrics and Indicators	Description
1- Publication by Year	Number of published works by year in the sample.
2- Journals	Number of journals in the sample and the number of references in each one. Only journals with two or more results were considered.
3- Co-occurrence of keywords	Network of co-occurrence of keywords with more than ten occurrences in the sample. The map was generated in VOSViewer software.
4- Process	Processes discussed in the papers, considering that one work can discuss more than one process. Categories: Regulation, Collection, Processing, Storage, Distribution / Disposal (McDonald, Velasco and Ilasi, 2010; Skeie *et al.*, 2014; Sanderson-November *et al.*, 2022; Uno, 2023).
5- Improvement Method	Improvement methods discussed in the papers, considering that one work can discuss more than one improvement process. Categories: Lean, Guidelines/Certification, Simulation, Strategy, Technology, Protocol.
6- Process vs. Improvement Method	Once the process and improvement methods analysis were conducted, it was also presented an analysis crossing both parameters, indicating the number of papers discussing some processes and improvement methods in jointly. The categories for Process and Improvement Method were also considered.

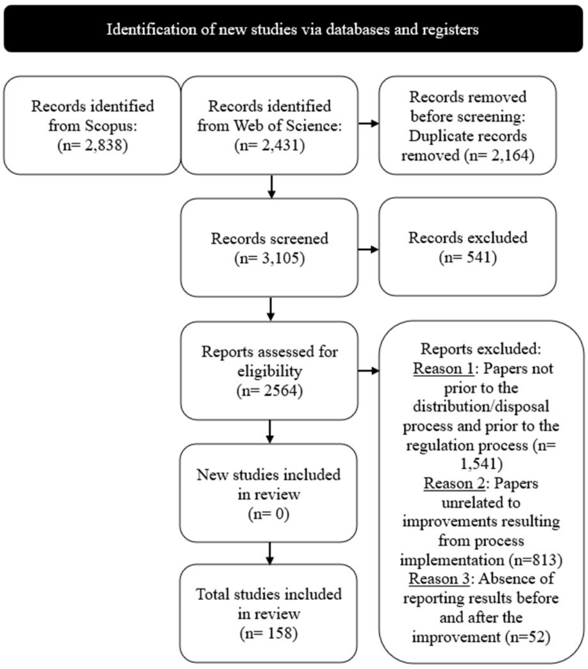

Figure 1 – PRISMA flow chart of the presented study (Page, McKenzie, *et al.*, 2021; Page, Moher, *et al.*, 2021).

For metrics “4- Process”, “5- Improvement Method”, and “6- Process vs. Improvement Method”, a general classification of papers was conducted according to the mentioned categories (Table 2). Each paper could be included in one or more categories related to process and improvement method, resulting in a total number of papers in each analysis higher than 158, as discussed in subsequent subsections. These bibliometrics will be further discussed.

RESULTS

Publication By Year

Figure 2 illustrates the evolution of the number of studies concerning improvement methods in biobanking and biorepository processes.

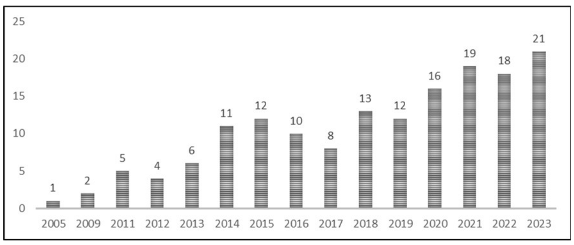

Figure 2 – Chart of publication years.

An initial effort was documented in 2005, with one published paper analyzing the best technical choice for a specific type of biobanks with research purposes (Nilsson *et al.*, 2005). This marked the first mention of the term in the sample, albeit from a “secondary” perspective, not necessarily focusing on processes but rather on an improvement impacting them. It was only in 2009 that two other works in the sample contributed to this aspect (Housseman *et al.*, 2009; Schulz *et al.*, 2009), focusing more on practical technologies to enhance conservation and treatment processes. Thus, the period 2005-2009 can be seen as the beginning of directed contributions.

From 2011 onwards, a more pronounced growth trend is observed, with a peak between 2014 and 2016, followed by irregular trends from 2017 to 2019. Despite a slight drop in 2022 compared to 2021, the highest number of publications in the sample was observed from 2020 onwards, indicating a new growth trend. Figure 2 demonstrates an increasing research interest during this period, with a more significant growth trend in recent years. The increased interest can be attributed to the development of the health sector, demanding more efficient and reliable structures, leading to discussions on process improvements in biobanks and biorepositories, which are crucial for medical and pharmaceutical advancements. Additionally, the period between 2020 and 2022 coincided with the COVID-19 pandemic, likely contributing to the heightened interest in the health sector, potentially impacting research. Nonetheless, the increasing trend in interest over time is evident.

Journals

Table 3 lists the journals identified in the sample with more than one occurrence and the number of works in each one, considering only journals with two or more published papers. Out of 158 works, 58 were included in this analysis, while the remaining 100 were found in different journals, including those from disciplines other than the areas addressed in this study.

Table 3 – Journals found in the present analysis with more than one occurrence.

Source Title Included	Publication Count	%
PeerJ	2	3%
Journal of Empirical Research on Human Research Ethics	2	3%
Cryo-Letters	2	3%
Animal Reproduction	2	3%
Scientific Reports	5	9%
PLOS ONE	6	10%
Cryobiology	6	10%
Animals	6	10%
Biopreservation and Biobanking	27	47%
Total	**58**	**100%**

Biopreservation and Biobanking feature the most papers, nearly 50% of the total, as expected, given its direct focus on biobanks and biorepositories, covering various scientific research aspects related to these structures. Following are Animals, Cryobiology, and PLOS ONE, associated with medical, pharmaceutical, and veterinary fields. Animals specifically caters to veterinary research, where biobanks and biorepositories play a crucial role. Cryobiology and PLOS ONE, on the other hand, cover medical research extensively, discussing biobanks and biorepositories in a broader context. Scientific Reports contain five published papers, while other journals each presented two. Table 3 highlights that research on process improvement methods in biobanks and biorepositories predominantly targets specific journals (Biopreservation and Biobanking), with additional research focusing on technical perspectives in both human and animal health, indicating targeted projects and ongoing research involving such structures.

Co-occurrence Of Keywords

Figure 3 illustrates the co-occurrence of keywords with more than ten occurrences, with different colors representing different clusters of the sample. The size of circles and labels corresponds to the number of publications using the specific keyword, while the distance and line thickness reflect the strength of the relation between keywords.

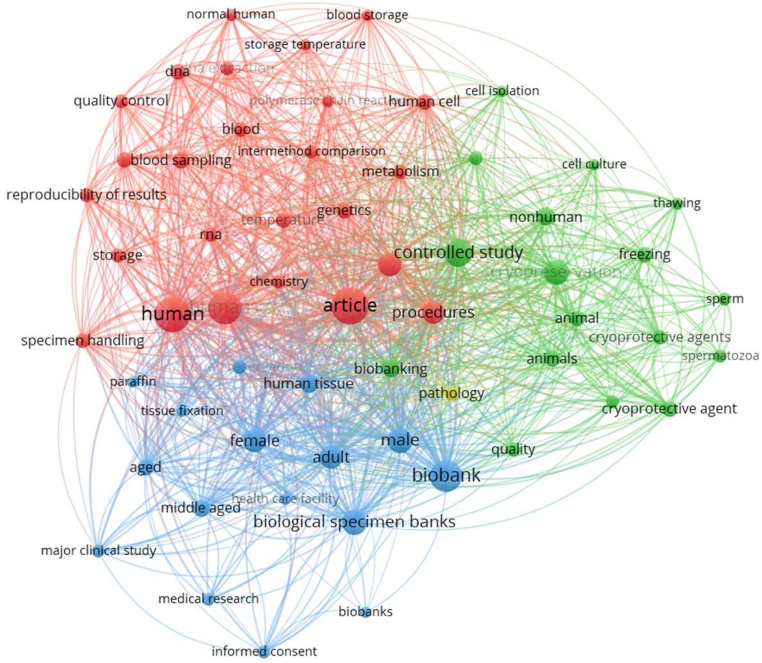

Figure 3 – Co-occurrence of all keywords with more than ten occurrences.

The red cluster pertains to publications discussing biological and biochemical concepts applied to specific medical and pharmaceutical procedures, involving technical research in the health sector that may include biobanks and biorepositories as supportive structures. Papers in this cluster discuss biobanks and biorepositories as support structures in more specific technical developments, such as projects aimed at scientific development in the health sector, with process improvements considered to support these results (Housseman *et al.*, 2009; Schulz *et al.*, 2009; Baatz *et al.*, 2014).

The second most prominent cluster is the green one, representing papers discussing techniques and procedures related to biobanks and biorepositories focusing on technology and structure. Terms such as “cryoprotective agents”, “cell culture”, and “sperm” refer to storage and analysis cultures, while “freezing” pertains to structural and technological aspects. Works in this cluster focus on process improvements concerning biobank and biorepository structures, discussing improvements applicable to any projects developed within these structures (Baatz *et al.*, 2014; King *et al.*, 2019; Howell *et al.*, 2023).

The third cluster (blue) encompasses wide-ranging discussions, incorporating keywords related to human and veterinary analyses resulting from developments in biobanks and biorepositories. Keywords such as “adult” and “male” refer to individual biological characteristics, while “human tissue” and “tissue fixation” relate to procedural perspectives. Some keywords refer to papers discussing biobanks from a broad structural perspective, focusing on their conceptual relevance and processes, such as “major clinical study”, “medical research” and “informed consent”. Notably, this cluster features an extensive use of “biobanks”, distinct from biorepositories. Examples include Georges et al. (2014), Cardoso et al. (2020) and Cai et al. (2022).

Lastly, there is a yellow cluster solely represented by the keyword “pathology”, referring to specific studies considering pathology facilities related to biobanks and biorepositories (Baatz *et al.*, 2014; Mandecki *et al.*, 2018; Rodríguez-Lee *et al.*, 2018; Verjans *et al.*, 2021; Alves *et al.*, 2022; Skoworonska *et al.*, 2023). These papers present a consistent use of the “pathology” keyword, distinguishing them within this small cluster.

Process

This subsection focuses on discussing bibliometrics related to processes and improvement methods. Initially, considering the perspective of processes in biobanks and biorepositories, Figure 4 highlights that a biobank or biorepository operational workflow includes five main processes and seven outputs. These classes were considered in the categories outlined in Table 2. Then, Table 4 presents data on the clusters of processes discussed in the literature and the number of papers related to each category.

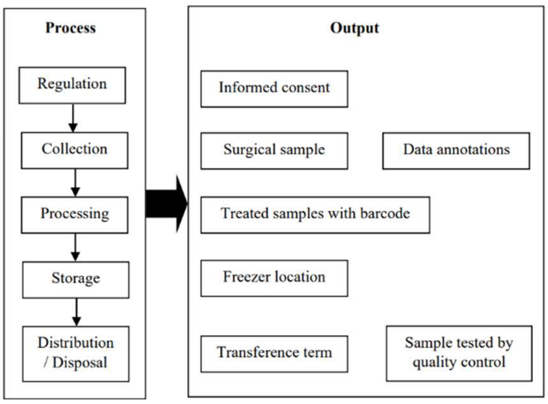

Figure 4 – Processes and outputs of biobanks and biorepositories.

Table 4 – Clusters of papers by process.

Categories	Publication Count	%
Processing	107	39%
Storage	97	35%
Regulation	28	10%
Collection	26	9%
Distribution/Disposal	16	6%
Total	**274**	**100%**

Table 4 indicates that most papers in the sample address processing in biobanks and biorepositories. Processing involves careful sample and materials handling and treatment, ensuring reliability and safety in biobank and biorepository operations, and is discussed in papers such as Raaijmakers et al. (2015) and Leonard et al. (2016).

The second significant group is related to storage processes, focusing on procedures and technologies to enhance storage capacity and efficiency, such as proposed by Abuja et al. (2015) and Kumar et al. (2023). Storage processes are fundamental in biobanks and biorepositories, requiring adherence to various protocols for environmental and operator safety.

Regulation and collection processes follow, with similar numbers of publications indicating their importance and direct impact on the structures and guidelines of biobanks and biorepositories. Regulatory processes involve stakeholders directing works towards comprehensive aspects of the health sector.

Lastly, distribution/disposal processes account for the minority of published papers, representing processes associated with the value chain of biobanks and biorepositories, addressing environmental and logistics discussions.

Improvement Method

Table 5 presents clusters of improvement methods discussed in the sample.

Table 5 – Clusters of papers by improvement method.

Categories	Publication Count	%
Protocol	100	60%
Technology	28	17%
Strategy	23	14%
Simulation	12	7%
Guidelines/Certification	2	1%
Lean	1	1%
Total	**166**	**100%**

As observed, protocols are the most frequently discussed improvement method, appearing in 60% of the papers, such as Heres, Troncoso and Paredes (2023) and Kumar et al. (2023). Protocols are significant and have garnered attention in scientific production. This may be attributed to the stringent and high-risk nature of biobanks and biorepositories, necessitating specialized procedures across various aspects. These procedures must be protocolized and tailored to specific situations. In this context, protocols influence governance management and the overall security of the structure, which contributes to their prominence.

In a second category, technology and strategy-related methods are included, representing 17% and 14% of the total sample, respectively. Papers in the former category involve technology and discuss potential enhancements in time, safety, operability, and the quality of results in biobank and biorepository processes. These works directly attribute technology to improvements and can be represented by papers such as Nilsson et al. (2005), related to technology, and Alves et al. (2022), relatively to strategy.

Papers discussing strategies adopt diverse approaches concerning biobanks and biorepositories, particularly focusing on their macro-level performance and how such actions could be optimized to yield other structural benefits. These discussions encompass methods that also consider aspects of the value chain and the ecosystem of biobanks and biorepositories, given their impact on focused strategies.

Following these categories, simulation is discussed in 7% of the papers, primarily applied to enhance predictability and process control in biobanks and biorepositories. These works, which are represented by papers such as Schuster, Tittmann and Wolf (2018) and Howell et al. (2023), offer practical applications with results typically linked to specified scenarios, contributing to the broader utilization of simulation methods for these facilities.

Lastly, methods of guidelines/certification and lean are represented by minimal percentages of the sample, suggesting they have not been a primary focus for researchers. Nonetheless, they may represent gaps in discussions and future research avenues. For instance, lean is a well-established concept in various domains that could potentially enhance biobanks and biorepositories.

Process vs. Improvement Method

To synthesize the previous analyses into an overview, Table 6 presents the clusters of papers categorized by process versus improvement method.

Table 6 – Clusters of papers by process vs. improvement method.

Process	Improvement Method	Publication Count	%
Regulation	Simulation	2	1%
Collection		4	1%
Processing		3	1%
Storage		9	3%
Distribution/ Disposal		1	0%
Regulation	Technology	6	2%
Collection		11	4%
Processing		9	3%
Storage		15	5%
Distribution/ Disposal		12	4%
Regulation	Protocol	0	0%
Collection		7	2%
Processing		93	32%
Storage		75	26%
Distribution/ Disposal		1	0%
Collection	Lean	1	0%
Processing		1	0%
Storage		1	0%
Distribution/ Disposal		0	0%
Regulation	Strategy	19	7%
Collection		3	1%
Processing		2	1%
Storage		2	1%
Distribution/ Disposal		2	1%
Regulation	Guidelines/ Certification	1	0%
Collection		2	1%
Processing		2	1%
Storage		2	1%
Distribution/ Disposal		2	1%
Total		**288**	**100%**

Several points previously discussed are corroborated by the data presented in Table 6. “Processing Protocol” (32%) and “Storage Protocol” (26%) emerge as the primary areas of interest in the literature. This underscores the emphasis on well-defined and stringent protocols to enhance control, particularly in processing and storage processes. These enhancements contribute to increased security and capacity for biobanks and biorepositories, garnering significant attention in the sample.

Following these categories, “Regulation Strategy” (7%) appears at a reasonable distance. This category pertains to works that analyze biobanks and biorepositories from a strategic perspective, considering holistic results and regulatory aspects. Such discussions are pertinent for defining the performance of biobanks and biorepositories.

Another notable category is “Technology” improvement method, which is applied to “Storage” (5%), “Distribution/ Disposal” (4%), and “Collection” (4%) processes. These papers focus on implementing technology in real-world scenarios, impacting various processes in biobanks and biorepositories. Technology offers benefits such as improved efficiency, safety, operability, and quality of results in processes, thereby shaping this research trend. Examples in this group include Mandecki et al. (2018) and Verjans et al. (2021).

Additionally, smaller groups of papers address specific cases, such as “Storage Simulation” (3%) and “Collection Protocol” (2%), along with other groups representing 1% of the sample. These findings suggest that the literature predominantly focuses on the three trends.

DISCUSSION

The proposed bibliometric analysis provided an overview of the referenced literature and revealed several key findings. Firstly, it is noteworthy that the results indicate a significant increase in research interest in the subject in recent years. Initially, this topic received little attention but gradually gained momentum. The analyzed sample can be deemed sufficient and demonstrated that the primary journal for research and publications on the topic is Biopreservation and Biobanking, which is specifically focused on discussions regarding such structures, as illustrated in Figure 2.

The co-occurrence of keywords highlighted three main clusters in the sample, yet the research trends are not disparate among these clusters. The first cluster adopts a supportive perspective of biobanks and biorepositories in specific processes and outcomes, presenting more technical discussions from the health area. The second group focuses on discussions related to techniques and procedures in biobanks and biorepositories, emphasizing technology. These papers concentrate on process improvements within the framework of biobank and biorepository structures, discussing enhancements applicable to any project developed within these structures. The third identified cluster presents connection perspectives to the other two, discussing technical and procedural analyses in biobanks and biorepositories and/or structural perspectives, with terms that can connect to the perspective of the "protocol" improvement method defined in Table 5, for example. Lastly, it is worth noting the existence of a fourth cluster represented by only one keyword (pathology), involving this specific perspective in some part of the sample.

Following this initial analysis, the categorization by processes and improvement methods yielded additional results for discussion. In the context of processes, the literature shows a considerable interest in processing and storage processes, likely due to their operational relevance and associated risks. It is essential for biobanks and biorepositories to have well-defined rules and protocols for safety and care when handling and storing materials, which may have influenced the results found in Table 4.

Moving forward in this perspective, the "protocol" improvement method garnered the most research attention in the present sample (Table 5), highlighting the emphasis on well-defined methods and rules that enhance the management and governance of biobanks and biorepositories. Other categories of improvement methods are less prominent, underscoring this finding. In the case of "lean" and "guidelines/certification", there appears to be a potential gap for future research.

Finally, considering the analysis of process versus improvement method, the results indicate three main research trends in the literature, corroborating previous analyses. Protocols, especially those related to processing and storage, received the most attention, followed by strategic discussions concerning the regulatory aspects of biobanks and biorepositories. Technology is predominantly applied across different processes and is also a relevant discussion point, although not as prominent as protocol discussions.

CONCLUSIONS

This study provided an overview of research trends in improvement methods related to biobanks and biorepositories' processes through bibliometric analysis derived from a PRISMA systematic review. There is a noticeable increase in research interest over time, leading to significant growth, particularly in recent years. The literature highlights research trends in the structural and technological aspects of biobanks and biorepositories, or in analyzing such structures in support of specific technical projects and developments, thereby undergoing improvements in their processes.

Storage and processing protocols have received greater research attention, reflecting a latent interest in improving aspects of security, governance, and efficiency of biobanks and biorepositories. Regulation strategies are also discussed in a significant portion of papers, and technology features specific applications aimed at contributing to the wide panorama of biobanks and biorepositories, addressing various discussed processes.

The present paper aimed to provide an overview of research developments and trends in process improvement for biobanks and biorepositories. These are often correlated with quality management systems that enhance processes in biobank and biorepository operations. In this sense, there are correlations between these topics that can be considered to improve the mentioned processes. Regarding regulation, it is expected that more mechanisms at different levels must be established and implemented for various contexts, extending beyond the specific institutions that currently regulate this field.

A potential gap in the literature is represented by the “distribution/disposal” process and the “lean” and “guidelines/certification” improvement methods. Both had little scientific production in the sample. However, considering that these processes and methods are well-established in literature across diverse areas, indicating consolidated results, these trends can be explored in biobanks and biorepositories to generate solid contributions in improvement methods for such structures.

Some limitations are evident in this paper. Firstly, the subject is represented only through the adopted English keywords in the processes from regulation to distribution/disposal in biobanks or biorepositories. Although such processes were included among the results, the focus varied, resulting in lower representation in the sample. Future research is recommended on this subject, especially studies debating regulation in biobanks and biorepositories.

Similarly, a second limitation relates to the oriented focus on processes and improvements, but not on regulation itself, which also leads to lower representation of these processes. Although this was a methodological choice, it does not negate the suggestion for studies debating regulation in biobanks and biorepositories.

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Overcoming Barriers to Foster Innovation in Collaborative R&D Projects

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STRUCTURED ABSTRACT

Purpose - In today's highly competitive business environment, companies face the challenge of survival in the context of market saturation. Failure to innovate and adapt can lead to stagnation and inability to generate value. Collaborative R&D projects have emerged as a solution to foster innovation by leveraging distinct knowledge and resources. Effective innovation management within collaborative R&D projects requires a deep understanding of collaborative dynamics and a creation of environments conducive to creativity and disruptive solutions. This paper aims to analyze barriers to attain innovation as an outcome of collaborative R&D projects and identify strategies to overcome them.

Design/methodology/approach - A case study method was employed. A qualitative multi-method approach was adopted, which included interviews, document analysis, and participatory observation of key stakeholders.

Findings - The research uncovered several significant barriers and corresponding strategies for overcoming them within collaborative project consortia. Among the major barriers identified were the lack of confidence, financial and lack of trust. The main strategies identified to overcome them were related to alignment workshops, the need for demonstration, the lack of qualified personnel and bringing teams together.

Strategies for overcoming these barriers involved actions such as ensuring alignment workshops among partners, by conducting demonstrations, providing training, hiring qualified personnel, fostering team cohesion, appointing a moderator during meetings; and raising project awareness among individuals and partners.

Originality/value - The main value of this paper lies in the proposal of strategies to overcome the barriers to foster innovation in collaborative R&D projects.

Keywords: Barriers, Strategies, Innovation Management, Project Management, Collaborative R&D Projects

Paper type: Case Study

INTRODUCTION

The world is constantly changing, and in an environment with so much disorder, project management plays a crucial role in helping companies achieve an end goal, ensuring that they do so on time and within budget (Fernandes, O' Sullivan, et al., 2020).

Dwight Eisenhower mentioned at a 1957 conference on National Defense, "Plans are nothing, but planning is everything" (Hadley, 2009). The world changes, and our plans change with it. Requirements change, people get sick, and suppliers are late. However, by investing time in analyzing different strategies, creating different scenarios, and defining a plan, success is closer to being achieved.

In a business environment marked by a saturated market and fierce competition, the survival of companies becomes a permanent concern. Those that fail to innovate and adapt run the risk of stagnation and become incapable of generating value through their innovations. In this challenging scenario, collaborative projects have emerged as an effective way of boosting innovation, bringing together diverse knowledge and resources. Innovation management in collaborative projects not only requires an in-depth understanding of collaborative dynamics, but also the ability to create environments conducive to creativity and the development of disruptive solutions (Fernandes, Domingues, et al., 2021; Fernandes, Dooley, et al., 2021).

The continuous implementation of innovation in companies is often confronted with obstacles arising from internal and/or external factors (Madrid-Guijarro et al., 2009). Investments in innovation by companies are made more difficult by daily routines and habits that prevent original thinking (Scott et al., 2019). Hadjimanolis (1999) identifies factors that inhibit innovation, categorized as barriers to innovation, focusing on the complexities throughout the innovation process. These barriers can be internal or external (Fernandes, Araújo, et al., 2020; Hadjimanolis, 2003; Madrid-Guijarro et al., 2009; Piatier, 1984; Stanislawski & Olczak, 2010).

A study carried out for Accenture by the Economist Intelligence Unit in 2007 revealed barriers to innovation, including needs related to the frequency, timing and speed of innovation, as well as challenges in changing organizational culture and reducing time to market (Accenture, 2008). Internal barriers, mainly associated with financial and human resources and organizational resistance, prove to be particularly challenging (Hadjimanolis, 2003; Madrid-Guijarro et al., 2009). Human resources become a significant internal barrier when the organizational culture lacks support for innovation. Studies emphasize the role of employee resistance arising from communication failures, existing corporate norms, lack of qualifications, insufficient skills and commitment of managers to innovation (Kane et al., 1999; Osterman, 2000; Zwick, 2002). External barriers include a lack of information on technologies and markets, difficulties in establishing partnerships and a lack of political initiative. For European countries, a lack of information and uncertainty about policies to support innovation give rise to significant barriers (Frenkel, 2003; Hadjimanolis, 1999).

The impact of barriers to innovation can be exacerbated by the persistence of challenges over the years. Baldwin et al. (2003) and Madrid-Guijarro et al. (2009) mention that small and medium-sized companies are the most affected by barriers to innovation. However, these companies are also heavily burdened by other types of barriers related to knowledge and the market.

Innovation in collaborative R&D projects has not only become an imperative for companies in a constantly changing environment, but it has also brought with it a series of challenges. These challenges include the increasing complexity of products, shorter lifecycles, higher research and development (R&D) costs, rapidly changing markets and geographically dispersed innovation teams (Dutra et al., 2010). In response to these challenges and in order to improve their innovative capabilities, certain companies have chosen to create innovation networks. The purpose of these networks is to carry out co-innovation in collaboration with suppliers, customers and other potential partners (Kuppers & Pyka, 2002; Valk et al., 2011).

The integration of appropriate participants in the new product development process triggers the generation of genuinely innovative designs, products and services, taking advantage of specific knowledge and experience (Kain et al., 2009). Innovation networks promote knowledge sharing and significantly reduce the time and costs associated with acquiring information, which results in the success of innovative initiatives.

Vertical collaborative innovation, which involves collaboration with suppliers and customers, offers companies the opportunity to gain insights into new technologies, markets and process improvements, resulting in a more substantial impact on both product innovation and process optimization (Miotti & Sachwald, 2003; Whitley, 2002).

Although collaboration, coordination and cooperation are often used interchangeably, it is important to note that there are significant differences between them. Collaboration is usually understood as a higher level of integration, involving lasting relationships between stakeholders who share similar responsibilities and authority in the project. This differentiates it from coordination and cooperation, which often involve informal relationships lacking a defined mission, structure or joint effort.

Collaboration is fundamental to the success of collaborative R&D projects, providing a solid basis for sharing ideas and innovation (Viel et al., 2012). Therefore, the main objective of this paper is to analyze the barriers to innovation in collaborative R&D projects and identify strategies/practices for overcoming them.

RESEARCH METODOLOGHY

Based on the pragmatist philosophy, which seeks to solve practical problems and contribute with solutions to future practice, this study adopted an inductive approach, using qualitative methods such as interviews to explore the phenomenon of integrating innovation management into collaborative R&D projects (Saunders et al., 2019). The research strategy chosen was a case study, allowing a detailed analysis of the R&D collaborative project INOV.AM - Innovation in Additive Manufacturing project, with the aim of deepening knowledge about innovation management and overcoming barriers to innovation in similar contexts. The study adopted a multi-method qualitative approach, combining interviews, document analysis and participant observation to collect and analyze non-numerical data (Saunders et al., 2019). The research was cross-sectional in nature, carried out over 14 months, with a defined start and end, without longitudinal comparisons. Data collection techniques included participatory observation, document analysis and semi-structured interviews within project members. Conducting pilot interviews was key to adjusting the interview questions and strategies to ensure effective data collection. The interviews provided an in-depth understanding of the innovation methods, daily routines and challenges faced by the interviewees.

Over the course of December 2023, nine interviews were conducted and analyzed with professionals involved in the INOV.AM project, covering different levels of the organizational hierarchy, such as members of the coordination team, the project management office (PMO) team, work package managers and technical team members. The Microsoft Office Excel tool and MAXQDA software, which is specialized in qualitative analysis (VERBI, 2022), were used to analyze the data obtained.

The qualitative analysis of the interviews involved several steps, including transcribing the interviews in full, familiarizing oneself with the content to understand the general context, coding the text segments using MAXQDA software, reducing the data to a summary of the coded findings, constantly comparing the data to identify patterns and themes, taking notes during the analysis process, verifying the findings with the respondents and, finally, presenting the conclusions reached. This approach allowed for an in-depth analysis of respondents' answers, going beyond numerical data and exploring the complexity of the information provided (Indeed Editorial Team, 2023).

RESULTS

Data

In order to gain a better understanding of the interviews, transcripts were made of each one and a detailed review of the transcripts was carried by the researchers and interviewees. In order to efficiently organize the insights gained, a comprehensive table of categories, subcategories and the topics within the subcategories was also drawn up using Microsoft Excel.

Following this familiarization, the data was divided into two categories:

- "Interviewee" where some information was taken from each participant, so that a characterization of each one could then be made;
- "Collaboration" where information related to collaboration between companies was collected.

This approach allowed for the systematic categorization of the main themes and concepts conveyed by the interviewees. The resulting table simplified not only the visualization and understanding of the data, but also served as a fundamental tool in preparing the data for subsequent analysis in the specialized software (MAXQDA).

After this familiarization of the data and the first analysis, it was possible to move on to the next phase of coding, which led to the branching of the categories and subcategories represented in the following figures.

Figure 1 shows some subcategories in the "Interviewee" branch. These serve to detail the interviewee's profile, as well as their background (gender, academic background, position held and years in the company).

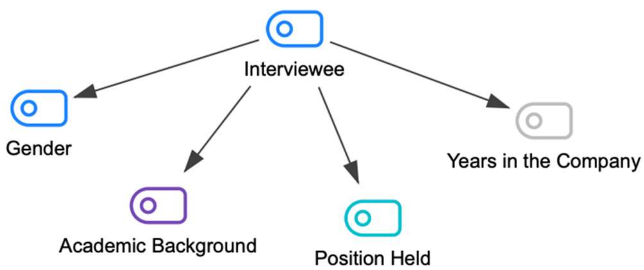

Figure 1 – "Interviewee" Category

In the "collaboration" branch, two subcategories can be analyzed (Figure 2):

- "Barriers" is divided into eight subtopics, where the interviewees reflect on the barriers/challenges to innovation in collaborative projects;
- "Practices to Combat Barriers" which, as the name suggests, are practices, in other words tools/techniques that the interviewees mention that can help overcome the barriers they mentioned.

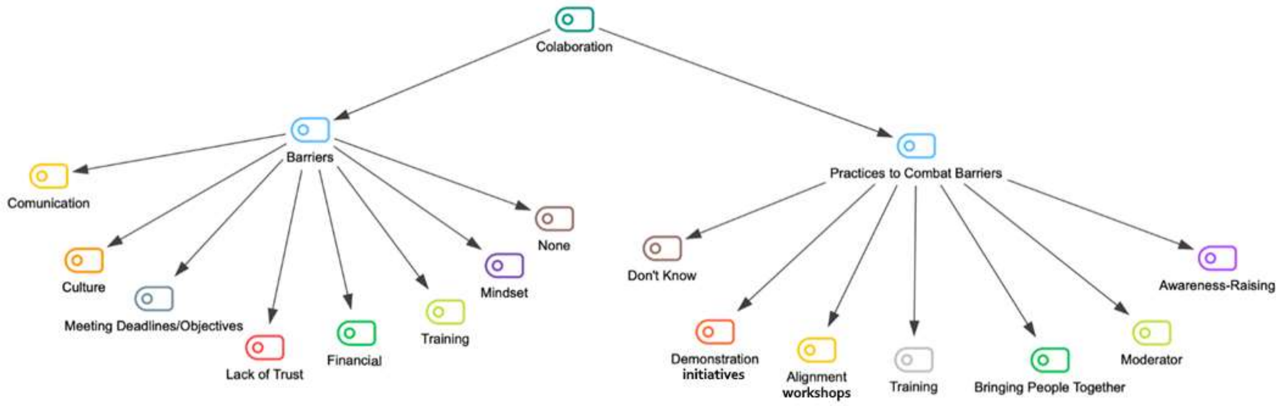

Figure 2 – “Collaboration" category

Interviewees Characterization

The interviewees were selected based on specific criteria aimed at ensuring a diverse representation of the members of the case study. For this reason, it was made a brief characterization of the interviewees by gender, academic background, position held in this project and how long they have been with their current company (INOV.AM partner entities).

22% of participants are female and 78% male. This fact of male supremacy in projects has been noted by other researchers such as Fernandes et al. (2014). All of the participants have higher education: 22% have a bachelor's degree; 34% have one or more postgraduate degrees; 33% have a master's degree; and 11% a doctorate.

Regarding the professional position of each interviewee, 11% are members of the project technical teams, 11% are members of the Project Management Office (PMO) team and 11% are members of the Project Coordination team, while 67% are project leaders. Most of the interviewees have been with the company for more than ten years. Only one of the interviewees has been with the company for less than a year, two interviewees between one and five years and one interviewee between five and ten years.

Barriers

The interviewees were asked "What are the main barriers to innovation in collaborative R&D projects?" and the answers obtained gave rise to eight subcategories, each represented by a color in Figure 3:

- Communication (yellow) - includes all mentions of communication failures between consortium members;
- Culture (orange) - includes references to different types of work culture, both nationally and internationally, as well as between organizations;
- Meeting deadlines/objectives (gray) - when the respondent mentions a lack of commitment in carrying out scheduled tasks and activities;
- Lack of trust (red) - when respondents mention that organizations are afraid to share their knowledge and know-how. Not only in sharing, but also in not being able to be sure that the work is going to be done well, and being able to "disconnect" from certain deliverables;
- Financial (green) - encompasses the answers given around financial investment. The investment that is needed for this type of (collaborative) project and the return it will bring, particularly in the case under study, due to the fact that it is part of the Recovery and Resilience Program and is dependent on public funding support;
- Training (light green) - encompasses all references to training and knowledge in different areas;
- Mindset (purple) - when people's way of thinking is mentioned;
- None (brown) - when the interviewee sees no barriers to innovation in collaborative R&D projects.

Figure 3 shows a more detailed analysis of what each interviewee said.

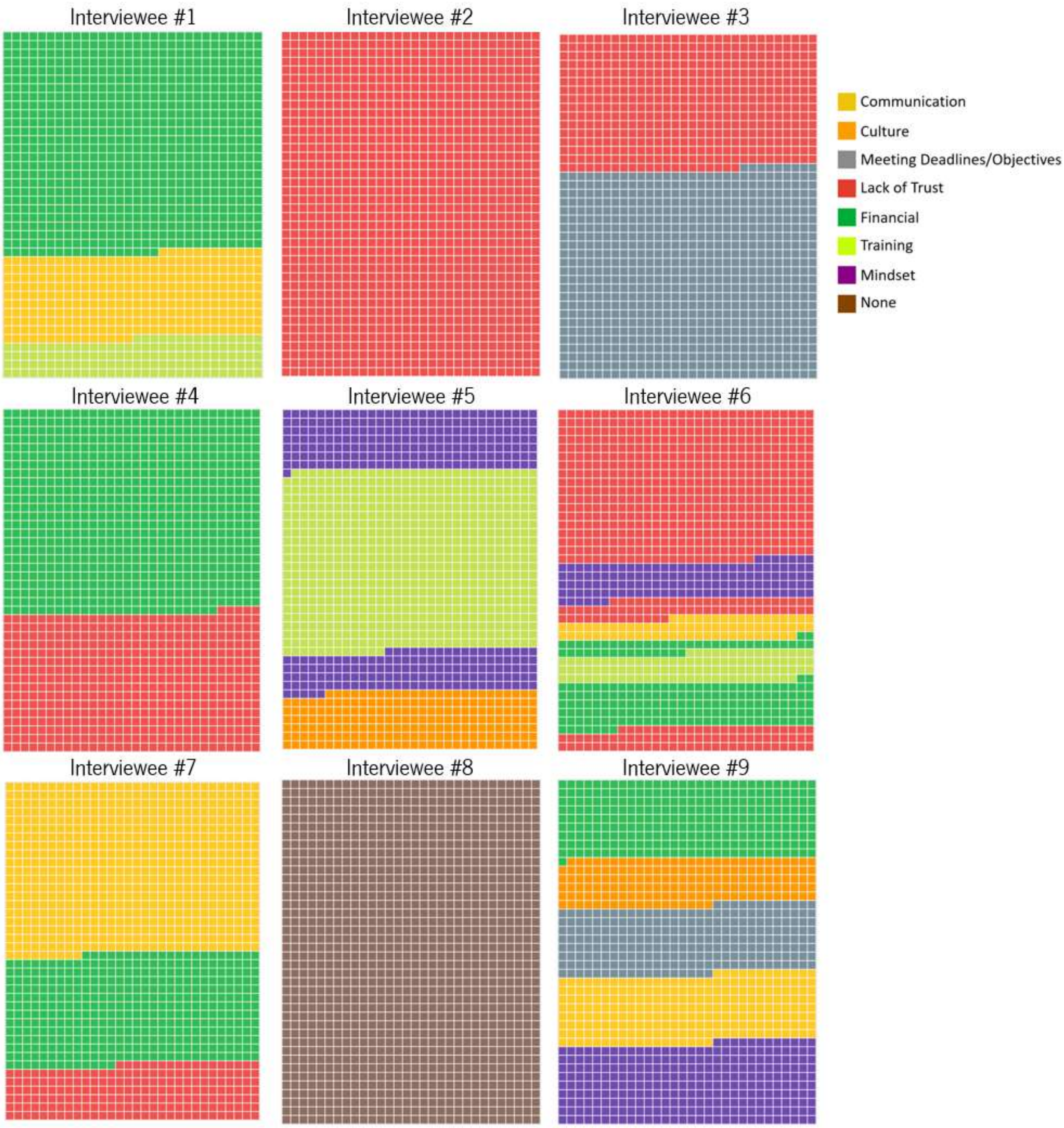

Figure 3 - Barriers to Innovation in Collaborative R&D Projects Mentioned by Interviewee

Figure 3 reveals that the color red – "Lack of Trust" – is the most predominant, followed by the subcategory "Financial" (green).

By analyzing the answers obtained by each interviewee, it is possible to see that the main barrier that Interviewee #1 mentions is related to the financial subcategory, he stated: "I would say that the big issue for me is that innovation happens when we make money out of it". He also mentions problems in terms of communication and training: “there’s still a lot of work to be done here (...), to know how to communicate with companies, to train people to use real demonstrations, to evaluate the processes themselves and the impacts of these processes”.

Interviewee #2 focuses solely on the lack of trust: “...the barrier is the fear of losing our know-how”, which is in line with Interviewee #3, who stated: “The first barrier is always the lack of trust between organizations...”, and adds the barrier “Meeting deadlines/objectives”, noting “Meeting deadlines in accordance with those agreed is also another barrier. Understanding ... what the project is actually about, what the objective is”.

Interviewee #4 mentions only two barriers. Curiously, these two barriers are quite prevalent in Interviewee #6 answers, namely funding (integrated in the subcategory “Financial”): “... many of our companies are ‘limited’ to whether or not there is funding”, and lack of trust: “we are always afraid that when I have a company that does more or less the same thing as me, I will say what I do and how I do it and associate myself with that company”. However, Interviewee #6 also mentions communication, training and people’s mindset, which go hand in hand with the barrier mentioned by Interviewee #5, who stated: “People’s mindset and the companies are very important and the other is the culture, also a bit of a mindset, but the company’s culture”.

Interviewee #7 mentions communication failures: the “lack of alignment between the promoters and the outcome of the project”, and the focus on funding: “the focus is more on funding than on the outcome of the research”, as well as a lack of trust, as the main obstacles and challenges to overcome.

Oddly, Interviewee #8 said there were no barriers to innovation in collaborative projects.

Like Interviewee #7, Interviewee #9 mentions limitations in terms of communication and financial issues, adding culture, meeting deadlines/objectives and people’s mindset: “...I think it’s a bit of a change in mentality”.

Figure 4 shows the number of times each of the eight subcategories under analysis was mentioned, as well as the percentage they correspond to.

	Nº de vezes Mencionado	Percentagem
Communication	4	8,2%
Culture	3	6,1%
Meeting Deadlines/Objectives	4	8,2%
Lack of Trust	15	30,6%
Financial	10	20,4%
Training	4	8,2%
Mindset	6	12,2%
None	3	6,1%

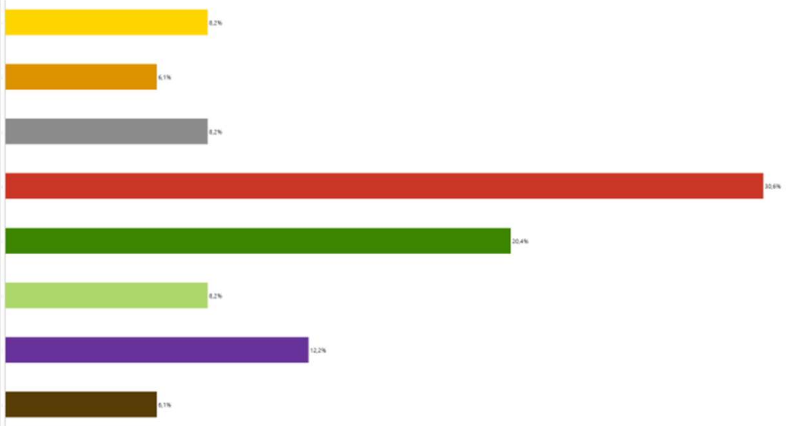

Figure 4 – Main Barriers to Innovation in Collaborative R&D Projects

The subcategory "Lack of Confidence" is the one with the most mentions, with a value of fifteen times (30.6%), followed by "Financial" which was mentioned ten times (20.4%).

The subcategories with the lowest value are "None" and "Culture", which were mentioned three times each, corresponding to 6.1%.

Strategies/Practices to Overcome Barriers

For the barriers mentioned in the previous section, the question was asked: "What strategies/practices could be implemented to overcome the barriers you mentioned?", thus creating the topic "Strategies/Practices to Overcome Barriers", which is divided into seven subcategories:

- Don't know (brown) - when the interviewee says they don't know any strategy/practice to overcome the barrier;
- Alignment Workshops (yellow) - involves the entities being aligned on the objectives of the project, the end product, everyone's tasks, deadlines, risks, among others;
- Demonstration Initiatives (orange) - includes the demonstration of cases: the execution of case studies and all that this entails;
- Training (gray) - when interviewees mentioned the need for training and hiring qualified people;
- Bringing People Together (dark green) - when interviewees mentioned bringing teams together and all kinds of examples that come from this (lunches, collective activities, face-to-face meetings, etc.);

- Moderator (light green) - when interviewees mentioned the existence of a moderator at meetings;
- Awareness raising (purple) - when interviewees mentioned raising awareness among people and organizations about certain aspects, one of them being the timings required for each phase of the project.

Figure 5 shows a more detailed analysis of what each interviewee mentioned.

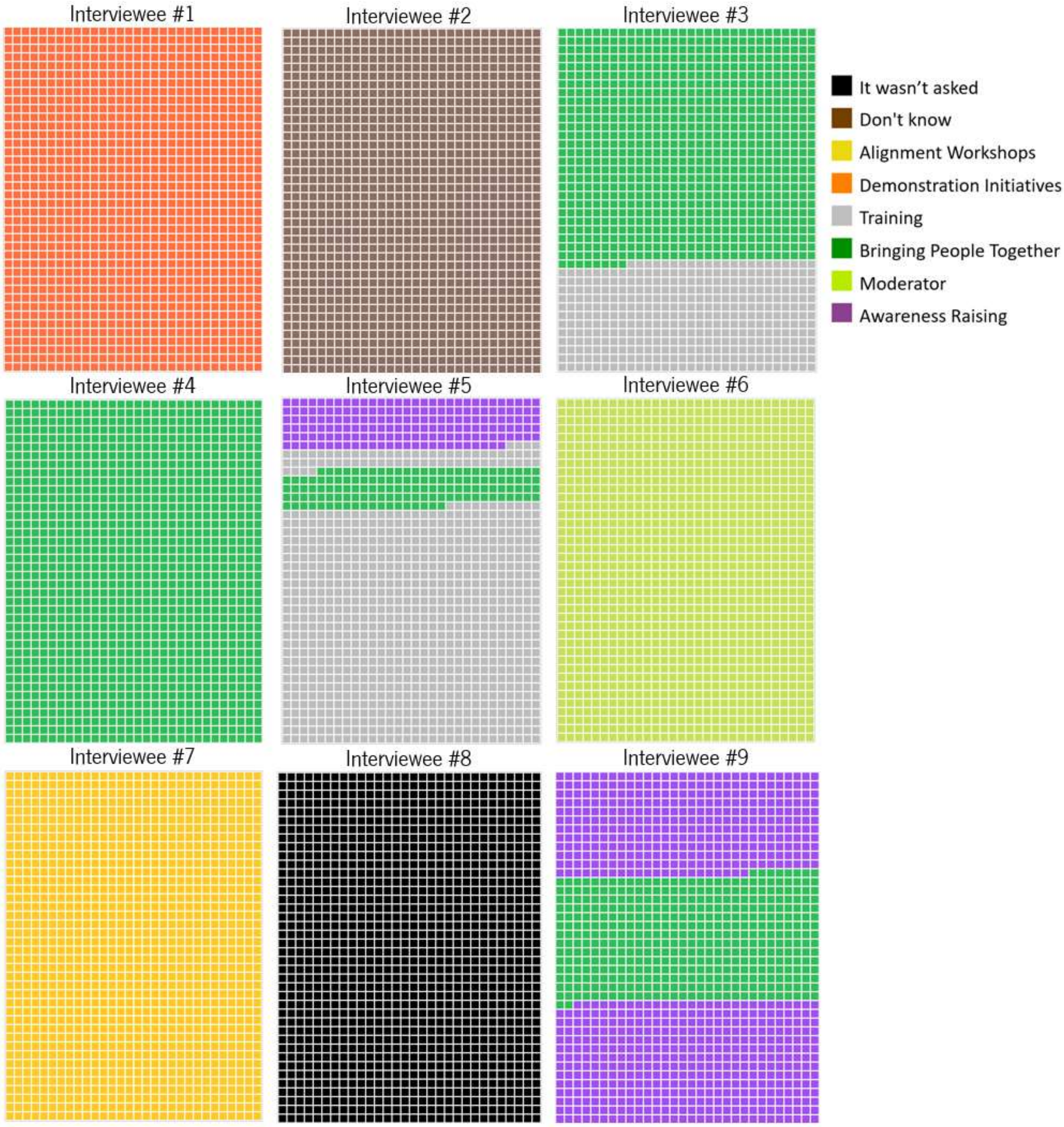

Figure 5 – Practices Mentioned by Interviewees

In Figure 5 it can be seen that the strategy/practice that Interviewee #1 mentions is demonstration initiatives: "...the best tool is always to demonstrate...". Interviewee #2 states that he doesn't know of any practice that could be put into practice, while Interviewee #3 mentions "Bringing people together": "...people need to spend more time together..." and "Training".

Interviewee #4 mentions the practice of "Bringing People Together" by mentioning: "A lot of the time it's about creating these links between organizations, between people, because organizations are, at the end of the day, the people who run them...", while Interviewee #5 mentions this practice, but adds "... a bit of awareness-raising, a bit of training,...", putting more emphasis on training.

Interviewee #6 highlights the topic of "Moderator": "Basically, there's a moderator, there's brainstorming, there's an animator or an enhancer, an enabler of the relationship", and Interviewee #7 mentions the practice of "Alignment workshops" where he referred: "...at the end of the day, everything comes together, which is the alignment of expectations...".

Interviewee #8 mapping is in black, since he didn't mention any of the barriers to innovation in collaborative R&D projects in his previous question.

Finally, Interviewee #9 mentions practices related to "Awareness Raising" and "Bringing People Together" when he mentioned: "...a bit of awareness, because we have more and more contacts with these companies, we're strengthening relationships, raising awareness of these issues...".

Figure 6 shows that each of the subcategories "Alignment Workshops", "Demonstration Initiatives", "Training" and "Bringing people together" was mentioned seven times during all the interviews, corresponding to 18.9%. The subcategory "Moderator" was mentioned five times and "Awareness Raising" only three times, corresponding to 13.5% and 8.1%, respectively.

	Nº de vezes Mencionado	Percentagem
Don't know	1	2,7%
Alignment Workshops	7	18,9%
Demonstration Initiatives	7	18,9%
Training	7	18,9%
Bringing People Together	7	18,9%
Moderator	5	13,5%
Awareness Raising	3	8,1%

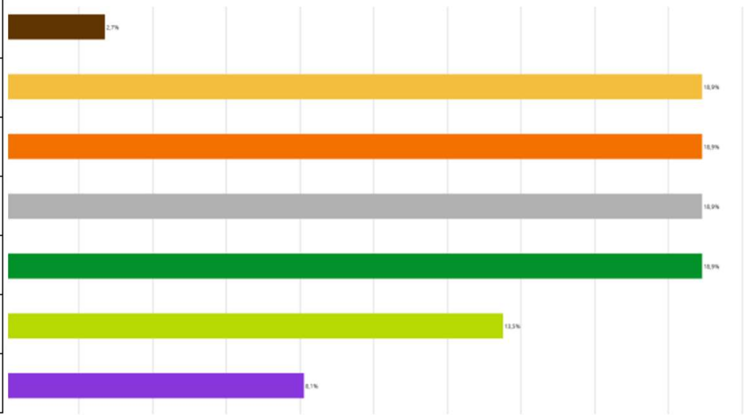

Figure 63 – Strategies/Practices to Overcome Barriers to Innovation in Collaborative R&D Projects

After asking the questions about the barriers to innovation in collaborative R&D projects and what strategies/practices could be used to overcome them, it can be concluded that the strategies/practices that include the subcategory "Alignment Workshops" are more in line with the barrier "Meeting Deadlines/Objectives"; those that include the subcategories "Training" and "Demonstration Initiatives" are more in line with the barrier "Training"; the subcategory "Bringing People Together" with the barriers "Lack of Trust" and "Communication". The subcategory "Awareness Raising", although it manages to answer a little to all the barriers, is more related to "Culture" and "Mindset" and the subcategory "Moderator", applied correctly, would manage almost all the barriers mentioned by the interviewees.

Proposed Strategies/Practices for Overcoming Barriers

In response to the research objective, which aims to analyze the barriers to innovation in collaborative projects and identify strategies/practices to overcome them, the analysis carried out provided significant information.

In this analysis, section *Practices to Overcome Barriers* highlights the relevance of the subcategories "Alignment Workshops", "Demonstration Initiatives", "Training" and "Bringing People Together", which were the most mentioned by the interviewees. In this context, practices are proposed to overcome the obstacles identified in order to boost innovation in collaborative projects.

Firstly, it is proposed that **Alignment Workshops** be held, which is essential for all stakeholders to agree on the project's objectives, deliverables and milestones.

Secondly, the holding of **Demonstration Initiatives**, because by demonstrating relevant case studies to team members, the sharing of ideas and experiences is stimulated, which encourages an environment conducive to innovation.

Thirdly, it is proposed to **Invest in Continuous Training Programs** in order to improve team skills. Teams should be encouraged to take part in courses, workshops and webinars in order to achieve an upward learning curve.

Finally, promote **Integration and Collaboration Events** such as lunches, team building activities and face-to-face meetings, in order to provide an informal space for the team to get to know each other better, strengthen bonds, promote trust, and facilitate more agile communication. By integrating these practices, collaborative projects will benefit from an environment that supports innovation and strengthens effective communication, promoting the sustainability of the partnership.

This research was performed by the study of only one case with its unique characteristics. Given the limited sample size with low representational degree, caution must be exercised against extrapolating the findings to other contexts without a thorough analysis of those contexts. Future research should be conducted to more case studies to allow the generalization of results.

CONCLUSIONS

The focus of this paper was the analysis of barriers to attain innovation as an outcome of collaborative R&D projects and identify strategies to overcome them, based on a specific case study - the INOV.AM Project - Innovation in Additive Manufacturing, to understand the context, the main barriers and challenges faced in terms of innovation in this specific context. Thus, the main contributions of this research consisted of presenting strategies/practices to be used to overcome the barriers identified in innovation management.

To achieve the main objective of this article: "analyze the barriers to innovation in collaborative R&D projects and identify strategies/practices for overcoming them", an in-depth analysis of the literature, as well as of the INOV.AM case, namely through participant observation by the researcher, during the course of this research work, was fundamental. The analysis of various project documents and work packages was also crucial, as well as the semi-structured interviews to better understand and analyze the case under study.

From the detailed analysis, it can be concluded that to overcome barriers linked to the commitment made by the partner entities, namely, commitment with deadlines, objectives or deliveries, it is proposed to hold alignment workshops. For barriers related to the lack of training and qualified human resources, it is considered important to develop demonstration initiatives, and also to create ongoing training programs. Finally, for barriers related to the fear of sharing know-how, the insecurity of the work done by partners and communication failures, integration and collaboration events should be promoted. By integrating these practices, collaborative R&D projects will benefit from an environment that supports innovation and strengthens effective communication, promoting the sustainability of the partnership.

For future work, it would be valuable to conduct interviews with a larger sample. Since the sample size in this study is small, the results cannot be generalized, nor can cross-analyzes be made of variables such as gender, position in the project, or other variables, as they would not be representative. Therefore, exploring the diversity of participants in the project would provide an important and enriching analysis.

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The impact of culture on the acceptance of Industry 4.0 technologies in Greek organisations: An empirical investigation of a lean digital transformation

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STRUCTURED ABSTRACT

Purpose- In the digital era, studying how employees interact with technology and what the role of management can be to foster this interaction are of the utmost strategic importance. In this sense, the purpose of this study is to measure the impact of a lean and digital form of organisational culture on the intention to use Industry 4.0 technologies.

Design/methodology/approach- This research draws on the socio-technical systems and the technology acceptance theories to analyse and measure people's attitudes on the road to digital transformation supported by lean principles. A comprehensive review of the literature led to the composition of a research model that highlights the intention to use digital technologies as a composite construct of effort expectancy, performance expectancy, and social influence moderated by user resistance and anxiety. An empirical survey was launched in Greek organisations over a three-month period. 452 usable responses were collected by employees of different positions and ranks. The validity of the integrated measurement model was then confirmed using partial least squares structural equation modelling (PLS-SEM).

Findings - Research limitations/implications- The results show a positive and significant relationship between lean-digital organisational culture and the intention to use Industry 4.0 technologies. Future research could test the model in other locations to increase generalisability.

Practical implications- From a practical viewpoint, the validated model can aid decision-makers by providing a foundation for developing targeted action plans to facilitate technology adoption.

Originality/value- This study is pioneering in bringing together the technology adoption intention and a particular organisational culture that merges lean management and digital transformation, offering novel insights to managers and researchers.

Keywords: organisational culture; digital transformation; Industry 4.0; lean management; UTAUT; theory of acceptance; socio-technical system

Paper type: Research paper

INTRODUCTION

The integration of Industry 4.0 technologies is increasingly becoming a central topic of interest for all organisations, regardless of size, sector or location. This integration aims to align companies with the benefits of digital transformation. Digitalisation addresses the fusion of Industry 4.0 technologies with established operations, involving people and processes. Management academics and professionals have long recognised the continuous interaction between people and technological systems in an intertwined sociotechnical web of processes. Employees have already been indicated as a primary stakeholder to sustainable development and decision making of organisations (Gianni and Gotzamani, 2020; 2023b). Hence, their engagement in the efforts of organisations to a successful transition from conventional to digital operations is critical.

Technologies like machine learning, deep learning, and artificial intelligence depend on the employees' collaboration to grow, adapt, and be smoothly adopted within organisations. Interestingly, the lack of people's competencies to implement I4.0 technologies is underscored as more important than the availability of the technologies themselves (Aghimien et al., 2021). Technical aspects go hand in hand with the social ones, since workers' perceptions can either foster or hinder the progress of technologies' integration into business operations (Sivathanu and Pillai, 2018). A coin side view can consider technological progress as either a development opportunity or as an unemployment risk (Ghobakhloo, 2020; Peters, 2020; Yu et al., 2023). From a strategic and leadership perspective, being able to predict and assess workers' inclination toward adopting new technologies would be advantageous and significant in decision-making and governance activities.

Lean principles can offer management professionals the key to address the challenges that are brought about by digital transformation. Drawing on socio-technical systems (STS) theory, lean is defined as a socio-technical system involving human and non-human components (Camacho-Miñano et al., 2013). Literature has highlighted the impact of lean management principles and practices in the digital transition. From a socio-technical stance, combining managerial and technical elements, employees' beliefs and behaviours on lean- and digital-related activities can contribute to the governance of Industry 4.0 technologies within organisations. This study merges lean with digital elements and takes a sociotechnical approach, in which people can play a key role in human-machine communication and overcome any drawbacks that may arise along the way.

This kind of information is integrated into organisational culture, in the long term. Organisational culture emphasises the significance of visible and invisible, tangible or intangible, intrinsic or extrinsic principles, values, beliefs, rituals, behaviours, and customs shared among employees. Prioritising organisational culture contributes to shift focus on people as both an enabler and an outcome of business sociotechnical systems. Taking into consideration the sociotechnical system approach of lean, assessing those elements of culture that are related to digital transformation potential is important to achieve a deep and focused awareness of factors that can advance the adoption of technologies by the employees.

Therefore, this study formulates the following research questions (RQs):

RQ1: What lean management principles and practices engraved in organisational culture can affect the intention of employees to use Industry 4.0 technologies?

RQ2: What digital transformation principles and practices engraved in organisational culture can affect the intention of employees to use Industry 4.0 technologies?

Apart from the cultural drivers, this study aims to assess the intention of employees to adopt Industry 4.0 technologies. To achieve this objective, this study draws on the technology acceptance theories and uses a longstanding, validated measurement instrument: the Unified Theory of Acceptance and Use of Technology (UTAUT) model. Hence, a third research question is formulated:

RQ3: What factors influence employees' intention to use Industry 4.0 technologies?

To address the aforementioned research questions, the present study developed a questionnaire based on a systematic literature review (Gianni and Gotzamani, 2022; Gianni and Gotzamani, 2023a). Multivariate statistical methods were used to analyse the collected data. Confirmatory composite analysis was firstly conducted. Next, certain research hypotheses have been tested through Structural Equation Modelling (SEM). The findings and the limitations of this study are discussed in the following sections. Finally, directions for future research are recommended.

LITERATURE REVIEW

Research into the synergies between lean and Industry 4.0 is still in its infancy. Systematic literature review evidence suggests that integrating lean principles with Industry 4.0 technologies can yield significant operational benefits and improve operational and sustainability performance (Buer et al., 2021; Vinodh et al., 2021). One of the few relevant empirical studies identifies two patterns of digital transformation: the sustaining and the disruptive. The first pattern consists of incremental and horizontal lean culture-oriented digital changes characterised by the involvement of people and the achievement of continuous process improvement, while the second consists of few and highly disruptive and radical changes (Rossini et al., 2021).

Surprisingly, lean manufacturing has not been linked to any kind of information technology in the past (Buer et al., 2018; Tissir et al., 2023). Probably due to the mistakenly identical interpretation of information and communication with Industry 4.0 technologies, research on digital technologies has developed rather independently from lean principles. Thus, there is a risk that I4.0 technological solutions that are incompatible with lean philosophy could lead to implementation failures, both in terms of productivity and ergonomics (Adrian et al., 2020). Furthermore, the autonomy principle of lean management (LM) is more relevant than ever. The lean philosophy relies on decentralised control by giving employees autonomy and insisting on simplicity and transparency (Buer et al., 2021). Following a lean-like evolution, traditional centralised IT systems are gradually being replaced by the decentralising (distributed) technologies of Industry 4.0, such as the Internet of Things and cyber-physical systems (Buer et al., 2021).

Lean thinking is seen as a way of tackling complex management problems effectively and efficiently. The ultimate goal of I4.0 technologies to connect humans and machines is by definition a highly complex endeavour. Therefore, lean-digital synergies are expected to manage complexity and improve performance (Tissir et al., 2023). The lean pillar 'jidoka' - a machine with human intelligence - defined artificial intelligence decades ago. Artificial intelligence (AI) applications can act as digital Andon warning systems, providing operators with just-in-time information that they could only guess at before AI (Liker, 2020). The successful Lean principle of empowering employees and treating them with respect as people, not just machines producing goods or providing services, can be applied to I4.0 technologies, where machines are to be treated as people. Following this line of thought, the present research focuses on the human factor, which appears to play a critical role in both lean management and digital transformation. The literature is reviewed through this lens, looking for commonalities and barriers to implementation. In addition, socio-technical and technology acceptance theories are drawn upon to identify potential links in favour of digital business transformation.

Digital transformation – Industry 4.0

Digital transformation is happening in the times of the fourth industrial revolution or otherwise called industry 4.0. The first industrial revolution was launched with the invention of the steam engine. The second industrial revolution used electricity for mass production. The third industrial revolution had its origin in the information and communication technologies for industrial automations. To date, the fourth industrial revolution is characterised by a fusion of technologies that is blurring the lines between the physical, digital (cyber), and biological spheres (Schwab, 2016).

The fourth industrial revolution has placed lean management practices in a new context. Industry 4.0 design principles are identified as: real-time capability, decentralisation, modularity, interoperability, and service orientation, i.e. service-oriented architecture and Internet-of-Services (Sanders et al., 2017). Industry 4.0 applications, including yet not limited to artificial intelligence, Internet of Things, cyber-physical systems, blockchain, cloud computing, unmanned vehicles, digital twins, augmented and virtual reality, smart applications, simulation, and robotics, gradually change production systems (Ghobakhloo, 2020; Khan et al., 2021; Sony, 2018).

Digital technologies contribute to the creation of new business economic-societal models. Digitalisation goes hand-in-hand with innovation. In a mutually beneficial relationship, innovation affects and is affected by digital transformation. Furthermore, digital innovation is not about products, processes or services. New business models enabled by digital technology platforms rely on digital innovation practices (Ciriello et al., 2018).

Digital transformation and people

Digital transformation reengineers human resource management (Longo et al., 2017). Nevertheless, there is an ongoing debate on whether net digitalisation effect on human resource management (HRM) is positive or negative (Aghimien et al., 2021; Ghobakhloo, 2020; Peters, 2019). Scholars emphasise that the DT-associated process and decision-making autonomation may bring about higher employee productivity rates, as well as improvement of organisational learning, recruitment and talent management (Ghobakhloo, 2020; Sivathanu and Pillai, 2018). On the other side, scholars argue that industry 4.0 comes with the risk of 'technological unemployment' (Peters, 2019). Furthermore, it is stressed that AI adoption may cause insecurity and drive employees to quit (Yu et al., 2022b). Alieva and Powell (2020) traced a dearth of research on the impact of digital transformation on employees and composed a model to understand how shop-floor employees' behaviours, i.e. intra-role behaviour, extra role-behaviour, personal development and growth, can be influenced by the digital transformation. There are several challenges to be addressed in everyday business activities, like the influence of robot design characteristics on the quality of the robot-mediated interaction between customers and service staff, and the employees' regulation of workflows in resonance with their robotic colleagues or the external environment.

Digital transformation barriers

The lack of coordinated national policies hinders the diffusion of I 4.0 technological innovations in developing countries (Raj et al., 2020). The lack of a digital strategy alongside resource scarcity emerged as the most prominent barrier for both developed and developing economies. The most important influencing factors identified for developing economies were 'lack of standards, regulations, and forms of certification' whereas the most important influencing factor in the developed economies was the 'low maturity level of preferred technology' (Raj et al., 2020).

Industry 4.0 barriers were found to condition SMEs' readiness for Industry 4.0, without hindering their exploitation of Industry 4.0 technologies. Barriers such as lack of knowledge, lack of standards and lack of employee readiness have a non-significant impact on the Industry 4.0 readiness or the adaptation of Industry 4.0 technologies (Raj et al., 2020). Lack of people's competencies to implement I4.0 technologies is underscored as more important than the availability of the technologies themselves (Aghimien et al., 2021).

Lean management and people

Lean literature is classified by scholars according to the three implementation phases, i.e. *before*: Lean definition, barriers-difficulties, training-knowledge, guidelines and methodology, and the human factor involved), *during:* waste management, implementation issues, product development, the inter-correlations among LM practices, and *after*: outcomes, benefits (Antony et al., 2021). Liker composed the Toyota Way Model (TWM) based on 14 principles grouped into four categories: Philosophy, Process, People and Problem Solving (Liker, 2020: p. 8). According to these principles, one of the key objectives of lean is to eliminate waste, which is defined as unnecessary work due to errors, poor organisation or communication, and underutilised talent. The latter type of waste reflects the importance of people's talent to the success of LM (Liker and Meier, 2007: p. 21). Lean has evolved from a set of tools and hard factors to a "human-centred and culture-developing approach" that includes soft factors. After all, "the main value of lean projects is in developing people who can solve problems and make improvements every day" (Liker and Meier, 2007: p. 8).

Gaiardelli et al. (2019) studied cause-effect and mediating relationships between lean (hard and soft) practices, physical work environment and job characteristics, as well as the effect of those factors on employee behaviour and operational performance. Hard lean practices include: autonomous maintenance, equipment layout for continuous flow, just-in-time delivery by suppliers, Kanban, set-up time reduction, and statistical process control. Soft lean practices include:

continuous improvement, small group problem solving, supplier partnerships, top management leadership, training. Interestingly, it is emphasised that implementing hard lean practices alone worsens employees' quality of work life (Sakthi Nagaraj and Jeyapaul, 2021). However, there is limited evidence on the ways soft lean factors interact with hard lean factors and influence operational and social performance (Salentijn et al., 2021).

Lean and Industry 4.0

Following the current wave of change, when designing and implementing Industry 4.0 systems, practitioners are expected to integrate lean management practices, to increase efficiency and add value (Sony, 2018). From a reciprocal perspective, scholars stressed that digital transformation enhances the Lean Production System, particularly with methods and tools on the shop floor (Schumacher et al., 2020). In general, however, the ability of conventional lean management tools to tackle the increasingly volatile customer demands and their compatibility and synergy with industry 4.0 are questioned (Buer et al., 2021). Research on lean and industry 4.0 integration highlights *total productive maintenance (TPM), Kanban, production smoothing, autonomation,* and *waste elimination* as the main aspects of lean manufacturing that will be positively affected by the fourth industrial revolution strategies, i.e. *real-time capability, decentralisation,* and *interoperability* (Buer et al., 2021). Autonomation is otherwise interpreted as 'automation with a human touch' lending a 'human-inclusive' approach to management (Romero et al., 2019). Industry 4.0 dependence on lean operations and human involvement may boil down to 'Jidoka 4.0', which reflects human-machine mutual learning, characterised by cyber-physical-social interactions that yield higher levels of automation and intelligence (Romero et al., 2019). Digital transformation is actually seeking ways to make machines as much 'humanised' as possible (Tissir et al., 2023).

Technology acceptance

For the purpose of this study, literature was reviewed to identify links between technological evolution and people's relevant attitudes and beliefs within organisations. The theories of technology acceptance emerged through this review (Venkatesh et al., 2003; 2023). All acceptance models are based on a sequence of users' or potential users' attitudes and behaviours. The individual reactions to using technologies affect the intentions of people to use those technologies, and their actual use, in turn. Numerous researchers use the Unified Theory of Acceptance and Use of Technology (UTAUT) model that lends an integrative view to user acceptance of new systems and technologies (Gupta et al., 2008). According to the theoretical foundation of the model, performance expectancy, effort expectancy and social influence define behavioural intention to use a system or technology, while the intention to use determines the actual usage (Venkatesh, 2003).

Performance expectancy reflects the expected benefits accrued from the adoption and consequent use of the relevant technology. In the particular research context, it can measure the extent to which employees believe that using industry 4.0 technologies will help them fulfil their work goals and improve their performance.

Effort expectancy reflects employees' perception of the challenges they may encounter when using digital technologies in their working environment. *Social influence* reflects employees' perceptions about what other stakeholders, such as their colleagues and managers, believe about them and their work. The *intention to use* reflects the extent to which the employees intend or continue to use industry 4.0 technologies in their work. The *use of technology* reflects the actual usage of digital technologies in terms of duration, frequency, and intensity (Venkatesh et al., 2003; 2023). Over the years, the UTAUT has evolved to include more factors, such as *anxiety* and user *resistance* (Donmez-Turan, 2020). Users of new systems or technologies feel anxious about losing control over their regular work activities and decision-making processes, and they resist the change that new technologies can bring about (Donmez-Turan, 2020). At a more intense level of anxiety, users of digital technologies fear being replaced by artificial intelligence or other digital advancements (Wang & Wang, 2022).

Culture and the intention to technology use

Certain UTAUT studies were motivated by the importance of soft, non-technical factors, such as culture (Dasgupta & Gupta, 2019), charismatic leadership (Neufeld et al., 2007), and team climate for innovation on technology use (Liang et al., 2010). Dasgupta and Gupta (2019) have focused on espoused organisational culture values and their potential influence on the employees' intention to use information systems.

Based on the existing theoretical and empirical background, this study identified two sub-dimensions of organisational culture, oriented towards lean management and digital transformation, in the belief that these two dimensions - whether combined or independent - can promote the adoption of I4.0 technologies. In other words, this study aims to test a structural model that links, for the first time, the binary form of lean-digital culture with the UTAUT model.

Research hypotheses

Within the proposed research framework, the following research hypotheses (RHi) are generated:

RH 1. *Lean-digital culture has a significant and positive impact on the Intention to Use I4.0 technologies.*

RH 2. *Lean-digital culture has a significant and positive impact on the Behavioural Use of I4.0 technologies.*

RH 3. *Lean-digital culture has a significant and positive impact on the Actual Use of I4.0 technologies.*

RH 4. *Lean-digital culture has a significant and negative impact on the Inhibitors to the Use of I4.0 technologies.*

RH 5. *The Inhibitors to the Use of I4.0 technologies have a significant and negative impact on the Intention to Use I4.0 technologies.*

RH 6. *The Behavioural Use of I4.0 technologies has a significant and positive impact on the Intention to Use I4.0 technologies.*

RH 7. *The Intention to Use I4.0 technologies has a significant and positive impact on the Actual Use of I4.0 technologies.*

RH 8. *The Behavioural Use of I4.0 technologies has a significant and positive impact on the Actual Use of I4.0 technologies.*

RH 9. *The Inhibitors to the Use of I4.0 technologies have a significant and negative impact on the Actual Use of I4.0 technologies.*

RH 10. *The Inhibitors to the Use of I4.0 technologies have a significant and negative impact on the Behavioural Use of I4.0 technologies.*

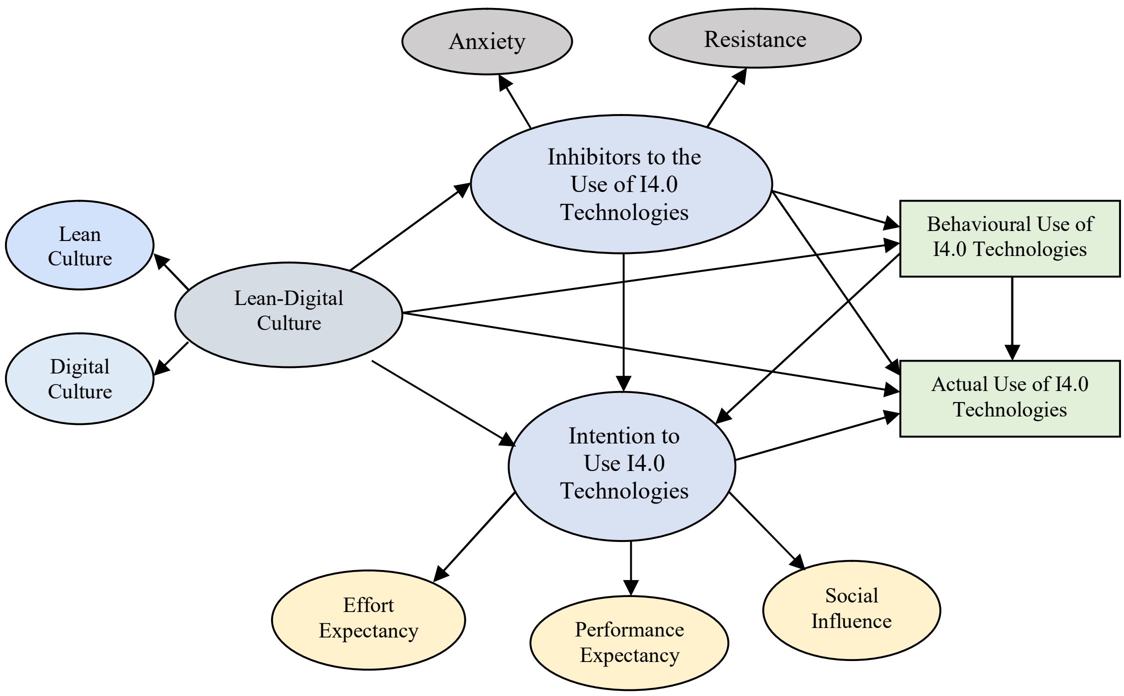

Figure 1: The conceptual model

The second-order constructs in the model are interpreted as follows:

The Lean-Digital Culture is reflected in the Lean Culture and the Digital Culture.

The Intention to Use I4.0 technologies is reflected in the Performance expectancy, the Effort Expectancy, and the Social Influence.

The Inhibitors to the Use of I4.0 technologies are reflected in the Anxiety and the Resistance to Use.

The conceptual model is depicted in Figure 1.

RESEARCH METHODS

The research instrument

This research aims to investigate the relationships among Lean Digital Culture, the Intention to Use, the Inhibitors to the Use, Behavioural Use, and Actual Use of Industry 4.0 technologies in Greek organisations. A survey was designed and a structured questionnaire with a 5-degree Likert scale was developed to collect the empirical data. The structural model was then tested using the PLS-SEM method. The questionnaire included:

- 36 questions for "Lean Digital Culture" that refer to Digital Organisational Culture (Martínez-Caro et al., 2020; Proksch et al., 2024; Wang & Wang, 2022), and Lean Organisational Culture (Bortolotti et al., 2015)
- 11 questions for the "Inhibitors" that refer to Anxiety, and Resistance to Use (Maruping et al., 2017; Donmez-Turan, 2020; Venkatesh et al., 2003; Aggelidis & Chatzoglou, 2009)
- 11 questions for the "Intention to Use" that refer to Performance Expectancy, Effort Expectancy, and Social Influence (Maruping et al., 2017; Donmez-Turan, 2020; Venkatesh et al., 2003; Aggelidis & Chatzoglou, 2009)
- 3 questions for "Behavioural Use" that refer to user behaviour regarding the I4 tools use (Maruping et al., 2017; Donmez-Turan, 2020; Venkatesh et al., 2003; Aggelidis & Chatzoglou, 2009), and

- 25 questions for “Actual Use of Industry 4.0 technologies”, representing a wide range of available I4.0 technologies.

The sample

The above-mentioned questionnaire was delivered to 57 companies in Greece. Employees of different positions and ranks completed a structured questionnaire distributed online. A total of 47 Greek organisations, both service and manufacturing, participated in the survey, providing 452 usable responses. The data collection took place from October 2023 to January 2024, administering the questionnaire through the Google Forms platform.

The validity assessment

Partial least squares (PLS) structural equation modelling (SEM) was used for the assessment of the research model and hypotheses testing with the "Smart PLS" software. PLS-SEM gained increased popularity over the years in social sciences (Xanthopoulou et al., 2023).

AVE (Average Variance Extracted), Cronbach's α, and composite reliability (CR) were used for the assessment of convergent validity and reliability. The "Fornell-Larcker" and "Heterotrait-Monotrait Ratio" (HTMT) criteria were used for establishing discriminant validity. Finally, the bootstrapping procedure was applied (5000 randomly drawn samples) for hypotheses testing.

Additionally, the Stone-Geisser Q-square test was employed to determine the predictive relevance of the model's quality. This analysis was performed in two phases with omission distances of 7 and 25, using the blindfolding technique in SmartPLS, to test the consistency of the outcomes (Q-squares > 0). In line with prior research (Xanthopoulou et al., 2023), the goodness-of-fit (GoF), as a criterion for evaluating PLS-SEM, was excluded, due to the criticism of its ability to accurately separate valid models from invalid ones (Hair et al., 2017).

RESULTS

Respondents profile

A total of 2485 people were employed in the participating companies (average: 51; median: 25) providing a response rate of 18%. Regarding company size distribution in the sample, 24.1% of the respondents work in companies with 101-250 employees, 23.2% in companies with more than 250 employees, 23.7% in companies with 21-50 employees, 14.6% in companies with 51-100 employees, and the remaining percentage ranges from 6-20 employees to 1-5 employees. As for the duration of employment at the company, 34.3% have more than 10 years, 19% have 3-5 years, 17.5% have 1-2 years, 14.6% have 0-12 months, 13.5% have 6-10 years, and the remaining percentage has 1-12 years.

Validity and Reliability

In this section, the results of the quantitative analysis conducted using the SmartPLS software are presented. Convergent validity and reliability were assessed using Cronbach's alpha and Composite Reliability (CR), with all values meeting the acceptable criteria. Furthermore, the loadings of all variables exceeded the threshold value of 0.5, indicating strong convergent validity.

Discriminant validity reflects the extent to which a construct is truly distinct from other constructs both in terms of how much it correlates with other constructs and how distinctly measured variables represent only this single construct. In other words, high discriminant validity provides evidence that a construct is unique and captures some phenomena that other measures do not (Hair et al., 2014: pp. 624-625). The average variance extracted (AVE) values for the Actual Use of Industry 4.0 Technologies and Lean-Digital Culture are found less than 0.50. AVE values should generally be higher than 0.5, yet lower values (between 0.4 and 0.5) can be accepted, when composite reliability is higher than 0.6, since the convergent validity of the construct is considered adequate (Fornell and Larcker, 1981; Gianni and Gotzamani, 2023b). It is also noted that AVE is a rather conservative measure and, therefore, reliability can be established through CR alone (Malhotra and Dash, 2016). Furthermore, in recent literature, a new criterion is used for testing discriminant validity that is called Heterotrait-Monotrait (HTMT) ratio (Henseler et al., 2015). HTMT analysis offers an alternative control when facing lack of discriminant validity with the conventional analyses, particularly in the attempt to operationalise novel variables and introduce new measurement scales (Gianni et al., 2003). To confirm the discriminant validity and, thus, exclude multicollinearity issues, the value of the HTMT ratio for all constructs in the model should be under 0.85 (Henseler et al., 2015). According to the HTMT analysis of the survey data, all HTMT ratio values are well below the threshold value.

Regarding the separate analyses with omission distances of 7 and 25, conducted using the blindfolding technique in SmartPLS, the values remained consistent; the Q^2 values exceeded zero. Consequently, there is evidence to suggest that the model was stable, and the criteria for predictive relevance were met.

Hypotheses testing

For the analysis of the structural model, the bootstrapping procedure was used, taking 5000 random samples. Hypotheses testing results are presented in Table 1.

Table 1: Bootstrapping results

	Original Sample (O)	Sample Mean (M)	Standard Deviation (STDEV)	T Statistic (|O/STDEV|)	P Value
Behavioural_Use -> Actual Use_Industry 4.0	0,048	0,045	0,068	0,700	0,484
Behavioural Use -> Intention to Use	0,503	0,505	0,046	10,957	0,000
Inhibitors -> Actual Use_Industry 4.0	0,139	0,140	0,055	2,508	0,012
Inhibitors -> Anxiety	0,815	0,815	0,021	38,934	0,000
Inhibitors -> Behavioural Use	-0,420	-0,418	0,053	7,972	0,000

Inhibitors -> Intention to Use	-0,029	-0,027	0,044	0,657	0,511
Inhibitors -> Resistance to Use	0,962	0,962	0,003	311,996	0,000
Intention to Use -> Actual Use_Industry 4.0	0,165	0,166	0,076	2,174	0,030
Intention to Use -> Effort Expectancy	0,792	0,792	0,024	33,662	0,000
Intention to Use -> Performance Expectancy	0,813	0,812	0,031	26,155	0,000
Intention to Use -> Social Influence	0,856	0,857	0,016	54,000	0,000
Lean-Digital Culture -> Actual Use Industry 4.0	0,390	0,393	0,057	6,836	0,000
Lean-Digital Culture -> Behavioural Use	0,253	0,254	0,050	5,006	0,000
Lean-Digital Culture -> Digital Culture	0,864	0,864	0,015	56,814	0,000
Lean-Digital Culture -> Inhibitors	-0,294	-0,295	0,045	6,498	0,000
Lean-Digital Culture -> Intention to Use	0,389	0,389	0,037	10,388	0,000
Lean-Digital Culture -> Lean Culture	0,946	0,946	0,006	157,535	0,000

The results reveal various dynamics within the modelled relationships. There was a negligible negative relationship between Behavioural Use and Actual Use of Industry 4.0 technologies, indicated by a coefficient of 0.048 and a non-significant p-value of 0.484 (the research hypothesis RH8 is rejected), suggesting an insignificant direct effect. Conversely, there was a strong positive relationship between Behavioural Use and Intention to Use, evidenced by a coefficient of 0.503 and a highly significant p-value (<0.001), indicating strong predictive relevance, thus leading to the acceptance of research hypothesis RH6.

Analysing the loadings of inhibitors, the loading of Anxiety is found significantly high (0.815) with a corresponding high T-statistic value of 38.934, and the loading of Resistance to Use, is found as high as 0.962 with an extremely high T-statistic of 311.996. However, the impact of the Inhibitors on the Intention to Use - although it was found negative, as expected, with a coefficient of -0.029 - it was statistically non-significant (p-value = 0.511), leading to the rejection of research hypothesis RH5.

Regarding the predictors of the "Intention to Use", Effort Expectancy, Performance Expectancy, and Social Influence all had strong positive effects, with all p-values being <0.001. Furthermore, a positive and statistically significant relationship was noted with the Actual Use of Industry 4.0 technologies, evidenced by a coefficient of 0.165 and a p-value of 0.030(<0.05), leading to the acceptance of research hypothesis RH7.

The impact of Lean-Digital Culture was also significant, having positive effects on the Actual Use and on the Behavioural Use, with corresponding coefficients of 0.390 and 0.253 (p-values <0.001), thus leading to the acceptance of research hypotheses RH3 and RH2 respectively. Factor loadings of both Digital Culture and Lean Culture on Lean-Digital Culture, exceed 0.85, underscoring the critical role of the proposed composite form of organisational culture in digital transformation. Additionally, a negative impact on the inhibitors was observed with a coefficient of -0.294 and a p-value <0.001, thus leading to the acceptance of research hypothesis RH4, indicating that Lean-Digital Culture effectively reduces barriers to adoption. Additionally, Lean Digital Culture has a significant and positive relationship with the Intention to Use I4.0 technologies, with a coefficient of 0.389 and p-value<0.001, leading to the acceptance of research hypothesis RH1).

Furthermore, the impact of the Inhibitors on the Actual Use was found positive (0.139) and statistically significant (p-value = 0.012<0.05), leading to the acceptance of research hypothesis RH9. A strong negative (-0.420) and statistically significant impact of the Inhibitors on the Behavioural Use was found, leading to the acceptance of research hypothesis RH10.

DISCUSSION

This research aimed to investigate the relationships among Lean Digital Culture, the Intention to Use I4.0 technologies, its Inhibitors, Behavioural Use, and Actual Use of Industry 4.0 technologies in Greek organisations. The impact of the inhibitors, i.e. anxiety and resistance to use, was found insignificant contradicting previous findings of weak yet significant effects (Donmez-Turan, 2020).

Anxiety and "resistance to use" influence strongly and negatively the behavioural intention of technology users. This finding underlines the psychological hindrances to technology adoption. However, the expected negative impact of the inhibitors on the intention to use is found statistically insignificant. This lack of finding can be attributed to the second-order structure of the model, since prior research has identified a significant and direct impact of user resistance (otherwise called "resistance to change") only on one of the three dimensions of the Intention to Use, i.e. the effort expectancy (Nov and Ye, 2009). Interestingly, the inhibitors are found to have a positive (albeit weak) effect on the actual use of I4.0 technologies. Nevertheless, this adverse finding should be treated with caution since the p-value is higher than 0.01.

The only significant (positive) and relatively strong relationship with the actual use is that of lean digital culture highlighting the role of organisational culture, as proposed in the model. Actual technology use was measured by the frequency of use of several I4.0 technologies on a scale of 1 to 5. Intention to use has a weak positive effect on actual use. Again this effect should be treated with caution as the corresponding p-value is close to 0.05. In a clearly insignificant mode (loading: 0.048, p-value: 0.484), behavioural use has no effect on actual use. The weak and insignificant effects on Actual Use indicate that it is less predictable than Behavioural Use. This difference can be attributed to the perceptual, soft, and humane nature of the latter construct compared to the less biased, hard, and technological nature of the former. Previous relevant research clearly separates the intention to use from the actual use (Venkatesh et al., 2023). More importantly, the very conception of the UATUT model includes behavioural and perceptual attitudes and behaviours. This interpretation of technology adoption relates well to organisational culture, which by definition is a set of norms, attitudes and beliefs.

One of the most important confirmations made possible by this empirical study is the strong, positive effect (almost 0.4) of culture on intention to use. A lean digital culture has a strong negative effect (0.3) on inhibition. Again, this effect highlights the role of culture in technology adoption. The data collected confirms that intention to use is correctly reflected by performance expectancy, effort expectancy and social influence. The proposed model includes three second-order constructs: lean digital culture, inhibitors and intention to use. However, prior research has also discussed some first-order (direct) underlying relationships, e.g. between resistance and effort expectancy (Donmez-Turan, 2020; Nov and Ye, 2009) and voluntariness of use and social influence (Venkatesh et al., 2003). In a next step of this research, the collected data can be used to test the possible direct effects of culture on anxiety and resistance, as well as on performance, effort expectancy and social influence.

Despite its contributions, the study suffers from certain limitations. The first limitation of this study is the small size of the sample at the organisational level. The validity of the model needs to be further tested by increasing the participation rate. Another limitation of this study is that data was collected only from Greek organisations, which limits the geographical scope of the research. Data from other countries would increase the validity and generalisability of the findings. Mediation and moderation analyses could provide further insight into the relationships identified. Intensity of use and facilitating conditions are some of the factors that could be used as moderating variables.

CONCLUSION

The results elucidate the complex dynamics between user behaviour, organisational culture, and the adoption of new technologies, highlighting the importance of managing inhibitors and enhancing potential enablers such as effort expectancy, performance expectancy, and social influence. Together, these factors may promote positive intentions to use and, in turn, actual use of advanced digital solutions in the workplace.

Theoretically, this study could enhance the conceptual framework surrounding digital transformation by providing empirical evidence on the impact of Lean Digital Culture. Digital transformation is not as closely linked to information technology and disruption as it is to value chain proposition, adaptation and change across the organisation (Furr and Shipilov, 2019; Neely and Leonardi, 2022). In this context, fostering a digital mindset is far more important than investing in costly infrastructure that may be under-utilized by reluctant or even fearful employees. Integrating lean principles, norms and beliefs into the digital mindset paves the way for successful transformation.

Furthermore, the proposed model extends the understanding of the barriers that inhibit the adoption of the Industry 4.0 technologies. In addition, it refines the behavioural models of technology acceptance providing new insights into the dynamics of Industry 4.0 adoption, highlighting specific cultural or economic factors relevant to Greek organisations. This research also has the potential to bridge the gap between the intention to use and the actual use of these technologies, clarifying the view of how behaviour translates into application in the workplace.

From a practical standpoint, the findings can inform strategic planning for managers and decision makers by underscoring the importance of addressing inhibitors and fostering a digital-friendly culture. The implications extend to policy development, suggesting the need for supportive policies to facilitate the integration of Industry 4.0 technologies. Furthermore, the empirical validation of the model highlights the importance of lean principles in the digital transformation and the trade-offs between the new, dynamic technologies and the conventional, more "static", nature of lean management. This "exchange" can address the shortcomings of lean management identified in literature (Tissir et al., 2023).

Organisations could use these findings to allocate resources more effectively, focusing on areas such as employee training or infrastructure improvements that significantly drive the adoption of Industry 4.0. Understanding the factors that lead to successful I4.0 implementation can help design more effective change management strategies and ultimately provide a competitive advantage through improved efficiency and innovation.

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Digital Traceability of Quality in the Food Processing Industry

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STRUCTURED ABSTRACT

Purpose - This study examines the enhancement of quality traceability in the food processing industry through modern digital tools such as, for example, the integration of blockchain technology. A literature review is combined with real-case studies analysis to explore this evolving field.

Design/methodology/approach - Adopting a mixed-method approach, the research first conducts a thorough literature review to understand current digital trends in the food processing industry. Then, it analyzes some real-case studies to assess the practical application of these technologies for quality traceability.

Findings - The study demonstrates that the approaches based on blockchain technologies significantly enhance supply chain transparency and quality management in the food processing industry. It highlights both the potential benefits and the concerns faced in practical implementations.

Research limitations/implications – This study is constrained by the current lack of cultural orientation in the food processing industry for an in-depth examination of modern digital tools and their practical application. The utilization of such tools is mainly limited to a few isolated case studies, rather than being explored through a structured and widespread experimental campaign.

Practical implications: The findings provide practical guidelines for businesses in the food processing sector looking to implement modern digital tools for improved quality traceability and management.

Social implications: This study highlights the critical role of modern digital tools in meeting societal demands for food safety and quality in the food processing industry, particularly emphasizing the importance of transparency in information related to raw materials, processing, and preservation methods.

Originality/value: Starting from literature review and case studies analysis, this paper provides a first comprehensive overview of the use of modern digital tools to enhance quality traceability in the food processing sector.

Keywords: Quality 4.0, Food Processing Industry, Traceability, Blockchain.

Paper type: Research paper.

INTRODUCTION

In the global food industry, traceability is crucial for ensuring food safety and quality, driven by the need for transparency following various food scandals. Traceability, defined as tracking an entity's history, application, or location through recorded identifications, meets consumer demands for safety and transparency while boosting business competitiveness and optimizing production processes (Corallo *et al.*, 2018).

In the European market, traceability is either mandatory or voluntary. Mandatory traceability, aimed at financial transactions, often lacks detailed quality information, while voluntary traceability allows for more comprehensive data collection (Demestichas *et al.*, 2020). The European Union (EU) reinforced traceability through Regulation (EC) No 178/2002, which established core food law principles and procedures, including the European Food Safety Authority (EFSA), to trace food, feed, animals, or substances through all production stages (European Parliament and of the Council, 2002). Technological innovations like the Internet of Things (IoT), Radio Frequency Identification (RFID), and blockchain have significantly advanced traceability systems, enhancing data management efficiency, accuracy, and reliability (European Commission, 2024).

The IoT has revolutionized data collection in the agri-food sector by using devices and sensors for continuous monitoring. RFID assigns unique identifiers for seamless tracking, and additional technologies like Wireless Sensor Networks (WSN), Near Field Communication (NFC), Datamatrix, and QR Codes further improve traceability by efficiently storing and providing detailed product information.

Despite improvements, IoT-based systems relying on centralized server-client models face vulnerabilities, such as data integrity and security risks, due to dependency on a single entity for data management (Feng *et al.*, 2020). The agri-food supply chain (AFSC) faces challenges including product theft, adulteration, and non-compliant labeling, demanding comprehensive solutions for transparency and reliability.

Developing a universal traceability system is challenged by standardization issues, as proprietary solutions lead to compatibility problems and higher costs. Efforts towards global harmonization have been made with standards like the European Article Numbering Uniform Code Council (EAN/UCC) (GS1) (European Commission, 2024). Blockchain technology offers a decentralized, secure ledger that enhances supply chain transparency, mitigates trust issues, and improves data integrity, supporting a comprehensive history of food products from origin to distribution (Feng *et al.*, 2020).

Blockchain, combined with IoT devices, promises end-to-end tracking of food products. Pilot projects indicate a trend towards more efficient and flexible traceability systems. Successful blockchain applications in the food sector require collaboration between multidisciplinary experts, including agri-food specialists and IT professionals, to address supply chain complexities effectively, as noted by Reddy et al. (2023).

In this framework, the purpose of this paper is to examine the enhancement of quality traceability in the food processing industry through the integration of modern digital tools, such as blockchain technology. The study combines a thorough literature review with the analysis of real-case studies to explore the practical application of these technologies and their potential to improve supply chain transparency and quality management.

Focusing on the transformation and distribution phase of the food value chain, the present paper aims to highlight digitalization's impact on supply chain transparency and quality management. The study evaluates digital trends and their practical applications, offering insights into how these tools can meet societal demands for food safety, quality, and transparency. It provides valuable insights and guidelines for the industry, underlining the need for transparency in handling information about raw materials, processing, and preservation.

Further, the paper highlights a crucial shift from traditional centralized data management systems towards a more decentralized, secure, and transparent approach facilitated by blockchain technology. This change aims to overcome challenges in current traceability systems like data integrity and stakeholder trust. Incorporating empirical case studies and tools like Business Process Modeling (BPM) and Unified Modeling Language (UML) diagrams, this research contributes to advancing the discussion on food supply chain management. It aims to pave the way for a universal traceability system that meets the varied needs of different food supply chains, marking a step toward enhanced quality assurance and transparency in the industry.

The rest of the paper is structured as follows. The “Background” section provides an overview of the agri-food industry and the role of digital tools in traceability. The "Methodology" section presents the mixed-method approach, including literature review and case study analysis. The “Literature Review” section reviews existing studies on blockchain and IoT applications in food traceability. The “Business Case Studies” section explores practical implementations of blockchain technology in the food processing industry. In section “Designing a Traceability System for the food processing industry”, a model for an effective traceability system using digital tools is proposed. Finally, the “Conclusions” section summarizes the study and suggests directions for future research.

BACKGROUND

The Agri-Food Industry

In the late 1960s, Louis Malassis defined a supply chain as the path followed by a product within the agri-food apparatus, involving all agents or actors and operations that contribute to the product's formation or transfer to its final use (Malassis and Padilla, 1986). The Food Value Chain (FVC) represents the complete process through which food is produced, processed, distributed, and made available to consumers, characterized by complexity and fragmentation (Nguyen and Do, 2018). Key features include:

- Short Life Cycle: Food products necessitate rapid processing and reduced storage times.
- Perishable Goods: Require specific transport and storage conditions.
- Agile Production Cycles: Adapt to frequent setup cycles due to product seasonality.
- Product Diversification: Numerous varieties and options within the chain.
- Rigorous Quality Controls: Strict adherence to national and international regulations.

Given its peculiarities, FVC management requires active cooperation and coordination among diverse actors to benefit all participants and satisfy consumer needs. Key actors include:

- Agricultural Producers: Growers, ranchers, and fishermen producing raw materials like fruits, vegetables, meat, fish, and dairy.

- Agricultural Input Suppliers: Companies providing fertilizers, pesticides, farming equipment, seeds, and other agricultural resources.
- Processors: Transform raw materials into packaged food products. Primary processing includes cleaning, peeling, grading, and packaging, while secondary processing turns ingredients into consumable foods.
- Distributors and Wholesalers: Purchase and distribute large quantities of food products to retail stores, restaurants, and other destinations.
- Restaurants and Retailers: Places where consumers purchase food, including restaurants, supermarkets, markets, and specialty stores.
- Transporters and Logistics: Handle the transportation of food products, ensuring safe and timely delivery to retail points.
- Food Safety and Regulatory Authorities: Government agencies ensuring food safety and compliance with health regulations.
- Consumers: Their choices influence food product demand and purchasing behaviors.
- Non-Governmental Organizations (NGOs): Address issues related to sustainable agriculture, food security, and combating food waste.
- Financial Service Providers: Offer lending and investment services to support food production and distribution.

In the paper, the focus will be exclusively on the second phase of the food value chain. This phase begins after the raw materials have been acquired by processing companies and encompasses the entire process of transformation and distribution.

Blockchain Technology in the Agri-Food Supply Chain

Blockchain technology, introduced by Satoshi Nakamoto in 2008, enables secure, transparent digital transactions through a decentralized ledger (Nakamoto, 2008). It records transactions in cryptographically linked blocks, ensuring immutability and data integrity through peer-to-peer (P2P) networks (Lee, 2015). Blockchain's evolution can be segmented into three phases:

- Blockchain 1.0: Focuses on cryptocurrencies and distributed ledgers for financial transactions.

- Blockchain 2.0: Offers greater complexity and flexibility, extending beyond cryptocurrency transactions to include smart contracts that automate agreements between parties. Ethereum is widely regarded as a significant example of Blockchain 2.0.
- Blockchain 3.0: Aims at optimizing performance to handle more transactions and data efficiently, focusing on interoperability among different blockchain networks, scalability, and expanding sector-specific applications, such as supply chains in the agri-food sector.

Blockchain technology can be categorized into several types, each with unique characteristics and suited for specific use cases:

- Public Blockchain: Open and accessible to anyone, public blockchains are secured through decentralized consensus mechanisms and offer transparency and security without requiring trust among users. Examples include Bitcoin and Ethereum.
- Private Blockchain: Controlled by a centralized entity or a limited group of participants, private blockchains regulate access and participation, offering faster transaction validation due to simpler consensus mechanisms.
- Consortium Blockchain: Governance is distributed among participating companies in a consortium, with access regulated by a select group sharing common interests. This type combines elements of decentralization with controlled access.
- Hybrid Blockchain: Combines features of both public and private blockchains, allowing for managed access and privacy while maintaining some decentralization.

Selecting the appropriate blockchain type is crucial for project success and optimizing supply chain management (Kramer *et al.*, 2021).

Conceptualized by Nick Szabo in the 1990s, smart contracts automate and enforce contract terms through code, activated by predefined conditions without intermediaries (Mohanta *et al.*, 2018; Szabo, 1996). These contracts, ranging from deterministic to non-deterministic, improve traceability and efficiency but require interdisciplinary expertise to address challenges (Bosona and Gebresenbet, 2023; Christidis and Devetsikiotis, 2016).

METHODOLOGY

This study adopts a mixed-method approach to examine the enhancement of quality traceability in the food processing industry through the integration of modern digital tools such as blockchain technology. The methodology consists of two primary components: a thorough literature review and a case study analysis.

Literature Review

The literature review provides a comprehensive understanding of current digital trends and technologies in the food processing industry, including IoT, RFID, and blockchain. It synthesizes findings from scientific articles, conference papers, book chapters, and reviews, highlighting the strengths, weaknesses, and gaps in existing research, forming a foundation for the case study analysis.

Case Study Analysis

The case study analysis involves an in-depth examination of real-world implementations of blockchain technology in the food processing industry. Several case studies are selected based on their relevance, diversity, and the depth of information available. The criteria for selecting these case studies include the scale of implementation, the specific digital tools used, and the documented outcomes in terms of traceability and quality management.

Detailed information about each case study was collected from multiple sources, including company reports, academic articles, industry publications, and interviews. A key contributor was an anonymous expert currently serving as a Tech Strategist at Microsoft, who previously held the position of Global Blockchain Traceability Product Strategy Lead and Innovation Manager at Ernst & Young (EY) and was directly involved with several blockchain projects, including those at Placido Volpone, Bofrost Italia, and Spinosa (see "Business Case Studies" section). This expert's testimony and access to internal documents provided invaluable insights. The collected data was systematically analyzed to identify common patterns, challenges, and successes in blockchain implementation. Key metrics included supply chain transparency, quality management improvements, and noted efficiencies or cost reductions. The analysis traced the evolution of blockchain from simple data notarization to more complex and verifiable traceability solutions involving multiple stakeholders.

Designing a Traceability System

In light of the insights gained from the literature review and case study analysis, the development of a standard reference model to address the complexities of the supply chain is proposed. It involves a detailed analysis of actors, processes, resources, and data flows to ensure seamless traceability. The approach utilizes Business Process Modeling (BPM) and Unified Modeling Language (UML) to create a comprehensive framework that integrates blockchain technology, enhancing data integrity and transparency across the food value chain.

LITERATURE REVIEW

The development of this research involved a thorough literature review, drawing from a diverse array of sources including scientific articles, conference papers, book chapters, and reviews. Initial observations indicated that studies prior to 2012 were primarily focused on traceability within the Agri-Food Supply Chain (AFSC) exploring Internet of Things (IoT) technologies. However, from 2016 to the present, a significant shift has been noted towards blockchain technology as a potentially more promising development for establishing an efficient traceability system. Notably, no publications on blockchain applications before 2016 were found, suggesting that research on Blockchain Technology (BCT)-based traceability in the AFSC has emerged recently but it is growing exponentially. To substantiate this observation, an analysis on Scopus database was performed, utilizing the search string ("Agri-food" OR "food") AND "blockchain" AND "traceability", without imposing any publication year restrictions (see the results shown in Figure 1). This search resulted in a total of 725 documents up to the end of 2023, each analyzing the role of blockchain across various segments of food supply chains, including meat, fruits and vegetables, grains and cereals, oil, wine, and fish. The publication curve demonstrates a consistent annual increase, marked by a notable surge in recent years. The increase in documents to 725 by the end of 2023 underscores the burgeoning interest and research activity in the intersection of blockchain technology and AFSC traceability, reflecting the sector's dynamic evolution and the growing recognition of blockchain's potential to enhance traceability systems.

Year	Documents
2023	216
2022	209
2021	131
2020	88
2019	56
2018	20
2017	3
2016	2

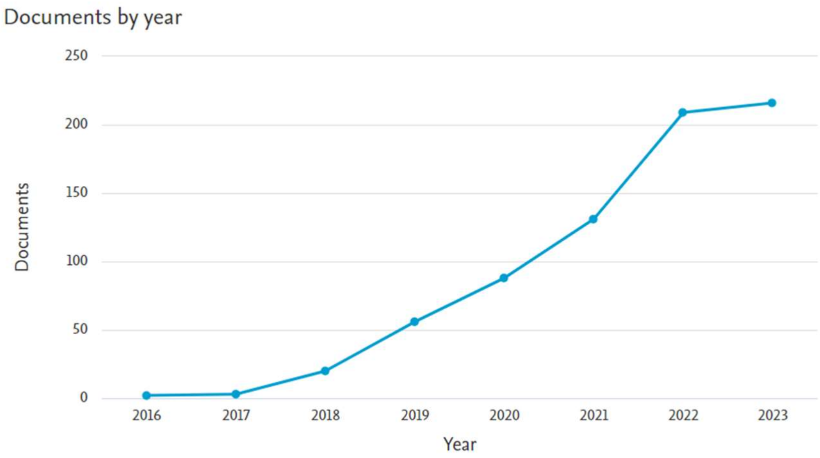

Figure 1 – Annual Count of Blockchain-Related Publications in Agri-Food Traceability (2016-2023). Source: Scopus.

Reviewed Articles and Key Insights

Yang et al. (2021) propose a blockchain-based system for the traceability of fruits and vegetables, integrating blockchain and databases to ensure data immutability and efficient queries. Keerthivasan et al. (2022) explore blockchain technology in the fruit and vegetable supply chain, noting adoption challenges like expert opinions, strategies, and administrative structures.

Tian (2016) analyzes blockchain and RFID technologies for fresh produce and meats, highlighting significant advantages and challenges compared to centralized solutions. Building on this, Tian (2017) incorporates IoT tools and HACCP analysis to enhance the decentralized approach. Xu et al. (2021), and Morais et al. (2023a) propose a blockchain-based traceability system for urban fruits, aiming to mitigate quality and fraud risks with IoT and smart contract models.

A solution for soy traceability using Ethereum blockchain technology with smart contracts and the Interplanetary File System (IPFS) for some data storage is introduced in the study proposed by Salah et al. (2019). This approach aims to prevent blockchain overload by utilizing associative storage space. Instead, Tse et al. (2017) focus on the increasing issue of food safety in China, presenting an environmental analysis based on Political, Economic, Social, and Technological (PEST) aspects to identify challenges and opportunities related to the proposed solution.

Kaijun et al. (2018) propose a dual-chain solution for the agricultural supply chain, improving transparency, confidentiality, and system efficiency. Caro et al. (2018) introduce AgriBlockIoT, a blockchain platform integrating IoT sensors with Ethereum or Hyperledger.

Koirala et al. (2019), Baralla et al. (2019), Lin et al. (2019), and Yang et al. (2021) advocate for a similar framework using consortium blockchains and smart contracts. Specifically, Baralla et al. (2019) and Yang et al. (2021) promote an on-chain/off-chain approach to manage data confidentiality.

The "BRUSCHETTA" project (Arena *et al.*, 2019) uses blockchain to trace and certify the Extra Virgin Olive Oil supply chain, leveraging IoT technologies. Following this, Fernandes et al. (2022) propose a similar application using smart contracts and Web DApps. Carrefour UAE's collaboration with IBM Food Trust was presented at the 2022 Arab International Conference on Information Technology (Eletter *et al.*, 2022).

Among the most recent documents reviewed, Gazzola et al. (2023a) analyze Lavazza's pilot project, which recently introduced a blockchain-tracked product on the market with the xFarm platform, showcasing the evolving landscape of blockchain application in food processing traceability.

Challenges and Advantages in the Application of Blockchain Technology

Selecting the appropriate blockchain type, such as "blockchain and database" (Yang *et al.*, 2021), Ethereum or Hyperledger applications (Caro *et al.*, 2018), dual-chain solutions (Kaijun *et al.*, 2018), or Blockchain for IoT (Arena *et al.*, 2019; Morais *et al.*, 2023a; Xu *et al.*, 2021), depends on the application domain's specific characteristics. This choice requires a detailed pre-evaluation of qualitative and technical aspects, drawing insights from literature.

Transitioning to blockchain in the food processing industry presents several challenges. Resistance to adoption is significant due to the disruption of established practices and stakeholder pushback. The digital transformation introduces complexity, involving numerous actors and layered responsibilities, complicating technological change management. Forming robust agreements on data storage and sharing is critical to safeguard sensitive company information, especially in the global agri-food context. Implementing blockchain traceability systems is financially and resource-intensive, requiring substantial investment in digital infrastructure and staff training. The digital divide between industrialized and developing nations raises concerns about the technology's cost-effectiveness and accessibility.

Conversely, blockchain technology offers numerous advantages for the agri-food supply chain. Its decentralized nature eliminates reliance on central servers, mitigating food security risks and fostering collaboration. Blockchain enhances security, efficiency, and fraud prevention, vital for maintaining food quality and ensuring consumer safety. The technology's ability to promptly detect system failures can significantly reduce food waste and losses, enhancing supply chain sustainability. Developing common standards and protocols is crucial for effective data sharing and collaboration among various blockchain and digital traceability systems.

Cybersecurity remains a critical issue. Blockchain's encryption and decentralization offer intrinsic security measures, but protecting sensitive information and preventing cyber-attacks require additional safeguards. Blockchain's transparency can engage consumers by allowing them to trace food origin and quality, emphasizing education and community awareness in fostering technology acceptance. Navigating the evolving regulatory landscape and ensuring compliance with laws governing blockchain and the agri-food supply chain are essential for successful implementation.

Looking forward, integrating blockchain with emerging technologies like artificial intelligence (AI) and IoT promises to advance traceability and supply chain management further, enhancing process efficiency and security in the agri-food sector.

BUSINESS CASE STUDIES

In the dynamic landscape of the food processing industry, blockchain technology stands at the forefront of revolutionizing traceability and establishing a culture of transparency and trust. This section delves into an array of practical blockchain applications within the agri-food supply chain, featuring compelling business cases that illuminate the path towards enhanced traceability and transparency. The exploration encompasses a spectrum of companies, i.e. Placido Volpone S.r.l., Spinosa S.p.A., Bofrost Italia, Carrefour Italia, Lavazza, and the innovative startup TATTOO WINE, each demonstrating pioneering efforts in leveraging blockchain for varied yet unified objectives.

The analysis begins with Placido Volpone S.r.l., a winery that has adopted blockchain to notarize data internally, marking a significant step towards greater traceability without external verification. This approach underscores both the progress and challenges associated with the absence of third-party validation, serving as a foundational model in the sector’s move towards transparency.

Progressing further, Spinosa S.p.A. and Bofrost Italia exemplify the next phase of blockchain application, focusing on verifiable and transparent traceability. These cases highlight the enhanced accountability and broader supply chain integration that blockchain facilitates. The quality control manager’s ability to record and make accessible comprehensive quality checks represents a leap towards encompassing external suppliers in the traceability process.

Building upon these cases, Carrefour Italia emerges as a trailblazer in the retail domain, being the first to implement blockchain for the traceability of food products, starting with its own-brand chicken. This initiative reveals the complexity of managing a vast network of suppliers and the resultant improvement in supply chain visibility.

Equally transformative, Lavazza's foray into blockchain showcases the technology’s application in a global supply chain, integrating IoT and Agriculture 4.0 tools for data notarization. This highlights the substantial efforts required to navigate the challenges of international supply chains and less industrialized farming contexts.

Completing the panorama, the TATTOO WINE project by Blockchain Wine Ltd. ventures into new territory by combining traceability with tokenization. This initiative opens up an online marketplace that connects companies and consumers globally, pushing the boundaries of what blockchain can achieve in the food processing industry.

These case studies collectively reflect the sector’s diverse approaches to adopting blockchain technology, from internal data notarization at Placido Volpone S.r.l. to the ambitious global marketplace envisioned by TATTOO WINE. Each story contributes to a richer understanding of blockchain’s potential to enhance brand transparency, foster trust among stakeholders, and improve the overall corporate image, thereby painting a comprehensive picture of the ongoing evolution toward more accountable, transparent, and integrated agri-food supply chains.

Placido Volpone Winery and Blockchain Implementation

Placido Volpone S.r.l., a venerable winery with origins in 1890, has taken a pioneering step by incorporating blockchain technology to notarize data for its "Falanghina" wine's production chain, a first in the wine industry. This initiative, spurred by a desire to combat counterfeiting and ensure product authenticity, was realized in collaboration with Ernst & Young (EY) and the tech startup Ezlab. The move to blockchain was part of a broader transformation that began in 2008, transitioning from personal grape production to commercial winemaking, and was further accelerated by a counterfeit incident in 2016, highlighting the need for a more secure system.

The "Wine Blockchain" project at Placido Volpone S.r.l. transitioned through several phases, from a detailed evaluation of winery processes to deploying a blockchain solution that encompassed smart contract creation, data notarization, and launching a consumer-facing landing page, using AgriOpenData—a platform by Ezlab—to simplify data management. This strategic implementation led to a notable 3.5% reduction in production costs and a consequential price increase of 6.2% per bottle, demonstrating a tangible return on investment (ROI) of 14.53%. This initiative, by significantly cutting bureaucratic tasks and boosting product quality control, not only showcases Placido Volpone's innovative approach in the wine industry but also highlights the tangible economic benefits and enhanced market perception achieved through blockchain adoption, thus serving as a compelling model for the broader food processing industry.

Spinosa S.p.A. and Blockchain in Dairy Industry

Spinosa S.p.A., a family-run dairy company famous for Campana DOP buffalo mozzarella, has integrated blockchain technology to ensure complete traceability of its products from farm to table. Starting as a small local dairy and evolving into an international brand, Spinosa's use of blockchain was driven by a need for transparency and certification, especially important as it expanded globally. The company utilizes QR codes on packaging, leading to a dedicated webpage where consumers input a batch code to access detailed information about the product's lifecycle, from breeding to distribution, all adhering to the Consortium for the Protection of Buffalo Mozzarella Campana DOP standards.

The project, leveraging the Ethereum-based Ops Chain Food Traceability platform, enables manual data entry at various production stages, offering an unparalleled transparency level. It covers breeding and milk collection details, processing at the facility, quality assurance measures, and distribution specifics, ensuring each process step is certified and notarized on the blockchain. Consumers can validate the authenticity and integrity of this information through the public registry on Polygonscan, enhancing trust and demonstrating Spinosa's commitment to quality and transparency.

Spinosa's approach exemplifies how blockchain technology can revolutionize traditional industries by providing end-to-end traceability and setting a new standard in the dairy sector. This case underscores the successful application of blockchain to improve brand reputation, consumer trust, and competitiveness, marking a significant advancement in the dairy industry's embrace of digital innovation.

Bofrost Italia's Blockchain Implementation for Frozen Food Traceability

Bofrost Italia has harnessed blockchain technology to revolutionize transparency and quality assurance in the frozen food supply chain. Collaborating with EY on a blockchain solution via the EY OpsChain Traceability platform, Bofrost initiated this innovative approach with Nordic Cod Fillets and Artichoke Heart Wedges, focusing on verifying supplier actions and guaranteeing product integrity. This system enables consumers to trace the journey of their food by scanning a QR code, aligning with increasing demands for product transparency.

The blockchain records essential details such as fishing practices, including MSC certification for sustainable fishing, and freezing processes ensuring fish are frozen promptly at the right temperature. It also tracks packaging, storage conditions, and quality control measures, down to the delivery phase, where transportation temperatures are meticulously monitored. This comprehensive transparency extends to making chemical and microbiological control reports publicly accessible, enhancing consumer trust, and demonstrating Bofrost's commitment to quality and safety.

Bofrost's initiative represents a significant advancement in the food industry, illustrating how blockchain can serve as a tool for ensuring food safety and strengthening supply chain accountability. By providing a detailed account of food products' lifecycles, Bofrost not only meets the growing consumer demand for information and authenticity but also establishes a new benchmark in the industry for transparency and trust. This case study serves as a model for leveraging digital innovation to enhance the integrity and reliability of food supply chains.

Carrefour Italia: Trailblazing Blockchain in Retail

Carrefour Italia set a precedent as the first major retailer in Italy to implement blockchain for food traceability, starting with its outdoor-raised, antibiotic-free chicken production chain in September 2018. This initiative now encompasses an expansive network including 29 farms, feed production sites, and a slaughtering plant. With plans to extend blockchain traceability to its own-brand citrus products, Carrefour's adoption of EY OpsChain Traceability underscores a significant leap towards comprehensive digital transparency. Consumers can access detailed product information - from farming practices and feed to slaughtering locations and transportation methods - simply by scanning a QR code. This approach has not only enhanced Carrefour's supply chain visibility but also significantly boosted sales and customer engagement, reflecting a growing consumer demand for quality assurance.

Lavazza S.p.A.: Infusing Blockchain into Coffee Production

In late 2022, Lavazza introduced "Noble Vulcano," a special blend under its "1895 Coffee Designers" brand, utilizing blockchain to assure sustainability and traceability (Beverfood.com, 2022; Gazzola *et al.*, 2023b). By integrating xFarm platform functionalities with blockchain technology, Lavazza provides transparent insights into the entire coffee production process. This includes detailed climatic and soil parameters collected by xFarm team members in Brazil, enhancing the quality metrics and sustainability practices of coffee farming. The project, aimed at harnessing cutting-edge IoT and blockchain solutions, offers a comprehensive view of the coffee supply chain, from cultivation to consumer, paving the way for a new standard in the coffee industry's digital transformation.

TATTOO Wine: Digitizing the Wine Market

Blockchain Wine Ltd., through its collaboration with EY OpsChain, has developed the TATTOO Wine marketplace to promote and sell premium wines globally, with a keen focus on rapidly growing Asian markets. This e-commerce platform leverages blockchain for wine traceability and tokenization, enabling consumers to purchase wines as digital tokens that represent ownership of uniquely identified wine batches registered on the Ethereum blockchain. This innovative approach to wine sales and supply chain transparency allows real-time tracking of shipments and customs processes, offering a secure and digitized solution for verifying supply chain data and automating procurement and inventory orders. The inclusion of NFC seals in rare wine bottles adds an additional layer of protection against counterfeiting, illustrating the project's comprehensive strategy to enhance product authenticity and consumer trust through blockchain technology.

DESIGNING A TRACEABILITY SYSTEM FOR THE FOOD PROCESSING INDUSTRY

The goal of designing a traceability system for the food processing industry is to establish a standard reference model addressing supply chain complexities. This requires a detailed analysis of actors, processes, resources, and data flows to ensure seamless traceability. A unified approach is proposed to overcome communication barriers between developers and users, utilizing interviews and collaborations to identify system requirements. This leads to a methodological framework using a formalized language for clear business management support, setting the stage for blockchain system design and its translation into executable code.

The methodology emphasizes the importance of Business Process Modeling (BPM) for understanding and supporting information systems (de Oca *et al.*, 2015). It involves a "farm to table" analysis to identify necessary data and responsible divisions, incorporating sensors for data collection. A key feature is the system's ability to monitor data at both intra-company and inter-company levels, enhancing business operations and trust among partners (Corallo *et al.*, 2018).

Business process modeling, used for business process improvement (BPI) and reengineering (BPR) (Anand *et al.*, 2013), represents organizational processes and their interactions. Tools like ADONIS, ARIS, and MS Visio aid in developing models to meet specific requirements, thereby enhancing business process management (Teixeira *et al.*, 2018).

Simplifying the Traceability System Design

This section proposes a model for agri-food traceability, offering guidelines for certification stages, production process mapping, and blockchain data integration. Addressing the diversity in organizational structures, it is crucial to understand each entity for precise planning and outcomes, requiring collaboration between technology and agri-food experts.

The approach can be based on integrated ARIS architecture principles, creating a business process model that simplifies complexities into manageable views.

To tackle the model's intricacy, it can be initially segmented into single views - Organizational, Functional, Product, Data, and Process - as shown in ARIS House (Grigoroudis and Doumpos, 2021) (see Figure 2). Each view utilizes specific diagrams and rules for a comprehensive reassembly of necessary information, relationships, and resources for each process.

The Functional View breaks down business processes into hierarchical functions, depicted through function trees. This includes modeling IT applications that support business functions in "Application System Type Diagrams," which are key for tracking blockchain data communication between company IT systems. The Organizational View charts the organizational structure to detail roles, responsibilities, and workflows, reflecting the company's hierarchy and operational flows, which is crucial for process modeling accuracy. The Data View focuses on structuring and utilizing information within the organization, using Entity-Relationship Models (ERMs) to map key data elements and their interrelations, which is pivotal for establishing a blockchain-based traceability system. Meanwhile, the Product View illustrates the flow from raw materials to finished goods, marking stages where traceability data should be captured for inclusion in the blockchain ledger. Finally, the Process View uses Business Process Modeling and Notation (BPMN) for a detailed representation of organizational operations, informing smart contract design for the blockchain system. This is complemented by Function Allocation Diagrams (FADs), which detail resource allocation and responsibilities within process stages, enhancing the understanding of blockchain's potential for transparency and verifiability.

Through this framework, businesses can develop an effective, blockchain-based traceability system by aligning technological requirements with business processes, ensuring extensive traceability within the food processing industry. This approach simplifies complex processes and underlines the necessity of a unified method for integrating blockchain technology effectively.

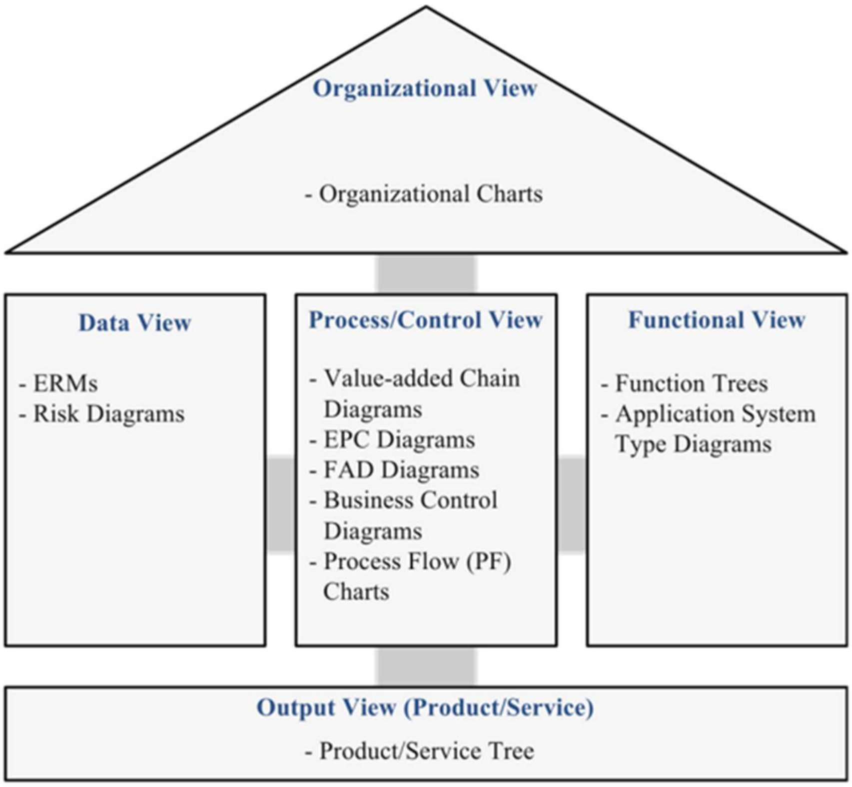

Figure 2 - The Different Views of "ARIS House" (Grigoroudis and Doumpos, 2021).

UML Diagram for Enhanced Traceability

Building on the foundations laid in the previous section, the integration of the aforementioned views culminates in the creation of a unified architecture for process chains (Figure 3). Analyzing multiple entities within the Food Value Chain (FVC) offers a holistic perspective on process integration, essential for strategic coherence and establishing traceability systems (Ciborra, 1997). The UML domain model framework presented by Morais et al. (2023b) details potential blockchain data and interrelations for traceability.

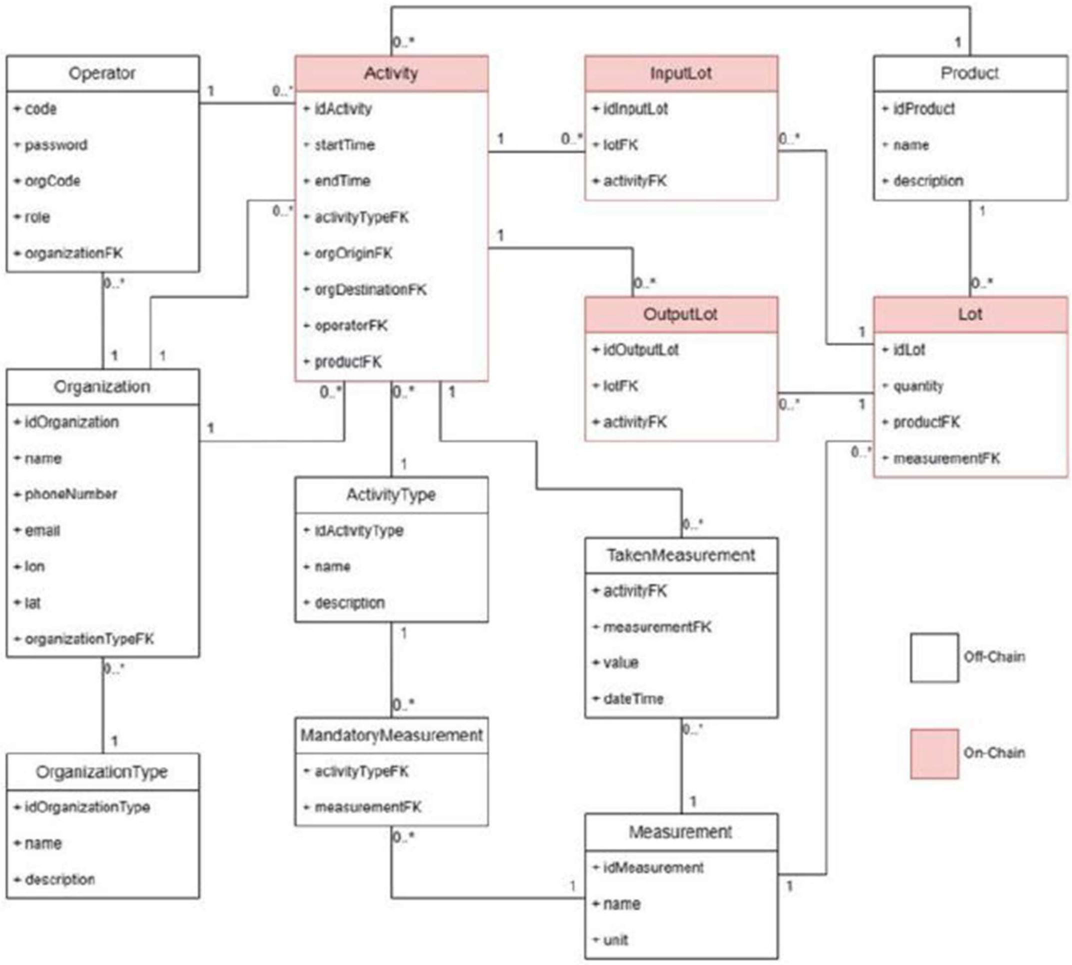

Figure 3 - UML Diagram for Traceability (Morais *et al.*, 2023b).

Implementing a "blockchain + database" methodology allows for the differentiation between data stored on-chain for transparency and off-chain for privacy, represented through distinct color coding (white and pink). The model categorizes eleven distinct classes, essential for the system:

- **Organization, Organization Type, and Operator**: Defines entities engaging in various activities within the chain, each with unique identifiers and roles, ensuring clear delineation of responsibilities and specialization areas.
- **Product and Lot**: Tracks products and lots, distinguishing between database-stored data and blockchain traceability data.

- **Activity Type, Measurement, Mandatory Measurement, and Taken Measurement**: Links activities and required measurements, recording specific data like temperature or pH for accurate and verifiable data capture.
- **Input Lot and Output Lot**: Illustrates dependencies on input and output lots, tracking these elements through the blockchain to maintain a comprehensive view of the product lifecycle.

This structured approach not only simplifies the incorporation of blockchain technology into the traceability system but also enhances the system's integrity and usability across the FVC, ensuring data privacy where needed and transparent traceability where possible.

Expected Outcomes for a Blockchain-based Traceability System in the food processing industry

Following the modeling considerations and deriving the requirements for a blockchain-based traceability system, experts in computing within the field are equipped with the necessary tools to develop an architecture as depicted in Figure 4.

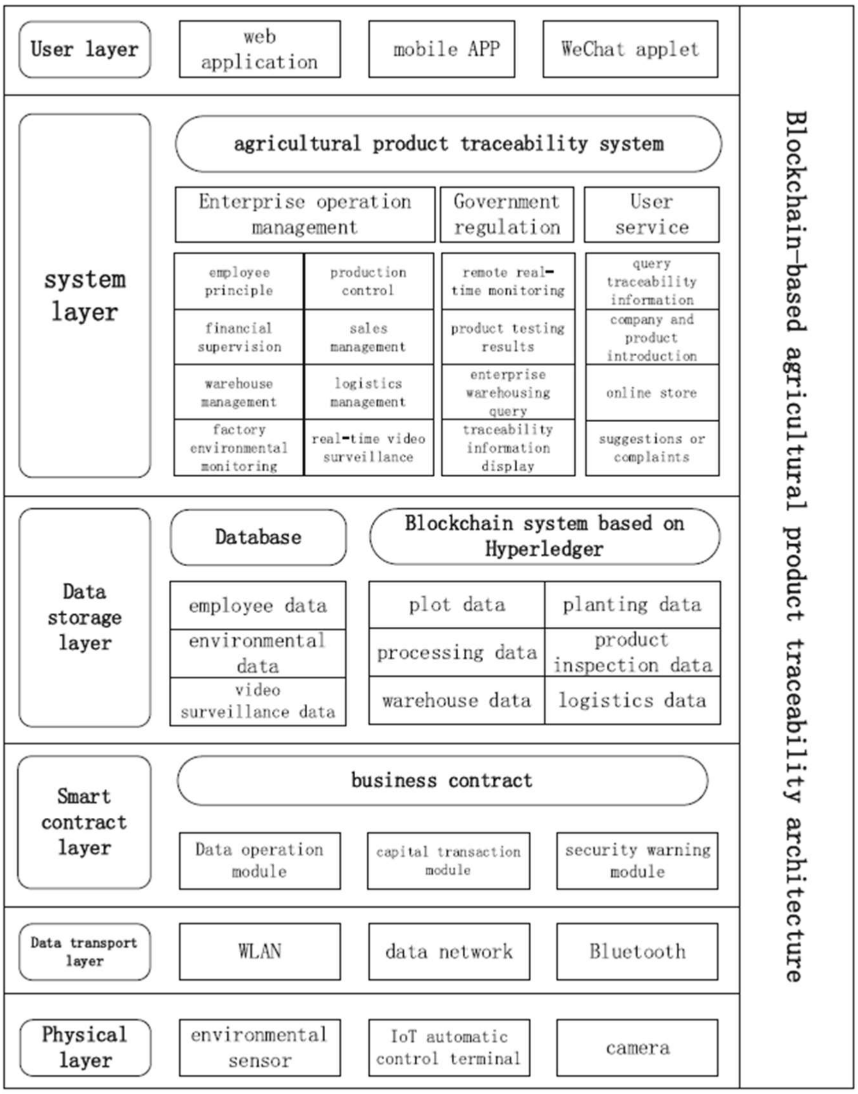

Figure 4 - Architecture of the Blockchain-based Traceability System (Wang and Liu, 2019).

The architecture of a blockchain-based traceability system is divided into six layers:

- **User Layer**: Interface between users (farmers, processors, manufacturers, distributors, regulators, and customers) and the system, facilitating integration with upper-level software systems.
- **System Layer**: Includes operational management software, government supervision software, and customer service software, acting as a control component for transforming user inputs and conveying information between the user and Data Storage Layer.
- **Data Storage Layer**: Responsible for data storage, with the blockchain as the core component. This layer includes a database for non-essential traceability information to prevent blockchain overload.

- **Smart Contract Layer**: Based on commercial agreements, this layer includes modules for data augmentation and retrieval, automated capital transactions, and security warnings for unauthorized access or data irregularities.
- **Data Transport Layer**: Conveys data from the hardware devices of the Physical Layer to higher levels, ensuring all participants are registered users with correct key pairs for digitally signing transactions.

According to Wang and Liu (2019), the operational model of a blockchain-based traceability system is structured as follows. The traceability process begins with the grower, who records details about food products and agricultural conditions using blockchain technology. Each process stage is stored in distinct blockchain blocks with timestamps. As food moves to processing, details are linked to the grower's block and recorded in the ledger. Each stage receives and adds information from the previous block. The final product reaches the consumer, who can access complete traceability of the food chain via blockchain, ensuring immutability and verifiability, enhancing transparency and safety.

CONCLUSIONS

Concluding this analysis on the role of digitalization in the traceability of the food processing industry, it is clear that transparency and accuracy in traceability are indispensable. Blockchain technology, with its decentralized and immutable structure, stands out as a promising solution for ensuring information integrity. However, for traceability to meet market needs effectively, manual data recording and entry into the blockchain, even when supported by specially formulated databases, may lead to errors and fail to guarantee the veracity of shared information. Thus, integrating Industry 4.0 tools with Blockchain Technology for automatic data recording emerges as a valuable approach.

Digitalizing processes presents significant investment and implementation challenges, particularly in less industrialized countries. The agri-food sector's operators may lack necessary training and show resistance to adopting innovative systems. Yet, successful case studies, such as the Placido Volpone Winery's blockchain implementation, demonstrate that innovation is feasible with tailor-made solutions, even though many are still in the pilot phase.

At this development stage, blockchain's impact on agri-food supply chain management doesn't lead to decentralization but strengthens existing networks. Typically, a central company takes on supply chain management responsibility, encouraging suppliers to join a blockchain-equipped supply chain network.

The future lies in the digitalization of all processes, but universal solutions are needed. Considering suppliers serving multiple processing companies, adapting to different traceability systems complicates achieving a standardized approach. For food supply chain traceability to become a shared benefit reality, technology usage must become universal. Humidity, location, pressure sensors, labeling, and reading systems should enable standardized, shared, and synchronized information flows, ensuring universal access across the supply chain following the same traceability standards.

The Baseline project (2022) by Microsoft Dynamics 365 exemplifies a potential future challenge. It aims to integrate informational systems across sectors, creating a shared and certified data ecosystem, allowing different systems to "communicate" and synchronize, sharing real-time data of any nature, such as quality data along the entire production chain. Baseline (2022) is a standard enabling state machines to achieve and maintain data consistency and workflow continuity, using a network as a common frame of reference. A toolkit helps companies coordinate complex and multilateral business processes and workflows while ensuring privacy and keeping data in record systems. This suggests a significant step toward solving the challenge of interoperability between different blockchain and digital traceability systems. Developing common standards and communication protocols is crucial for effective data sharing and consistency across the supply chain, facilitating collaboration among sector actors.

In summary, addressing the current gaps in the food processing industry to enhance traceability requires a strategy based on the complete digitalization of processes through the implementation of Industry 4.0 tools, ensuring data authenticity. To assure information immutability and transparency, decentralized systems like blockchain technology are the most reliable solutions in terms of security and privacy protection. Moreover, secure data synchronization and sharing through system interoperability would be a fundamental added value for an efficient traceability system.

This study, through a literature review combined with real-case studies analysis, including the pioneering blockchain implementation by Placido Volpone Winery, has shown that blockchain-based approaches significantly enhance supply chain transparency and quality management in the food processing industry. While highlighting the potential and challenges of practical implementations, it underscores the crucial need for modern digital tools to meet societal demands for food safety and quality, particularly emphasizing transparency concerning raw materials, processing, and preservation methods. This comprehensive overview of modern digital tools' role in improving quality traceability in the food processing sector is not only original but offers valuable insights for businesses aiming to adopt these technologies for better quality management and traceability.

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Lean, Six Sigma and ISO Management Systems Standards: An Integration Framework

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STRUCTURED ABSTRACT

Purpose- This paper proposes a conceptual framework to integrate three relevant business models: Lean Management, Six Sigma and international ISO Management Systems Standards (MSS). It explores the multiples synergies among them from an organizational excellence viewpoint.

Design/methodology/approach- From the literature review, Lean Management, Six Sigma, and international Management Systems Standards based on the Annex SL common structure provided by ISO are thoroughly discussed and compared. From this, logical synergies and complementarities between these three approaches are identified, explored and discussed. Altogether, those linkages will drive the development of a conceptual framework to guide their integration.

Findings- The integration model relies on many organizational excellence principles and its guidelines help managers and team leaders to properly utilize a set of Lean and Six Sigma methods and tools according to their purpose. In addition, the model provides a clear relationship between those tools and the clauses of requirements included in the ISO Management Systems Standards.

Research limitations/implications- The framework does not cover other normative references for management systems that are not published by ISO, such as SA 8000 on social accountability systems. In addition, it does not discuss management standards for specific sectors of activity, such as IATF 16949 for the automotive industry, ISO 13485 for medical devices, among others.

Practical implications- The model and its guidelines are useful for all those organizations that developed or intend to develop management systems based on ISO standards.

Originality/value- As far as the authors of the paper are aware, this is the first paper that proposes a conceptual model generalizing the integration of Lean and Six Sigma with certifiable ISO management systems standards that applies to all type of organizations, regardless of their size and sector.

Keywords: Lean, Management Systems Standards, Organizational Excellence, Six Sigma.

Paper type: Conceptual paper.

INTRODUCTION

The past decades have witnessed the widespread diffusion of internationally recognized management systems standards (MSS) and their respective certification schemes (Lo and Young, 2018). Before the early 2000s, they tended to focus primarily on quality management systems, but since then their scopes has diversified substantially, currently covering many of the aspects of a modern management system, including: quality, environment, energy efficiency, information security, occupational health and safety, social accountability, among others (Kohl, 2020). This evolution was induced by the globalization process, which has led many organizations to seek to implement standards that helped them to improve their management practices and thus remain competitive in the market (Cabecinhas et al., 2021). In this regard, certifiable international standards published by the International Standards Organization (ISO) are particularly relevant. Although they can be helpful for companies to improve their overall performance, they are limited in terms of providing the tools for them to perform sustainability-improvement activities (Souza and Alves, 2018). Lean and Six Sigma are two well-known approaches that provide the means to conduct business process improvement initiatives (Ahmadi and Rahmani, 2023; Marques et al., 2016), as they also contribute to promoting a culture of continuous improvement, hence sustaining organizational management systems (Kelly, 2016).

The proliferation of ISO standards for management systems in most countries, especially over the last twenty years, led to the development of MSS integration models (Barbosa et al., 2022; Bernardo et al., 2018). The history of integrated management systems began when the ISO 14001 standard for environmental management systems was launched in 1996 (Gianni and Gotzamani, 2015), due to the need to articulate it with the already existing ISO 9001 for quality management systems. From the early 2000s onwards the number of new MSS issued by ISO has increased tremendously (Ferradaz et al., 2022; Asif et al., 2010). Nevertheless, ISO 9001 and ISO 14001 remain the most certified management systems standards worldwide (Hernandez-Vivanco and Bernardo, 2023; Cabecinhas et al., 2021), Other relevant international generic MSS include ISO 45011 for occupational health and safety systems, ISO 50001 for energy management systems, ISO 55001 for asset management systems, ISO 21001 for educational management systems, ISO 22301 for business continuity management systems, ISO/IEC 27001 for information security information systems, ISO 44001 for collaborative business relationship management systems, and ISO 22316 for security and resilience management systems (Kohl, 2020).

Many organizations expect to increase the economic benefits from their ISO certification, but to that purpose they need to pursue changes in their governance (Cândido et al., 2021) and business models

(Azevedo and Almeida, 2021). To foster productivity, many of them are seeking the adoption of more advanced management approaches, including Lean Management and Six Sigma, (Sá et al., 2022). More mature companies are even looking for an even broader perspective by pursuing the development of company-wide management systems based on the guiding principles and best practices provided by the organizational excellence models (Santos and De Waal, 2019). Despite the inherent advantages, this reality raises major practical challenges in terms of integrating this set of models. There is a high risk of creating redundancies and duplications of procedures. Symptoms of this fact include the creation of an excessive number of documents, unclear or overlapping responsibilities and authorities among functional areas of the organization, incrementation of bureaucracy in business processes, just to mention a few (Souza and Alves, 2018). The challenge is therefore to develop a framework that allows management systems based on the requirements of international ISO standards to be effectively integrated – given the reality of their spread in companies operating in Portugal – with Lean Management and Six Sigma programs – which will help to improve and sustain productivity and efficiency gains in various types of organizational processes.

The development of integration frameworks to link Lean Management and/or Six Sigma with quality management systems based on ISO 9001 and with few other relevant ISO MSS has been explored by various authors, but so far, no integrative model has been proposed that can be generalized to several management standards at the same time. This paper explores a conceptual integration framework capable of taking advantage of multiples synergies between Lean and Six Sigma with the common high-level structure for all generic ISO management systems standards provided by Annex SL. The framework that supports the proposed integration model consists of four interlinked blocks that together comprise all the main activities for managing an organization, hence relying on many of the core organizational excellence principles.

LITERATURE REVIEW

The overview of the literature has been conducted through extensive research in books, scientific papers, and conferences proceedings using keywords such as 'lean iso', 'six sigma iso', 'lean six sigma iso', 'lean management systems standards', 'six sigma management systems standards', 'lean six sigma management systems standards', 'lean iso management systems', 'six sigma iso management systems', 'lean six sigma iso management systems', etc. Moreover, the search tools of 'google scholar' and 'books.google.com/ngrams' have been used for the quantification of the researched terms appearance over the past 30 years.

Born from many of the Total Quality Management (TQM) principles, both Lean and Six Sigma philosophies have captured increasing interest over the years (Sreedharan and Sunder, 2018; Andersson et al., 2006) by both the scientific and business communities. Lean and Six Sigma have different focus, but they are complementary, so they are often used in conjunction with an approach usually known as Lean Six Sigma (Yadav and Desai, 2016). Lean principles and tools focus on improving process flow/speed and eliminating waste (Onofrey et al., 2021), while Six Sigma aims to minimize the occurrence of defects by reducing process variability (Marques et al., 2016). Both Lean and Six Sigma tools can be used throughout improvement projects following the well-known five-step DMAIC roadmap (Define-Measure-Analyze-Improve-Control) roadmap (Trubetskaya et al., 2023; Snee, 2010).

The normative references for quality systems are the foundations of today's management systems standards (MSS). The first quality management standards derived from the architecture of military quality standards, as they were elaborated in the US and UK between 1940 and 1980 (Gibbon, P. and Henriksen, 2011). In 1979, The British Standards Institution eventually developed the military standards into BS 5750 series (parts 1, 2 and 3), being the source for the publication of the first versions of the ISO 9000 family of standards in 1987 (Ho, 1994). The ISO 9000 standards have resulted in a significant worldwide phenomenon, considering the impressive growth and diffusion of certification according to the ISO 9001 standard in several countries and different kinds of organizations (Ikram et al., 2021; Sampaio et al., 2009). Since the publication of the ISO 14001 for environmental management systems in 1996 and the 2000 version of ISO 9001, the world witnessed a proliferation of many other generic MSS (Barbosa et al., 2022; Gianni and Gotzamani, 2015). Because many organizations have been increasingly adopting different general and sectorial MSS, the International Organization for Standardization promoted the integration of MSS with the publication of the High-Level Structure, known as Annex SL, in 2012 (Silva et al., 2020). According to the results available in the 2022 ISO Survey of Certifications (ISO, 2023), ISO 9001 remain by far the standard with the highest number of certificates issued, followed by ISO 14001. After these, the list of generic MSS with the highest number of certifications worldwide comprises the following ranking: ISO 45001, ISO/IEC 27001, ISO 22000 (food safety management systems), ISO 50001, ISO/IEC 20000-1 (information technology service management systems), ISO 37001 (anti-bribery management systems), ISO 22301 (business continuity management systems), ISO 39001 (road traffic management systems), and ISO 50001.

The results of the literature review regarding the integration of Lean and/or Six Sigma with a set of generic MSS published by ISO are summarized in Table 1. The following conclusions can be derived:

- Attending to the search criteria described in the first paragraph of the "literature review section, a total of 55 references were identified matching the criteria, the first of which was in 2003.
- 37 of the references (i.e. 67%) focus on the integration with ISO 9001: 16 of them refer to synergies with Six Sigma, 7 with Lean, and 14 with both Lean and Six Sigma.
- The integration of Lean and/or Six Sigma with ISO 14001 is dealt with by 4 references, with ISO 45001 and ISO 55001 by 1 reference each, with ISO/IEC 27001 or ISO/IEC 27002 by 3 references, and with ISO 55001 by 2 references.
- Only 7 of the 55 references concern the integration of Lean and/or Six Sigma with two or more generic management systems standards.
- The first publications focused mainly on integrating Six Sigma with the ISO 9001 standard, but since 2010, the trend has been to extend the integration frameworks to an ever wider set of MSS and to include the Lean Management aspect as well.

The literature review and the conclusions drawn from it allowed to identify the following research gaps:

- There is still no framework that integrates Lean and/or Six Sigma with ISO management systems' standards from an organizational excellence, company-wide, perspective.
- There is still a lack of integration models that generalize the synergies between continuous improvement approaches and all the international ISO MSS based on the high-level structure provided by Annex SL.
- To the best of our knowledge, no publication has yet described a clause-by-clause applicability of Lean and Six Sigma tools to assist organizations in meeting the requirements of ISO standards for management systems.

These gaps are addressed by the conceptual model proposed in the next section of this paper, thus contributing to the evolution of the state of the art in this field of science. The model also has practical implications for already certified companies, regardless of their size or business sector, namely by providing guidelines to help them develop initiatives for continuous improvement and organizational excellence, based on their existing management systems.

Table 1 – Literature focusing on the integration of Lean and/or Six Sigma with generic ISO MSS.

Reference	Integration scope	Description
Trubetskaya et al. (2023)	Lean and Six Sigma with ISO 55001	Present a Lean Six Sigma project conducted in an Irish dairy plant operation that resulted in an optimization of the energy consumption, hence demonstrating how Lean Six Sigma can be used in the context of an energy management system (ISO 55001).
Farahbod et al. (2022)	Six Sigma with ISO/IEC 27001	It is explored the role that Six Sigma can have in the enhancement of the information security management system (ISO/IEC 27001) effectiveness, in particular improving the cybersecurity methods and practices.
Farrukh et al. (2022)	Lean and Six Sigma with ISO 55001	Two case studies are conducted in Pakistani companies to assess if Green Lean Six Sigma practices, including the integration of Lean Six Sigma with ISO 14001, have a significant impact on environmental performance as well as on personnel safety.
Nedra et al. (2022)	Lean and Six Sigma with ISO 9001	From data collected through quantitative surveys and interviews conducted in 85 small and medium enterprises (SMEs) in the textile industry, it was concluded the ISO 9001 standard has a significant influence in the successful implementation of Lean Six Sigma (LSS), and this conclusion was validated through four case studies.
Vanichchinchai (2022)	Lean with ISO 9001	Based on data that was collected from 516 manufacturers in Thailand, it is examined if ISO 9001 certification impacts their Lean programs and the supply chain relationship.
Sá et al. (2022)	Lean and Six Sigma with ISO 9001	Propose an ISO 9001:2015 interface model with the integration of Lean Six Sigma tools and methodologies for all the standard's sections containing clauses of requirements
Velmurugan and Dhingra (2021)	Six Sigma with ISO 55001	Present the sequence of stages to develop an asset maintenance strategic plan to achieve maintenance excellence, which include some synergies between asset management related international standards, in particular ISO 55001, and the Six Sigma DMAIC roadmap that is adopted to promote continuous improvement.
Souza (2021)	Lean with ISO 9001, ISO 14001, ISO 45001, and ISO 26001	Describe the steps to implement the Lean-Integrated Management System for Sustainability Improvement (LIMSSI) model, hence developing a combined quality (ISO 9001), environmental (ISO 14001), occupational health and safety (ISO 45001), and social responsibility (ISO 26000) management systems standards with Lean tools.
Minovski et al. (2021)	Lean with ISO 9001	Investigate the global impact that the implementation of the Lean tools has on ISO 9001 certified companies in North Macedonia as well as such Lean tools are applicable throughout the ISO 9001 requirements.
Betegon et al. (2021)	Lean with ISO 9001	Illustrate the implementation of a quality management system based on ISO 9001:2015 at an Advanced Simulation Center (ASC), a training facility of a health and social care organization, also making use of Lean principles and tools.
Nevels et al. (2020)	Lean and Six Sigma with ISO 45001	It is explored how a wide set of Lean and Six Sigma tools can be utilized by occupational health and safety professionals in the context of a management system, including for the ISO 45001 standard.
Kaganov (2020)	Lean with ISO 9001, ISO 13485, ISO 14001, and ISO 45001	Propose the use of Lean tools, including visual management, to simplify the documentation system inherent to different types of ISO MSS and to prevent over-detailed standard operating procedures.
Veena and Prabhushanka (2020a)	Six Sigma with ISO 9001	The critical success factors for the implementation of Six Sigma are identified and then allocated to the different sections of clauses comprising the ISO 9001:2015 standard.
Veena and Prabhushanka (2020b)	Lean and Six Sigma with ISO 9001	Suggest a roadmap towards the implementation of Lean Six Sigma through the structure and requirements of a quality management system based on the ISO 9001:2015 standard.
Djapic et al. (2019)	Lean with ISO 9001	Propose a conceptual model that provides logical interconnections between: organization planning activities, PDCA cycles methodology, clauses of requirements from the ISO 9001:2015 standard, and a set of applicable Lean tools.
Marques et al. (2019)	Lean and Six Sigma with ISO 9001	A conceptual model is proposed to integrate Lean and/or Six Sigma methods, and tools with the clauses of the ISO 9001 standard using the high-level structure of Annex SL.
Veena and Prabhushankar (2019)	Lean and Six Sigma with ISO 9001	A comparative study among Lean, Six Sigma, and the 2015 version of ISO 9001, from which a conceptual framework to integrate them is proposed to fill the identified challenges and limitations.

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Table 1 – Literature focusing on the integration of Lean and/or Six Sigma with generic ISO MSS. (*continued*)

Reference	Integration scope	Description
Bacoup et al. (2018)	Lean with ISO 9001 and ISO 14001	Propose a Lean quality management system (LQMS) model that enables the combination of the 2015 versions of the ISO 9001 and ISO 14001 standards with Lean Management.
Souza and Alves (2018)	Lean with ISO 9001, ISO 14001, ISO 45001, and ISO 26001	Propose a Lean-Integrated Management System for Sustainability Improvement (LIMSSI) model that incorporates correlations of quality (ISO 9001), environmental (ISO 14001), occupational health and safety (ISO 45001), and social responsibility (ISO 26000) requirements with the principles and tools of Lean manufacturing.
Ismyrlis and Moschidis (2018)	Six Sigma with ISO 9001	Based on a research survey study involving a sample of Greek companies, it is investigated whether Six Sigma, from a managerial point of view, have the potential to benefit the implementation of an ISO 9001 quality management system, and it was concluded that in general the answer is positive.
Fonseca and Domingues (2018)	Lean and Six Sigma with ISO 9001	Study the level of adoption of Lean, Six Sigma, and other continuous improvement (CI) methodologies by Portuguese ISO 9001 certified organizations, having concluded that there is a moderate degree of use of these (CI) approaches.
Bakator et al. (2018)	Lean and Six Sigma with ISO 9001	The concepts of Total Quality Management (TQM), ISO 9001, Lean, and Six Sigma are presented, and their differences, similarities, and success factors are identified so that synergies can be exploited between them.
Zenchanka. and Malchenka (2017)	Lean with ISO 9001, ISO 14001, ISO 50001 and ISO 45001	Analyze the relationship between Lean and the requirements of various generic MSS, including ISO 9001(quality systems), ISO 14001(environmental systems), ISO 50001(energy systems), and ISO/DIS 45001(occupational health and safety systems).
Olaru et al. (2017)	Six Sigma with ISO/IEC 27001	Explore multiple application possibilities of making use of Six Sigma tools to strengthen the effectiveness of information security management systems based on ISO/IEC 27001.
Mkhaimer (2017)	Lean and Six Sigma with ISO 50001	Develops the Lean Six Sigma energy management model (LSS_EnMS) that articulates the requirements contained in the ISO 50001 standard for energy management systems with the DMAIC roadmap used in Lean Six Sigma projects.
Marques et al. (2016)	Lean and Six Sigma with ISO 9001	Propose an integration framework where the life cycle stages inherent to a Lean and/or Six Sigma project can be systematically related with the applicable clauses of requirements contained in ISO 9001:2015.
More and Pawar (2015)	Six Siga with ISO 9001	Discuss the implementation of Six Sigma along with ISO 9001 quality management systems in the textile industry of India.
Karthi et al. (2014)	Lean and Six Sigma with ISO 9001	Compare the results obtained by two ISO 9001:2008 certified enterprises that employed the L6QMS-2008 model in effectively adopting Lean Six Sigma practices within their quality management system.
Adina-Petruţa and Roxana (2014)	Six Sigma with ISO 9001	Describe synergies between Six Sigma and quality management systems based on the model provided by ISO 9001 to promote the development of continuous improvement efforts in higher education institutions.
Kurdve et al. (2014)	Lean with ISO 9001, ISO 14001, and OHSAS 18001	Propose integration guidelines to articulate relevant production systems models, including Lean, with environmental management based on the ISO 14001 standard and related issues such as quality (ISO 9001) and safety (OHSAS 18001).
Vanzant-Stern (2014)	Lean and Six Sima with ISO 9001	Presents how Lean and Six Sigma tools can play a key role in ISO 9001 certification or recertification efforts.
Chiarini and Vagnoni (2014)	Lean and Six Sigma with ISO 9001	Based on the investigation of how a group of 23 manufacturing organizations committed with Lean Six Sigma programs conduct efficient and effective shop-floor audits, a set of good practices patterns are identified and then compared with the more formal audit pattern used for evaluating compliance with the ISO 9001 standard.
Karthi et al. (2013)	Lean and Six Sigma and ISO 9001	Description of a case study of implementing the L6QMS-2008 model to integrate Lean Six Sigma with ISO 9001:2008 in a textile mill.
Marques et al. (2013)	Six Sigma with ISO 9001	Provide a set of guidelines to combine and integrate the activities of a Six Sigma program with the clauses of the ISO 9001:2008 standard.

Table 1 – Literature focusing on the integration of Lean and/or Six Sigma with generic ISO MSS. (*continued*)

Reference	Integration scope	Description
Swink and Jacobs (2012)	Six Sigma with ISO 9001	The impact that a previous ISO 9001 certification has on the adoption of a Six Sigma program by organizations is studied, with the conclusion that such certification is not a determining maturity factor in this adoption.
Sivaram et al. (2012)	Lean with ISO 9001	By establishing a set of connections between the elements, models, tools, and techniques inherent to the total productive maintenance (TPM) and the clauses of requirements contained in the ISO 9001:2008 standard, an integration roadmap is proposed.
Karthi et al. (2012)	Six Sigma with ISO 9001	Literature review regarding the integration between Six Sigma and ISO 9001-based quality systems.
Habidin and Yusof (2011)	Lean Six Sigma with ISO 14001	The effect that ISO 14001 certification has in the relationship between Lean Six Sigma and Operational Performance is analyzed based on a case study conducted in the Malaysian automotive industry.
Marques et al. (2011)	Six Sigma with ISO 9001	Propose ways to integrate Six Sigma with a quality management system based on ISO 9001 by making use of the structure and common elements of the ISO Guide 72.
Karthi et al. (2011a)	Lean and Six Sigma with ISO 9001	Propose the L6QMS-2008 framework for integrating the DMAIC methodology and the typical belt-based training infrastructure of a Lean Six Sigma program with the eight clauses of requirements the ISO 9001:2008 standard.
Karthi et al. (2011b)	Lean and Six Sigma with ISO 9001	An alternative version of the ISO 9001:2008 standard is proposed by adding specific Lean and Six Sigma requirements to the existing underlying structure.
Chiarini (2011)	Lean with ISO 9001	Explores the specific role that Lean tools and principles can have under each clause of the ISO 9001:2008 standard, formulating integration guidelines for all of them.
Johannsen (2011)	Six Sigma with ISO 9001	Review of the literature concerning the integration of techniques and methods in quality management, including the combination between Six Sigma and ISO 9001 for quality management systems.
Salah et al. (2010)	Lean and Six Sigma with ISO 9001	A high-level integration perspective called Total Company-Wide Management System (TCWMS) is presented, being regarded as an expansion for Total Quality Management (TQM) by incorporating synergies between continuous improvement methodologies like Lean Six Sigma and ISO 9001 quality management systems.
Marsh and Perera (2010)	Lean and Six Sigma with ISO 14001	Based on a research survey, it is concluded that by integrating business improvement tools and techniques such as Lean Six Sigma with ISO 14001 will contribute to increase the effectiveness of problem-solving efforts within the environmental management system.
Bewoor and Pawar (2010)	Six Sigma with ISO 9001	Propose two frameworks to integrate ISO 9001 and Six Sigma, one at a managerial/macro level (links Six Sigma with ISO 9001 attending to the quality management principles) and the other at an operational/micro level (relates the clauses of requirements of the ISO 9001:2008 standard with the five stages comprising the six Sigma DMAIC roadmap).
Micklewright (2010)	Lean with ISO 9001	Establish relationships between Lean principles and the quality principles grounding the business practices promoted by ISO 9001 and propose guidelines regarding the adoption of Lean tools and practices in the scope of the ISO 9001 standard.
Marques and Requeijo (2009)	Six Sigma with ISO 9001	Discuss how a SIPOC diagrams often used in Six Sigma projects can play an important role in mapping and interrelating key processes that are managed in the scope of an ISO 9001 quality management system.
Laddychuk (2008)	Lean and Six Sigma with ISO 14001 and OHSAS 18001	Present a case study at Alcan that illustrates how the company adopts Lean Manufacturing and Six Sigma to foster continuous improvement, one of the building blocks of the existing integrated management system based on the ISO 14001 and OHSAS 18001 standards.
Yeung (2007)	Six Sigma with ISO 9001	Based on the experience obtained from two ISO 9001 certified secondary schools in Hong Kong, it is concluded that incorporating the standard's clauses of requirements into a Six Sigma program can benefit the organizational cultural environment.
Saleh et al. (2006)	Six Sigma with ISO 17799	Present an approach to apply the ISO 17799:2005 standard (current ISO/IEC 27002) to manage information security systems attending to the phases of the DMAIC roadmap, by considering the basic domains of 'strategy, technology, organization, people, and environment' (STOPE).

Table 1 – Literature focusing on the integration of Lean and/or Six Sigma with generic ISO MSS. (*continued*)

Reference	Integration scope	Description
Tice et al. (2005)	Lean with ISO 14001	Identify a set of similarities between Lean Production principles and tools and the requirements of an environmental management system based on the ISO 14001 standard.
Lupan et al. (2005)	Six Sigma with ISO 9001	Propose an integration strategy between Six Sigma and ISO 9001:2000 by linking the DMAIC method used in Six Sigma with the PDCA cycle.
Pfeifer et al. (2004)	Six Sigma with ISO 9001	Suggest a systematic integration model that explores multiple synergies between a set of ISO 9001 requirements and the activities developed under a Six Sigma program.
Warnack (2003)	Six Sigma with ISO 9001	Proposes a Six Sigma and ISO 9001 integrated Quality Management System 7-step roadmap to achieve the integration.

PROPOSED CONCEPTUAL INTEGRATION FRAMEWORK

The proposed framework aims to integrate the three management approaches depicted in Figure 1: Six Sigma, Lean Management, and non-sectorial management systems standards (MSS) published by ISO whose high-level structure is provided by Annex SL. Each one of them is herein described:

- ***Six Sigma***: is a project-by-project approach (Kane, 2020), hence being driven by the typical life cycle stages of a project (Padhy, 2017): i) project identification; ii) project selection; iii) project planning, execution, and planning; iv) post-project. Potential Six Sigma projects are identified based on the analysis of existing or proactively gathered data, which can be collected both internally and externally (Marques et al., 2014). From the pool of candidates, the most impactful projects are prioritized, in what is one of the most critical activities of a Six Sigma or Lean Six Sigma program (Singh and Rathi, 2018). Two kinds of Six Sigma projects can be conducted: quality or process improvement efforts by following the DMAIC roadmap, or Design for Six Sigma (DFSS) for product and/or process design (Yang et al., 2022). There are plenty of DFSS roadmaps, but usually two are adopted: DMADV (Define, Measure, Analyze, Design, Verify) and IDOV (Identify, Design, Optimize, Verify) are used (Tesfay, 2021). The post-project review process is of great importance to assess the project success measured by the results achieved (Furterer, 2009), along with the compilation of the lessons learned from the project (Sunder M., 2016), which gives this phase an important role in the knowledge transfer process regarding future improvement initiatives (Tukel et al., 2008).
- ***Lean Management***: it is mainly focused on value-creation by identifying and removing all types of waste that can exist in a process. The "Lean House", or "Toyota Production System (TPS) House", is a recognizable symbol and a visual model of this management approach (Höök and Stehn, 2008). Its roof is customer-centric and contains the company's true north (i.e. the ultimate goal) of achieving significant business growth by providing high-quality

products or services, at the lowest possible cost, in the shortest possible period of time (Dennis, 2016). There are two pillars holding up the house: Just-In-Time (JIT) and *Jidoka* (Autonomation). The former emphasizes the elimination of inconsistencies and waste factors in the processes to promote a pulled and continuous flow, while the objective of the latter is doing it right the first time (Pessôa and Trabasso, 2016). The combination of JIT and *Jidoka* means that problems, when they inevitably occur, can never be hidden (Liker and Convis, 2012). Leveled up production (*Heijunka*) and standardized procedures are two foundational elements of the house that support each one of the corresponding pillars. The whole system is built on a logic that is necessary to perform both monitoring and control activities to promote stability in the organizational processes and improvement (*Kaizen*) activities to enhance their performance, hence combining SDCA (Standardize, Do Check, Act) and PDCA (Plan, Do, Check, Act) cycles (Gitlow, 1995). Cultural enablers, including the quality of the leadership, peoples' knowledge, skills, and ability to solve problems, are the bedrock of the Lean house. Lean principles and tools are often combined with Six Sigma, since they are complementary approaches, despite their inherent differences (Rodgers et al., 2019; Marques et al., 2017), so it is important to look at them in a unified way.

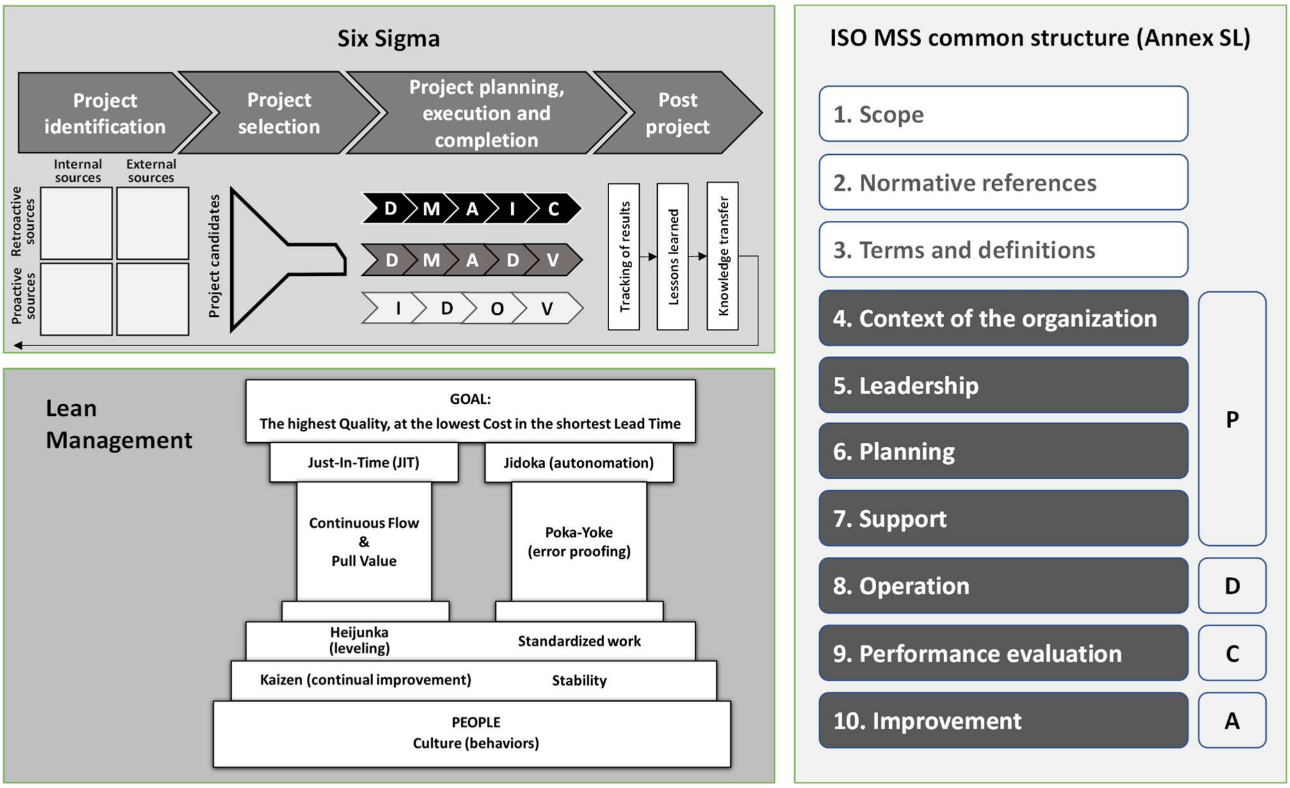

Figure 1 – Characteristics of the three management approaches to be integrated.

- ***ISO MSS common structure***: currently all generic standards for management systems issued by ISO rely on the High-Level Structure, known as Annex SL, that provide the same title and core text for the clauses of requirements, standard terms, and definitions (Roncea, 2016). Every MSS is organized around ten sections, with the requirements for the management system starting with section 4 being arranged according to the reasoning behind the PDCA cycle (Silva et al., 2020).

The structured model depicted in Figure 2, which consists of four interlinked blocks, was developed under the scope of this research and serves as support to the conceptual integration framework herein proposed. Altogether, the blocks comprise the main activities that are required for managing an organization in a sustainable way, also encompassing all organizational levels – strategical, tactical, and operational level – that are needed to develop an effective TQM system (Dahlgaard et al., 2019) or Business Excellence Model (BEM) (Leonard and McAdam, 2002). Each block herein proposed consists in the following:

- The ***Leadership and Strategy*** block is at a strategic management level, involving long-range business planning, monitoring, analysis, and evaluation of all relevant areas for an organization to meet its aim and core objectives. Setting the strategic plan and deploying the strategic objectives in the entire organization are responsibilities of senior management (Watson, 2020). A set of opportunities derives from organizational strategy, feeding a portfolio of potential initiatives and project-based improvement projects (Vilarinho et al., 2018), which, according to the ISO 21502 (2020) standard, should be continuously managed to prioritize the most promising ones (Snee, 2002). Moreover, when executive team members act as role models and create constancy of purpose, they are enabling a culture of Excellence within the organization (Butterworth, 2019). Top management is also accountable for making good decisions towards the definition of proper organizational governance and structure of business processes (Plenert, 2021).
- The ***Initiative Management*** block, also referred to as project management or cross-functional management (Salah et al., 2011), corresponds to the tactical level where strategy is translated into deliverable or achievable initiatives (Leonard and McAdam, 2002). The prioritized strategic-oriented improvement initiatives can be more or less disruptive, (Marques et al., 2014), from kaizen events to breakthrough Six Sigma projects (Miller et al. 2014). The tracking or periodic review of the impact these initiatives are having in processes' performance and the extent to which the strategic goals are being met at departmental level (Leonard and

McAdam, 2002) are important outcomes taking place in this management block. Post-project activities, including the compilation of lessons learned and the transfer of the project/initiative deliverables to daily work and operations (Czarnecki, 2018), are also relevant.

- The ***Daily Management*** block involves the formalization of organizational processes and the management of the standards that drive the teams' daily efforts, tracking and reporting of performance metrics, and solving everyday problems (Vinardi, 2023). It helps to sustain and widen improvement efforts, linking it to daily performance (Cornider et al., 2023). Routine process planning and control activities are herein conducted by empowered and well-trained personnel who, by ensuring that standardized work is carried out, promote the stability of the processes they work in (Buttherworth, 2019).
- The ***Support*** block consists of a set of processes ensuring that activities encompassing the three management levels are running properly. Support processes provide relevant resources such as competence of personnel, technology, and knowledge (Abuhav, 2017) to the management system. It also involves the management of documented information and communication channels (Kohl, 2020) as well as the development of training, coaching, and mentoring activities (Miller et al., 2014),

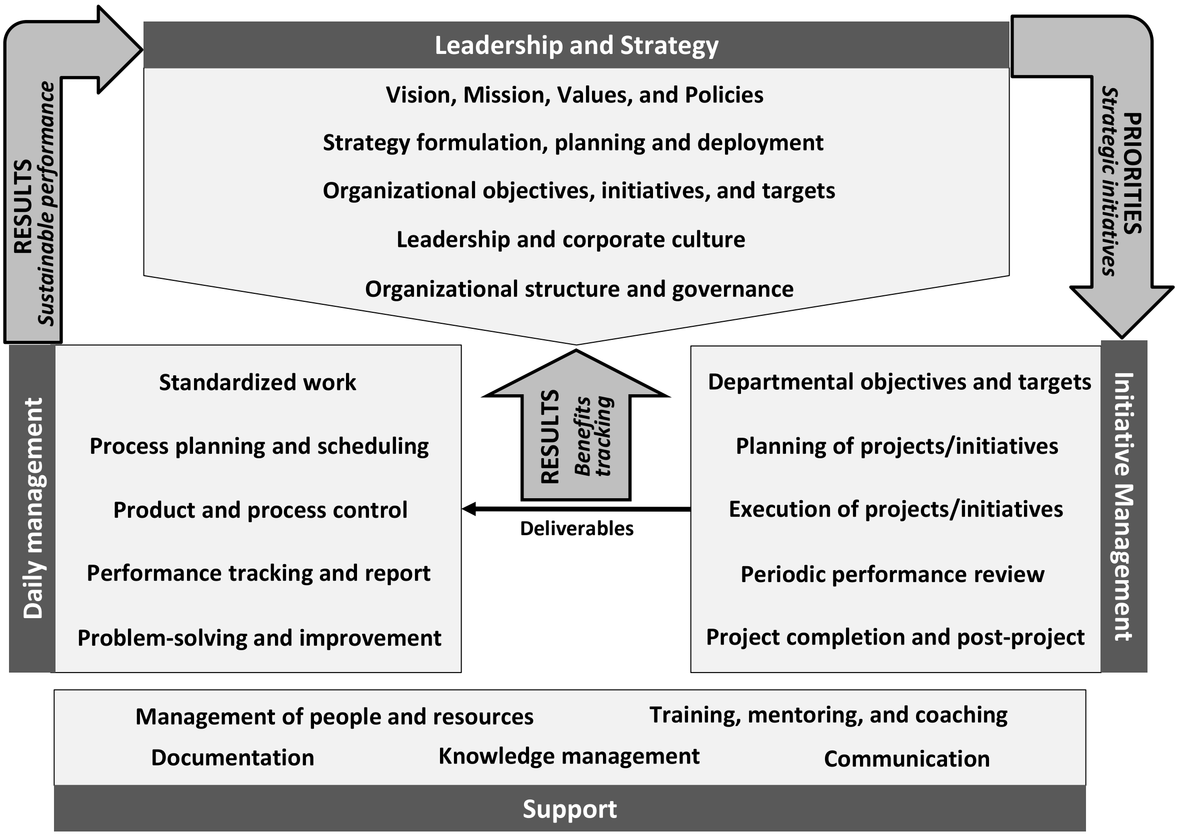

Figure 2 – Conceptual model that supports the integration framework.

The main activities conducted in each of the mentioned blocks have been related to the clauses of requirements contained in the high-level structure, provided by Annex SL, commonly adopted by the MSS issued by ISO. Furthermore, the applicability of various Lean and/or Six Sigma methods and tools for each of that relationships have been proposed. These integration synergies are exhibited and described from Tables 2 to 5, one table per management block. The integration framework also considers the existing individually specific clauses of requirements (Rajabzadeh et al., 2023), not covered by Annex SL, of certain ISO MSS, with emphasis to the ISO 9001:2015 standard, that are relevant regarding the integration with Lean and/or Six Sigma.

Table 2 – Integration framework for the "Leadership and strategy" block.

Main activities	ISO MSS high-level structure (Annex SL)	Applicable methods/tools	Usually adopted in	Applicability
Vision, Mission, Values, and Policies	5.2. Policy	Hoshin Kanri	Lean	Enables policy setting, where organizational values and beliefs, vision and mission are stated. It helps to align the Policy describing the intentions and direction of the management system with the purpose of the organization
Strategy formulation, planning and deployment	4.1. Understanding the organization and its context	PESTLE (Political, Economic, Sociological, Technological, Legal, Environmental) analysis.	Six Sigma	Relevant to define the organization's purpose and strategic direction
		SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis	Six Sigma	Assists in evaluating the internal and external business environment of the organization.
		Hoshin Kanri	Lean	Setting the long-term strategy plan to promote the strategic objectives
	4.2. Understanding the needs and expectations of interested parties	CVCA (Customer Value Chain Analysis)	Six Sigma	Allows the organization to identify relevant stakeholders and understand the way they relate to each other
		VOC (Voice Of the Customer) tools	Six Sigma	These are tools used in Design for Six Sigma, including: interviews, focus groups, surveys, Kano Model, among others. They are helpful in determining the stakeholders' requirements for the management system
		Affinity Diagram	Six Sigma	Organize qualitative information regarding the needs and expectations of stakeholders
	6.1. Actions to address risks and opportunities	SWIFT (Structured What If Technique)	Six Sigma	It can be used to identify and assess different types of organizational risks and opportunities, including strategic risks

Table 2 – Integration framework for the "Leadership and strategy" block. (*continued*)

Main activities	ISO MSS high-level structure (Annex SL)	Applicable methods/tools	Usually adopted in	Applicability
Organizational objectives, initiatives, and targets	6.2. XXX objectives and planning to achieve them	X-Matrix from Hoshin Kanri	Lean	The X-Matrix helps maintain coherence between the long-term strategy and the targeted annual objectives, and among the latter and the initiatives to be developed to achieve them. Similarly, it makes it possible to relate the Policy to the objectives for the management system and the latter to the actions to be planned to achieve them
	9.3. Management review	Obeya Room	Lean	It visually displays the data and information that are essential for strategy decision-making or for reviewing the management system
		Prioritization matrix	Six Sigma	The portfolio of potential initiatives and improved-based projects can be evaluated during management review sessions to prioritize the most impactful and strategic-oriented ones. To this purpose, this quality planning and management tool can be utilized
	9.1. Monitoring, measurement, analysis, and evaluation	Obeya Room	Lean.	Perform monitoring, measurement, analysis, and evaluation of the visually displayed strategic and management key performance indicators and other types of relevant data
		Benchmarking	Six Sigma	Compare organizational performance with best-in-class companies
Leadership and corporate culture	5.1. Leadership and commitment	Gemba Walk	Lean	Reinforce trust between them and the different hierarchical levels of the organizations, contribute to foster a culture of continuous improvement, and enhance the perceived commitment of senior leadership with the management system.
		Leader Standard Work (LSW)	Lean	Provides a structured set of routines and tasks that contribute to demonstrate leadership and commitment
Organizational structure and governance	4.3. Determining the scope of the XXX management system	Is / Is Not	Six Sigma	Distill what elements are within the scope of the management system and those that are not
		5W2H (What? Where? When? Who? Why? How? How much?)	Six Sigma	Encourages asking basic questions that are useful to determine the context of the management system within the organization and its governance model
	4.4. XXX management system	SIPOC (Suppliers., Inputs, Process, Outputs, Customers)	Six Sigma	Facilitates the determination of the organization's core, support, and management processes and how they relate to each other, hence enabling the definition of a network or structure of processes
		VSM (Value Stream Mapping)	Lean	Provides an holistic perspective to establish, maintain and continually improve the organizational processes
	5.3. Organization roles, responsibilities, and authorities	Standardization	Lean	Standardization is a core principle from Lean management and can be adopted to define and deploy job descriptions for all relevant organizational functions
		Help Chain	Lean	Define responsibilities and authorities for backup systems and escalation of problem-solving situations.

Table 3 – Integration framework for the "Initiative Management" block.

Main activities	ISO MSS high-level structure (Annex SL)	Applicable methods/tools	Usually adopted in	Applicability
Departmental objectives and targets	6.2. XXX objectives and planning to achieve them	Hoshin Kanri	Lean	Coherently deploy the strategic objectives down to the different departmental levels of the organization, hence the management system objectives can be strategically aligned when they are breakdown to lower levels
Planning of projects or initiatives	10. Improvement	Action Priority Matrix	Six Sigma	Prioritize departmental or cross-functional actions/initiatives attending to their potential impact and effort needed.
		Project management planning tools: e.g. Project Charter, Gantt Chart, WBS (Work Breakdown Structure)	Six Sigma	Company-wide and departmental initiatives can be planned by making use of project management tools
	6.1. Actions to address risks and opportunities	PDPC (Process Decision Program Chart)	Six Sigma	One of the quality planning and management tools, which can be adopted to perform project risk analysis
Execution of projects or initiatives	10.2. Continual improvement	Gemba Kaizen Events	Six Sigma	Promote focused, short-term, and cross-functional improvement efforts to improving process efficiency and effectiveness
		Value Stream Management	Lean	Map and analyze a specific key process to identify activities not adding value from the customer's point of view and introduce a set of process flow improvements attending to the designed vision of its future state
		DMAIC roadmap	Six Sigma	Conduct projects related to breakthrough problem-solving initiatives
		SMED (Single minute Exchange of Die)	Lean	Reduce changeover or setup time of a machine or equipment
	8.3. Design and development of products and services (ISO 9001:2015)	DFSS (Design for Six Sigma) roadmaps, such as DMADV and IDOV.	Six Sigma	Design methodologies to conduct new product/service development projects
		Lean Design.	Lean	Optimize the efficiency of the design and development process to minimize time to market
Periodic performance review	9.1. Monitoring, measurement, analysis, and evaluation	Obeya Room	Lean	Visually display relevant data from the prioritized initiatives and improved-based projects to monitor, measure, analyze, and evaluate their status, performance, and results
		Visual Management Boards	Lean	Monitor, measure, analyze, and evaluate the levels of performance being achieved by a certain department or unit area
		Gate Reviews.	Six Sigma	Conduct steering and review of improvement projects or initiatives
		A3 Project Report	Lean	Present the status of an initiative or project in a visual and objective way during a gate review
Project completion and post-project	7.1.6. Organizational knowledge (ISO 9001:2015)	A3 Project Report	Lean	When an initiative or project is completed, lessons learned are documented and reported
	10.2. Continual improvement	Value Stream Costing	Lean	Quantify the financial benefits of increased process efficiency
	10.3. Continual improvement (ISO 45001:2018)	Lean Safety	Lean	Lean Safety initiatives can contribute to improve health and safety performance

Table 4 – Integration framework for the "Daily Management" block.

Main activities	ISO MSS high-level structure (Annex SL)	Applicable methods/tools	Usually adopted in	Applicability
Standardized work	8.1. Operational planning and control	SOP (Standard Operational Procedures) and OPL (One Point Lesson).	Lean	Provide a visual and objective way of describing a procedure for carrying out a job or task, hence promoting standardized work
Process planning and scheduling	8.1. Operational planning and control	Job Sequencing	Lean	Effective short-term scheduling approach to allocate and prioritize demand orders available facilities, equipment, or other type of resource
		P-FMEA (Process Failure Mode and Effect Analysis)	Six Sigma	Identify and assess risk factors that may be present in a process, so preventive and mitigation actions can be defined, planned and implement to reduce the level of risk
		QFD (Quality Function Deployment).	Six Sigma	Provide process planning and production planning matrices to properly design or plan the operations of a process
	8.2. Requirements for products and services (ISO 9001:2015)	VOC (Voice Of the Customer) tools	Six Sigma	Gather and analyze statements made by customers and other stakeholders regarding the product or service, helpful to determine their needs and wants
		Affinity diagram	Six Sigma	Organize a wide set of qualitative customer statements, particularly their needs and wants gathered from VOC tools
		Kano Model	Six Sigma	Typify and prioritize customers' requirements
		CTQ Tree	Six Sigma	Translate a broad set of customer needs into a more focused and measurable set of technical requirements for the product or service
		QFD (Quality Function Deployment)	Six Sigma	Convert customer needs and expectation into functional requirements for the product or service and corresponding specifications
Product and process control	8.1. Operational planning and control	SPC (Statistical Process Control)	Six Sigma	Make use of control charts which provide an effective way to analyze whether a repetitive process is stable/predictable or not
		Lot Acceptance Sampling Plans	Six Sigma	Control and evaluate the quality and compliance of externally provided materials
		Kanban	Lean	Regulate operational workflows as well as to control inventory levels throughout the production processes
		Andon	Lean	Visually highlighting the status of operations in an area at a single glance, such as production status or an abnormality
Performance tracking and report	9.1. Monitoring, measurement, analysis and evaluation	MSA (Measurement System Analysis)	Six Sigma	Ensure the reliability of data collected during process measurement and monitoring
		Process capability studies	Six Sigma	Assess how consistently an in-control process is capable to produce parts within specifications
	9.2. Internal audit	5S audits	Lean	Conduct audits in the workplace to evaluate compliance with the established housekeeping procedures and can be combined with internal safety and quality audits
		Kamishibai (also known as K-Cards)	Lean	Visually signaling whether a standard is being complied or not
Problem-solving and improvement	10.1. Nonconformity and corrective action	A3 Problem-Solving Report	Lean	Provide a structured, visual, and standardized method for management and operational teams to summarize their problem-solving exercises
		Quality Circles	Lean	Autonomous group of workers to collectively identify problems in their workplace, analyze them, and provide effective solutions

Table 5 – Integration framework for the "Support" block.

Main activities	ISO MSS high-level structure (Annex SL)	Applicable methods/tools	Usually adopted in	Applicability
Management of people and resources	7.1. Resources	TPM (Total Productive Maintenance)	Lean	Optimize operational infrastructure in terms of preventing breakdowns, small stops, defects, or workplace accidents
		Kobestsu Kaizen	Lean	Encourage autonomous maintenance of automation equipment
		Team Work Plan	Lean	Display on visual team boards the daily and /or weekly plan regarding the allocation of people that perform certain job functions to specific tasks
Training, mentoring, and coaching	7.2. Competence	Skills Matrix	Lean	Provide a grid that shows the levels of proficiency or competency of an employee regarding a specific task or job.
		Training Plan	Lean	A training plan stems from the existing gaps between the levels of competence required to perform a job or task and the actual levels of competence. These gaps can be identified by analyzing the teams' skills matrices
		TWI (Training Within Industry)	Lean	To accelerate the acquisition of knowledge and skills of an employee to execute a job in a proper, productive, and safe manner
	7.3. Awareness	Coaching Kata	Lean	Promote the sense that every leader should be a mentor and that one of his/her main responsibilities is to promote awareness of individuals about the importance of adopting scientific thinking when conducting problem-solving efforts
Documentation	7.5. Documented information	OPL (One Point Lesson)	Lean	Provide a short (usually a single page length), objective, and visual format to display a work instruction or procedure
		Visual SOP (Standard Operating Procedure)	Lean	Visual and objective way to describe the step-by-step activities necessary to successfully complete an operational task
		Swimlane Diagram	Six Sigma	Visually and effectively depicts a process mapping, so it can be used as the main tool to develop the required process sheets that are used in the scope of management systems
Communication	7.4 Communication	5S and visual management	Lean	Promote an environment where communication become simpler, more intuitive and effective, hence contributing to improve quality, process flows, and safety
		Daily team meetings	Lean	provide the opportunity to discuss the team performance, their improvement or problem-solving actions. Holding these meeting contribute to engage all team members
		Communication Plan	Six Sigma	Clarify how communication will occur with the stakeholders of a project or initiative
Knowledge management	7.1.6. Organizational knowledge (ISO 9001:2015)	Benchmarking	Six Sigma	The introduction of internal and/or competitive benchmarking practices encourages team leaders and managers to introduce proven best practices in the organization

CONCLUSIONS

The objective of this paper is to develop a conceptual framework to integrate the generic management systems standards published by ISO, whose high-level structure of requirements follow Annex SL, with Lean Management and Six Sigma. The framework that supports the proposed integration model consists of four interrelated blocks encompassing all organizational levels – strategical, tactical, and operational level – hence providing a company-wide perspective for managing an organization.

The following relevant topics were addressed in this paper:

- A thorough and extensive literature review was carried out to identify existing publications proposing guidelines, models, and frameworks on how to integrate the clauses of requirements from different types of ISO management system standards with Lean Management and/or Six Sigma.
- The literature review led us to conclude that existing integration frameworks still lacking to provide clause-by-clause relationships with the available toolbox from Lean Six Sigma.
- The main characteristics and features of the three management approaches being integrated were described, providing an initial insight into the natural synergies between them.
- A structured model consisting of four blocks covering all the main management activities of an organization were developed, providing the means to develop the integration framework where the joint use ISO management systems standards, Lean Management, and Six Sigma fit the vision of an organization-wide perspective of management.

The main contributions of this paper are the following:

- The proposed conceptual framework is not limited to integrating the requirements of ISO 9001 or to a single standard but has the capacity to be used to integrate Lean and Six Sigma with any set of ISO management systems standards.
- The integration guidelines are organized per clause of requirements contained in Annex SL, which contains the common high-level structure of requirements of ISO standards for management systems.
- A unique aspect of the proposed framework is that it is based on an interconnected set of good practices conducive to a company-wide perspective for managing an organization, as emanated from the principles of business excellence.
- From a practical viewpoint, it provides organizations with a set of good practices and guidelines to incorporate recognized business management models, such as Lean and Six

Sigma, into their management systems often designed based on the ISO standards. This is a worth contribution so they can avoid duplications, namely unnecessary documents and overlapping of authorities and responsibilities, and unnecessary efforts to sustain the management system as a whole.

- Attending the literature review conclusions, this is the first conceptual framework that integrates Lean and/or Six Sigma with ISO management systems standards from an organizational excellence, company-wide, perspective.

Nevertheless, the research conducted has some limitations. Attending to them, future research is also proposed:

- The proposed framework does not cover generic management systems standards that are not issued by ISO, including relevant ones such as SA 8000 on social accountability systems, and OHSAS 18001 for health and safety systems. In the future the conceptual framework can evolve to include other non-ISO relevant MSS.
- The framework is also not directly applicable to the majority of the MSS that are applicable to specific sectors of activity, such as IATF 16949 for the automotive industry, and ISO 13485 for medical devices. This provides another opportunity for the conceptual framework to evolve in the future.
- Finally, the developed framework does not fit the integration of Lean Six Sigma with the ISO 17000 series of standards related to "conformity assessment" (certification and accreditation), including the well-known ISO/IEC 17025 for the accreditation of testing and calibration laboratories. The conceptual framework can also be expanded to include this scope.

DISCLAIMER

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Framework Proposal for Preventive Maintenance in Third-Party Suppliers: An Action Research in the White Goods Industry

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STRUCTURED ABSTRACT

Purpose - In the white-goods context studied in this research, applying preventive maintenance principles in the supply chain is a major challenge due to the lack of communication, integration and cooperation between customers and suppliers. Thus, this study proposes a framework that presents concepts incorporated into a new software to support maintenance management of tools at third-party suppliers.

Design/methodology/approach - To achieve this objective, the action research method composed of three cycles was applied, being the first cycle a development step, the second cycle an implementation step of the process in a first supplier and the third cycle responsible for expanding the process to a second supplier.

Findings - As a result of the study, the structured framework used for the proposed software is presented. The framework indicates a path for implementing preventive maintenance at suppliers based on theory. Additionally, the action research showed the proposed framework is capable of generating higher integration and cooperation between the client company and its suppliers, increasing the performance levels of companies in the supply chain. The implementation of the framework through software and dashboard allowed the preventive maintenance implementation, resulting in improved quality levels in supplier parts and less line stoppages .

Research limitations/implications - The limitations of the work are linked to the impossibility of generalizing the results found through action research and also related to the lack of quantitative analysis of the results obtained.

Keywords: Framework, Supplier Quality Management, Total Productive Maintenance, Supply Chain Integration

Paper type: Research paper

INTRODUCTION

In the dynamic and complex context of industries, the internalization or externalization of productive activities are strategic decisions that depend on factors such as seasonality, with periods of high production alternating with idleness (Cerra et al., 2014). Externalization allows productive activities, even the most complex ones that rely on outsourced suppliers, to be outsourced (Cunha, 2003). However, some of these externalizations involve the dynamic of the supplier working with the client company's tool. Additionally, the performance and efficiency of tools play a crucial role in the competitiveness of operations and affect their level of success (Ng et al., 2012). Moreover, to produce quality products at the lowest possible cost, the availability and reliability of production lines are key factors (Basri et al., 2017). Inefficient tool and equipment management directly impacts the productivity and profitability of organizations. In this sense, reliable equipments can be attributed as one of the main contributors to good performance in these organization indicators (Bakri et al., 2014). Not only for productivity, organizations' concern also stems from the high costs of these tools and equipment, which, coupled with increasingly shorter product life cycles, necessitate quicker equipment amortization. This factor culminates in the need to develop efficient systems for maintaining equipment and tool conditions, increasing their lifespan and minimizing the need for new high investments (Bakri et al., 2014; Ng et al., 2012).

Despite their importance, tools which are in third-party hands have their structural condition gradually affected by lack of maintenance, as there is no clarity on how the supplier is taking care of this asset and whether preventive maintenance is being performed. Thus, due to the significance of equipment in various industries, the implementation of a more proactive maintenance system becomes necessary, many companies have been applying Total Productive Maintenance (TPM) as an operations strategy approach to address equipment inefficiency issues (Ng et al., 2012). In this sense, TPM emerges as an alternative focusing on improving equipment availability and utilization, enhancing operational performance, generating maximum returns and enabling organizations to compete more efficiently in the market (McKone-Sweet and Weiss, 1999).

In the market scenario and context of various industries, including the appliance and white goods industry, applying concepts of preventive maintenance (Mourtzis et al., 2018) and thus keeping equipment in good condition when they are allocated to suppliers is a complex challenge (Liu et al., 2024). The dynamics of asset movement are carried out through the transfer of ownership of the stamping tools owned by the client company. For this reason, an asset loan agreement governs the granting of these tools to third-party suppliers, assigning responsibilities for their care and management to these assets. Both the manufacturer and the supplier have to make tradeoffs between equipment quality and maintenance service to maximize their own profit, which can lead to supply chain conflict (Jiang et al., 2022). In many cases, part of the responsibility for the asset still lies with the client organization, while part is transferred to the third party, which generates the need for information exchanges between client and supplier, periodic monitoring of the tool's condition, as well as management of maintenance activities. Research shows that maintenance at third-party suppliers is a complex issue, and the preventive maintenance strategy can reduce excess maintenance cost as lending period increases (Liu et al., 2024). There are software proposals for preventive maintenance analysis in different contexts (e.g., Ramírez-Hernández, 2012; Garg, 1998), however, the software does not address the issue of the tool being loaned to a supplier, limiting the application to the context studied. .

Therefore, this research aims to develop a framework to support the maintenance management process of the company's assets at its third-party suppliers. The framework is based on literature in the maintenance management field, as well as the problems arising from the relationship between client company and supplier in the tool/equipment loan situation. The framework served as the basis for the development of software and a dashboard to facilitate communication and maintenance management between the client company and suppliers.

This article is structured into five sections. The first, Introduction, presents the conceptualization of the research topics and objectives. The second section presents the Literature Review, emphasizing the importance of maintenance planning and integration with suppliers. The third section presents the Method, the fourth section presents the company, the process under study and the results of the work, followed by the Conclusions section.

LITERATURE REVIEW

Maintenance Approaches

Among the main maintenance approaches, which encompass method, objective, and maintenance benefits, are corrective, preventive, and productive maintenance (Ahuja and Khamba, 2008).

Corrective maintenance is classified as a reactive maintenance approach, comprising repairs, replacements, or other restoration actions. It is called reactive because it always occurs after a failure has happened (Nakajima, 1988; Ahuja and Khamba, 2008).

Preventive maintenance is classified as proactive, aiming to act on a system before a failure occurs, thus preventing interruptions, major damages, and increasing the equipment's lifespan. It is characterized by performing maintenance activities such as inspection, cleaning, lubrication, retightening, adjustments, and component replacements (Ahuja and Khamba, 2008; Kimura, 1997). These activities are carried out through a maintenance schedule with generally constant intervals, which can be based on time periods or equipment utilization rates (Misra, 2008).

Total Productive Maintenance (TPM), also known as productive maintenance, is a proactive approach that goes beyond the concept of maintenance as it seeks to improve the overall equipment effectiveness, encompassing aspects related to availability, performance, planning, and utilization (McKone-Sweet and Weiss, 1999).

TPM is considered a philosophy of continuous improvement, a break from the traditional view of corrective maintenance, which seeks to eliminate barriers between maintenance and production departments (Bakri et al., 2014). It promotes teamwork focused on maintaining equipment's baseline conditions and increasing its lifespan (Ahuja and Khamba, 2008). It adds broader and more strategic objectives to the maintenance function, such as increasing administrative efficiency, reducing organizational costs, increasing levels of flexibility, quality, delivery, and innovation (McKone-Sweet and Weiss, 1999). An important premise for TPM is maintenance planning. Below some maintenance planning methods within TPM are presented.

Maintenance Planning

Cost-based planning takes into consideration all expenses incurred with maintenance, analyzing repair costs, component replacement costs, and labor costs. Additionally, it considers the cost of downtime, such as the cost of equipment unavailability for use, the cost per unit not produced due to downtime, and their impacts on the company's overall return. Through methods and tools, such as those listed in Table 1, all these values and the benefits of maintenance execution are analyzed, leading to an optimal maintenance plan that minimizes the cost per unit produced (Basri et al., 2017).

Time-based planning is based on the relationship between the duration of a specific intervention, the allocation of resources in this intervention, and the frequency interval at which this intervention occurs. It considers the time spent repairing or replacing a component, downtime, the time needed to obtain spare parts, and the return time. Here, Mean Time to Repair and Mean Time Between Failures are also considered (Ng et al., 2012). Table 1 below also lists the main methods and tools used in this category, aiming to reduce production delays caused by failures and maximize the utilization of maintenance resources, as well as to find the shortest time possible to conduct maintenance activities during a downtime (Basri et al., 2017).

The third category of maintenance planning, failure-based planning, takes into account information about the deterioration of a system or component. Through historical data on previous failures and breakdowns, critical analyses are conducted, mainly using tools like Failure Mode and Effects Analysis (FMEA), to assess the cause, criticality, and predictability of a breakdown, getting to the most appropriate intervention interval for the system. In this category, the component's useful life method can be utilized, allowing the creation of component groups based on wear similarity, optimizing maintenance frequencies, and increasing equipment reliability (Basri et al., 2017). The table below summarizes this content:

Table 1 – Maintenance planning categories, tools, and analysis methods. Source: Adapted from Basri et al. (2017) and NG et al. (2012).

Planning category	Tool type	Method
Cost-based	Artificial Intelligence (AI)	Monte Carlo, Genetic Algorithm, Markov Chain
	Simulation	SIMAN Simulation
	Mathematical Formulation	Weibull Distribution, Exponential and Weibull Distribution, Linear, Non-Linear, and Hybrid
	Matrix formation	Analysis of Variance (ANOVA)
	Multi-criteria	Analytical Hierarchy Process (AHP)
Time-based	Mathematical Formulation	Rolling Horizon Dynamic Programming, Genetic Algorithm
	Artificial Intelligence	Fuzzy Logic, Heuristic, Tabu, and Bayesian Logic
	Simulation	Witness Simulation
Failure-based	Critical Analysis	Failure Mode and Effects Analysis (FMEA), Aging Replacement Model, Tree Diagram, Probabilistic Critical Analysis
	Matrix Formation	Similarity Coefficient Matrix, Load Balancing and Regression Analysis

Supplier Quality Management

Throughout the supply chain, suppliers are also responsible for addressing the high levels of quality expected by end consumers. Particularly in a scenario with customers filled with dynamic desires and expectations, some studies have discussed how Supplier Quality Management (SQM) can increase organizations' competitiveness by minimizing operational costs, reducing cycle times, improving quality, and maximizing customer satisfaction (Caddick and Dale, 1987; Carr and Pearson, 1999; Shin et al., 2000).

Especially, SQM reinforces its importance as supply chains have become increasingly complex, integrated, and globalized, resulting in companies' dependence on their suppliers (Yoon et al., 2018). Therefore, increasing quality levels, decreasing production costs, reducing delivery delays and supply problems, and improvements in lead time are not clearly achievable without reliable suppliers. The overall quality performance of an organization can be strongly influenced by the performance of its suppliers (Lo, Sculli and Yeung, 2006). Additionally, delays and lack of materials can lead to production line disruptions and stoppages, causing significant losses for organizations (Aksoy and Ozturk, 2001; Sawik, 2018).

In this perspective, supplier quality management refers to a set of management activities and efforts focused on increasing suppliers' performance and quality levels through closer and more effective management (Caddick and Dale, 1987; Carr and Pearson, 1999; Shin et al., 2000). These efforts seek harmony and connection between the activities of the buying company and the selling company, aiming for engagement and communication between the two parties (Chakravarty, 2014).

An important dimension of SQM is supplier integration, which refers to a set of activities resulting in close coordination and collaborative relationships between buyers and sellers. Working in an integrated manner in the supply chain means the existence of connections between internal and external processes in the buyer-supplier relationship, sharing of information, and even management information systems, intertwining the activities of the two organizations (Mentzer et al., 2001; Omar et al., 2012; Zhang et al., 2018).

This dimension advocates for the creation and coordination of operations among chain companies, leading to the redesign of business processes and ways to measure indicators such as cost, quality, flexibility, and delivery speed (Hammer and Champy, 1994; Burgess, 1998). Corbett (2006) points out that suppliers commit to implementing the same quality management systems as their customers, seeking even similarity and adaptation in management routines.

Integration levels can be in tangible and intangible dimensions, such as dividing responsibility for transportation, handling, and storage of materials and information flows. The goal is to optimize the value chain through sharing demand vision, production and inventory levels, bottleneck processes, and production rescheduling. There is also a mindset and posture of sharing knowledge and technology in both directions of the chain, communication occurs bilaterally, working together and oriented towards researching and solving problems (Bennet and Klug, 2012; Dyer and Hatch, 2004).

RESEARCH METHODOLOGY

This study adopts a qualitative research approach, emphasizing the acquisition of descriptive data through direct interaction of the researcher with the situation under study. This choice is grounded in the need to understand the meanings and situational characteristics of the investigated phenomenon (Martins, 2012). In this approach, the researcher observes the problem in the context in which it occurs, focusing on processes and understanding how the results unfold. Furthermore, it highlights the importance of considering the individual perspective of the participants, their interpretations, and subjectivity, forming a complex mosaic that requires the researcher's attention to capture different perspectives (Martins, 2012; Cauchick, 2012).

The qualitative approach seeks to deal with the complexity of problems through the use of multiple sources of evidence, thus avoiding personal opinions or speculations (Martins, 2012; Cauchick, 2012). The construction of objective reality results from the combined analysis of the researcher's perspective, grounded in theoretical references and experience, and the perspective of participants and research environment, obtained from various sources of evidence (Martins, 2012).

When referring to research methods related to the qualitative approach, the most appropriate ones are the case study and action research (Näslund, 2002). While the case study implies a certain degree of interaction of the researcher with the participants and does not necessarily involve interventions in the object of study, action research is intrinsically linked to the implementation of organizational changes (Martins, 2012). Given the purpose of the research in question, focused on modifying asset management, the choice of action research proved to be more suitable, given its ability to understand and intervene in the investigated processes. In this premise, the researcher assumes an active role, collaborating with a multidisciplinary team, in which each member performs distinct and complementary functions (Martins, 2012; Coughlan and Coughlan, 2002). This team is presented in the figure below:

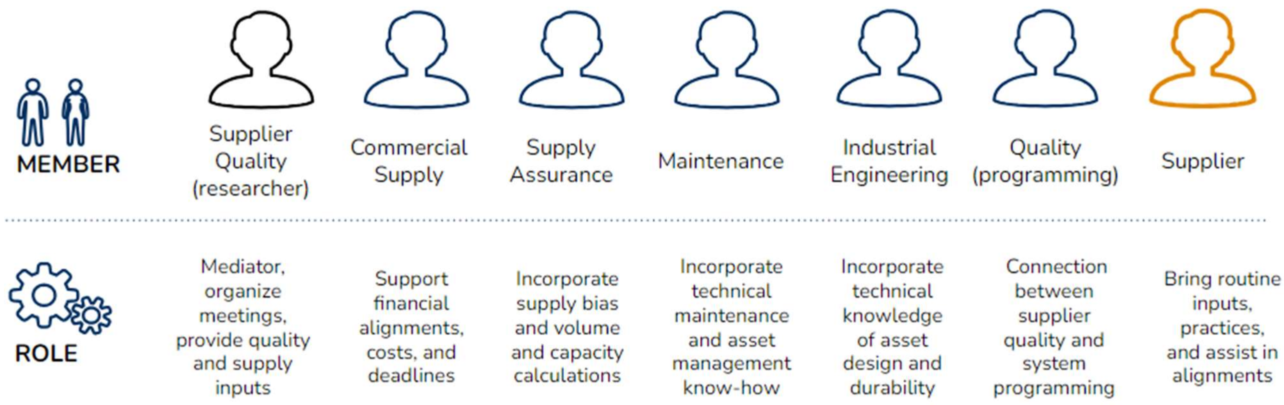


Figure 1 – Research multifunctional team. Source: created by the author

Action research is also characterized by the simultaneity between research and action, conducting research both on theoretical frameworks in literature databases and within the organization (Oliveira, 2022). To accomplish this, action research employs a cyclical method, with rounds and well-defined milestones for its execution (Coughlan and Coughlan, 2002). This method consists of six stages and one meta-stage. They are defined as follows: data collection; data feedback; data analysis; action plan; implementation, and, finally, evaluation and validation of reports and results. The meta-stage is defined as a monitoring stage, during which notes, analyses, and reports are made, and it is also during this stage that the research dissertation is written (Coughlan and Coughlan, 2002). The figure below illustrates the cycle of the six stages of the action research method, as well as the meta-stage.

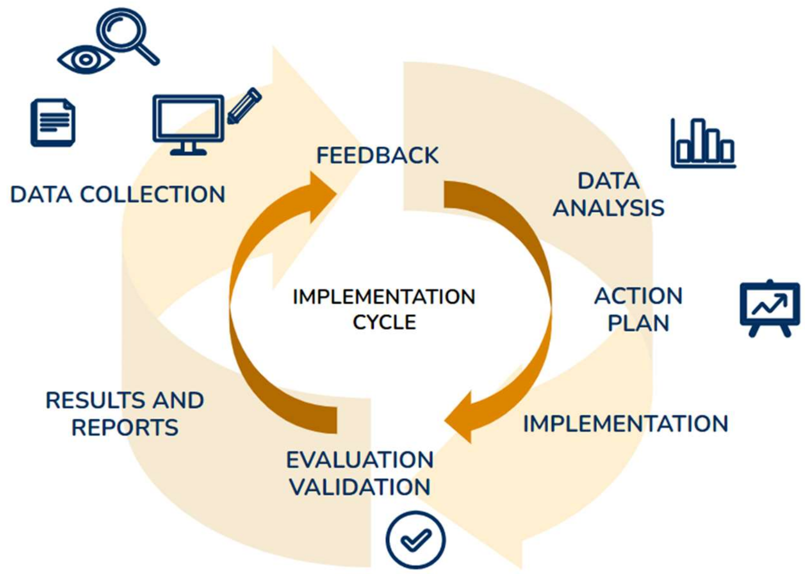


Figure 2 – Six-stages cycle of action research. Source: adapted from Goughlan and Coughlan (2002)

The plan for this project consisted of applying the action research cycle three times, being the first cycle for the development of the new tool management software; the second for pilot implementation and testing of this software at a supplier, feedback, improvement, and creation of a dashboard to display maintenance information; and the third cycle to expand the concept. Stage three is similar to the second, applying the same steps for a different supplier. Therefore, the same platform was used and the same analyses as the first pilot project. In Tables 2 and 3 below, you can see a detailed outline of the method and tools used in each cycle:

Table 2 – Steps, research tools, description and departments involved in the 1st cycle

Step	Research tools	Description/Departments
Data Collection	Non-structured interviews	Quality: Problems with quality in supplier parts; Maintenance: Planning and execution methods of maintenance; Industrial Engineering: Technical performance and lifespan of tools.
	Direct Observation	Visual analysis of parts and the physical/structural condition of tools at the supplier; Audit of the maintenance management system at the supplier; Inventory of tools at the supplier.
	Documents analysis	Maintenance reports from the supplier; Technical reports on tool failures; Non-conformity reports of parts in the client's and supplier's companies.
Feedback and Data Analysis	Data spreadsheet and storage Cross-referencing theoretical data with collected data. Critical analysis, root cause analysis, feasibility analysis of resources	Storage of supplier and client company data in the cloud. Team members discussing in a weekly forum. Analysis of financial, time, and personnel resources available to build the solution.
Planning and implementation	Theoretical Framework Brainstorming sessions Programming	Selection of theoretical model for execution. Software programming for maintenance planning and execution. Programming focused on process automation and data integration
Approval and Validation	Critical analysis through video calls.	Approval and validation by leaders from quality, maintenance, and industrial engineering departments.

Table 3 – Steps, research tools, description and departments involved in the 2nd 3td cycles

Steps	Research tools	Description/Departments
Data Collection	Documents analysis	Responses from data sent by the supplier via online checklist
	Direct observation	Software functionality monitoring
Feedback and data analysis	Data spreadsheet and storage Critical Analysis, Root Cause Analysis, Resources Feasibility Analysis	Sending information through meeting minutes to project members and leaders. Analysis of reports on problems with tools and parts. Analysis of programming errors in the software. Critical analysis of data format and availability.
Planning and implementation	Brainstorming Programming Critical analysis forum Cause and effect analysis Risk management	Dashboard programming for displaying data in graphical format Periodic discussion for taking preventive actions on tools and containment of quality problems Increase in quality inspection level Planning interventions on tools (repairs and replacements) Planning resources for interventions and tool replacements
Approval and Validation	Critical analysis through video calls	Leaders from the quality, maintenance, and industrial engineering areas

The method used in the third cycle of action research was similar to the one presented in Table 3 as it involved expanding the process to a second supplier. The cycle followed the same development premises used with the first supplier.

RESULTS

This section is dedicated to presenting the results of this research project. The section is structured into subsections divided into each of the action research cycles conducted during the development of the work, which guided the development of the software and dashboard and led to the creation of a framework supporting the implementation of the tool management maintenance process at third-party suppliers.

Company Studied

The company studied in this project belongs to the household appliances sector, more specifically white goods, and presents problems because it cannot work in a coordinated manner with its suppliers, mainly regarding the commitment and alignment in the way of conducting maintenance of the equipment/tools on loan. The repercussions are not only seen in product quality issues but also in tool productivity due to constant interruptions, either due to breakdowns or adjustments. Quality is impacted because often the tool problem is identified only through the lack of quality of the products produced. Lower productivity, in turn, increases the cost of the part, negatively impacting the cost of the final product and posing risks to the company's supply. Finally, another consequence of this inefficiency is observed in administrative costs to deal with unforeseen events; several professionals are involved in reacting to quality problems and financial impact problems, and in some cases, they have to act quickly in risk scenarios of supply disruption, either due to lack of good parts or tool unproductivity and lack of part delivery. More specifically, the object of study of this research was the asset management process of the company in its suppliers. This process also includes understanding the flow of information and the level of information sharing between the client and the supplier; the place and time at which information arrives or should arrive to direct preventive actions; the activities that are performed and their responsible parties; the existence or possibility of existence of a system or software governing the activities and responsibilities; the current structure or possible structure to mediate this management.

First Cycle

The first stage of the first cycle of action research was the selection of a partner supplier to develop the project. A strategic and collaborative supplier providing critical parts for the products was selected from the six suppliers in the base. Subsequently, data collection methods were applied, such as unstructured interviews with members of the quality department about the quantity and frequency of non-conforming parts from suppliers; with members of the maintenance department on maintenance planning and execution methods; with members of the industrial engineering department about technical performance and tool life. At the supplier's company, an interview was conducted with a high-level representative on all three of these topics. During two visits to the suppliers, visual analyzes of parts with quality problems were performed, the physical state of the main tools was analyzed, the tool management system and planning and execution of maintenance were audited, and a general inventory of the tools present at this supplier was also carried out. In addition to the data collection methods mentioned above, document analysis was also carried out, through analysis of maintenance reports; technical reports of problems in tools and reports of non-compliance analysis of parts were also analyzed, aiming to close the correlation of the data collected in practice with the content acquired in the literature review. After collecting the information, the next step was the development of the software to support the management of tool maintenance at suppliers. Development began with the construction of the tool maintenance plan, initially prepared in a spreadsheet, based on the failure-based approach proposed by Basri et al. (2017) and Ng et al. (2012), arguing that maintenance should be based on wear and usage rates of the asset, linked to production demand volumes and time periods. The maintenance checklist was adapted to follow the client company's maintenance script standards, for example, including a field for the date of execution of periodic maintenance; the parts produced by the tool; the field for entering the supplier's name. The checklist items were entered into an online software capable of sending periodic emails automatically to the supplier. After this step, the software was programmed to automatically communicate to the supplier the maintenance needs of the tools, following the maintenance plan spreadsheet developed in the previous step. The software was also developed to follow up in cases of delays in sending the executed maintenance checklist responses. To gather the data and generate information exchange, the maintenance execution responses sent by the suppliers through the checklist were connected to the maintenance plan spreadsheet and the automatic follow-up email system. Finally, the evaluation, validation, and feedback stages were conducted through an online video call presentation of the concept to the leaders of the quality, maintenance, and industrial engineering departments who, after critical analysis, approved the concept.

Second Cycle

The second cycle was characterized by monitoring the functioning of the software and correcting programming errors, considering the data sent by the supplier through the online checklist, the integration of the supplier's responses with the maintenance plan spreadsheet, and the follow-up system. In this cycle, the software was evolved to also be able to process and present the data in graphical format through a dashboard, discriminating information by maintenance plan, by tool, by part, and by supplier, and it is possible to filter the information by different periods of time. This improvement allowed the information presented on the dashboard to serve as guidance for discussion and decision-making in cases of quality problems in parts stamped by the monitored tools, as well as in cases of performance problems in these tools. The information enabled the creation of a routine of analysis and planning of various preventive actions, such as: preventive increase in quality inspection levels on parts produced by tools identified with problems; preventive intervention of repair of tool components; budget planning for purchase of spare parts and new tool projects; tool replacement plan at end of life. This second cycle was presented in an online video call meeting, being evaluated and validated, receiving good feedback from the project leaders, for bringing a routine for problem resolution in a systemic way.

Third Cycle

The third cycle was characterized by expanding the dynamics to a second partner and strategic supplier, also responsible for supplying critical parts for the products. During this phase, training material was built to facilitate supplier training and increase expansion speed. The supplier was trained at the beginning of the process, and the implementation was agile and similar to the first stage.

Framework

Summarizing all the stages, from the incorporation of the theoretical framework (Figure 3), data collection, development, implementation to expansion and consolidation of results, the main product of this research project materializes in a framework, which illustrates the main activities to guide the implementation of this process in other asset management problem scenarios at suppliers. The framework is presented in the figure below.

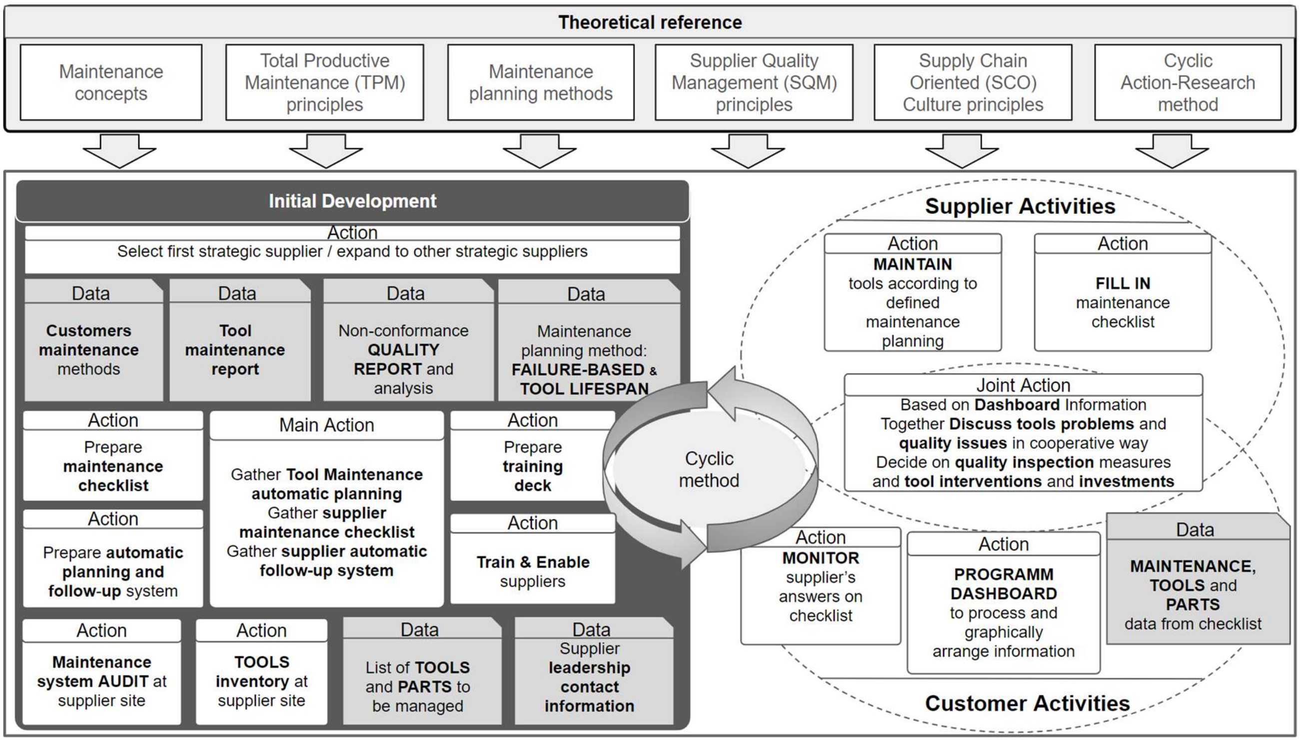


Figure 3 – Process implementation Framework. Source: developed by the authors.

The framework built has as its premise the theoretical bases necessary to start the research and development the process, for this reason, it is presented at the top. On the left, the data collection and development action steps are illustrated, that is, for the execution of the first cycle of action research. On the right, the main activities are presented, the responsibility of the client company and the supplier, as well as the relationship between the two activities for the creation of a management routine and systemic problem solution of quality and tool problems. In the center of the framework, it is possible to visualize the concept of continuous improvement, represented by the arrows of the cyclical action research method, indicating the continuous interaction between the stages, which allows the expansion of the process to more suppliers. Based on the action research cycle, all data collection information for tool development is presented under the title "Data". Feedback on the data collected will be provided through action research implementation cycles. The data were analyzed, following the action research method, mainly based on the theoretical framework. After analysis, "actions" are proposed by the action research team and implemented. Feedback from the implementation team is provided after the implementation actions, evaluating and validating the results.

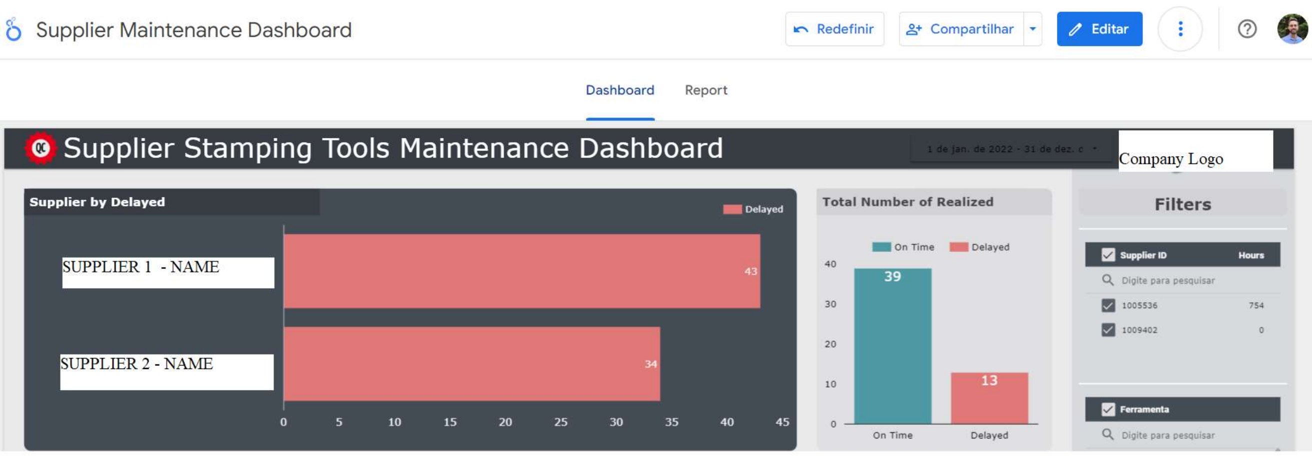
Software and Dashboard

The developed software allowed more effective communication with the supplier, indicating the parameters for carrying out maintenance (tool usage time based on usage rate), warnings for carrying out preventive maintenance for each tool, asset management, or that is, information about the tools that are at the supplier, how long these tools are at the supplier, in addition to receiving feedback information from the supplier about maintenance delays and warnings about maintenance carried out.

The Dashboard (Figure 4) built in the second cycle is able to display data graphically, discriminating information about the execution of maintenance plans, tools, produced parts and even between suppliers at different periods of time.

The following figures present the categories of information displayed in graphical format, as well as an overview of the user interface with the platform.The dashboard has information on the following

Figure 4 – Supplier information on Dashboard. Source: developed by the authors.



categories: customer stratification, delayed planned maintenance time, amount of maintenance carried out on time and amount late. The Dashboard also allows details on the number of corrective maintenance hours per tool, an indication of the effectiveness of corrective maintenance when carried out (Figure 5) and analysis of planned maintenance versus those carried out each month of the year. The dashboard summarizes the main indicators obtained during the use of the software, such as maintenance per tool, number of maintenance planned versus carried out per supplier and temporal analysis of the supplier's performance in relation to maintenance.

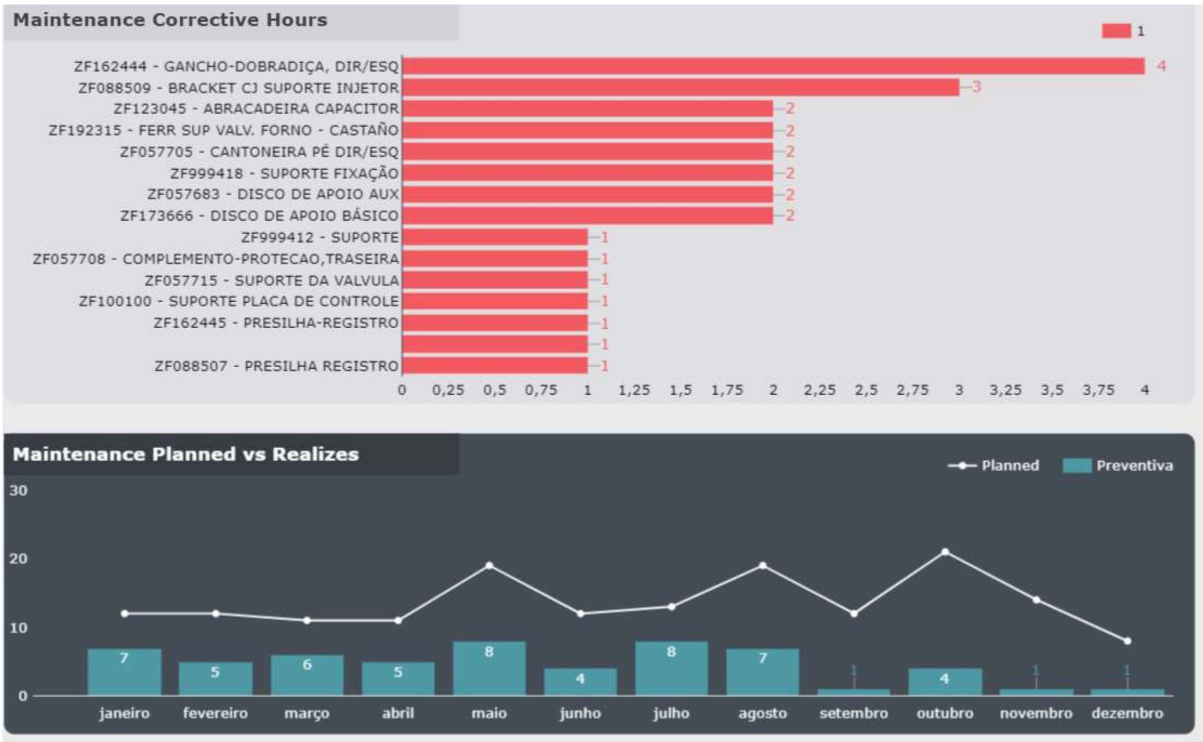


Figure 5 – Tools and maintenance information on Dashboard. Source: developed by the authors.

Figure 6 displays the possibility to work with filters by different suppliers, by tools (ferramentas - in portuguese) and by PNs (manufactured parts ID). This allows the team to more easily investigate issues based on more detailed and directed information.

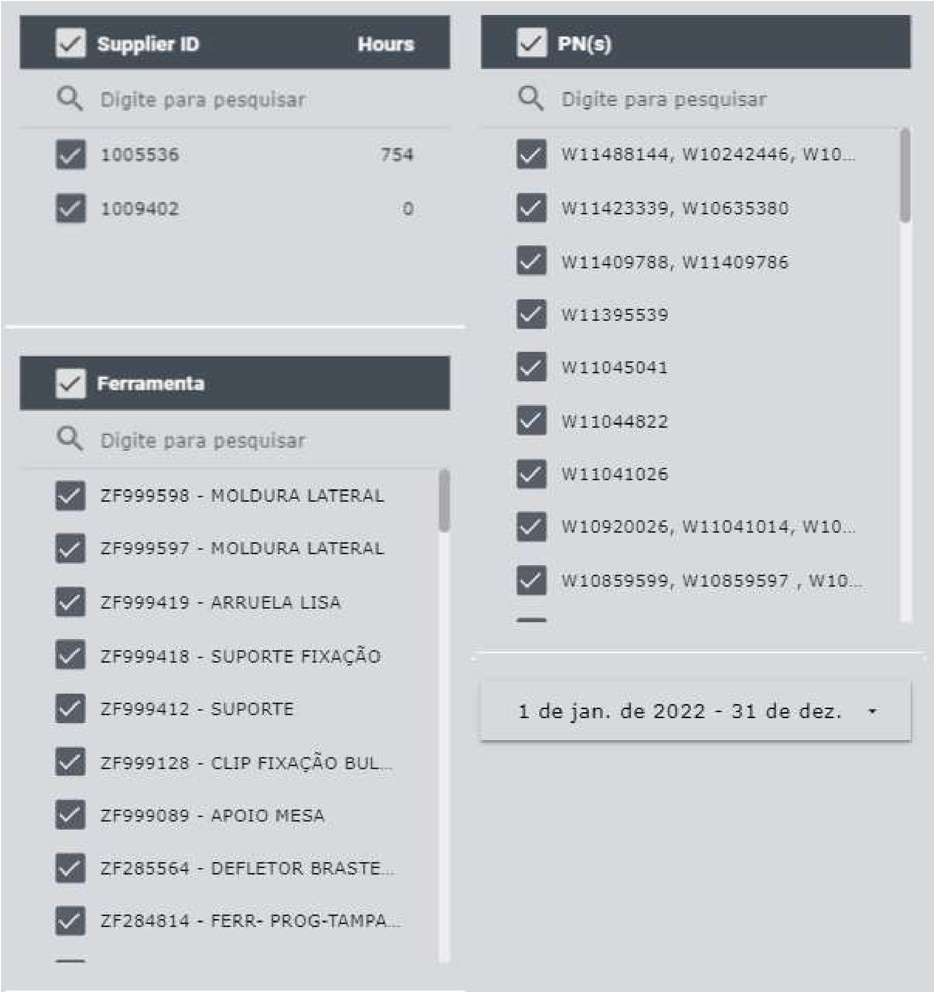


Figure 6 – PNs, tools and period information on Dashboard. Source: developed by the authors.

CONCLUSIONS

The research developed a framework to support the maintenance management process of the company's assets at its third-party suppliers. The framework is based on premises from the literature on TPM (Total Productive Maintenance) and maintenance planning. Maintenance planning considers tool utilization rate, equipment lifespan, and utilization rate based on demand (Basri et al., 2017; NG et al., 2012). The framework also demonstrated the interaction of activities and communication between the client company and the supplier, as well as the steps for implementing an asset maintenance planning and control tool.

The logic of the framework served as the basis for the development of software and a dashboard to facilitate communication and maintenance management between the client company and suppliers. The software was tested and applied to two suppliers of the client company and demonstrated success by enabling greater communication between the companies, a direct communication channel, maintenance management by the client company, and support to the supplier for performing preventive maintenance.

The framework is a research outcome that can be used by other organizations wishing to implement more effective communication with suppliers using their assets. Through the framework and the implementation of a maintenance plan, effective changes in communication, machine downtime, line supply issues, part quality, and communication and integration with the supplier can be generated.

Additionally, the action research showed that the proposed framework is capable of generating greater integration between the client company and its suppliers, allowing automatic sharing of information and preventive maintenance in potential tool failures, resulting in the reduction of quality problems in critical parts, line stoppages and higher levels of quality inspection at the supplier and customer. Therefore, as an academic implication, the research allowed the use of preventive maintenance concepts to establish maintenance plans in outsourced production suppliers. The framework presents a logic for organizations to deal with the maintenance of third-party tools, mainly favoring the exchange of information and two-way communication, generating integration, cooperation and increasing the performance levels of companies in the supply chain.

The limitations of the work are linked to the impossibility of generalizing the results found through action research, allowing for the dissemination of results in only one company from the application of the software and dashboard developed based on the framework. As the research was targeted and tested in a particular company, the research can be biased in its conclusions (Oliveira, 2022). There was also no quantitative analysis of the results obtained, only a qualitative analysis of the generated benefits. There are opportunities for future studies on the application of the premises used in the framework to a greater number of companies, as well as the quantification of the results obtained.

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Integrating TQM and Industry 4.0 for Enhanced Sustainability Performance: An Empirical Primary Results from Saudi Arabia Manufacturing Organizations

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STRUCTURED ABSTRACT

Purpose - This study delves into the integration of Total Quality Management (TQM) and Industry 4.0 technologies to advance sustainability in manufacturing organizations within developing countries, focusing on Saudi Arabia as a pivotal case. It aligns with Saudi Vision 2030's sustainability and economic diversification goals, emphasizing the broader implications for similar transitional economies.

Design/methodology/approach - Utilizing a dynamic capabilities framework, the research employs a survey methodology aimed at senior management in Saudi manufacturing firms. Structural Equation Modeling (SEM) is used to analyze the relationship between TQM, Industry 4.0, and sustainability performance, highlighting the moderating role of dynamic capabilities.

Findings - Primary findings suggest that integrating TQM with Industry 4.0 significantly improves sustainability performance, with dynamic capabilities playing a crucial role. The study underscores the importance of this integration for achieving sustainability objectives, particularly in the context of developing countries aiming for sustainable industrial growth amidst challenges such as resource constraints and environmental degradation.

Research Limitations/Implications - While focused on Saudi Arabia, the findings highlight the need for further research in other developing countries to validate the generalizability of the results.

Practical implications - Provides strategic insights for the adoption of TQM and Industry 4.0 technologies in pursuit of sustainability, offering a model for policymakers and industry leaders in developing countries.

Social implications - Supports the objectives of Saudi Vision 2030 and similar initiatives in developing countries, aiming for sustainable economic growth and industrial diversification.

Originality/value - Bridges the literature gap by empirically examining the integration of TQM and Industry 4.0 within a dynamic capabilities framework, offering a novel perspective on enhancing sustainability in manufacturing sectors of developing nations.

Keywords: Total Quality Management, Industry 4.0 Technologies, Sustainability Performance, Dynamic Capabilities, Developing Countries, Manufacturing Organizations.

Paper type Research paper

INTRODUCTION

In today's global economy, the concept of sustainability has become a cornerstone for industries aiming to secure long-term viability and compliance with international standards. This is particularly critical in the manufacturing sector, where environmental concerns and social responsibilities are increasingly at the forefront of business strategies. Total Quality Management (TQM) and Industry 4.0 are two pivotal methodologies that, when integrated, can significantly enhance the sustainability performance of manufacturing organizations. This research focuses on Saudi Arabia, a country undergoing rapid economic transformation under its Saudi Vision 2030, which emphasizes sustainability and economic diversification.

The intersection of Total Quality Management (TQM) and Industry 4.0 in the manufacturing sector presents both challenges and transformative potential. While TQM emphasizes systematic quality improvements and customer satisfaction, Industry 4.0 introduces advanced digital technologies that can significantly enhance operational efficiencies and environmental sustainability. In Saudi Arabia, the manufacturing sector plays a crucial role in the national economy, contributing significantly to GDP growth. However, the integration of these practices also poses unique challenges, particularly in environmental management. The application of Industry 4.0 technologies, such as IoT and AI, in traditional manufacturing processes has the potential to dramatically reduce waste and energy consumption, lower greenhouse gas emissions, and optimize resource use (Sader, Husti, & Daroczi, 2019). Despite these advancements, the sector is also responsible for substantial environmental impacts, including high energy consumption and waste generation, necessitating a strategic balance to achieve the ambitious sustainability targets set forth in Saudi Vision 2030 (Aichouni, Silva, & Ferreira, 2023). The integration of TQM and Industry 4.0 has also led to enhanced safety protocols, reducing risks associated with hazardous materials and industrial operations, thereby protecting workers and local communities (Zaidin, Diah, & Sorooshian, 2018). Notably, recycling initiatives within the sector remain limited, with a significant portion of industrial waste not being effectively repurposed, leading to increased landfill use (Najmi et al., 2021). Advanced technologies emerging from Industry 4.0, such as predictive analytics and smart sensors, offer promising solutions to these enduring challenges, enabling more sustainable manufacturing practices that align with global sustainability standards. Furthermore, these technologies facilitate continuous improvement and operational excellence, core principles of TQM, by providing real-time feedback and data-driven insights that enhance decision-making processes (Cresnar, Potočan, & Nedelko, 2020), (Tortorella & Fettermann, 2018), (Baran & Korkusuz Polat, 2022). The convergence of TQM and Industry 4.0 is increasingly recognized as essential for fostering sustainability in manufacturing, driving innovations that reduce environmental impact while boosting economic and social welfare (Florencio de Souza et al., 2021), (Samadhiya, Agrawal, & Garza-Reyes, 2022). Numerous studies have corroborated the positive impact of this integration on sustainability performance across various sectors, including automotive and electronics, where significant efficiency gains and waste reductions have been documented (Komkowski et al., 2023), (Foidl & Felderer, 2015), (Tortorella, Fogliatto, Cauchick-Miguel, Kurnia, & Jurburg, 2021). The environmental benefits are particularly notable in reduced emissions and conservation of resources, with value stream mapping tools being employed to optimize the use of materials and energy (Asif, 2020), (Zulqarnain, Wasif, & Iqbal, 2022). Economically, the synergy between TQM and Industry 4.0 has been instrumental in enhancing product quality and market competitiveness, leading to increased profitability and market share (Pozzi, Rossi, & Secchi, 2021). Socially, the adoption of these integrated practices has markedly improved working conditions and employee safety, contributing to the overall well-being and quality of life of the workforce (Yanamandra, Abidi, Srivastava, Kukunuru, & Alzoubi, 2023), (Psarommatis, Sousa, Mendonça, & Kiritsis, 2021). Research continues to explore the broader implications of this integration, with studies like those conducted by Chiarini & Cherrafi (2023), which demonstrated the scalability of TQM and Industry 4.0 practices in enhancing sustainability across different industries, further affirming the critical role of these methodologies in achieving sustainable development goals (Gundogan, 1996), (Pop, Țîțu, & Pop, 2023).

Collectively, the integration of Total Quality Management (TQM) and Industry 4.0 technologies is markedly enhancing the sustainability of manufacturing organizations. This combination proves particularly effective in reducing waste and operational costs in areas where traditional methods fall short (Aichouni, Silva, & Ferreira, 2022). Moreover, the incorporation of Industry 4.0 technologies alongside TQM principles helps in curtailing the high initial costs associated with implementing these advanced technologies alone. Few studies have explored the detailed relationship between these two frameworks across diverse manufacturing settings (Psarommatis, Sousa, Mendonça, & Kiritsis, 2021). TQM brings robust process improvement and quality control methodologies, which are complemented by the innovative and automation capabilities provided by Industry 4.0 (Abbas, 2020). This integration also addresses and mitigates barriers that typically impede the application of sophisticated manufacturing technologies (Enyoghasi & Badurdeen, 2021). The availability of real-time data facilitated by Industry 4.0's digital tools, such as IoT and advanced analytics, plays a crucial role in identifying and rectifying inefficiencies through sophisticated diagnostics and process mapping (Samadhiya, Agrawal, & Garza-Reyes, 2022).

The literature review underscores a significant gap in research concerning the combined impact of Total Quality Management (TQM) and Industry 4.0 technologies on the sustainability performance of manufacturing organizations. Notably, only a limited number of studies have explicitly examined the interplay between TQM principles and the advanced technologies of Industry 4.0 in enhancing sustainability outcomes. This paucity of studies is particularly glaring given the pressing environmental and economic challenges faced by the manufacturing sector in developing countries, such as Saudi Arabia. The few existing studies mainly focus on specific industries or regions, such as a notable investigation into the Indian manufacturing sector, which remains one of the few to analyze these relationships in depth (Felsberger & Reiner, 2020). The limited research highlights the urgent need for comprehensive studies that delve into how the strategic integration of TQM and Industry 4.0 can drive substantial improvements in sustainability performance across various manufacturing contexts. This research gap not only indicates a significant academic oversight but also suggests a crucial area for potential exploration that could provide valuable insights into achieving the ambitious sustainability goals outlined in Saudi Vision 2030.

This study is distinguished by its investigation into the causal relationships between Total Quality Management (TQM), Industry 4.0 technologies, and sustainability performance within the manufacturing sector of Saudi Arabia. It explores how the integration of TQM with advanced Industry 4.0 technologies impacts the environmental, economic, and social dimensions of sustainability in manufacturing processes. Furthermore, the study examines whether dynamic capabilities mediate the relationship between TQM practices and the effective deployment of Industry 4.0 technologies. This research offers fresh perspectives on how TQM and Industry 4.0 can collectively enhance sustainability performance, providing substantial theoretical and managerial implications for the sector. Despite Saudi Arabia's position as a leader in the global market, particularly in oil and gas, many of its manufacturing firms remain at the Industry 3.0 stage, with limited adoption of advanced Industry 4.0 technologies. Additionally, there is a notable research void concerning the synergistic effects of TQM and Industry 4.0 in Saudi manufacturing organizations. This gap underscores a critical opportunity for local decision-makers to foster the adoption of these advanced technologies and management practices, positioning Saudi firms to better align with international standards and improve their global competitiveness. The findings of this study are intended to serve as a strategic resource for policymakers and business leaders as they devise tactics and frameworks to excel in sustainability and innovation. Unlike many previous studies that rely on generalized expert opinions across various industries, this focused examination within the Saudi context aims to provide a more detailed and applicable understanding of how TQM and Industry 4.0 can be leveraged to enhance sustainability outcomes effectively.

To achieve the objectives of this study, a conceptual framework was constructed based on a thorough literature review of Total Quality Management (TQM) and Industry 4.0 technologies. Hypotheses were then formulated to assess the integration of these methodologies within 30 Saudi manufacturing organizations. Data collected from these organizations were analyzed using Structural Equation Modeling (SEM) to empirically validate the model. The results substantiate the theoretical framework and highlight practical implications, providing valuable insights into the synergistic effects of TQM and Industry 4.0 on sustainability performance. These findings offer guidance for policymakers and industry leaders in enhancing operational efficiency and achieving the sustainability goals of Saudi Vision 2030.

THEORETICAL BACKGROUND AND MODEL DEVELOPMENT

Integrating Total Quality Management (TQM) principles with the advanced technologies of Industry 4.0 offers a strategic route for organizations to elevate their quality and operational efficiency, ultimately leading to enhanced sustainable performance. TQM focuses on enhancing processes and ensuring customer satisfaction (Nguyen, Phan, & Matsui, 2018), which complements the capabilities of Industry 4.0, such as predictive analytics, automation, and artificial intelligence. This integration aids in refining quality management practices (Pozzi, Rossi, & Secchi, 2023) and promotes better decision-making, cross-departmental cooperation, reduced environmental impact through more efficient use of resources, and improved safety at work (Sader, 2020; Ben-Eli, 2018). Employing Industry 4.0 within a TQM framework allows organizations to achieve greater sustainability, supporting the view that the merger of TQM and Industry 4.0 is crucial for excellence and sustainability in today's manufacturing environment (Saha et al., 2021).

Figure 1 illustrates a path diagram for the research model based on a literature review. The hypotheses developed in this study are rooted in an in-depth analysis of the interaction among Total Quality Management (TQM), Industry 4.0 technologies (I4.0), and Sustainability Performance (SP), within the context of dynamic capabilities (DC). The initial hypotheses, H1 and H2, assert that TQM and I4.0 technologies directly enhance sustainability performance, underscoring the importance of quality management principles and advanced technologies in achieving sustainable results. Hypothesis H3 asserts a significant link between the application of TQM principles and the use of Industry 4.0 technologies in manufacturing organizations, which together improve Sustainability Performance (SP). Hypotheses H4 consider dynamic capabilities as a moderating influence, suggesting that an organization's ability to adapt, integrate, and reconfigure internal and external resources could enhance or modify the impact of TQM and I4.0 on sustainability performance. These hypotheses aim to clarify the direct, indirect, and moderated interactions between these factors, providing insight into how manufacturing organizations can utilize TQM and I4.0 technologies to boost their sustainability efforts, aligned with strategic initiatives like Saudi Vision 2030.

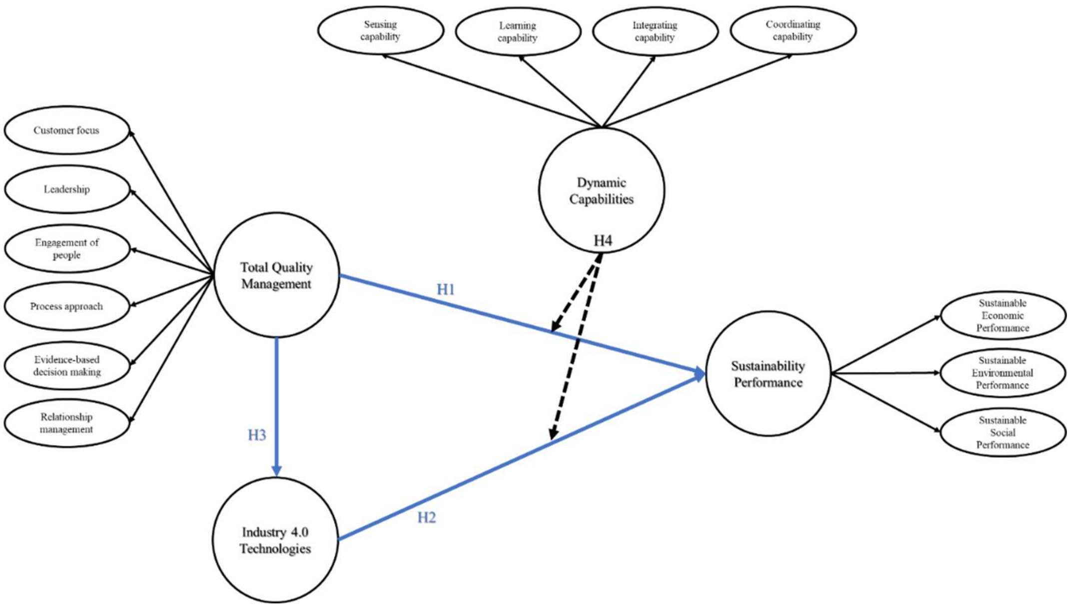

Figure 1 – Proposed research framework.

RESEARCH METODOLOGHY

Following the example set by Forza et al. (2002) in maintaining methodological rigor, our research applied a survey-based approach to examine theories in operational management, carefully developing and reviewing the process. The initial survey was refined through discussions with experienced TQM and operations management scholars and tested in a pilot study with experts from Saudi Arabia and Portugal. This process of iterative refinement, including minor edits for enhanced clarity based on feedback from these experts, aimed to boost the survey's reliability and validity, a process similar to the one detailed by Zhao et al. (2007). The development of our research tool involved a thorough review and validation stage, incorporating expert interviews and scholarly evaluations to align with recognized academic practices.

In this analysis, we precisely measure each variable using validated scales to understand the relationships among Total Quality Management (TQM), Industry 4.0 technologies (I4.0Ts), Sustainability Performance (SP), and Dynamic Capabilities (DCs), including control variables like Environmental Uncertainty and Company Size. Sustainability Performance is quantified using a comprehensive measure of the Triple Bottom Line, incorporating economic, environmental, and social indicators as seen in Alsawafi, Lemke, & Yang (2021) and Yong et al. (2019). TQM is assessed through various quality-centered dimensions from frameworks by Samson & Terziovski (1999) and Zhang, Waszink, & Wijngaard (2000), focusing on leadership, customer orientation, and continual improvement. The degree of I4.0Ts implementation is measured using indicators that reflect the integration of cutting-edge manufacturing technologies, as per Huang, Wang, Lee, & Yeung (2023). Dynamic Capabilities are seen as a moderating factor and measured by the organization's ability to adapt and innovate, using criteria from Teece, Pisano, & Shuen (1997) that emphasize sensing, seizing, and transforming business opportunities and threats. All variables are evaluated using a five-point Likert scale, ensuring a detailed and accurate analysis that sheds light on the interaction between quality management practices, technological implementation, dynamic capabilities, and sustainability outcomes in the manufacturing sector.

Data Analysis

In our study, we employed rigorous analytical techniques to ensure the robustness of our data and the validity of our models before drawing any conclusions. Initially, we addressed potential biases, specifically common method bias, using Harman's single-factor test as recommended by Podsakoff et al. (2003), aiming to detect undue variance from the survey instrument itself. According to this method, a single factor explaining less than 50% of the variance is considered acceptable, which helps confirm the data's integrity. To further assess data quality, we performed tests for data normality by examining the kurtosis and skewness of each variable, as well as internal consistency checks using the Cronbach's alpha coefficient and the Kaiser-Meyer-Olkin (KMO) measure. Norm values for the Kaiser-Meyer-Olkin index often exceeds 0.9 for high-quality data sets, and acceptable values for Cronbach's alpha are generally 0.7 or higher, indicating good internal consistency (Mejía et al., 2022). Additionally, the individual constructs of Total Quality Management, Industry 4.0, and Sustainability Performance were rigorously tested, showing high reliability scores and supporting the structured factor analysis. This step confirms that our constructs correlate strongly with related variables and weakly with unrelated ones, essential for validating the scale's accuracy. Through meticulous external and internal review processes, including feedback from a panel of academic experts and a dual communication strategy for survey administration, we ensured that our questionnaire accurately reflected our research objectives and covered all relevant study variables. These measures collectively confirm the effectiveness of our questionnaire in accurately gauging the principal constructs within Saudi manufacturing organizations, thereby enhancing the credibility and applicability of our findings.

Further, our models were tested using Structural Equation Modeling (SEM) implemented via the SMART-PLS 4 software. This method allows us to explore the relationships and causality within our model comprehensively. We ensure the model's fit through confirmatory factor analysis (CFA), checking the chi-square, degrees of freedom, and standardized root mean square residual (SRMSR) to confirm the hypothesized measurement model's accuracy. This thorough validation process, from addressing non-response bias through targeted sampling of initial non-respondents to confirming construct validity via CFA, underscores our commitment to empirical rigor. Our methodology, rooted in the traditions of meticulous empirical research, aims to establish a robust foundation for interpreting the interrelations between Total Quality Management (TQM) practices and sustainability within the Saudi Arabian industrial sector. These efforts are designed to enhance the credibility and relevance of our findings, contributing substantively to the discourse on quality management and sustainability in emerging markets.

Sample and Data Collection

In this exploratory research, we examined the relationship between Total Quality Management (TQM) practices and sustainability in the Saudi Arabian industrial sector. Utilizing a comprehensive database from the Ministry of Industry and Mineral Resources of Saudi Arabia, our initial data included 10,966 industrial entities as of May 2023, including those under construction. To enhance the study's robustness and account for potential non-responses, we broadened our outreach to include 1000 companies. This sample was deliberately selected to represent a wide range of the industrial sector, from emerging businesses to well-established manufacturing firms, capturing a variety of operational and strategic contexts. Our data collection is centered around a carefully designed electronic survey, distributed via Google Forms over two distinct phases from 2023 to 2024. Senior managers were primarily targeted as respondents, including Owners, Managing Directors, Board

Members, Executive Managers, Department Managers, and Supervisors/Section Managers, based on their crucial role in shaping organizational policies and their deep understanding of TQM and sustainability practices. This method was chosen to ensure a diverse and thorough representation of the industrial sector's adherence to quality management and sustainability standards. Despite expected challenges in engaging this high-profile respondent group, the survey achieved a response rate above 20% to date. The participants, predominantly male and largely aged between 31 and 40 with a master's degree, provided a valuable dataset that was demographically diverse and indicative of a high level of expertise and commitment to the study's focal points. The collected data, representing various sectors within the Saudi Arabian industrial landscape, allowed for an in-depth analysis of the prevalence and effects of TQM and sustainability practices throughout the sector, supporting the empirical investigation of these essential management practices. Table 1 displays the profile of the participants and companies and their associated sectors (up to Jan 2024).

Table 1 – Participants' and Organizations' Profiles.

Participants' profile

Gender	%	**Age (Category)**	%
Male	90	31 to 40 years	33
Female	10	21 to 30 years	27
Educational level	%	41 to 50 years	23
Master's degree	37	51 to 60 years	17
Bachelor's degree	28	**Current position**	%
Diploma or other	20	Department Manager	22
Doctoral degree	15	Supervisor / Section Manager	22
Professional experience	%	Other	21
11 to 20 years	26	Executive Manager	17
6 to 10 years	22	Owner / Managing Director	13
More than 20 years	20	Board Member	6
1 to 5 years	18		
Less than 1 Year	14		

Organizations' profile

Nature of the organization	%	**Business sector**	%
Saudi National Company	51	Other Manufacturing Sector	16
Multinational Company	27	Mining industries	12
Partnership (Joint Venture)	22	Mechanical industries	11
Number of employees	%	Oil, Gas and Petrochemicals	10
250 or more (Large enterprises)	43	Utilities Production (water, electricity)	9
More than fifty and less than 250 (Medium enterprises)	21	Food and beverages industries	9

More than ten and Less than 50 (Small enterprises)	19	Aerospace and aviation industries	8
Less than 10 (Micro enterprises)	18	Services for the Manufacturing (Testing and Inspection)	8
		Electrical and electronics industries	6
		Pharmaceutical industries	5
		Metals and Plastic industries	5

RESULTS

Measurement Model

To ensure the external stability and validity of our survey questionnaire, we engaged a panel of academic experts in industrial management and a Scientific Committee specializing in Total Quality Management, whose expertise supported a thorough review process. This panel refined the questionnaire to accurately reflect our research objectives and cover all relevant study variables. This refined version was further scrutinized by a group of six distinguished academics and managers from various universities, consultancy centers, and a major global petroleum company, who enhanced the clarity and phrasing of the questions. We adopted a dual communication strategy—telephonic and online—to maximize response rates and data quality, with additional feedback from manufacturing managers helping to further streamline the questionnaire. A pilot test was conducted to verify the clarity of the instructions and the effectiveness of the administration procedure. Following expert recommendations, we developed an electronic survey that was sent out via email to targeted respondents, with strategic follow-ups to overcome typical low response rates associated with e-surveys and offering a summary of key findings as participation incentive. Internally, the reliability and validity of the questionnaire were assessed using the Cronbach's alpha coefficient and the Kaiser-Meyer-Olkin (KMO) measure, with an overall Cronbach's alpha of 0.9 and a KMO of 0.8, indicating excellent reliability and data suitability for factor analysis. The Total Quality Management construct exhibited high reliability ($\alpha = 0.9$) with a KMO of 0.9 across the survey questions covering dimensions such as Customer Focus and Leadership. Similarly, the Industry 4.0 and Sustainability Performance constructs showed strong reliability scores ($\alpha = 0.8$ and $\alpha = 0.8$, respectively) and KMO values (0.9 and 0.8), supporting the structured factor analysis. The Dynamic Capabilities construct also demonstrated robust reliability ($\alpha = 0.9$) with a KMO of 0.9, ensuring internal consistency across the scales measuring Sensing, Learning, Integrating, and Coordinating capabilities. Additionally, the data were analyzed for common method bias using Harman's single-factor test, which indicated that a single factor accounted for only 20% of the variance, suggesting minimal influence from common method bias as this is significantly below the 50% threshold. These measures collectively confirm the effectiveness of our questionnaire in accurately gauging the principal constructs of Total Quality Management, Industry 4.0, and Sustainability Performance within Saudi manufacturing organizations.

Hypothesis Testing

The complete model comprises of thirty latent factors out of which twenty-six were first order, four were second levels. The model was created from seventy-six constructs. The structural equation modeling (SEM) was then analyzed to evaluate the hypothesis in affirmative or negative. In order to confirm the mediating impact of Industry 4.0 technologies on Total quality management and sustainability performance, it was essential to analyze its effect as it could indicate: no mediation, partial, and full mediations. No mediation happens if both the direct and indirect effects are unsubstantial. Partial mediation occurs if both the direct and the indirect effects (of Total quality management on sustainability performance, through Industry 4.0 technologies) are substantial. Full mediation happens when the direct effects (of Total Quality Management on sustainability performance) in the presence of Industry 4.0 technologies is not substantial, while the indirect effects of Total Quality Management on sustainability performance is substantial. Based on the above criteria, the model is evaluated for mediation effects using the SMART PLS4. Employing bootstrapping methodology, the direct and indirect influence of Total Quality Management were analyzed.

Direct Impact of Total Quality Management

In our exploration of the effects of Total Quality Management on sustainability performance (H1) and its influence on the adoption of Industry 4.0 technologies (H2) within manufacturing organizations in Saudi Arabia, the structural equation modeling (SEM) technique, specifically the bootstrapping method, was employed. The analysis confirmed that Total Quality Management significantly enhances sustainability performance, as evidenced by a strong beta coefficient (β = 0.57), a p-value of less than 0.001, and a T-value of 7.81, indicating a robust impact. Furthermore, the positive influence of Total Quality Management on the uptake of Industry 4.0 technologies was also supported, shown by a beta coefficient of 0.194, a p-value of 0.028, and a T-value of 2.20. These results affirm the pivotal role of Total Quality Management in promoting both sustainability and technological advancement within the sector.

Mediating and Moderating Effects

The analysis then proceeded to evaluate the mediating role of Industry 4.0 technologies in the relationship between Total Quality Management and sustainability performance (H3). Contrary to expectations, the mediation was found to be non-significant, with a beta coefficient of 0.05, a p-value of 0.098, and a T-value of 1.65. This suggests that the direct influence of Total Quality Management on sustainability performance does not significantly depend on the presence of Industry 4.0 technologies. Moreover, initial investigations into the moderating effects of dynamic capabilities (H4) indicated a potential for these capabilities to enhance or alter the impact of Total Quality Management and Industry 4.0 on sustainability performance. However, these findings are preliminary and indicate a need for further detailed studies to determine the nature and extent of these moderating effects more accurately. The exploration of dynamic capabilities as a moderating factor is especially crucial, as it may provide insights into how organizations can better integrate and leverage Total Quality Management and Industry 4.0 technologies to achieve enhanced sustainability outcomes (see Table 2).

Table 2 – Summary of Hypothesis Testing Results.

HYPOTHESIS	Description	β	P-Value	T-Value	Outcome
H1	TQM influences sustainability performance positively.	0.57	<0.00	7.81	Supported
H2	TQM influences Industry 4.0 technologies positively.	0.19	0.02	2.20	Supported
H3	Mediating effect of Industry 4.0 on TQM and sustainability.	0.05	0.09	1.65	Not Supported
H4	Dynamic capabilities moderate TQM and Industry 4.0's effects.	-	-	-	Further Investigation

DISCUSSION

Total Quality Management (TQM) and Industry 4.0 technologies are increasingly recognized as crucial drivers for enhancing sustainability and operational efficiency in manufacturing sectors across Saudi Arabia. While the manufacturing industry significantly contributes to the nation's economic prosperity, generating employment, and improving overall living standards, it faces substantial challenges in environmental and social sustainability. This sector's lag in adopting advanced sustainable practices has imposed considerable strain on both societal welfare and environmental health. However, the integration of Industry 4.0 technologies, along with robust Total Quality Management practices, has started to draw significant interest from both academic researchers and industry practitioners. These modern approaches are facilitating the manufacturing sector's transition towards more sustainable and efficient operations, helping to address and alleviate the issues traditionally associated with manufacturing activities. As such, the adoption of these technologies and management practices is becoming increasingly vital for ensuring the long-term sustainability and competitiveness of Saudi Arabia's manufacturing landscape.

This paper explored the direct impacts of Industry 4.0 technologies and Total Quality Management on the sustainability performance of manufacturing organizations in Saudi Arabia. Additionally, it examined the integrated influence of Industry 4.0 technologies on enhancing sustainability within these sectors. The findings reveal that manufacturing organizations in Saudi Arabia are progressively adopting Industry 4.0 technologies, with a notable direct and positive influence on sustainability performance. This supports the hypothesis that Industry 4.0 technologies significantly contribute to sustainability measures in the manufacturing sector, aligning with previous research that has demonstrated a relationship between advanced technological adoption and improved sustainability outcomes (Ghaithan, Khan, Mohammed, & Hadidi, 2021).

This study explored the direct impacts of Industry 4.0 technologies and Total Quality Management on the sustainability performance of manufacturing organizations in Saudi Arabia, with a special focus on the gradual transition from Industry 3.0 to Industry 4.0. This transition reflects a significant technological shift that influences not only operational efficiencies but also sustainability outcomes across various industrial sectors. Furthermore, the analysis delved into the integrated influence of these technologies on enhancing sustainability performance. The findings indicate that the adoption of Industry 4.0 technologies such as the Internet of Things, big data analytics, and cloud computing is prioritized due to their significant potential to reduce production times, lower operational costs, and thus enhance customer satisfaction and market share. Conversely, technologies like robotics, augmented reality, and additive manufacturing are less prioritized for their sustainability impacts.

This study also highlighted that many Saudi industries, particularly small and medium-sized enterprises, are in the midst of transitioning from Industry 3.0 to Industry 4.0. This shift suggests a gradual but significant move towards more digitally integrated and sustainable manufacturing practices. Notably, the mediating role of Industry 4.0 in enhancing Total Quality Management's impact on sustainability performance may not have been significant (Hypothesis 3), potentially due to the ongoing transition phase from Industry 3.0 to Industry 4.0, which might be causing inconsistencies in technology adoption and application. This transitional dynamic is crucial as it encapsulates the broader challenges and opportunities faced by the sector during this pivotal transformation period (Salah et al., 2020). The evolving nature of industrial operations under the ambit of Industry 4.0 presents a complex scenario where the benefits of sustainable practices are increasingly recognized, yet the full potential is still being realized as industries adjust to new technologies and processes.

Building on this context, the exploration of Hypothesis 4 delves into the moderating effects of dynamic capabilities, highlighting their potential to refine the impact of Total Quality Management (TQM) and Industry 4.0 technologies on sustainability performance. The initial findings indicate that dynamic capabilities could significantly mediate the relationship between these factors and sustainability outcomes, especially during this critical transition period. Dynamic capabilities, particularly those oriented towards sustainability, enable organizations to integrate and reconfigure internal and external competencies to effectively navigate rapidly changing environments (Dangelico, Pujari, & Pontrandolfo, 2017). These capabilities support the adoption of green innovations and eco-design practices that significantly influence market performance. Furthermore, in the context of small and medium-sized enterprises (SMEs), dynamic capabilities have been shown to positively impact the social, environmental, and economic dimensions of sustainability performance. Integrative dynamic capabilities, which involve the adept coordination of external and internal resources, are particularly crucial for achieving these sustainable outcomes (Eikelenboom & Jong, 2019). Additionally, the role of sustainable supply chain management practices, bolstered by dynamic capabilities, is demonstrated to significantly enhance enterprise performance. This interaction underscores the importance of nurturing capabilities that support both environmental and economic objectives simultaneously, particularly during the ongoing shift from Industry 3.0 to Industry 4.0, ensuring that sustainability is embedded in the core strategic processes of industries (Hong, Zhang, & Ding, 2018).

CONCLUSIONS

This article's investigation into the integration of Total Quality Management (TQM) and Industry 4.0 technologies within Saudi Arabia's manufacturing sector provides crucial insights into the advancement of sustainable practices. As Saudi Arabia positions itself to meet the ambitious goals of

Vision 2030, the role of modern technological adoption in improving environmental and operational efficiency cannot be overstated. The study confirms that the synergy between TQM and Industry 4.0 technologies not only enhances sustainability performance but also propels manufacturing firms towards more advanced stages of technological integration. Despite challenges associated with transitioning from Industry 3.0 to Industry 4.0, such as inconsistencies in technology adoption and application, the overall impact remains significantly positive. This transition is critical as it encapsulates a broader shift towards a more digitally integrated and sustainable manufacturing approach. Moreover, the findings suggest that dynamic capabilities play a vital role in this process, enabling organizations to adapt to rapid changes and integrate new technologies effectively. These capabilities are crucial for fostering innovation and driving the adoption of sustainable practices within the manufacturing sector. They allow firms to respond dynamically to environmental pressures and market demands, thus enhancing their competitive edge and sustainability outcomes. In conclusion, this research underscores the importance of a strategic approach to integrating TQM and Industry 4.0 within manufacturing processes. It highlights the need for ongoing support and adaptation of policies that facilitate this integration, ensuring that the manufacturing sector in Saudi Arabia can meet its sustainability goals while continuing to contribute significantly to the nation's economic growth. The insights gained from this study provide a valuable blueprint for other developing countries aiming to enhance sustainability through technological and quality management advancements..

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Contribution to Reduce Type II Error at the End-of-Line Inspection at an Automotive Industry Supplier

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STRUCTURED ABSTRACT

Purpose - In the automotive industry, it is necessary to create improvement opportunities to increase customer satisfaction and to stand out from the competition. Components to be assembled in a car are subject to a final end-of-line (EOL) inspection, which are measured using numerical and attributive variables, with a final result of OK / NOK. However, this inspection is not perfect. In this paper, a method is proposed to increase the detection rate of products with components in a pre-failure state, which pass the EOL inspection.

Design/methodology/approach - The logistic regression method made it possible to identify an explanatory model, based on real data from a company of the automotive industry, that allows the product to be categorised into one of two groups: "0km" (customer claim) or "Regular" (conforming product).

Findings - It was possible to explore the Type II error reduction through the usage of logistic regression.

Originality/value – The logistic regression proved to be valuable in classifying at EOL potential pre-failure devices, having the potential to reduce the Type II error. It also identifies the key variables that support the classification.

Keywords: 100% End-of-line inspection, Logistic regression, Pre-failure, Type II error

Paper type: Research paper

1. INTRODUCTION

Electronic products are made up of various components, such as, mechanical (e.g., metal and plastic parts), electronic (e.g., microprocessors, resistors, capacitors, and coils) and electromechanical. In the case of the automotive industry, customers expect an improvement in product quality and periodic reductions in purchase costs. In this sense, it is necessary for each supplier to create opportunities for improvement in order to increase customer satisfaction and to stand out from the competition.

In industrial processes there is always natural variability, which is the consequence of small causes inherent in the process and which are unavoidable (Sousa et al., 2018). In the statistical quality control system, if a process is only under the effect of random causes of variation (inherent and unavoidable), the process is said to be under statistical control and is predictable . However, other types of variability can be present in the process output. According to Serban et al. (2014), printed circuit board assembly (PCBA) failures can be divided into three main categories:

- Failures caused by components that do not fulfil the design specifications;
- Process faults caused by manufacturing processes such as assembly or welding;
- Performance failures generally resulting from a design problem or dynamic device failures.

These types of causes induce very large variabilities when compared to the effect of the causes inherent in the process. If a process is producing under these non-random causes, the process is said to be out of control (Montgomery, 2009), and consequently the proportion of non-conformities may increase significantly.

To manage process variability and faulty components, manufacturers of electronic components invest millions in equipment and resources to test their products before sending them to their customers (Grzelak and Blackwell, 2000).

The context of this research consists of a Tier 1 supplier of car assembly plants, which manufactures electronic parts that are sold directly to automotive OEM. In the automotive industry, typically, all the components produced by the suppliers of the car assembly plants are subject to a final inspection of a large set of functional characteristics, containing numerical and attributive variables, the final result of which is an OK / NOK, corresponding to a compliant or non-compliant assessment, respectively. However, this inspection is not perfect, so NOK products are sent to customers (Type II error) just as compliant products are sent for repair (Type I error) (Reis et al. 2024). A detailed description of these inspection errors is provided by Montgomery (2009). Most of the products complained about by the company's customers come from products produced as first time quality

(FTQ), having passed the End-of-Line (EOL) test as compliant products using the current method based on OK / NOK results. It is therefore necessary to identify alternative, more effective control methods to reduce the number of products considered internally compliant that could fail at the customer's companies. One way is to improve the process by reducing the percentage of defects. The other way is to improve the inspection process, reducing the Type II error. This paper focus on the improvement of the inspection process.

As manufacturing processes improved over time, in-circuit test (ICT) systems became more and more reliable, and an increasing proportion of faults fell into the category of functional faults (Scheiber, 2001). As a result, board manufacturers returned to functional testing as the main test strategy, to comprehensively demonstrate that the board worked according to specifications or design. Another reason why functional PCBA testing has become increasingly more important than ICT is the miniaturisation of digital electronic components, which makes it more difficult to perform conventional PCBA testing using needle platforms. This problem is caused by the integration of large-scale integrated circuits (IC), available in ever-smaller dimensions, requiring the provision of an ever-increasing number of test pins (in the hundreds). This had a direct impact on the print circuit board (PCB) design, as the distance between the copper rails became smaller and smaller and the number of layers involved increased. Test needle platforms became increasingly complex to the point of making conventional ICT testing unfeasible (Albee, 2013).

Thus, main objective of this paper addresses is to reduce the Type II error during EOL inspection of components for the automotive industry. In this competitive industry, any reduction on Type II error will have a positive effect on the supply chain and in companies' competitiveness.

This research is fundamentally explanatory in nature (Saunders et al, 2007), as it seeks to explain why a phenomenon, false conformities at the EOL inspection, occurs and predict future occurrences, establishing causal relationships between variables. For this purpose a logistic regression will be used. It is quantitative in nature, as it consists of a positivist and deductive approach (Saunders et al, 2007) and in which the selected variables are operationalized in terms of a numerical scale.

As for the method, the data initially collected is non-probabilistic and intentional, as it is chosen from the group of products claimed by customers and later confirmed as true non-conformities (NOK). These form the case study, as we intend to learn more about this sampling of the total population produced. The data to be used is secondary and of a documentary type, coming from written material:

that is, it is production data, previously existing on the organization's server, which was collected for the purposes of 100% process control.

This paper is organized as follows. The next section (2) presents a detailed description of the problem. The following section (3) proposes a model of logistic regression to address the problem and presents an analysis and discussion of the results. The paper ends with conclusions and directions for future research.

2. PROBLEM DESCRIPTION

This work uses the applicable nomenclatures and defect classifications, referenced to the IPC-A-610 standard. The company currently manufactures its products with defect acceptance criteria based on class 3. The electronic circuits are mostly digital, with a small percentage of analogue circuits.

The product under study is an infotainment device (Figure 1) with some variants that have more complexity and functionalities. The circuit is both digital and analogue in nature, although it is predominantly digital. It receives analogue signals from the outside and transforms them into digital signals in order to process them. Likewise, before sending the signals to the outside, it converts them into analogue. It also receives digital signals from the outside. All signals received from the outside are processed in binary format, internally in the circuit, as this is faster from the point of view of processing speed when compared to a purely analogue circuit. The product has approximately 2600 components spreading over two PCB, depending on the complexity of the variants.

Figure 1 – Studied product.

2.1 False conformities

Even after 100 per cent inspection at EOL of the products manufactured by the company, there are NOK products identified by customers (OEM manufacturers), which leads to "0 km" claims (i.e., claims that do not leave the customer's factory) and warranty claims (i.e., claims that arise from the end customer during the warranty period). It is therefore important to reflect on NOK products that pass the 100 per cent inspection, resulting in false conforms, i.e., Type II error.

2.2 Defining the problem

Most of the products complained about by the company's customers come from products produced as first time quality (FTQ), having passed the EOL test as compliant products. After being returned for analysis, they are subsequently confirmed as NOK on the analysis bench and in EOL. This indicates that if there are initial signs of pre-failure, they are not detected by the current method when the products are produced.

In the period between 01 January 2022 and 20 June 2023, the total proportion of devices claimed as defective (detected by the clients and confirmed in subsequent analysis) was 131 PPM, i.e., PPM of true NOK products that were falsely classified at EOL as OK.

Components with mechanical anomalies (in the form of microcracks, raised pins or debris) manifest themselves in the form of various electrical defects: intermittent contact, variable resistance, loss of capacitance and current leakage. Such behavioural anomalies can also occur with defective components. Kyrychenko et al. (2013) refer to the uncertainty in detecting failure modes associated with mechanical stress during the production process. Later, however, these faults can cause permanent damage to the component or indirectly to other components connected to it in the circuit. This can happen later, at 0 km or under warranty. After power-up, the electronic circuits in this product typically take 20 minutes to stabilise. This is the ideal amount of time to wait before starting to assess the condition of the circuit. But due to the takt time, such a time interval would make the cycle time longer than it is, and therefore incompatible with the daily quantities ordered. For this reason, the concept and principle of functional testing is geared towards cycle time rather than failure, in order to fulfil the takt time.

On the other hand, regardless of the cycle time applied, it is assumed in this study that a percentage of components in a pre-failure state show deviations or anomalies in the IC, directly or indirectly influencing the values of variables in the EOL.

2.3 Electrical tests

2.3.1 End-of-Line tests

Each functional characteristic tested at EOL corresponds to a certain number of numerical and attributive variables. In EOL testing, the test equipment stacked in a rack is connected to a switch or router. This, in turn, is connected to a local computer (PC) via protocol and Ethernet cable. From this local PC, the signal will connect to another local switch, also via the ethernet protocol. This, in turn, connects via optical cable to a remote server within the company. The local system tells the remote system which variant is in each test bench (Figure 2). From this remote server, the test sequence to be used for the variant being produced is sent and downloaded by the local PC to start the test.

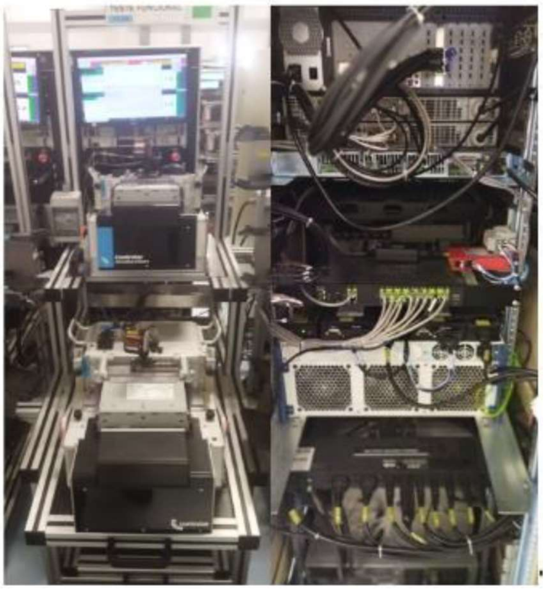

Figure 2 – An EOL test bench: front and back.

Each product is powered by a supply voltage of 14.4 Volt. The voltage is used and required to calibrate and memorise the nominal battery voltage in the product, under normal vehicle use conditions by software (SW) parameters. The product is also supplied with a current limited to 3.0 amperes (A). The final test is carried out with the product in recovery mode. The product is controlled via the universal asynchronous receiver-transmitter protocol, using a connector for this purpose. This is because the data is transmitted more quickly. In parallel, all the other connectors are connected via contact pins to test their functionality, either directly or indirectly. For example, the Universal Serial Bus (USB) is used to load the test SW into the product, and indirectly indicates whether the connector works. Other connections such as low-voltage differential signalling (LVDS) are used for image testing. The product is subjected to a power-up, which remains active throughout the test, and is subjected to three power-cycles. Some functions in recovery mode are tested in loop mode. Examples include the Digital Audio Bus (A2B), Media Oriented System Transport, Controller Area Network (CAN) and LVDS-IN. The tests with the longest cycle times involve LVDS, Wireless Networking Technology (Wi-Fi), Bluetooth® and Brother Reach.

The total time for the final test, per device, varies on average between seven minutes (for the simplest variants) and 10 minutes (for the most complex variants). The test is programmed for a test time of more than ten minutes due to the variability of test times between products, which is monitored daily and subject to periodic adjustments. Typically, the greatest variability of behaviour in measurement response times occurs when the product is switched on for the first time. This is because when the product is switched on, the various circuits start up and interact for the first time, establishing communication with each other. If the product is tested again, and therefore subjected to a new power-up, the dispersion in response times is generally smaller, because various communication protocols have already been finalised at the time of the first power-up.

The test system sends each command several times and continuously, through several loops (therefore, in a logic of number of attempts/loops and not of response timeout), for which it waits for a response; The priority of these commands sent is, at the hierarchical level, the lowest. The highest priority, by default, is to run several hardware (HW) diagnostics. This is essentially due to safety reasons (e.g.: the circuit's internal power supply must follow a starting sequence). On the same test bench, variables can be measured sequentially or alternately and in parallel. This follows a logic of resources (equipment) available per bench and cycle time optimization per test. It is, for example, sequential when the equipment is shared by each test bench: examples of this are the Amplitude Modulation (AM) / Frequency Modulation (FM) / Digital Audio Broadcasting (DAB) signal generators or the multimeter digital. On each bench, these devices can only measure one device at a time. On the other hand, there are tests that are carried out simultaneously, as they do not depend on shared equipment: this is the case of the Wi-Fi functionality. The fact that the equipment is shared is relevant, as it has a potential impact in the absence of distribution normal in the variables studied.

The dependent variable, which defines the status of the product at the end of the EOL, is categorical and dichotomous in nature, that is, each product has a result of “OK” or “NOK”. Products are considered NOK at EOL when one of the following conditions occurs when:

- the numerical variable is outside the specification range, defined between the lower and upper specification limits.
- the number of attempts/loops to obtain the value of a variable reaches the limit, without any response. The maximum number of loops is established according to the characteristic in question. The time interval between each loop varies between 100 and 200 milliseconds, depending on the characteristic in question.

- the total time expected for the test to be completed is exceeded. In this project, for example the test time limit is currently set at 1000 second (and is periodically reviewed).

The total number of variables measured in the EOL test is 325: 149 variables (45.8%) o numerical in nature and 176 variables (54.1%) categorical in nature.

2.3.2 OEM Customers' Tests

At the OEM customers, the product is mounted on the vehicle and subjected to testing. The products are connected via the CAN protocol and tested in Production Mode. The tests are aimed at checking the connection states of the peripherals, through communication with them. There are normally no dedicated tests for end customers nor are communication protocols used with peripherals, due to cycle time limitations. The results of tests with peripherals are obtained by Diagnostic Trouble Code (DTC) or via visual inspection by operators (example: activating reverse gear in the vehicle and checking whether the camera is active). Each DTC is classified into one of three categories:

- Black List: if these codes appear in the tests, the products or vehicles are rejected as NOK;
- White List: if these codes appear in the tests, the products or vehicles are assumed to be OK; codes are "ignored" in tests because they are outside the real usage scenario;
- "Third category": the existence of key DTCs that must be allowed, i.e., "guaranteed" that occur; indicates that certain features are OK.

After each vehicle completes testing, the product of this study moves from "production" mode to "customer" mode with the aim of shipping to dealers. The test drive of vehicles is currently carried out by sampling. This is managed by a SW program that accumulates the production parameters of all vehicles daily. To be eligible for a test drive, it selects the vehicles with the most critical performance indicators in terms of quality over time.

3. DETECTION OF PRE-FAILURE DEVICES AT EOL THROUGH LOGISTIC REGRESSION

3.1 Methodology

The first stage of the analysis was the acquisition of data, starting with the complaint data existing in the database and the investigation of the identified causes. It was decided to focus the study on the units claimed for 36 months (from 2021 to 2023, June), which were shipped to customers and later, upon complaint, confirmed by the Company as NOK (NOK). Of these units claimed, cases related to

1) process and 2) material (i.e., supplier-related defects) were selected; process cases, in turn, were grouped by the following categories: damaged components, welding problems and foreign bodies (waste or other components). Based on the sampling criteria, 107 analysable cases were identified. Note that less than half of these cases were rated by clients with a specific symptom (see Table 1).

Table 1 – List of customer symptoms associated with “0km” claims.

Customer symptoms – 0 km	Quantity
General description (does not communicate, internal error, electrical failure, no function, black screen)	34
A2B	1
USB	1
Wi-Fi	1
short microphone	1
optical connection	1

Most of the description of symptoms in clients is very generic in nature, with no understanding of the specific characteristic in failure. This can only be determined after return and analysis of the failure.

The second stage was the pre-processing of the EOL data, with data collection and identification of the variables to be analysed. The initial database of this study had 252 cases, including 95 “0km” and 157 “regular” cases selected from EOL records according to the following sampling plan:

1. for each complaint “0km”, 6 regular cases produced on the same line were identified, 3 produced immediately before and 3 immediately after.
2. then the sample of “regular” cases was reduced through random sampling selection to approximately 26%, to increase the predictability of fitting “0km” and “regular” cases into the explanatory model.

In view of the high number of variables in the EOL and the product variants (base, high, premium), it was decided to consider the variables common to all variants of the selected product that indicate the general operating state of the PCBA (temperature, current, power voltage, response time); within this category, two subgroups can also be considered: one for those variables that measure the operating values of the circuit (current, power tension, decibels, etc.). The second one belongs to the variables related to the duration of response to a functional variable or feature (which can contain several variables), which were primarily designed to support calculations of EOL cycle times. This resulted in a total of 42 quantitative variables considered eligible as explanatory variables of the “0km” cases.

The next step in the analysis was the definition of a logistic regression model and the analysis of results.

This study presents an analysis that aims to identify key factors that affect the claimed cases. Since the dependent variable represents two situations, “0km” claim (value “1”) or “Regular” (value “0”), the statistical analysis used was logistic regression. Logistic regression gives an output of 0 and 1 that can be explained as “0km” claim probability.

3.2 Results and Discussion

The logistic regression was performed using IBM® SPSS® Statistics (version 28) and eliminated 88 cases for missing values which resulted in an analysis of 164 cases: 68 "0km" and 96 "regular". The initial logistic regression analysis used the enter method, considered 35 variables, and obtained a pseudo Nagelkerke R^2 of 0.498 (Figure 3). In terms of correctly classified “0km” cases, it obtained a sensitivity value of 67.6% (i.e., correctly classified “0km” cases) and, in “regular” cases, it obtained a specificity value of 84.4% (i.e., cases “regular” correctly classified) (Figure 4).

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	146,896[a]	,370	,498

a. Estimation terminated at iteration number 9 because parameter estimates changed by less than ,001.

Figure 3 – Model Summary (SPSS output).

Classification Table[a]

Observed			Predicted: TIPO REGULAR	Predicted: TIPO 0 KM	Percentage Correct
Step 1	TIPO	REGULAR	81	15	84,4
		0 KM	22	46	67,6
	Overall Percentage				77,4

a. The cut value is ,500

Figure 4 – Classification Results.

The success rate of the developed model in this study, which is 77.4%, can be relatively good. As in this estimation it is verified that there are variables without explanatory capacity in the model (p>10%), a Stepwise Logistic Regression with “Backward: Wald” method was used to refine the explanatory model. In backward stepwise regression, the process starts with a full model that includes all predictors. Then, based on statistical tests criterion (such as the Wald test), it systematically removes one predictor at a time, evaluating the impact on the model fit. This eliminating process results in a model simpler and more interpretable. Table 2 presents the model fit results with the number of steps of the model and indices such as - 2 Log likelihood (-2LL), Cox & Snell R-square, and Nagelkerke R-square. The Omnibus test Chi-square indicates a significant performance improvement of the final model.

Table 2: Model fit indices ("Backward: Wald" method)

	N. Steps	-2LL	Cox & Snell	Nagelkerke	Chi-square	p-value
Forward:Wald	26	173.225	0.260	0.350	49.293	p<0.001

The model used 26 steps and managed to correctly classify 58.8% of the "0km" cases (i.e., 40 cases out of 68) and 87.5 % of "Regular" cases (i.e. 84 cases out of 96). The overall success rate was 75.8%, which remains relatively good (Table 3).

Table 3 – Classification Table[a].

Observed			**Predicted**		
			Regular	**0 Km**	**Percentage Correct**
Step 26	Type	Regular	84	12	87.5
Step 26		0 Km	28	40	58.8
Step 26	*Overall Percentage*				75.8

[a] The cut value is 0.500.

The results retained 10 variables with explanatory capacity (Table 4): six variables associated with response duration and four associated with measurement quantities of the product itself.

Table 4 –Logistic regression model ("Backward Wald", step 26).

Predictor	**B**	**S.E.**	**Wald**	**Df**	**Sig.**	**Exp (B)**
101010ChecknormalCurrent (X_1)	0.001	0.001	3.317	1	0.069	1.001
101101EnterDiagDuration (X_2)	1.766	0.981	3.243	1	0.072	5.847
109100TempMainboard (X_3)	0.241	0.119	4.061	1	0.044	1.272
109111TempMOSFOT (X_4)	-0.003	0.002	5.282	1	0.022	0.997
CANDuration (X_5)	-2.598	0.985	6.960	1	0.008	0.074
DiagDuration (X_6)	1.148	0.510	5.067	1	0.024	3.152
HWDuration (X_7)	0.782	0.390	4.026	1	0.045	2.186
HW_ethernetDuration (X_8)	4.430	1.604	7.632	1	0.006	83.928
ProgrammingDuration (X_9)	-0.095	0.045	4.340	1	0.037	0.910
127100CheckStandbyCurrent (X_{10})	0.014	0.006	6.204	1	0.013	1.014
Constant	-9.108	6.350	2.057	1	0.151	0.000

The B values show the correlation coefficients and the signs of the effects. But the Exp(B) analysis, or odds ratio, allows the interpretation of the magnitude of the effects in terms of the probability for the "0Km" claims. For example, the variable "HW_ethernetDuration" has a positive effect on "0km" claim, but more specifically, an increase of 1 unit in this variable (keeping the other explanatory variables constant) will increase the odds of a case to be classified in the “0Km” group by a factor of 83.928 or 8392.8%. On the other hand, if the CANDuration that presents an Exp(B)=0.074 increase 1 unit (keeping the other explanatory variables constant), the odds of being classified in the group of “0Km” reduces by a factor of 0.074 or 7.4%, and therefore increases the chance of being classed in the “regular” group.

The ‘B’ values are the logistic coefficients that can be used to create a predictive equation (similar to the b values in linear regression). In this study:

$$Prob = \frac{1}{1 + e^{-(0.001X_1+1.766X_2+0.241X_3-0.003X_4-2.598X_5+1.148X_6+0.782X_7+4.430X_8-0.095X_9+0.014X_{10}-9.108)}}$$

The equation can be useful to predict a new case. By calculating the probability of the case resulting in a future “0km”, cases identified as suspects in the EOL can be identified and reassessed. The classification made by this logistic regression model reduces type II risk, but, on the other hand, the use this classification model in addition to the classification in the EOL, there is a potential risk of 12.5% of good parts being classified as potentially defective (the model only hit 87.5% of the “regular” parts that are qualified as “regular”). Thus, in order to improve the model, it is necessary to identify in the process additional explanatory variables that can be considered.

4. CONCLUSIONS

It is evident in this study that carrying out 100% measurements for each product is not enough, since defective units still reach the customer, thus supporting the findings of Pyzdek (2003). A logistic regression model was developed that allows classifying 58.8% of defects in the EOL inspection that would only be detected at the customer. The identification of these pre-failure devices can encourage a more careful re-inspection of these parts, allowing the type II error to be reduced. This would bring additional EOL inspection costs but reduce costs associated with complaints. However, this improvement in type II error would be accompanied by an increase (12.5%) in the classification of good parts into defective parts (Type I error), which would bring internal re-evaluation costs.

Logistic regression model made it possible to retain 10 variables measured at EOL out of 149 eligible for the explanatory model. The identification of 10 variables to help clarify why the parts considered OK at the EOL of the factory, come to the customer as NOK, is a starting point for the research.

In terms of future work, additional studies are planned for each of the selected variables, as well as the identification of critical values in their operation. It is expected to use, additionally, process control methods to predict future process variability. This is a topic of further development of this work.

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Adaptation of the QRQC Methodology to a Manual Intensive Industry

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STRUCTURED ABSTRACT

Purpose - This study aimed to reduce the response time to quality issues on a manual intensive industry by adapting and implementing the Quick Response Quality Control methodology (QRQC) to the enterprise context.

Design/methodology/approach - The case described took place on the assembly line of a precision optical devices company, a manual intensive industry, to understand if this method can have the same good results in other industry fields, that may not have the same characteristics as the automotive industry.

Findings – The QRQC methodology acts as problem solving mechanism, alternative to the 8D, in the scope of managing sporadic problems. The pilot implementation occurred during a time frame of five weeks. Four problems were solved during the period undergoing the thinking process and tools provided in the methodology. The study was able to reduce the internal rejection rate in 72%, from 5% to 1.4% and the response time for solving problems from 56.7% to 100%.

Originality/value – The QRQC is a not well-known methodology with scarce literature around the topic. A limiting factor described by most studies is the lack of bibliographic material that serves as a guide for potential researchers, particularly outside the automotive sector. The work intents to enrich a field of knowledge that has potential for the development of considerable improvements in the operational and administrative procedures of organizations.

Keywords: Quality Management, Quick Response Quality Control (QRQC), Performance Indicators, Problem Solving.

Paper type: Research paper.

INTRODUCTION

The competitiveness experienced by industrial sectors has created a new context, in which, for companies to remain in business it is necessary to search for practices that allow them to improve customer satisfaction. The speed of diagnosis and effectiveness of the response are factors that determine the chances of maintaining a competitive position in the market (Teczke & Obora, 2018). In the last decades, changes occurred in the degree of complexity of products, which combined with problems originating from random causes, makes it essential to understand how these problems occur and act on them (Souza et al., 2020).

In the ever-evolving landscape of the automotive industry, a confluence of factors has intensified competition, raising the bar for excellence and innovation. This sector, known for its dynamic nature and constant technological advancements, operates within a framework defined by stringent exigence norms and quality standards. Process maturity emerges as a critical dimension, epitomizing the sector's pursuit of operational excellence through meticulous stages of manufacturing intricately connected. In the automotive industry product complexity strongly affects quality losses and researchers describe assembly complexity as one of the most complex processes (Schuh et al., 2015; Reis et al., 2024). Thus, the quality practices in this sector may be seen as a benchmark for other industry sectors.

Problem solving methodologies consist of the logical process of structured and systematic thought oriented towards solving unwanted situations, while quality improvement tools are the means to achieve this end. The main methodologies of problem solving are grouped into two categories – methodologies that aim to respond to sporadic problems and methodologies that aim to respond to chronic problems (Hamoumi et al., 2021). The differences between the methodologies relates with the logical thinking processes. The Quick Response Quality Control (QRQC) is a methodology mostly used in the context of sporadic problems, being an alternative to methods such as the PDCA cycle or Six-Sigma (Juran and De Feo, 2017). While the 8D method (Riesenberger and Sousa, 2010) has become an industry standard to manage sporadic problems, the QRQC is a not well-known methodology with scarce literature around the topic (Nedeliaková et al., 2018).

Quick Response Quality Control comes from the association of the term Quality Control – which is the control of quality – and the term Quick Response – which means a quick response (Škůrková & Prajová, 2022). It is an effective and detailed problem-solving methodology designed to prevent problems from recurring by introducing continuous improvement and changing the management approach of the organization (Aikens, 2011). The methodology was applied for the first time at the French company Valeo in 2002 (Brito et al., 2017). The organization must embrace quality as a philosophy, not as a requirement. In this way, the QRQC implementation process is facilitated, if quality is seen as a philosophy, not as a requirement, resulting in management support and employees' involvement in the implementation process (Coltro et al., 2012). The QRQC methodology is versatile because it can be applied in a wide range of processes. It is mainly used in influencing product quality, production processes, logistics, internal and external complaint handling, occupational safety and health hazards, and efficiency measurement.

The QRQC methodology promotes actions to improve and correct processes when identifying the opportunity or deviation, addressing the factors: object of improvement, problem identified, cause of the problem, action to be taken to correct it, responsible for improvement action, and deadline for completion (Gonzalez & Martins, 2015). Tools are used sequentially, in order to treat the problem at its root cause(s), avoiding recurrence. The cycle begins with problem detection, communication, and problem definition. After analysing and determining the solution, verification determines whether the chosen solution was correct and the desired result achieved (Aoudia & Testa, 2012). The methodology allows for effective time management since for each phase there is a specific deadline for carrying out the actions.

According to a study carried out in a car company, in Brazil (Coltro et al., 2012), the implementation of QRQC methodology promoted responsiveness dealing with deadlines agreed with the customer, which generated a trust-based relation. Prior to the project, response deadlines were not met. At the level of internal processes, the impact of the project was measured through the number of complaints, which saw a decrease with the implementation of the project. Previously, the company was at a point where it was impossible to manage the number of complaints received - there were improvements of around 90% in terms of reducing non-conformities and complaints. At the same time, improvements were reported in several processes, mainly regarding the level of employee awareness of the importance of complying with each stage of the process. In relation to costs, a minimum financial investment is mentioned, corresponding to the creation of the appropriate size filling form and training of the personnel involved, and non-estimated returns associated with cost reduction due to the non-reoccurrence of problems.

Considering the constant search by companies for efficient and definitive solutions to the difficulties encountered in the daily industrial environment, the QRQC methodology has become a useful instrument for the market, as it allows the solution and the elimination of "bottlenecks" while avoiding the expansion of problems that originate from their non-prevention (Rocha et al., 2012). From the study carried out by Moreira (2023), it was possible to highlight essential information for verifying the factors that lead to the incidence of this "bottleneck", making its definitive resolution possible. It was possible to demonstrate that this instrument would contribute to ensure continuous improvement in the enterprise, as it allows for a considerable reduction in costs, in addition to there being no restrictions regarding the areas or sectors in which the methodology can be applied.

A QRQC methodology implementation conducted in an automotive enterprise to address a specific problem in seats manufacturing has resulted in a reduction oof almost 50% over six months (Škůrková & Prajová, 2022). The study was based on the analysis of facts, i.e., the actual situation on the production line, demonstrating how a quality problem can be solved in a simple, easy, and fast way and that combined with the knowledge and experience of the team, the application of modern quality tools offers concrete and measurable effects and allows for solving problems. The QRQC methodology addresses an identified problem definitively, preventing recurrence. However, there are certain limitations that can influence the output of implementing a project of this type (Coltro et al., 2012):

- Application of the methodology depends directly on the human factor, so the different degree of involvement of stakeholders can make it difficult application of the methodology in full;
- There is a need for continuous monitoring, due to short response times;
- Lack of technical knowledge of quality tools.

A limiting factor described by most studies is the lack of bibliographic material that serves as a guide for potential researchers, particularly outside the automotive sector (Brito et al., 2017). The QRQC can become an effective problem-solving tool, not only in the automotive sector, but also in other industries. Thus, it seems to emerge one research gap, related with lack of bibliography and case studies explaining how to successfully apply the QRQC methodology outside the automotive sector. This paper describes a QRQC methodology implementation on a manual intensive industry, to understand if this method can have the same good results in other industry fields, that may not have the same characteristics as the automotive industry. Being a way of enriching a field of knowledge that has potential for the development of considerable improvements in the operational and administrative procedures of organizations.

RESEARCH METODOLOGHY

To address the research question "how to successfully apply the QRQC methodology in company not included in the automotive industry?" a case study methodology will be adopted. This research methodology is useful for comprehending intricate organizational difficulties (Yin, 2012). Moreover, to gain a comprehensive understanding of the motivations, issues, and ramifications associated with dashboard development, a deep knowledge of the organization is essential. Different types of case studies exist (Yin, 2012). For the current investigation, an explanatory case study was considered most suitable, as it aims to explain the underlying causes and mechanisms of particular events. The researcher should establish the unit of analysis and delineate the case study protocol (Hussey and Hussey, 1997). The unit of analysis serves to clarify the boundaries and scope of the study. In this research, the unit of analysis includes the processes from the Quality and Engineering departments. The case study protocol consists of:

1. Defining the initial state of the problem, including quantification of existing sporadic problems;
2. Describing the adaptation of the QRQC methodology to the specific context;
3. QRQC implementation; and
4. Presenting and discussing results.

CASE STUDY

Context and initial state

The case study described in this paper took place on the assembly line of a precision optical devices company. This company produces a wide range of products, being characterised by small production quantities and intensive manual labour with high level of precision. Due to the manual labour is common to have many (sporadic) product quality problems to manage at once, which delays the problems' resolution. It is usual to have different, small and specific problems to solve and with no structured methodology to guide the resolution process. The reality is that the response time defined of two weeks is not met in most situations. In this context, the QRQC methodology was chosen as the way to answer the need of meet the response time internally defined.

The stability and robustness of the assembly process was analysed, from the perspective of product quality, through the Key Performance Indicators (KPI), internal rejection and response time (to the problem) from the 52 weeks before QRQC implementation, to describe the initial (as-is) state.

The average internal rejection was 5.0%, with a peak of rejection in week 44 of 23.4%, resulting from a sporadic quality problem. This situation shows the impact that sporadic spikes of non-quality can have on KPI. If this problem had not occurred the annual internal rejection rate would be 4.1%, 0.9% lower than reality.

The repetition throughout the year of each type of defect was analysed. Table 1 summarizes the number of occurrences of each defect detected during the period. The number of occurrences represents the number of times that a defected were detected, not corresponding directly to the total number of defected parts rejected (e.g., the detection of five non-compliance parts in the same period correspond to one occurrence). The rejection rate per defect represents weight of each defect considering all defects detected, is the percentage of the total of defective products of each defect by the total defective products.

Table 1 – Defect occurrences detected in assembly section during 52 weeks before QRQC implementation.

Defect code	**Number of occurrences**	**Average number of occurrences per week**
3.1	58	1.12
99	35	0.67
1.1	32	0.62
3.2	30	0.58
3.3	27	0.52
1.2	21	0.40
2.1	17	0.33
2.2	4	0.08
4.3	1	0.02
4.4	1	0.02
total	*226*	*4,35*

The defect code with the highest number of occurrences is defect code 3.1 is related with aesthetic optical requirements. The defect code 99 is related to multiple non-quality issues during the assemble process.

The response time corresponds to internal deadlines for solving a sporadic quality problem. The typical deadline is 14 days since problem detection. Analysing the response time, the results show that 43.3% of the problem resolution processes are completed late and 92.3% of those are completed more than two weeks late. In terms of the origin of the problems, 36.67% are related with the non-quality of the suppliers. The detection of quality deviation of the supplier material on the assembly line increased during the year.

Adaption of the methodology and Implementation

The adaptation and implementation of the methodology in the particular case was structured in five stages: planning, proposal presentation (approval was required), pilot implementation, results analysis and generalization of findings.

In the planning phase, the focus was on adapting the QRQC methodology to the organization's reality. The head of the quality department considered necessary to: outline procedures that delimit the scope of action of the method; prepare the methodology support material; carry out a survey of stakeholders to participate in the project; define indicators for project evaluation.

The objective was to define a systematic way of action with a view to eliminate/mitigate quality problems, of a non-chronic nature, detected internally. In this scope, the methodology must be applied to sporadic quality problems that fall within the definition of "non-compliances that result from seemingly micro, operational-level causes" and whose detection took place in the assembly section and/or upstream and affects the assembly. Figure 1 represents the adaptation of the traditional QRQC cycle to the reality of the company under study.

The flowchart consists of 16 activities, that detail the implementation of the QRQC methodology to be adopted in the company and informs about the team/person involved in each activity. It was developed by the quality department based on company context and literature review on QRQC, during the period of four weeks.

The QRQC team is composed of three to five people depending of the problem type – optical components deviations, mechanic components deviations, purchase components deviations and assembly (process) deviations. The team members have specific knowledge and are directly involved on the topic.

The time frames defined of the QRQC cycle are shown in Table 2. Day 1 corresponds to the day when the problem is detected. Each empty cell has the maximum limit of next value (not null). Deadlines are defined as good practices, with the purpose of re-establish the normality of the production process and eliminate the occurrence of new non-conformities within the expected period of seven working days. Most of the activities end in seven days and, after 30 days, it is suggested that an audit be carried out about the product/process for the purpose of reviewing and verifying the conformity of changes.

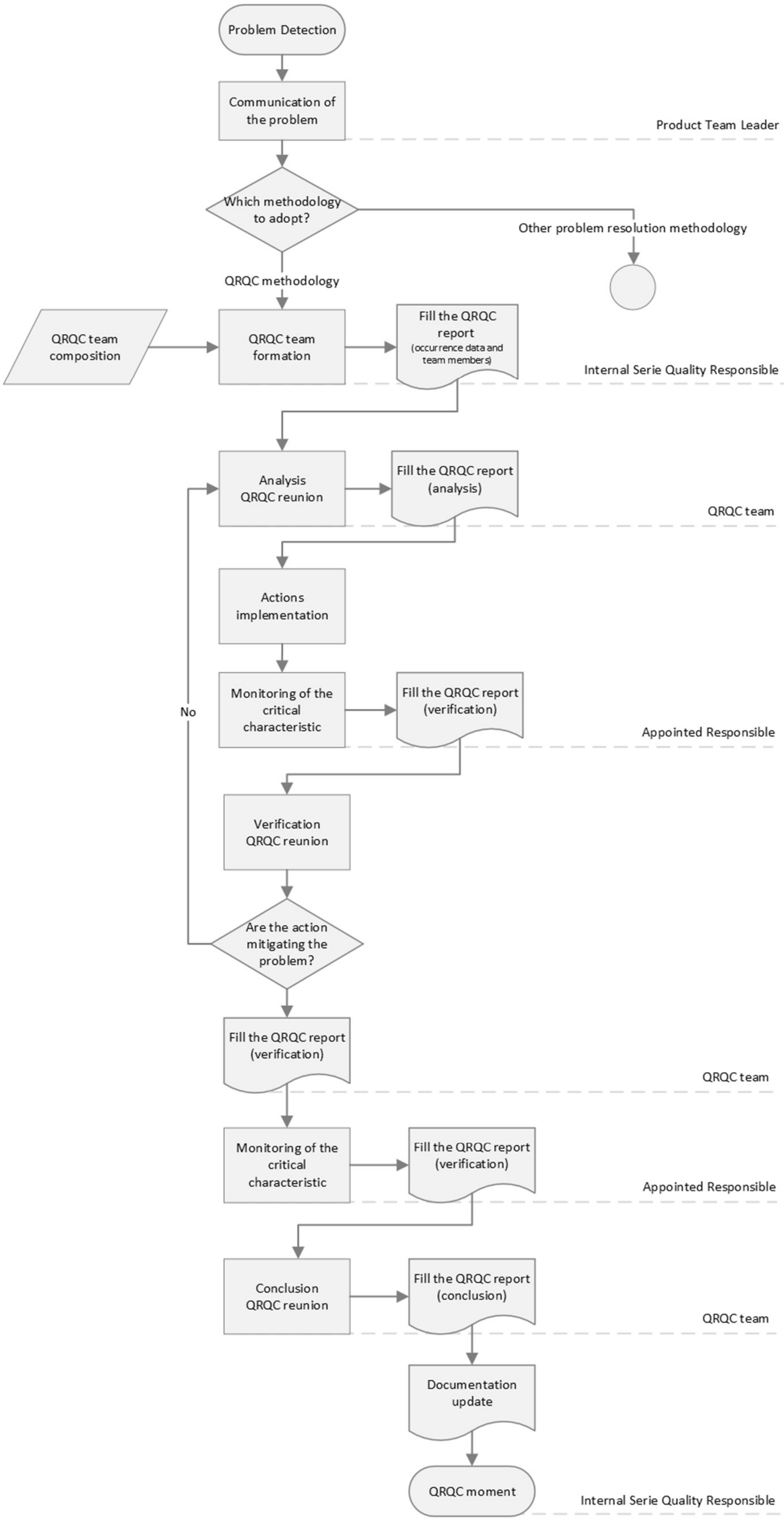

Figure 1 – Flowchart of QRQC implementation.

Table 2 – Deadlines for QRQC activities.

Stage	Activity	Time frame
Detection	Problem detection	Day 1
Communication	Problem communication	Day 1
	QRQC team formation	
Analysis	Analysis QRQC reunion	Day 1
	Actions implementation	
	Monitoring of the critical characteristic	
Verification	Verification QRQC reunion	Day 3
	Monitoring of the critical characteristic	
	Conclusion QRQC reunion	Day 7
	Documentation update	
	QRQC moment	
	Audit	Day 30

In the pilot implementation phase, the focus was on solving real problems with the QRQC methodology. This stage occurred during a time frame of five weeks with the intent to validate the usefulness of QRQC methodology in the enterprise. Four problems were solved during the period undergoing the thinking process and tools provided in the QRQC methodology.

The QRQC report obey to a pre-determined template. The tools used were mainly the 5W2H, the it Is/Is not analyses for the problem specification, the 5Why's for the analysis phase, and the bar chart for the monitoring stage.

Results

The QRQC cycles mentioned in Table 3 arose from the problem detection of operators at assembly stations. The follow-up period of each occurrence was 1 month.

Table 3 – QRQC problems solved.

Problem code	Detection date	QRQC beginning date	QRQC closing date
MD001	23/06/2023	23/06/2023	30/06/2023
MD002	27/06/2023	27/06/2023	06/07/2023
MD003	06/07/2023	06/07/2023	11/07/2023
MD004	19/07/2023	19/07/2023	27/07/2023

The average internal rejection was 1.4% during the five weeks period, which is a drop from the initial state (with a one-year average of 5.0%). This reduction suggests a positive result from the implementation of the QRQC methodology, particularly the training provided with focus on quality issues.

The repetition of each defect throughout the weeks was analysed. None of the problems addressed through QRQC repeated in the period 23/06/2023 – 27/07/2023. Other causes of defects are summarised in Table 4.

Table 4 – Defects detected in assembly section during five weeks.

Defect code	**Number of occurrences**	**Average number of occurrences per week**
3.2	3	0.6
99	3	0.6
1.1	2	0.4
2.1	1	0.2
2.2	1	0.2
total	*10*	*2*

The defects codes with the highest impact (defect codes 3.2 and 99) during this period are related with movements/re-adjustments and non-quality during the assemble process. Three out of the four QRQC cycles completed were related with movements/re-adjustments problems the period, the other cycle relates with a problem during assembly.

The problems were the QRQC cycle was applied were sporadic non-compliance. The response time of seven days since problem detection was meet in the four cycles, with none of the processes being completed late.

Discussion of results

In the final state an assessment survey was carried out, aiming to understand the perspective of the team involved on the work carried out. The QRQC team was composed by the product team leader, quality engineer, process engineer and assembly responsible. In terms of benefits, the four respondents highlighted:

- Greater team cooperation;
- Greater commitment and efficiency in solving problems;
- Reduction of in-line defects.

The main limitations were:

- Lack of familiarity with the methodology;
- Lack of discipline;
- "Blindness" of "Blindness" of the 5WHYS tool as an analysis instrument.

Regarding responsiveness, it was highlighted that "there is a lack of practice with methodology to notice improvements in response capacity" and that "the team is just starting out but is heading in a good direction." Although the opinions are positive, it was clear that a longer test would be necessary for opinions to be consolidated. In terms of compliance with established deadlines, all three reunions took place within the deadlines defined.

Communication was an aspect in which improvements were felt. However, the big improvement was not in verbal communication, but in the report of information. One of the members highlighted that although communication was good between internal team members, it had improved with external team members (other departments interactions).

In terms of improvements, the need to review some response timings was mentioned, since the internal responses are generally longer than those predicted by the methodology, and there is a need of a greater involvement of internal suppliers in the resolution process.

The duration of the activities of the QRQC methodology was rated as adequate by everyone involved. However, about the time interval between meetings and the 7-day deadline, there was no consensus. The gaps can be short due to lack of priority of the topic, due to "some problems require more time to implement actions". About the period of seven days to complete a QRQC cycle, the dissenting comments state that the period may be short due to the typology of problems that the methodology seeks to solve.

Regarding the tools selected to operationalize the rapid response, the stakeholders agree to be sufficient to guide the resolution, being a good practice for the entire team to have the same view on the problem. Verification is the QRQC step flagged as the most difficult to implement. The following-up of the actions did not occur as expected. Because the problem was seen as resolved by the team members, the report of the Ok/NOk quantities during the verification phase were not always updated in the due time.

The number of occurrences was 10 during the implementation. Out of the 10 occurrences in five weeks, three were related to chronic issues, outside the scope of this methodology, and seven problems were sporadic. For four out of the seven problems the QRQC methodology was applied.

The scale of the results was bigger in the automotive industry case studies. However, the outcome of the study is provided by only one enterprise context. The study was able to reduce the internal rejection rate in 72%, from 5% to 1.4%. Also, the number of occurrences per week declined from averaging 4 to 2 per week, indicating a lower number of sporadic problems.

The response time was the indicator where the QRQC methodology had the biggest impact, going from being meet in 56.7%, less than 3 out of 5 problems, to 100% in the cases where the QRQC methodology was implemented.

The study made possible to signal relevant advantages of the QRQC methodology:

- Reduced implementation cost;
- Levelling and mainstreaming knowledge about quality tools;
- Easy application.

The industry characteristics can heavily influence the potential gains of the usage of a methodology like QRQC. In mass production contexts the gains are reflected sooner and with more expression in the KPI's. The company where this study was carried is known for their mass customization, producing a wide range of products in small production quantities. In this context the QRQC methodology is required to answer the need of meet the response, what was accomplished.

The intensive manual labour is also a point that reflects the lower gains compared with automotive industries, where there are higher levels of automatization.

CONCLUSIONS

The QRQC methodology constitutes an innovation in the field of quality control, to solve sporadic production problems. However, implementing something new within an already consolidated structure is not an easy task. Initially, difficulties are expected in accepting the QRQC methodology, associated with resistance to change and the need for training on quality tools arising from the possible lack of people's knowledge of them. To address this, the company must have Quality as a philosophy, not as a requirement, in this way, the process of implementing any tool becomes easier, because with the support of management, employees feel more involved in the implementation process.

The four phases of the QRQC cycle described in literature were detailed into 16 activities, including team involved, and deadlines. This was to facilitate the training of the people involved and standardize its application. The deadlines were defined to facilitate monitoring of the respective application.

The QRQC methodology addresses the quality problem definitively, preventing recurrence. It was applied four times, during a period of five weeks, and the problems were solved within the deadlines defined, something that was not happening before the QRQC application where about half of the problems were not resolved within the defined deadlines.

There are certain limitations that may influence the effectiveness of implementing a project of this type. The outcome of the study is provided by only one enterprise context. Focusing on a specific case to create generalizations limits the robustness of the conclusions reached and creates internal validation challenges. The application of the QRQC methodology depends directly on the human factor and not all people have the same degree of involvement. The dependence on culture compatibility organization of the company means that the methodology may not be successful in many contexts.

This study is a contribution for the understanding of the QRQC, highlighting the "how to" implement the methodology in a manual intensive industry and comparing the scale of results achieved with the results shown in the automotive industry.

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Novel applications of silver-nanoparticles in food contact material: A systematic review

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STRUCTURED ABSTRACT

Purpose - The purpose of this study is to outline the gap of knowledge in the current legislation and regulations regarding the use of silver nanoparticles (AgNPs) in novel applications and to present the risks in those gaps for further consideration.

Design/methodology/approach - A systematic literature review, using exclusive keywords, specific inclusion and exclusion criteria and quality assurance was used to consolidate information from accredited databases and present relevant regulatory context applicable to the application of AgNPs.

Findings - The results of this study indicated that there are no specific legislation and regulations regulating AgNPs in the food industry. Hence, there is a gap in governance and there is ambiguity regarding their risk. This is causing a quandary for the regulators and manufacturers when trying use these particles in applications.

Practical implications – Although this technology is very useful to solve real-world concerns, this uncertainty in practice for researchers, developers and manufacturers prevent nanotechnology from recaching its full potential.

Social Implications – The inconsistency among experts causes misperceptions among potential customers or consumers on the safety of products containing AgNPs.

Originality/value - This study provides valued insights concerning the potential of using AgNPs in packaging material. It will also provide mitigation around the risks associated with AgNPs, with a view of protecting consumers from any potential toxic effects identified. Moreover, the study evaluates the gaps of knowledge in the current legislation and regulation and the danger of those gaps being overlooked for future applications. The adoption of a systematic review is a suitable data collection tool as it allows this paper the rigour to gather information and views of among peers.

Keywords: Silver Nanoparticles, Regulation, Precautionary Principal, Legislation

Paper type: Literature review

INTRODUCTION

Silver nanoparticles (AgNPs) have attracted great attention and gained importance and popularity in recent years due to their antimicrobial activities and other features such as heat resistance, high stability, non-linear optical behaviour, surface-enhanced Raman scattering, magnetic and high electrical and thermal conductivity (Abdelaziz *et al.* 2022 and Zhang *et al.* 2022). In light of their tremendous antibacterial properties, AgNPs have been extensively used in the packaging of multiple food products such as fresh produce, meat and meat products, milk and milk products and others (Skalska et al. 2020). Thus, to date, AgNPs are incorporated with polymers to improve fresh produce's quality and product shelf life. Additional research has been conducted on the antimicrobial properties of AgNPs particularly to find cost-effective and advanced technical methods of synthesising these particles in mass production.

For the past decade, AgNPs have been widely used in the preservation of fresh produce (Nasrin *et al.* 2022, Adeyeye and Ahmad *et al.* 2021). Fresh produce is highly perishable, most of them are consumed fresh. This has increased the application of AgNPs in fresh produce over the past decades to safeguard the produce from degradation because of microbial effects. There appears to be similar thoughts between Bhatnagar *et al.* (2022) and Nasrin *et al.* (2022) on changing customer demands for safe and healthy food. They have probed the researchers specialising in the field of food manufacturing and agriculture to develop and adopt novel approaches for upholding product safety, quality organoleptic and acceptance together with maintaining nutritional content. The study by Bianchi, Souza and Santos (2023) reported that fresh produce is the greatest utilised commodity and they are frequently consumed raw. Bhatnagar *et al.* (2022) mentioned that fresh produce is a great source of numerous nutrients such as vitamins, minerals, phenolic compounds, and dietary fibers, which keeps the body healthy, boosting the immune system and controlling diseases. With the growth in the supply chain, fruit and vegetables can now be exported globally. Therefore, fresh produce is classified as perishable food and requires more novel preservative measures to maintain its quality throughout the vast supply chain. To ensure fresh produce throughout the supply chain, there is a growing demand for polymer films to be incorporated with AgNPs to serve multiple functions such as antimicrobial activities and antioxidants to prolong the shelf life of fresh produce. Therefore, it can be deduced that active packaging material (polymer plus AgNPs) enhances the functions of polymers.

Despite the revolution in technology and innovation, AgNPs can result in the risks associated with the migration of silver nanoparticles from food packaging to food products. This has raised safety concerns among the public, scientists and government agents (Abdelaziz *et al.* 2023 and Liu *et al.* 2022). Laloux *et al.* (2019) agreed that AgNPs were detected in multiple food products compared to other nanoparticles. Janzadeh *et al.* (2022), estimated that approximately 30% of nano-enabled products contain AgNPs. Yet, there is a predicament regarding the safe dose and regulatory aspects regulating the application of AgNPs in the food industry (Adeyeye and Ashaulu 2021, Ahmad et al. 2021 and Ahari and Lahijani 2021). According to Andreoli *et al*. (2021), there are inconsistent findings regarding the potential toxicity of indirectly ingesting AgNPs. Of concern, Adeyeye and Ashaulu (2021) are of the notion that the migration limits of AgNPs from food contact material are not robustly regulated. Thus, this creates a gap of knowledge around the safe use of these particles. It has also raised the question of what is a safe dose for human health if AgNPs is consumed or if one is exposed to it? What are the potential risks associated with the migration of silver nanoparticles from food packaging to food products? What is the current legislation and regulations regarding the application of AgNPs in food contact materials? and what are the possible risks in the gaps of knowledge in these regulations?

Consequently, this study intends to explore the efficacy of silver nanoparticles in enabled food contact materials. This study aims to establish the following objectives with data obtained via a systematic literature review. Firstly, this study assesses the potential risk that emerges from the consumption and exposure to AgNPs that may have migrated from food contact material. Secondly, it evaluates the gaps of knowledge in the current legislation and regulations and presents the risks in those gaps for further consideration. Moreover, it endeavours to explore suitable mitigation strategies for the gaps identified. A systematic review, using exclusive keywords, inclusion and exclusion criteria and quality assurance is used to consolidate information from accredited databases and presents relevant regulatory context applicable to the application of AgNPs.

LITERATURE REVIEW - THE PRESERVATION ABILITIES OF AgNPs

In recent years, extensive research has been conducted to evaluate the effectiveness of incorporating AgNPs in food contact polymeres to improve the shelf-life of fresh produce. For instance, Motlagh *et al.* (2020) performed a study to determine the effectiveness of low-density polyethylene (LDPE) reinforced with NPs in strawberries, using two different concentrations of 0.5% and 1% of AgNPs. Three samples were prepared, Sample 1 (LDPE only), Sample 2 (LDPE and 0.5%) and Sample 3 (LDPE and 1%). The results indicated that the growth of mould and total bacteria count in sample 3 decreased, followed by Sample 2 and then Sample 1. AgNPs in Samples 2 and 3, maintained the quality and extended the shelf-life of strawberries from 10 to 15 days respectively from 5 days without the AgNPs. The organoleptic attributes (apparent colour, texture, taste, odour, and total acceptance) of Sample 1 deteriorated. However, with the increasing storage time of strawberries in Samples 1, 2 and 3, a decrease in organoleptic properties was observed. Likewise, Saravanakumar *et al.* (2020) presented a study that evaluated the effectiveness of 72 and 98 mgmL^{-1} of AgNPs if embedded in polyvinylpyrrolidone against Bacillus cereus and E. coli. The result showed that AgNPs did not only prevent the development of *B. cereus* and *E. coli* in stored pepper chili for 15 days at 15 ◦C, but they also inhibited the growth of grey mould. According to Glodjinon *et al.* (2020), pepper chilies are highly susceptible to grey mould growth due to inadequate agricultural practices and improper postharvest storage conditions. Furthermore, grey mould is highly hazardous as it produces mycotoxins. In this context, the incorporation of AgNPs in polymers has been proposed to be useful for packaging and controlling post-harvest metabolism, microbial growth, and spoilage. Therefore, it can be inferred that the modification of polymers with AgNPs has been beneficial and is efficacious in this field.

Overview of Migration of AgNPs and its Challenges

The AgNP-containing polymers are widely used due to their fascinating advantages of antimicrobial effects to extend food product shelf-life. Despite the novel application of AgNPs as an antimicrobial agent in food packaging, its rapid production has raised concerns by the public and academics regarding the adverse impact of the release of AgNPs from polymer to food products (Ahmad et al. 2021, Kumar *et al.* 2021 and Trbojevich *et al.* 2020). Numerous studies [Babu, Tirkey and Rao (2021), Zhu *et al.* (2020) and Azeredo *et al.* (2019)] have reported that the migration of AgNPs to various food products has been observed. The European Food Safety Authority (2021) presented compelling evidence indicating that if a small amount (0.025% w/w or 250 mg silver/kg) of AgNPs is infused in a non-polar polymer (polymer that does not swell), the NPs of Ag does not migrate to foodstuff. It resists the discharge of AgNPs via abrasion hence, the possible health risks were neglected. On the other hand, the EFSA Panel observed that Ag can be solubilised and leached out in ionic form, thus, the risks of exposure to Ag ions must be evaluated.

According to Ahmad *et al.* (2021), the accumulation of AgNPs were found in various organs of the human body, which include the brain, liver, testicles and kidneys. Numerous in-vitro studies have revealed that the consumption of AgNPs even in small traces can induce genotoxicity and cytotoxicity in mammalian cells located in any part of their body, including reproductive organs, brain, vascular system, skin, liver, and lungs (Ahmad *et al.* 2021, Kumar *et al.* 2021 and Morais *et al.* 2020). Evidently, numerous animal studies have demonstrated that Ag ions can penetrate through human skin or mucosal barriers, move around through blood circulation and build up in internal organs and tissues, resulting in damaged liver cells, immune cells, and nerve cells of the organism (Ahmad *et al.* 2021 and Trbojevich *et al.* 2020). Other scholars Babu, Tirkey and Rao (2021), Lui *et al.* (2021) and Morais *et al.* (2020) demonstrated that Ag ion do not only induce the production of cellular oxidative stress in the cells of microorganisms but also does the same in mammalian cells, including human cells. On the contrary, Zhu *et al*. (2020) offered a different perspective, indicating that the consumption of AgNPs only in excessive quantitative amounts can cause health risks to consumers. In Agreement, Perez *et al*. (2021) reported that there were no significant health effects associated with the consumption of AgNPs that were detected in animal studies. However, the toxicity of AgNPs was found to be dose dependent. Therefore, it can be presumed that the use of AgNPs as an antimicrobial agent in the polymer matrix is a hidden hazard in the food packaging industry. Moreover, it can be deduced from literature that there are conflicting views among scholars of whether it is AgNPs or Ag ions that migrate from food contact polymers that result in health risks to the consumers.

RESEARCH METHODOLOGY

An intensive electronic search was conducted utilising various credible databases like PUBMED, Wiley Online Library, Taylor and Francis Online, Scopus, Wed of Science and Google Scholar. A meta-analysis (PRISMA) was employed for an adequate data screening process. Various phrases were used for the search such as “regulating application AgNPs polymer” or “regulation Silver nanoparticles food contact materials”. The inclusion criteria for selection of articles were English language, peer-reviewed journals or peer- reviewed conference proceedings published from 2018 to 2024. The raw data was extracted from its source to Endnote.

Table 1 outlines the databases used to select articles and the number of articles used before and after evaluation.

Table 1: Databases used and the number of articles identified to meet the criteria after evaluation

Database	Number of articles identified in the initial search	Number of articles identified to meet the criteria after evaluation

PUBMED	16	8
Science Direct	20	10
Scopus	23	11
Springlink	6	5
Taylor and Fancis Group	8	6
Wiley online library	26	16
Google Scholar	8	7
Total	107	63

Figure 1 presents the steps undertaken to screen and select appropriate articles.

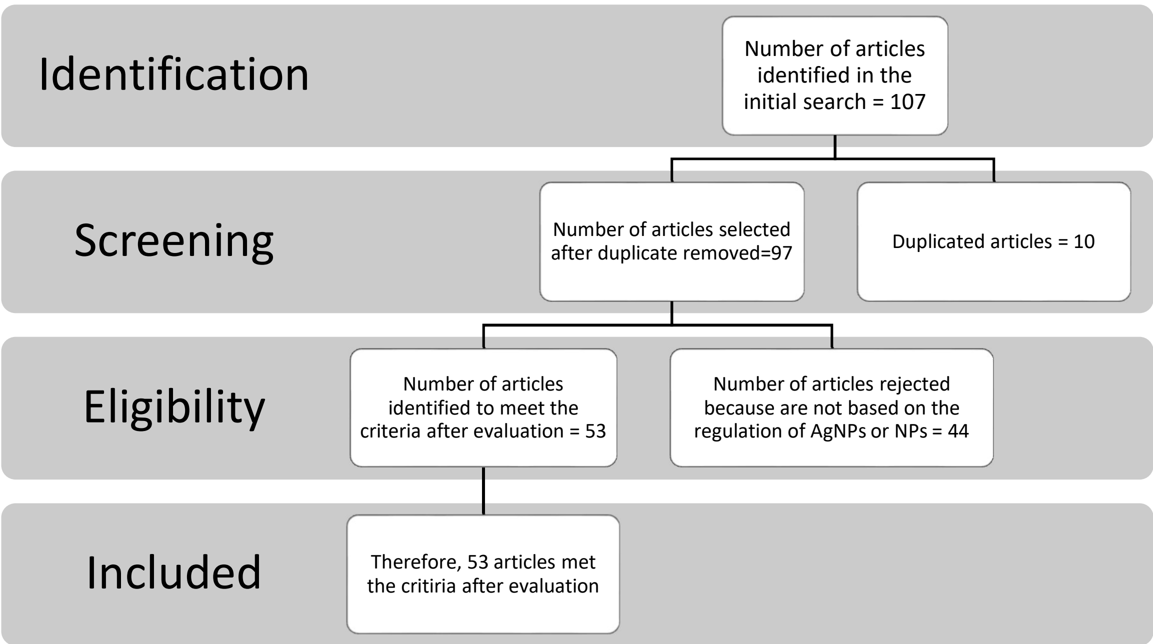

Figure 1: Shows the different phases of Meta-Analyses (PRISMA)

The first phase included the screening of titles and abstracts. The 10 articles were rejected because they were duplicated articles. The second screening included reviewing full studies, after reviewing data a total of 53 articles were found to meet the criteria of the research and were selected.

RESULTS AND DISCUSSION: REGULATORY ASPECTS

The findings of this study indicated that there was an abundant use and increased production of AgNP-containing polymers in the food packaging sector. It also indicated that the migration of AgNPs to food products remains a primary health concern. Researchers advocate that a stringent regulatory framework is required (Yeap, Rajendra and Wahab 2022 and Istiqola and Syafiuddin 2020). According to Thirupathi Vasuki *et al.* (2023), a polymer infused with AgNPs must comply with the specific regulatory requirements developed by the authorities of the country of manufacture. According to Istiqola and Syafiuddin (2020) and Lotfi, Ahari and Sahraeyan (2018), there is insufficient knowledge of the migration of AgNPs to food components thus, there is a debate on the authorised or acceptable migration dosage and threshold. Various regulatory bodies have implemented programs, regulations, and guidelines to protect the public from the application of nanotechnology, while others are still in the foundation phase. Their initiatives are further discussed below.

In the European Union

The European Commission is an independent arm of the European Union (EU) which is responsible for proposing new legislation once approved by the European Parliament. Additionally, the European Food Safety Authority is the EU-funded agency that provides the EU with independent scientific advice regarding the risks and emerging risks associated with food. They also conduct research and provide guidelines on the application of nanotechnology (EFSA 2022). Azeredo *et al.* (2019) are of the view that even though there is still a gap in knowledge regarding the migration of AgNPs from polymer film to food and there is insufficient risk assessment evaluating the possible health effects after consuming AgNPs. In response to this, the EU has laid the foundation to regulate nano-based food contact polymers. In agreement, Basavegowda, Mandal and Baek (2020) are of the view that only the European Commission associate states including France, Switzerland, Sweden, Belgium, Denmark have developed more legislation and regulations for some nanoparticles or nano-enabled products.

As far as regulation is concerned, the EU devised various pieces of regulations controlling the development and manufacturing of nano-enabled products ever since 2003, starting with EC 1935/2004, EU 450/2009, 10/2011 and 1169/2011(Reddy and Singh 2022). Notable, Adeyeye and Ashaolu (2020) reported that the EC 1935 of 2004 ensures that any nano- substance used as part of food packaging must be free from hazards. According to Fu and Dudley (2021) the EU number 450 was published in 2009, which regulates the application of active and intelligent packaging. This regulation requires the use of antimicrobial agents in active packaging to comply with migration limits. In addition, antimicrobial agents embedded in the food contact polymer or articles must be subjected to migration analysis as per the EU No 10/2011 (De Oliveira Mallia *et al*. 2022 and Mackevica, Olsson and Hansen 2016). Furthermore, EU number 10 (2011), stipulates that a migration test must be conducted using either, food simulant or food packaged with nano-enabled packaging under specified conditions (temperature and duration). Moreover, the European Commission (2011) emphasised that spectroscopy and chromatography are specific analytical techniques that must be used to determine the migration of chemical substances from polymer to food substances. In agreement, Barciela *et al.* (2023), EU number 10 (2011) and EEC 89109 (1988) cited that the EU regulation number 10 of 2011 stated that the risk assessment must be conducted on nanoparticles (including AgNPs) as they may show toxicological properties that are not present in similar substance in bulk or conventional size. Thus, specific risk assessment is required, and those nanoparticles must only be used after authorisation (Adeyeye and Ashaolu 2020).

According to Babu, Tirkey and Rao (2021) the EFSA has developed guidelines for conducting risk assessments of NMs directly used in contact with food in the food industry. Secondly, the EFSA emphasised the necessity of characterising physicochemical properties of the original NM after it was embedded in packaging materials or food products. Thirdly, the EFSA guidelines, state that the application of AgNPs in the food industry either as a food supplement or as a component of packaging materials must be authorised by the European Union. Furthermore, Andreoli *et al.* (2021) and Carbone *et al.* (2016) reported that the EFSA published an article outlining a set of analyses that must be conducted on the NP before the nano-enabled product being commercialised, including in vitro-genotoxicity, enzyme-modified comet essay, metabolism, distribution, and excretion tests. Lastly, the EFSA published a scientific opinion directing both public and private organisations on genotoxicity testing strategies suitable for NPs analysis (Aris and Syafiuddin 2020).

According to the EU regulation number 1935 of 2004, before the commercialisation of a new chemical substance or before it is added to the EU positive list, the substance must be submitted to the EFSA for authorisation and it must go hand-in-hand with its relevant information (for example: chemical identity, physicochemical characteristic of the NPs before and after it is embedded in the polymer, intended use and authorisation, the manufacturing process of the substance and polymer, potential migration and residual content of the substance)(EC No 1935/2004). The EFSA is required to conduct a risk assessment and provide independent scientific opinion. For instance, the EFSA published a study based on the safety assessment of AgNPs incorporating polymer after the authorisation request. The risk assessment method was in line with the OECD (2001) guidelines used

0.025% w/w of AgNPs embedded on the nonpolar polymer (LDPE) for 24 h at 40°C. The results indicated that no migration of AgNPs was observed, hence the applicant was granted the authorisation to use this nanoparticle in food contact polymer provided that the non-polar polymer is used and the concentration of AgNPs does not exceed 0.025%w/w. Although the release of Ag ions was observed and a toxicology study was performed (the toxicological result demonstrated a toxic effect from excessive amounts), the panel concluded that the risks were negligible (EFSA 2021). From the existing literature, it can be deduced that this regulation or scientific opinion published by the EFSA causes ambiguity for developers to understand the behaviour and safety migration limits. The scientific opinion published was based on the authorisation of AgNPs infused in direct food contact polymer, yet it provided safety limits for the migration of Ag^+ and does not stipulate if Ag^+ are in nano-form or bulk-form. This also raises confusion on whether these ions agglomerate after release from the polymer. However, the study of Choi *et al*. (2018) long-established that once the Ag ions leave the polymer, they agglomerate on the surface of a food product. Despite this, more rigour and conclusive data is required to provide a better understanding of the form of Ag ions after they have leached out of the polymer.

Table 1- Author's perspective on the regulation of AgNPs infused with polymers.

References	**Ag NP or Ag^+**	**Scholar's perspectives**	**Authorised by**
Paosen et al. 2021	AgNPs	≤ 0.05mg/kg in food and 0.05 mg/L in water	EFSA
Costa Brito et al. 2024	AgNPs	≤ 0.05 mg/kg	EU
Kumar et al. 2021	Ag^+	≤ migration limit of 0.05mg/kg	EFSA
Braun et al. 2021	Ag^+	migration limit of 0.05 mg Ag per kg food	EFSA
Ahmad et al. 2021	Ag^+	≤ migration limit of 0.05mg/kg	EFSA
Aris and Syafiuddin 2020	Ag^+	≤ migration limit of 0.05mg/kg	EFSA

Scarpelli et al. 2020	Ag^+	≤ migration limit of 0.05mg/kg	EFSA
Carbone et al. 2016	Ag^+	≤ migration limit of 0.05mg/kg	EFSA
Mackevica et al. 2016	Ag^+	≤ migration limit of 0.05mg/kg	EFSA
Becaro et al. 2021	Ag^+	≤ migration limit of 0.05mg/kg	EFSA
Enescu et al. 2019	AgMPs	≤ 0.05 mg/kg food or food stimulant	EFSA
Simbine et al. 2019	AgNPs	≤ 10mg/Kg	Article 14, EC 450/2009.
Azlin-Hasim et al 2016	AgNPs	≤10mg/Kg	Article 14, EC 450/2009.
Rezvani et al. 2019	AgNPs	allowed dosage exposure or migration limits of AgNPs in foodstuff is less than 25m/Kg and 20m/g surface area	Article 14, EC 450/2009.
Krasniewska et al. 2020	unauthorised NPs to be used indirect contact with food	≤ 0.01 mg/L or 0.01 mg/kg	Article 14, EC 450/2009.
Adeyeye and Ashaolu, 2020	unauthorised NPs to be used indirect contact with food	≤ 0.01 mg/L or 0.01 mg/kg	Article 14, EC 450/2009.
Vishnuvarthanan and Rajeswari 2019	unauthorised NPs to be used indirect contact with food	≤ 0.01 mg/L or 0.01 mg/kg	Article 14, EC 450/2009.

EC number 450 (2009)	unauthorised NPs to be used indirect contact with food	≤ 0.01 mg/L or 0.01 mg/kg	Article 14, EC 450/2009.
Yeap, Rajendra and Wahab 2022	AgNPs	Not permitted	Ag in nano form is not permitted in the EU
Fu and Dudley 2021	AgNPs	Not permitted	EU
Azeredo et al. 2019	AgNPs	Not permitted	EU
Ricardo at al. 2021	AgNPs	Banned	EU

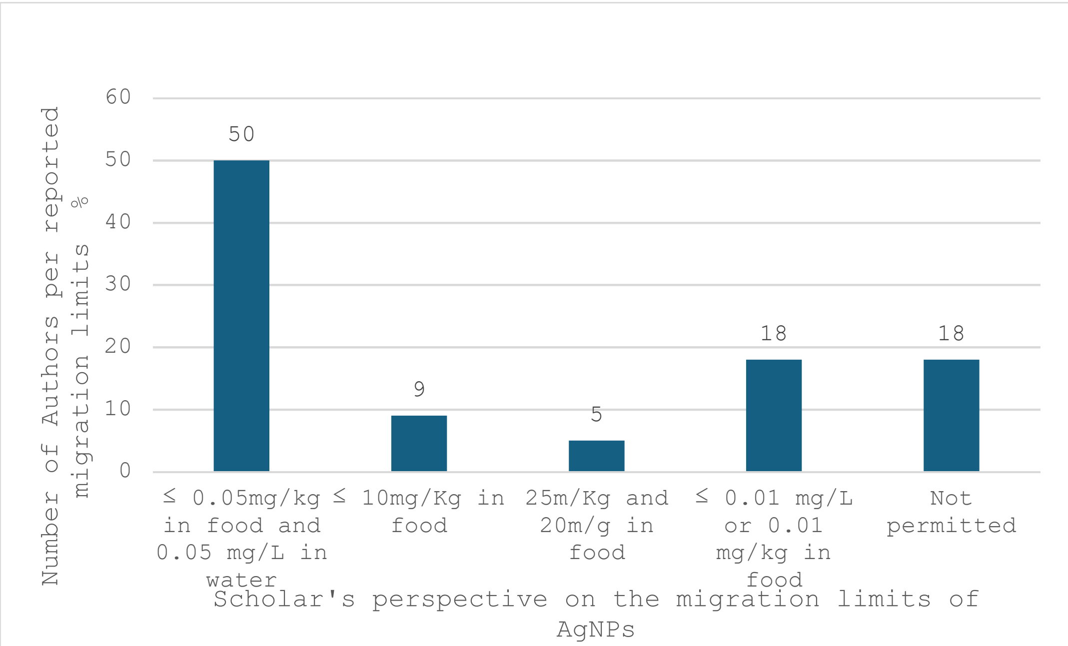

Figure 2: Scholars perspectives with regards to the migration limits

Figure 2 shows varying perspectives of authors about the possible migration limits of Ag NPs or ions. The results indicate that 50% of the authors agree that the migration limit of is authorised for silver ions, 18% of authors state that the migration limits of 0.01 mg/L or 0.01in food is acceptable, 18% of authors state that AgNPs in food products and food packaging is not permitted or banned and 5% of the authors are of a perspective the migration limits of AgNPs in foodstuff should be less than 25m/Kg and 20m/g in foodstuff.

Significantly, another school of thought mentioned by Paosen *et al.* (2021) states that the maximum allowance for AgNPs migration limits is 0.05mg/Kg in food and 0.05 mg/L in water and these limits were set by the EFSA. There is a wide agreement among 50% scholars [Kumar *et al.* 2021, Ahmad *et al.* (2021), Aris and Syafiuddin (2020), Scarpelli *et al.* (2020), Carbone *et al.* (2016), Becaro, Puti, Panosso, Gern, Brandao Correa and Ferreira (2021) and Mackevica, Olsson and Hansen (2016)] that the migration limit of 0.05mg/Kg is authorised for silver ions, not AgNPs. On the other hand, Simbine *et al.* (2019) and Azlin-Hasim *et al.* (2016) believe that the limit for AgNPs is 10mg/Kg. Another point of view indicated that the dosage exposure allowed or migration limits of AgNPs in foodstuff is less than 25m/Kg and 20m/g surface area, is the safety dose (Rezvani *et al.* 2019). An alternative perspective was presented by Krasniewska Galus and Gniewosz (2020), Adeyeye and Ashaolu, (2020), Vishnuvarthanan and Rajeswari (2019) and EC number 450 (2009) stating that unauthorised NP have been used indirect contact with the food product 0.01 mg/L or 0.01 mg/kg is the migration limit allowed by Article 14, EC 450/2009. Conversely, Ag in nanoform is not permitted in the EU due to their perceived toxicity and unknown long-term effects after the consumption or use of AgNPs (Yeap, Rajendra and Wahab 2022, Fu and Dudley 2021 and Azeredo *et al.* 2019). According to Ricardo *et al.* (2021), the incorporation of AgNPs in food-contact polymers is banned in the EU, with the exclusions of specific Ag rubber and zeolite seals. Therefore, it can be inferred that migration limits and safety thresholds for AgNPs are still not established by the EU or are still debatable. Furthermore, it was drawn from the plethora of literature that there is great confusion among scholars regarding the safety threshold and acceptable migration limits due to the lack of specific and detailed migration limits prescribed by the government regulator. Therefore, a conclusive regulation for monitoring the use of AgNPs in polymer is required.

With all being said, the scientific opinion published by the EFSA (2021) concluded that AgNPs remains entrenched in the polymer and resists migration via an abrasion hence, there is no migration of AgNPs or toxicity associated with it. However, Ag ions are released from the polymer and the maximum migration limit must not exceed 6 μg/Kg food. It was reported that at this level silver ions does not pose a toxicity effect to either animal or human beings in this amount.

United States of America

In the United States, three regulatory agencies regulate the application of nanotechnology, these are; the United States Food and Drug Administration (US FDA or FDA), agency of the Institute National Occupational Safety and Health (NIOSH) and the Environmental Protection Agency (EPA) (Pena, Cueva, Bartolome 2020 and Moreno-Arribas 2020). However, the US FDA and EPA have more prudential regulations on nanoparticles in food. According to Adeyeye and Ashaolu (2020), the FDA regulates the application of nanotechnology in the United States (US), as well as the pre-approval of nanomaterials. For instance, the organisations that produce nanomaterials are responsible for seeking pre-approval of the newly developed NMs via Food Contact Notification (FCN) or Food Additive Petition (FAP) system. Nevertheless, NMs that are under Generally Recognized as Safe (GRAS) list are not expected to be submitted for premarket authorisation. Of concern, the organisations can market their nano-enabled food products given that they have published an explicit risk assessment of a product in an accredited peer-reviewed scientific journal.

Similar to the EFSA, the US FDA (2014) published guidelines for food packaging materials to evaluate the toxicity of infused nanoparticles (Aris and Syafiuddin 2020 and Carbone *et al.* 2016). Furthermore, the US FDA suggests that organisations must examine the toxicological profile of nanomaterials employing a case-by-case approach (Paosen *et al.* 2021 and Carbone *et al.* 2016). As argued by Fu and Dudley (2021), there are no specific migration tests established by the US FDA for antimicrobial agents in the food polymer film except a general guideline for migration tests applicable to all food contact material. A different point of view was presented by Paidari *et al.* (2021) that even though the US FDA has provided manufacturers with guidance on the evaluation of nanomaterials, they discourage the use of nanomaterials or the application of nanotechnology as it might harm human health and environmental effects.

A study by Ahmad *et al.* (2021) found that the USEPA permits the use of silver in bulk form if its migration limit does not exceed 0.10mg/Kg in food or f 0.10 mg/L in drinking water. Additionally, the EFSA (2021) clarifies that AgNPs dissolve from the packaging, migrates as Ag ions to the surface of the product and coagulates to form silver microparticles (AgMPs). Hence, regulating Ag micro particles (MPs) is applicable for this scenario. However, Aris and Syafiuddin (2020) and Carbone *et al.* (2016), are of the perspective that USEPA has forbidden the use of AgNPs in packaging material in the USA because it is not evaluated by the USFDA using their standards. Although AgNPs presents fascinating antimicrobial effects in food packaging, the limitations remain relating to its migration to food products and its potential to cause health risks (Ahmad *et al.* 2021). In light of the regulatory aspects of AgNPs, Zorraquín-Peña *et al.* (2020) reported that the food-addictive silver in the nano form does not appear on the GRAS list. In this regard, it can be inferred that all scholars agree that the US regulatory authority does not approve the use of AgNPs for direct use in food or incorporated in food contact material. In this case, perhaps, the Precautionary Principal consideration can be considered to control the use of AgNPs in the market. OECD (2023) and EU (2016) described the precautionary approach as a broad of legal, philosophical, and epistemological approach taking preventative measures where there is a lack of scientific certainty.

Chavez-Hernandez (2024) is of a different notion that the USA regulatory approach is different when compared with the EU regulatory approach. For instance, it adopts a soft or voluntary approach. In this case, the primary focus is to ensure that nano-enabled products are free of any toxic effects, eliminates the risks associated with exposure of employees during handling through occupational safety and health and control environmental exposure. Furthermore, the regulation of nanomaterials in the USA represents an alternating approach compared to the traditional politics and food laws. Hence, this regulator adopted a case-by-case approach because of the ambiguity and unpredictability of nanoparticles, while, the commercialisation of nanoparticles and their by-products are still associated with negative effects on humans and environments (Reddy and Singh 2022, Paosen *et al*. 2021 and Carbone *et al.* 2016). Therefore, the FDA drives a critical and feasible alternative regulation for the relevant industries to adopt and comply, while demonstrating the degree of responsibility and compromise in the application of nanoparticles in packaging. Significantly, the US FDA is responsible for monitoring the registration of NMs, labelling, issuing codes of NMs, risk management systems, guidelines and establishing technical standards (Chavez-Hernandez 2024). In essence, the US FDA issued a guideline based on the application of nanotechnology in either food or packaging materials directly in contact with food and suggested that the food producers must examine and study the toxicological profile of the packaging material incorporated with nanoparticles individually (Zorraquín-Peña *et al*. 2020).

Other Countries

The Korea Ministry of Food and Drug Safety (MFDS) is responsible for running various projects based on the safety evaluation of nanoparticles used either in food or food packaging. Therefore, developing safety guidelines and regulations about nano-safety is part of plans intended by the Korean government. Even, though in Malaysia, the Nanotechnology Directorate has carried out numerous projects regarding the application of nanotechnology in the food and agriculture sector, the guidelines, and regulations for conducting risk assessment of nanoparticles in these areas are still limited. Like

Indonesia, no specific regulations nor safety assessment has been established regarding nanoparticles in the food and agriculture sectors (Paidari *et al.* 2023). Furthermore, Caleb and Belay (2023), Reddy and Singh (2022) and Carbone *et al.* (2016) reported that Canada and Japan have not developed any regulatory framework regarding the use of any nanoparticles. Moreover, in many other countries, food safety regulations are still in the foundation phase or being introduced.

In South Africa

Like other countries, South Africa has not developed any regulatory framework for the use of nanoparticles in the food and agricultural sector. Nevertheless, some broad existing legislation and regulations are also applicable to these substances or nano-enabled products such as the Hazardous Substances Act (15 of 1973), the Occupational Health and Safety Act (85 of 1993) and the National Environmental Management Act (107 of 1998). Furthermore, another Act that may be relevant and applicable to indirectly regulate the use of nanoparticles in food products is the South African Foodstuffs, Cosmetics and Disinfectants Amendment Act (39 of 2007) (Caleb and Belay 2023).

For instance, it focuses on outlining the standardised analytical procedures, suitable personnel qualified to perform the examination and the frequency in which each analysis must be performed (Foodstuffs, Cosmetics and Disinfectants Amendment Act, 2007). Additionally, Nanotechnology Innovation Centres and National Nanotechnology Strategy have been established in South Africa for future nanotechnology-related research (Reddy and Singh 2022). Furthermore, Reddy and Singh (2022) accomplished a comprehensive study reporting that goods used for commercialisation and consumption must be free of any defects. To clarify, this means that suppliers are required to evaluate and verify accordingly that nano-enabled products are free from any significant harmful effects after consumption. Nonetheless, there are limitations concerning the standardised procedures to be adopted when performing those analytical tests, making those results invalid, unreliable and not trusted. On the other hand, Bedi and Krishan (2020) suggested that OECD guidelines can be adopted for analyses of toxic chemicals or the toxicity of NMs and meet internationally acceptable standards.

CONCLUSION

As far as the regulatory framework of AgNPs incorporated with food contact polymer at a national level is concerning as there is no specific legislation and regulations governing AgNPs in the food industry. Hence, there is a gap in governance and ambiguity regarding their risk and therefore, causing a quandary for the regulators. From the wide use of AgNPs in various applications, guidelines and broad regulations may be adopted to offer a hint on conducting risk assessments and toxicological evaluations. However, a case-by-case approach is required. Hence, a need for specific regulation, irrespective of the vast existing regulations that will continue to be relevant. This is because nanoparticles pose dynamic physicochemical properties, and their behaviour or reactions cannot be predicted, hence, a one-size-fits-all approach is not suitable.

There is a necessity for collaboration amongst relevant stakeholders including government regulators, voluntary organisations, research institutions and scholars to discuss issues hindering the development of stringent regulations specifically for the application of AgNPs in the food packaging industry to provide mitigation in identifing challenges and develop a standardised robust regulatory framework applicable to all countries.

From this data, it was mentioned that if AgNPs stays infused in the polymer it does not leach out and transfer into food, making it a non-potential toxic threat. Therefore, the polymer can be treated with a high-pressure to prevent the dismantling of polymer molecules and strengthen the integrity of a polymer. By doing this, the amount of NP migrated will be minimised, or no AgNPs will be released to food products.

Another element to consider is the use of green AgNPs. Scholars have brought to light that the biological synthesis of AgNPs is more endorsed compared to physical and chemical methods. This is because the biological synthesis of AgNPs is comparatively eco-friendly, less energy ergonomic, safe and non-toxic. Also, the production of AgNPs on a large scale using biological synthesis is more convenient and cost-effective.

From the forgoing narrative, it is reasonable to consider a precautionary approach. In this context of the application of AgNPs to improve the antimicrobial properties of the polymer, regulatory bodies must decide to either, allow AgNPs for direct use and provide a safety threshold or prohibit its commercialisation. Either way, both decisions go hand in hand with risks. The first risk includes permitting the use of AgNPs even though warnings of long-term effects have been presented. The second decision is based on the economic effects. The biggest concern lies with denying the nation the benefits associated with AgNPs while there are no coherent reasons.

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Data-based University Quality Assurance: Whether ranking results and performance indicators interrelate?

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STRUCTURED ABSTRACT

Purpose– The correct choice of key performance indicators (KPI) is an essential part of the university's quality management system. As universities are being evaluated from different external organizations there is a need to synchronize the set of performance indicators for the university quality system. The aim of this research is to analyze the performance indicators from theoretical and international university rankings perspective, and to identify performance indicators that measure university sustainable governance.

Design/methodology/approach– Literature review and qualitative content analysis with open coding were used to identify the indicators from scientific research papers and analysis of performance indicators from methodologies of university rankings was done.

Findings– The finding include the identified sets of indicators with adapted weights for universities with different focuses. Furthermore, the research paper identifies the linkages between different sets of indicators.

Research limitations/implications- In the analysis of university rankings only three rankings were included - Academic Ranking of World Universities, Times Higher Education University Ranking, QS University Ranking.

Practical implications- The sets of indicators can be used for analyzing and benchmarking different university quality management systems.

Originality/value (Mandatory)- Identified set of performance indicators for evaluating the sustainability of university quality management system and overall university sustainable

governance. The indicators were compared with indicators of the three most known university rankings – ARWU ranking, QS WUR and THE WUR.

Keywords: Key performance Indicators, quality management system, indicators, university, rankings.

Paper type- Research paper

INTRODUCTION

New solutions aimed to sustainable university governance and the effectiveness of quality assurance are in need. For many years universities have used different university ranking systems for evaluating and benchmarking their performance in certain fields such as studies, research, innovation and sustainability (Calderon, A. 2023, Bautista-Puig, N. et. al., 2022, Hazelkorn E., Mihut G., 2021). Sustainability has become an arising focus area for universities. The element of sustainable governance is being integrated in all university processes and as new university rankings are arising with new methodologies for evaluating sustainability, should internal quality assurance process keep up with these changes?

The aim of this research is to analyze the performance indicators from theoretical and international university rankings perspective, and to identify sets of performance indicator that measure university sustainable governance.

Universities are continuing to adapt and integrate comprehensive quality approaches and business models in their management and operations. These approaches result in large number of performance indicators. As organizations measure their performance indicators consistently and systematically for improvement, accountability and sustainability (Yeung, 2018) it becomes even more important to have comprehensive and timely quality assurance process in place that is integrated to university strategy and governance.

Development and implementation of the university's strategy, like the improvement of processes, is an endless set of activities aimed at the efficiency and excellence of the university's operations. These activities need to be evaluated systematically. Setting up the quality management system is not enough to meet the strategic objectives. Already in the 1996 Kaplan and Norton emphasised the importance of transferring and linking the organisational vision and strategy with real action to ensure sustainable organisational performance results (Kaplan & Norton, 1996). Some authors argue the importance of recognising that KPIs on their own can be dysfunctional unless they are grounded within the culture of a strategy-focused organisation (Cullen et al., 2001). Juran defined strategic quality management as a systematic approach for the whole organisation to ensure meeting the organisational objectives (Juran, 1991). Constant review is necessary for the processes and the university's strategy (Cullen et al., 2001). Constructive alignment of processes with institutional strategy can be accomplished with commitment from management, employee support, ongoing communication, review process, verification and validation (Yeung, 2018).

The important success factor is that all developed strategies align with the university's central vision (Nguyen, 2015). In this way, it is possible to develop different groups of KPIs that are integrated into strategy-focused organisation operations (Cullen et al., 2001).

In this research authors are looking to identify the theoretical sets of indicators that universities are using as their key performance indicators in their strategies. From external point of view authors will look at international rankings to determine if the sets of indicators interrelate.

RESEARCH METODOLOGHY

Literature review and qualitative content analysis with open coding were used to identify the indicators from scientific research papers and analysis of the performance indicators from methodologies of university rankings was done. The authors defined two main questions for the research:

1. What performance indicators are used for evaluating university performance?
2. Do the defined groups of indicators interrelate with indicators in university rankings?

The identified publications from Scopus and Science Direct databases were 7379. During the research paper selection phase, a total of 5287 publications were excluded because they did not meet the open access criteria, 1 publication was excluded because it was not available in English, 2024 publications were excluded because duplicates were identified, the full text of the publication was not available, or the abstracts of the research papers were not relevant to the research question. A detailed process of identification and selection of scientific articles can be seen in the PRISMA flow diagram created by the authors:

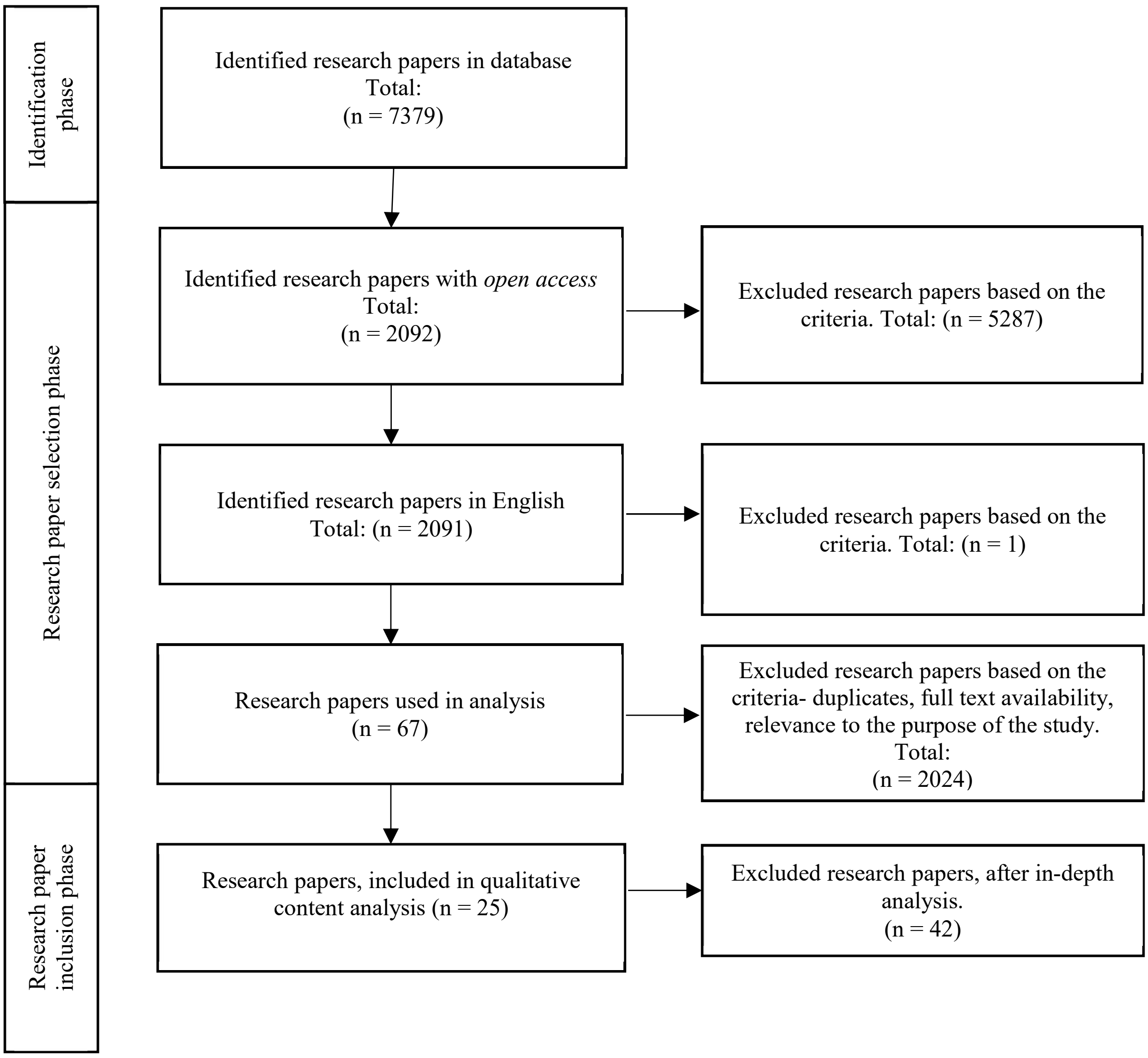

Figure 1 – PRISMA diagram for research paper identification (created by authors)

The authors used scientific literature content analysis, which consisted of the following stages:

1. The authors selected articles from two scientific databases – Science Direct and Scopus. In total 67 scientific articles were selected using keywords:
2. “KEY PERFORMANCE INDICATORS”, “STRATEGY”, “QUALITY”, “DEVELOPMENT”, “UNIVERSITY” and, according to them, the number of citations.
3. The selected scientific articles were reviewed. After a critical analysis, only 25 articles were used for the next stage – content analysis.
4. The selected 25 articles were used for qualitative content analysis with open coding.
5. Finally, results analysis and grouping of KPIs were performed.

The authors compared the discovered groups of KPIs with performance indicators from university rankings methodologies.

The authors defined the research limitations and implications. This research is focused on the 3rd generation universities, which are defined by combining study, research, and technology transfer activities. Three ranking methodologies were used in the analysis - Academic Ranking of World Universities, Times Higher Education University Ranking, QS University Ranking.

IDENTIFYING UNIVERSITY PERFORMANCE INDICATORS

In order to answer the first research question, the authors used qualitative content analysis with open coding. Authors analysed what indicators are used for evaluating university performance and identified the main groups of KPIs used for university performance evaluation in the context of sustainable governance. By analysing the selected scientific articles, seven groups of KPIs were identified. The main groups in order of frequency mentioned in the articles are shown in Figure 1.

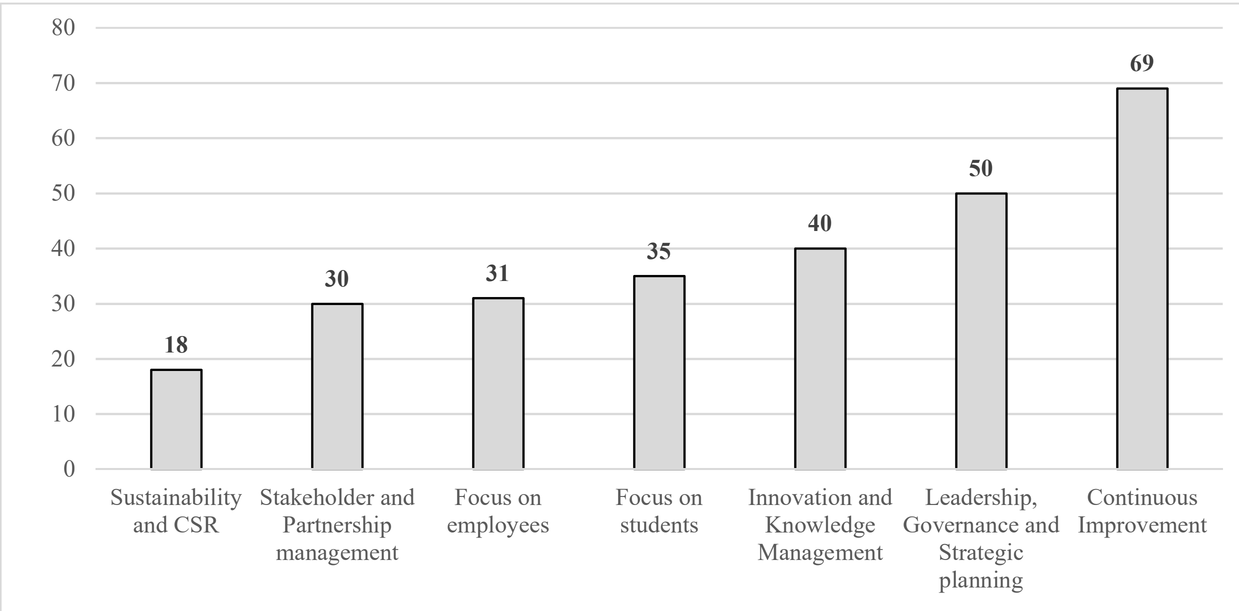

Figure 2 – Groups of KPIs in order of frequency mentioned in the articles (created by authors)

Each group of KPIs consists of a set of indicators that have been measured or mentioned as possible measurements to determine the university's performance. All of these groups of KPIs show a different dimension of university measures towards sustainable governance and strategy implementation. Further in the research, the authors used literature review to determine the main elements and indicators used in previously discovered groups of KPIs. Authors mention the main ideas and indicators from research articles that described the groups of KPIs. These groups were only analysed in the context of the sustainability of the university's governance and institutional strategy by keeping in mind the key university stakeholder groups.

Sustainability and Corporate Social Responsibility (CSR)

- CSR can be seen from the perspective of stakeholder theory or resource-based theory; both conclude that legitimacy by stakeholders can be achieved by involving and informing the stakeholders (Choi & Yoo, 2022).
- Through enhancing educational development and social contributions, more universities have been making efforts towards understanding their impact on society, in other words - introducing university social responsibility practices (Usak *et al.*, 2021).
- Corporate Social Responsibility should be integrated into the university's comprehensive quality assurance system (Yeung, 2018).
- More indicators are needed for measuring the implementation of environmentally-friendly concepts in the key processes for sustainable performance in higher education, for example, the teaching and learning processes (Yeung, 2018).
- At the university and the strategy level, sustainability can be included in a management system for quality assurance that facilitates monitoring and continuous development of the processes (Holm *et al.*, 2012).
- Universities need in the long run sustainable performance results while enhancing the corporate competitive position in higher education (Kocmanova & Simberova, 2012).

The main indicators mentioned in the articles were based on the economic, social and environmental focus. Additional measurable indicators were *the level of implemented CSR, openness and adaption to change in the university.*

Stakeholder and Partnership Management

- Stakeholder-centred perspective should be considered as one of the main perspectives rather than a shareholder of top management perspective in strategy development (Choi & Yoo, 2022).
- Engaging diversified stakeholders in devising a fit-for-purpose policy in the quality assurance system (Yeung, 2018).

- Nowadays, partnership management is becoming more crucial. The development of focused research-based universities allows for building closer links with the industry (Albats, 2017).
- Long-term relationships with university partners ensure operations’ stability, especially for research-oriented universities (Chen et al., 2017).
- The basis of stakeholder management is satisfying the needs of stakeholders (Chen et al., 2017).
- Identifying and categorising the main partnerships allows understanding of the partnership management and relationship with them (Holm *et al.*, 2012; Secundo *et al.*, 2017).
- It is needed to develop strategic international partnerships that would allow the university to be more competitive and more recognisable (Cullen *et al., 2001;* Starostina *et al.*, 2016).
- Working with rapidly changing demands from stakeholders can be challenging. For a wide scope of stakeholders, the principle of the exchange of views and the search for consensus can be applied (Starostina *et al*., 2016).
- It is necessary to manage stakeholders and understand the importance of certain groups of stakeholders for the university, such as the government (Eacott, 2016).
- Engaging stakeholders to take part in strategy development and evaluation (Holm *et al.*, 2012). Allowing them to give suggestions (Nguyen, 2015).
- It is necessary to develop, analyse and improve strategies for each stakeholder group (Soria-García & Martínez-Lorente, 2013).
- It is crucial to increase partners' awareness and knowledge on achieving and improving the university quality objectives (Soria-García & Martínez-Lorente, 2013).
- Stakeholders want to know how they influence university strategy (Breakwell & Tytherleigh, 2010).

Stakeholder grouping and management lets universities determine different strategic approaches. Some of the indicators mentioned in the articles were: *stakeholder involvement, stakeholder satisfaction, and stakeholder strategy implementation.* Regarding partnerships the main indicators mentioned in the articles were: *the number of partnerships, partnership efficiency, the number of contracts regionally and internationally, the value of the partnership and the partnership satisfaction rate.*

Focus on employees

- Improving quality performance in the university by focusing on human resource planning, development and employee relationship management (Chen *et al*., 2017).
- Focusing on engaging employees in university activities and decision-making (Yeung, 2018).
- Employees' involvement is an essential component of quality management in a university. Involvement is a way of qualifying employees, giving them information, increasing their knowledge and rewarding quality performance (Soria-García & Martínez-Lorente, 2013).
- At research-intensive universities, building human resources management capacity has become the main approach to enhancing a university's research performance (Nguyen, 2015).
- Teamwork, competent staff, customer focus orientation, and visionary leadership are the most crucial human resource-related factors critical for successful strategy implementation (Ali et al., 2014).

The main indicators mentioned in the articles were: *employee involvement, engagement in decision-making, employee turnover, level of quality culture in the university, employee satisfaction and the number of employee-generated ideas for university improvement.*

Focus on students

- Focus on students and abundant resources for providing a learning environment are key factors for establishing the study process (Liu *et al*., 2019).
- Universities have to focus on student learning and monitoring individual learning outcomes (Yeung, 2018).
- For example, many universities focus on students' employability, providing processes, activities and plans that allow students to participate in different trainings and internships (Chen *et al*., 2017).
- Practical implications highlight the importance of adapting the customer relationship management strategy in higher education and the creation of a student-oriented environment by constantly adapting its processes in accordance with indicators of student satisfaction (Hrnjic, 2015).
- Using indicators such as student satisfaction, universities are creating strategies to ensure student retention by focusing on a student-centred education approach (Hrnjic, 2015).
- Many university strategies emphasise the focus on students (Andrews *et al*., 2012).

The indicators and ratios mentioned in the articles that describe university student focus were: *student satisfaction, student retention rate, student graduate rate, value creation for the student, student-to-faculty ratio and cost per student.*

Innovation and Knowledge Management

- Innovative policies strengthen organisations and enable the development of innovative products, services or approaches (Robertsone, Lapiņa, 2023, Annamalah *et al.,* 2022).
- Technology transfer has been identified as the foundation of open innovation, and it contributes to organisations' innovative performance and overall development (Alkhazaleh *et al*., 2022).
- To strengthen the organisation's innovation culture, it is necessary to regularly evaluate and improve previously implemented innovation measures (Suwignjo et *al.,* 2022).
- An organisation's capacity is crucial in managing and developing knowledge and ensuring that the organisation is capable of utilising the knowledge (Annamalah et al., 2022).
- One of the key factors for enhancing knowledge management in an organisation is the development of a collaborative environment (Alkhazaleh *et al*., 2022).
- In relation to knowledge management, universities should also focus on their employee competencies (Yeung, 2018).
- Innovation is one of the quality dimensions in universities, especially for research-based universities (Chen et al., 2017).
- Universities with third mission goals focus on three interrelated areas: research, including technology transfer and innovation, life-long learning and social engagement (Secundo *et al.*, 2017).
- Knowledge management is also linked to knowledge transfer. Universities, like businesses, need to become more knowledge-based (Chen *et al*., 2017).
- Knowledge management is considered as one of the quality dimensions in universities (Chen *et al.*, 2017).
- Intellectual capital is increasingly important in the university value-creation process (Secundo *et al.*, 2017).
- Innovative practices positively influence the university's performance (Zeps & Ribickis, 2016).

- Knowledge management has an essential role at research-based universities, where the focus is on research performance (Nguyen, 2015).
- Innovation management is an integral part of university processes, as innovation is included not only in the research and study process (Ņikitina et. al., 2023) but also in the development of the university's quality system (Soria-García & Martínez-Lorente, 2013).
- A university in a continuous learning process requires a culture promoting continuous improvement and knowledge management (Soria-García & Martínez-Lorente, 2013).

The main indicators for measuring innovation management were: *innovative thinking, number of employee-created ideas, R&D budget, innovative environment, organisation`s innovation culture, and active projects*. In the analysed articles, knowledge management was mentioned in different measurements such as *knowledge transfer, innovation capacity, number of internal training of employees, and number of documents related to knowledge management being reviewed.*

Leadership, Governance and Strategic planning

- Appropriate university governance and emphasis on effectiveness are important indicators for performance improvement and strategy development (Liu *et al*., 2019).
- Organizational performance includes measures of governance, operation management and dealing with stakeholder issues (Yeung, 2018).
- Leadership should be measured in higher education similarly to other industries (Chen et al., 2017).
- The defined KPIs for strategy should align with and reflect the values leadership promotes throughout the university (Secundo *et al.*, 2017).
- University strategies are developed in collaboration with the main stakeholders (Albats, 2017).
- Risk management and risk awareness are essential elements of organisational performance management. They should be integrated with process management (Samani *et al.*, 2017).
- To develop a quality system in a university, change management should be a part of organisational management. Organisational change can take additional resources and time (Eacott, 2016).
- Some of the elements describing organisational performance are value orientation, content, operational activity, and result-evaluation modules (Kalimullin *et al*., 2016).

- The important success factor is that all developed strategies align with the university's central vision (Nguyen, 2015).
- Universities need to focus more on highly skilled employees and identify leaders among them (Hrnjic, 2015).
- Visionary leadership is one of the main critical factors in ensuring successful quality management system implementation (Ali et al., 2014).
- The role of leadership in organisations is vital to achieving successful quality and organisational performance (Soria-García & Martínez-Lorente, 2013).
- Nowadays, decision-making flexibility is an essential aspect for university management (Holm *et al.*, 2012).
- Institutional performance is linked to leadership and management of the organisation. Leadership effectiveness needs to be measured accordingly (Breakwell & Tytherleigh, 2010).
- A variety of strategies, such as information, engagement, and human resource planning strategies, are a part of the integrated quality system in the organisation (Corrall, 2007).
- Formulating and implementing a strategy integrated with Total Quality Management principles ensures quality management system development (Tummala & Tang, 1996).
- Strategic planning involving strategic quality planning and quality improvement strategy is one of the key concepts for integrating quality into the organisation's strategic decisions (Tummala & Tang, 1996).
- It is essential to formulate and implement quality improvement strategies in organisational performance that are fact-based (Tummala & Tang, 1996).
- Desirable results cannot be achieved without the active leadership of senior managers (Juran, 1991).

Organisational performance indicators depend on the specifics of the university. Some of the general indicators mentioned in the articles were: *strategy fulfilment, performance analysis of certain activities and organisational goal fulfilment.* Indicators mentioned in the articles for measuring university efforts towards leadership and strategy were: *involvement in decision-making, ability to change, identification of leaders in the organisation, value promotion, interest in organisational development and cooperation with stakeholders, strategy implementation analysis, strategy engagement, strategy integration and alignment, stakeholder involvement and collaboration*

Continuous improvement

- One of the critical quality indicators in the university that shows a positive effect is improving performance by redefining processes (Chen *et al*., 2017).
- It is necessary to analyse KPIs and compile an improvement plan to ensure continuous improvement of the university (Iljins *et al.*, 2017).
- Management systems and processes are significantly more complex and flexible in higher education than in general service industries (Chen *et al*., 2017).
- Rapidly changing demands of stakeholders create a need to form a system of continuous improvement in all university operations (Starostina *et al.*, 2016).
- Continuous improvement is not something that organisations have or do not have, but is part of a cultural transformation journey in the whole organisation (Fryer & Ogden, 2014).
- The quality of service that universities must provide to their students is permanently integrated into university operations, meaning that the processes should be integrated, too (Ali *et al.*, 2014).
- Universities require a culture of promoting continuous improvement. It is crucial to share continuous efforts and the same direction at all university levels (Soria-García & Martínez-Lorente, 2013).
- Our current social frame is asking to optimise the process and improve the educational results (Soria-García & Martínez-Lorente, 2013).
- The quality of education depends not only on the quantity of the resources but also on how the resources are used and how the system is organised and managed (Soria-García & Martínez-Lorente, 2013).
- The university should apply system thinking to increase the performance level in programme delivery, social responsibility and system performance (Soria-García & Martínez-Lorente, 2013).
- Universities should focus on continuous improvement of processes and results to ensure stakeholder satisfaction and organisational performance development (Tummala & Tang, 1996; Holm *et al.*, 2012; Yeung, 2018).
- Universities need to define and manage processes, for example, using the ISO 9001 Standard, which is focused on process orientation (Tummala & Tang, 1996; Yeung, 2018).
- Using risk management combined with quality management results in better process outputs, process efficiency and effectiveness (Samani *et al.*, 2017).
- Universities have to focus on improving the value-creation process (Secundo *et al.*, 2017).

- Organizations can document policies, processes and procedures for an effective quality system, for example, using the ISO 9001 Standard (Tummala & Tang, 1996).

From the analysed articles, the focus areas for continuous improvement in the context of quality system development were process, system and stakeholders. *Focusing on performance analysis, factors influencing improvement and feedback* is also important. A basic systematic orientation is necessary to develop the quality management system. The main indicators mentioned in the articles for measuring system orientation in the university were: *the level of process development, level of process integration and documentation coverage*. As continuous improvement is linked with all previously mentioned groups of KPI in the next chapter authors are defining the group of KPI as a horizontal set of indicators that are integrated with rest of the groups as shown in Figure 2.

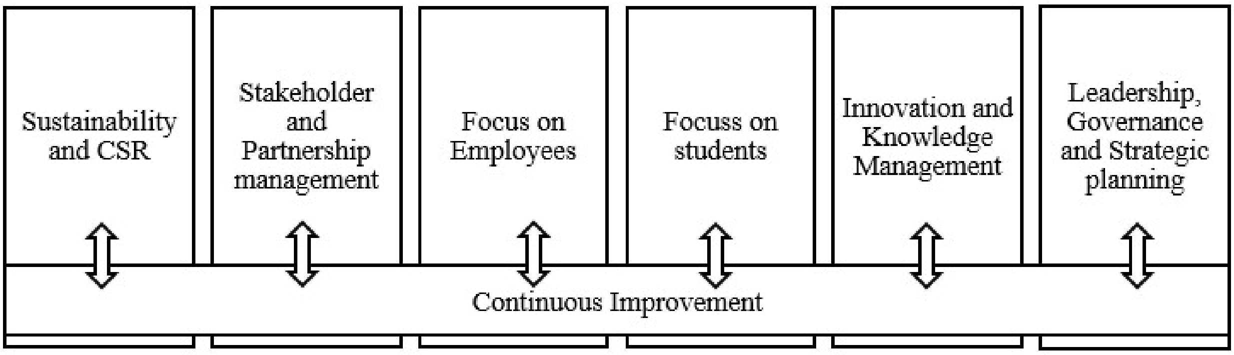

Figure 3 – Integrating Continuous Improvement with other sets of indicators (created by authors)

The list of indicators identified under the *Continuous Improvement* complements other sets of indicators and ensures measures of effectiveness and improvement of a certain process. These are more process focused indicators.

UNIVERSITY EVALUATION THROUGH RANKINGS

University ranking provide the possibility to benchmark and analyse universities through certain set of indicators. Authors have chosen three ranking methodologies for the evaluation - Academic Ranking of World Universities (ARWU), Times Higher Education University Ranking (THE WUR), QS University Ranking (QS WUR). These three ranking systems are well known and established.
The UK-based Times Higher Education (THE) World University Rankings (WUR) rating was initially started in 2004. However, subsequent to 2010, two distinct and independent ratings emerged, now recognized as THE WUR and QS WUR ratings. The ARWU also called as Shanghai Ranking

was developed in China in 2003. These rankings have different inclusion thresholds, for example to be considered in the ARWU ranking university should have Nobel Laureates, Fields Medalists or Highly Cited Researchers. QS WUR and THE WUR rankings have for example subject related and number of publications in certain timeframe as inclusion criteria.

Authors have analyses the differences between these rankings by sorting them in categories shown in Table 1.

Categories from theory	**ARWU ranking**	**QS WUR**	**THE WUR**
Leadership, Governance and Strategic planning	• *Per capita academic performance of an institution*		• *Institutional Income* • *Research income*
Innovation and Knowledge Management			• *Patents* • *Industry Income*
Focus on Students	• *Alumni of an institution winning Nobel Prizes and Fields Medals*	• *Faculty Student Ratio* • *International Student Ratio* • *Employment Outcomes*	• *Student staff ratio* • *Doctorate bachelor ratio* • *International students*
Focus on Employees	• *Staff of an institution winning Nobel Prizes and Fields Medals Highly Cited Researchers*	• *International Faculty Ratio*	• *Doctorate staff ratio* • *International staff*
Stakeholder and Partnership management		• *International Research Network* • *Academic Reputation* • *Employer Reputation*	• *International co-authorship* • *Teaching reputation* • *Research reputation*
Sustainability and CSR		• *Sustainability*	
Focus on Research	• *Papers published in Nature and Science* • *Papers indexed in Science Citation Index-Expanded and Social Science Citation Index*	• *Citation per Faculty*	• *Research productivity* • *Citation impact* • *Research strength* • *Research excellence* • *Research influence*

By analyzing university ranking methodologies in relation with identified indicator categories from theory authors see topics that overlap. Each of the three university rankings are with different focus areas that are shown by indicator weigh – ARWU focus is on academic performance and recognition, QS WUR focuses on academic and employee reputation and THE WUR on research quality. All of the rankings are focusing on students, employees by analyzing ratios such as student – staff ratio, international student or employee ratio. There has been identified focus on partnership management, with other universities or research institutes in field of research and subordinate cooperation with industry in field of innovation that is measured by industry income in THE WUR ranking. ARWU and QS ranking does not focus on innovation and knowledge management. Only QS WUR ranking has included sustainability as an indicator in their methodology. This is new indicator in QS WUR methodology that has been introduced in 2023 and it is based on QS WUR sub-ranking called QS WUR Sustainability Ranking.

In all three rankings focus on research was highlighted as important measure. Authors have highlighted these indicators separately as a new category. From the content analysis done previously the indicators related to research were identified as research process performance results.

Category - Leadership, Governance and Strategic planning does not show significant list of indicators in rankings that contribute to sustainable university governance. All three ranking methodologies lack indicators that could be considered as focused on continuous improvement and overall quality system. The rankings are focused on result-based indicators with the exception on reputation indicators that show other stakeholder perception indicators. To answer the second research question authors, conclude that the defined groups of indicators somewhat interrelate with indicators in university rankings but the ranking indicators does not show indications of university sustainable governance. The ranking indicators are good starting point for evaluating university year on year performance and benchmark these indicators with other universities in particular in the research indicators. However, it should be noted that the indicators are being normalized in these rankings that limits the direct comparison of certain data.

CONCLUSIONS

KPIs for strategy and process evaluation have become more integrated and diversified. Indicators can be grouped into different sets and levels based on the purpose. Authors conclude that the importance of evaluating not only the processes in the university but also the strategies has been emphasised by several researchers. The relationship between a university's strategic view and performance measures creates many indicators. Indicators can be grouped in different sets and levels, based on the purpose of the indicators in the institution. A wide range of indicators describe the system or process, but not all indicators are related to the sustainable university governance. The analysed university rankings show different focus areas in their methodologies. These focus areas are research and university reputation from stakeholders. University ranking indicators partly identify the areas in which universities should also focus, based on the theoretical research. These areas are governance, knowledge management and sustainability.

By using qualitative content analysis, the authors discovered seven groups of KPIs that measure university performance. The strongest identified group was continuous improvement, which was identified in all indicator groups as an integrated set of indicators. Authors used this group of indicators as the basis for all groups that resulted in six groups of KPI to be analysed in comparison with three university rankings – ARWU ranking, QS WUR and THE WUR.

The authors agree with Kaplan and Norton's point of view (Kaplan & Norton, 1996) of emphasising the importance of transferring and linking the organisational strategy with operational actions. The important success factor is that all developed strategies align with the university's central vision (Nguyen, 2015). In this way, it is possible to develop different groups of KPIs that are integrated into strategy-focused organisation operations (Cullen *et al*., 2001). Universities that promote continuous improvement culture at all levels of the organisation can easily adapt to change and new KPIs if necessary (Soria-García & Martínez-Lorente, 2013). The authors agree that continuous improvement culture in an organisation positively influences the strategy development process and implementation process. The importance of evaluating not only the processes in the university but also the strategies has been emphasised by several researchers (Tummala & Tang, 1996; Cullen *et al*., 2001; Nguyen, 2015).

Further research possibilities would be to analyze research indicators and reputation indicators from university rankings to understand if there is correlation between these indicators and identified indicator groups from theory. Additionally, authors consider further research by analyzing different university case studies by looking at universities in different rankings and different positions.

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Circular economy and sustainability for a higher quality tourism experience: a systematic literature review

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STRUCTURED ABSTRACT

Purpose - the present study aims to understand how and to what extend the concepts of circular economy (CE) and sustainability are discussed in the tourism field and to depict their role in the definition of a higher quality tourism experience.

Design/methodology/approach - To achieve the paper's aim, a Systematic Literature Review (SLR) is conducted according to the PRISMA protocol (Pickering & Byrne, 2014; Pickering et al., 2015) and 64 records were considered for the study. A content analysis is adopted to examine and categorize the documents (Pasca et al., 2021; Rahman, 2021).

Findings - The study provides a comprehensive understanding of the concepts of sustainability and circularity in the tourism field by identifying three categories of analysis distinguished by the scope of the studies and the main aspects explored related to the issue of interest. Moreover, current gaps and future research agenda were depicted as well as the different implications in defining the quality of the tourism experience.

Keywords: tourism, sustainability, circular economy, tourism experience quality.

Paper type: literature review

INTRODUCTION

Tourism is considered an engine of socio-economic growth, producing many positive impacts on various parallel fields. It is considered a successful economic activity that contributes significantly to GDP and employment in many countries, representing in some of them the most viable option for social development and reduction of poverty levels (UNWTO, 2020). The increase in the average income of global consumers and the digital revolution and innovation foster the growth of the sector, contributing to the creation of one of the most important service industries in the world. According to Statista (2022), in 2019 tourism contributed about 9.6 percent to global GDP and provided 333 million jobs. International arrivals increased from 900 million to over 1.4 billion in just ten years and are expected to reach 2.7 billion by 2027 (Voukkali, 2023).

With an increasing number of tourism destinations, it becomes imperative to focus on the creation of distinctive, high-quality attractions and experiences to win over tourists' attention (Iniesta-Bonillo et al., 2016). Attractiveness of a destination is influenced by the presence of cultural, social and environmental aspects that represent the uniqueness and authenticity of a place. Historical and cultural attractions (Kladou & Mavragani, 2015), natural attractions (Mak, 2017), entertainment (Folgado-Fernández, Hernández-Mogollón, & Duarte, 2017), outdoor/leisure activities (Lee & Jeong, 2018) are all factors that have been studied in relation to a destination's image. However, the evaluation of the destination in terms of sustainability principles has been observed as another crucial determinant of tourist satisfaction and competitiveness of a tourism destination ((Lee & Xue, 2020; Baxer, 2020; EP Kusumah, 2024, Gidey and Sharma, 2017). Indeed, the tourism industry contributes to the promotion of global natural and cultural heritage but is equally responsible for its degradation due to multiple unsustainable practices (Costa et al., 2020). In this context, sustainability of the environment, culture and heritage resources become paramount by shaping products and services of multiple tourism destinations.

The principles of sustainability in tourism field have been discussed among stakeholders since 1990s and the concept of sustainable tourism has emerged to reduce the negative impacts of tourism activities. Sustainable tourism can be defined as the "tourism that takes full account of its current and future economic, social and environmental impacts, addressing the needs of visitors, industry, environment and host communities" (UNWTO and UNEP, 2005). It aims to "satisfy the need of tourists and hosting regions and, at the same time, preserves and improves future opportunities" (UNWTO, 1998). It promote i) the optimal use of environmental resources, maintaining essential ecological processes and contributing to conserve natural heritage and biodiversity, ii) respect for the socio-cultural authenticity of host communities iii) ensuring long-term, profitable economic operations, that provide socio-economic benefits to all stakeholders with stable employment and income-earning opportunities and social services to host communities, and iv) providing meaningful experiences to tourists to assure high levels of visitor satisfaction (World Tourism Organization, 2004; Girard and Nocca, 2017).

At present, tourism services are increasingly focused on social, environmental and economic aspects. Sustainable tourism has become crucial in improving the quality of tourist destinations and increasing the customer satisfaction experience. Moreover, green practices are more demanded by clients, and authenticity, linked to socio-cultural aspects, is increasingly tied to the quality of the experience. Some scholars claim that sustainable attributes moderate the relationship between service quality and customer satisfaction (Merli et al., 2019) and argue that this relationship can be enhanced if service quality practices are coupled with socially and environmentally responsible practices (Kassinis and Soteriou, 2008).

Seeking the transition to a more sustainable future, the concept of the circular economy emerged as a new approach to sustainability. According to Ellen MacArthur Foundation circular economy is established on the three key principles of preservation and enhancement of natural capital, optimization of resource yields and system effectiveness (Schulze, 2016). They define "CE an industrial system that is restorative or regenerative by intention and design. It replaces the 'end-of-life' concept with restoration, shifts towards the use of renewable energy, eliminates the use of toxic chemicals, which impair reuse, and aims for the elimination of waste through the superior design of materials, products, systems, and, with this, business models", thus highlighting the relevance of "reuse" and "recycle" of resources and products as well as "re-duction" of environmental and social impacts" (EMF, 2015).

The "touristisation" of places results in negative impacts on the preservation of the authenticity and identity of a destination, leading to negative impacts on both the host communities and the tourist experience itself due to increased cost of living and accommodation, real estate speculation, and infrastructure congestion (Benner, 2019). Moreover, the sector generates great pressure on the health of the destination in terms of the amount of land use, excessive consumption of water, energy and food that produce large amounts of waste, as well as in terms of noise and air pollution (Rico et al., 2019). In some destinations, all these problems and negative externalities are compounded by the concentration of visitors in time and space due to the seasonality of tourism activity, coupled with the fact that some destinations may not be designed to withstand such pressures (Florido et al., 2019).

Following the discussion on the limits to growth in industrial development, the currently debated phenomenon of growing tourism and related negative impacts calls for a parallel discussion in future sustainable tourism development. As the industrial development needs to be driven by qualitative and not quantitative growth, also the tourism development needs to reorient itself away from the goal of ever-increasing tourist arrivals according to economically driven tourism development towards broader objectives of socially, culturally, and ecologically sustainable qualitative growth (Benner, 2019). The focus on social, environmental, and economic issues is widely recognized in the field of tourism. However, integrating these three areas is imperative, as the sustainability of environmental and social resources underpin the high quality and attractiveness of a destination. According to Ghisellini and Ulgiati (2020), the implementation of CE practices promotes repurposing customer services in a more qualitative and sustainable way and contribute to the shift from linear to circular economic model.

Sustainability is relevant for destinations that aim to improve their market position and provide greater value to visitors and other stakeholders. Furthermore, circular economy principles can contribute to the implementation of more sustainable practices among all stakeholders in the tourism supply chain and destinations. However, a comprehensive understanding of the circular economy and sustainability in tourism remains to unfold.

Against the above background, the purpose of this paper is to analyse the concepts of CE and sustainability in the tourism industry by performing a Systematic Literature Review to explore the knowledge of the current issues in the field and their role in defining a higher quality tourism experience. The paper is structured as follows: after the introduction of the relevant research topics, the authors describe the methodology adopted and present the main results of the analysis. Finally, conclusions are provided.

RESEARCH METODOLOGHY

To achieve the paper's aim a Systematic Literature Review (SLR) is carried out to understand how and to what extend the concepts of circular economy (CE) and sustainability are discussed in the tourism field and to depict their role in the definition of a higher quality tourism experience.

The SLR is useful for understanding the relationships between studies and how each contributes to a specific field (Rahman et al., 2020; Booth et al., 2012). It allows to define directions for future study (Pasca et al., 2021) and to identify areas that require further investigation (Snyder, 2019); it is considered "systematic" due to the robust, transparent, and repeatable nature of the selection and identification process (Pickering and Byrne, 2014; Tranfield et al., 2003; Mariani et al., 2018). The research adopts a systematic quantitative approach (Pickering & Byrne, 2014; 2015), to pinpoints essential components of phenomena (Pasca et al., 2021), defines what is known and what is undiscovered (MacInnis, 2011), and identify research gaps (Pickering et al., 2015).

The literature search was developed during the first week January 2024 by searching for keywords focused on the object of the analysis, within the two scientific databases: Scopus and Web of science. The keywords "sustainability", "sustainable development", "circular* ", and "tourism" were input and a total of 428 records were identified. The keywords search was limited to “Abstract, Title and Keywords” for Scopus and to “Topic” for Web of science (WoS), using the Boolean operations “OR” and “AND” to fix the research process. Moreover, the following criteria regarding the characteristics of the publications were set (Pickering and Byrne, 2014; Moher et al., 2009): *(i)* Conference papers, book chapters, reviews, and articles, *(ii)* English language, *(iii)* published studies considering the entire available time span. The studies were collected within an Excel spreadsheet (Følstad and Kvale, 2018).

The first screening concerned the elimination of duplicates from which the initial number of records identified dropped to 294. The second screening concerned the analysis of Title, abstract and keyword. Inclusion criteria was set to include only articles focusing on circular economy and sustainability in the tourism field. At the end of the process, we gathered 114 eligible articles. The final screening considered a full paper analysis to include in review investigation only articles that are consistent with the research purpose. The link to the circular economy and sustainable development was considered in this study. Based on previous research, the authors argue that the circular economy is a tool for operationalizing the goals of the 2030 Agenda. Only articles that discuss the concept of circular economy with reference to sustainable development issues were included in the sample. Records that do not have direct reference to the relevant concepts were considered out of topic and eliminate.

The final body of literature consists of 64 records useful for the qualitative and quantitative synthesis. All the records were examined and categorized using the content analysis approach (Pasca et al., 2021; Rahman, 2021; Eloranta and Turunen, 2015) to define main aspects analyzed by the authors under the sustainability and circularity domains in the tourism industry. This process led to the identification of three main themes recurring in the sample. Based on Moher et al. (2009), a PRISMA flow chart was developed to illustrate the SLR process (Figure 1).

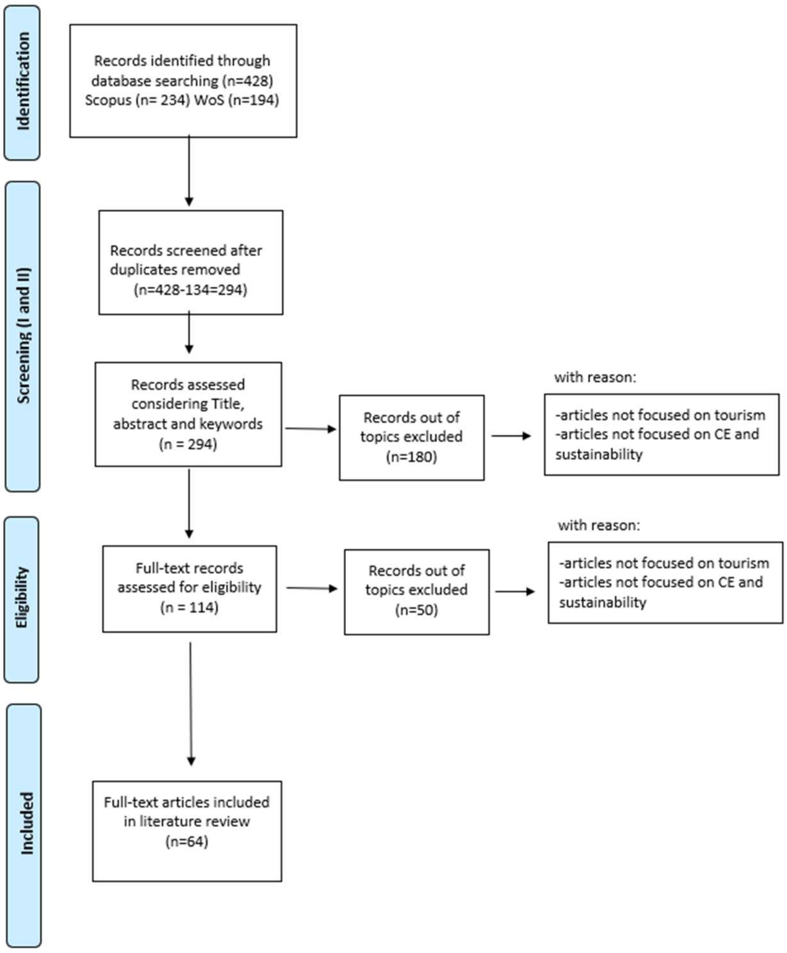

Figure 1: Prisma diagram

RESULTS

The objective of the study was to investigate how the concepts of circular economy and sustainability are understood in the tourism literature and to determine their role in defining a higher quality tourism experience. To meet the research objective, we analyzed 64 articles. First studies on the concepts of circular economy and sustainability in the tourism sector appear relatively recently. Although in our sample the first study on the concepts was conducted in 2010, most of the publications are concentrated in the last four years (Table 1).

Table 1: publication per year

Year	Fq
2010	1
2013	1
2017	2
2018	3
2019	4

2020	9
2021	12
2022	12
2023	19
2024	1

Most of the studies reviewed were conducted in European countries, with a focus on Spain, with 14 publications, and Italy, with 12 publications.

From the analysis and interpretation of the documents, three main themes emerged that represent the most explored circular economy and sustainability aspects in the field of tourism: 1) conceptualization of circularity and sustainability in tourism: opportunities and barriers 2) circular transition of tourism destinations 3) CE principles among service users and providers.

Theme	Fq	References
Conceptualization of circularity and sustainability in tourism: opportunities and barriers	27	Fang and Zhang, 2010; Girard & Nocca, 2017; Manniche et al., 2021; Vargas-Sanchez 2018; da Silva et al., 2021; Naydenov K.2018; Kaszás et al., 2022; del Vecchio et al., 2022; Tomassini and Cavagnaro, 2022; Saura et al., 2022; Vargas-Sanchez,2023; González-Sánchez, 2023; Jones and Wynn, 2019; Jaroszewska et al., 2019; Sorensen and Baerenholdt, 2020; Vatansever et al., 2021; Bosone and Nocca; 2022; Patti, 2017; Cornejo-Ortega and Dagostino, 2020; Sorin and Sivarajah, 2021; Khan et al., 2023: Costa, Rodriguez and Pacheco, 2020; Joshi et al., 2020; Rodrígues, Florido and Jacob, 2020; Falcone, 2019; Rodríguez, Jacob and Florido, 2020;La gioia et al., 2024

Circular transition of tourism destinations	24	Florido et al., 2019; Rudan et al., 2021; Nunes et al., 2021; Vythoulka et al., 2021; Voukkali et al., 2021; Hutsaliuk et al., 2021; Xu et al., 2022; Makprasert, 2022; Martín et al., 2022; Zafeirakou et al., 2022; Moon et al., 2022; Kitriniaris, 2022; Erdiaw-Kwasie et al., 2023; Rudan, 2023; Esteban-López et al., 2023; Nocca et al., 2023; Pongsakornrungsilp at al., 2023, Vardopoulos et al., 2023; Gustafsson and Amer, 2023; Gabor et al., 2023; Zhang et al., 2023; Martinez-Falco, 2023; He and Mai, 2021; Jiménez-Arias et al., 2020
CE principles among service users and providers	13	Song, 2013; Arzoumanidis et al., 2021; Bonanno et al., 2018; Khodaiji and Christopoulou, 2020; Costa, Rodrigues and Moreno, 2020; Camilleri 2021; Soegoto et al., 2022; Voukkali et al., 2023; Axhami et al., 2023; Bux and Amicarelli, 2023; Oarga-Mulec et al., 2023; Santos-Peñate et al., 2023; Li et al., 2023

Conceptualization of circularity and sustainability in tourism: opportunities and barriers - The documents included in this category focus on the understanding of the concept of circular economy and the different application of its principles within the tourism sector. The circular economy is defined as the most suitable tool to operationalize the principles of sustainable tourism in line with the goals of the 2030 Agenda. Circular tourism is defined by the authors as" a model able to create a virtuous circle that produces good and services without losing the limited resources of the planet, which limits the impact on the environment and where travelers, hosts, tour operators, and suppliers adopt an ecological and responsible approach" by creating positive effect on human service systems. The potential of the tourism sector in advancing the literature on EC was highlighted, underlining how its multi-sectoral nature can enable the creation of collaborations in a circular perspective leading to environmental, social, and cost-saving impacts. Furthermore, the contribution that new digital technologies in the development and promotion of circular economy practices is stressed. Numerous studies have focused on identifying the barriers and challenges facing the tourism sector in the transition from a linear to a circular economy. They point out how the transition is still at an early stage since the awareness of the CE principles is still low among both tourism providers and consumers. In assessing the level of awareness of tourism operators, the studies observe how some are ready for the transition while others still seem unprepared due to lack of information, expertise, and high initial investments with low economic returns. Furthermore, the lack of social responsibility actions and innovative technologies seem to limit the implementation of circular practices. Another key issue that tourism companies face is the belonging to supply chains managed according to linear logics. Therefore, "stepping outside the box" is difficult for a company involved with stakeholders sharing different values. It is therefore necessary to develop circular value networks able to create synergies and promote the circular transition of the sector. Within the circular value network, the tourists assume an important role as they are both producers and consumers of their own tourism experiences. Circular tourism requires travelers to adopt a responsible approach at all stages of their stay, from travel preparation to the local experience. It is necessary to focus on the definition of a comprehensive circular strategy involving all actors and areas of the tourism sector, on how to attract tourists to circular facilities, as well as on identifying the most circular customer profile. Social acceptability is crucial in the transformation of the tourism experience, even though most of the barriers are of institutional nature as policies in different sectors remain conducive to a linear growth model. Furthermore, excessive bureaucratization of administrative practices limits rapid development.

Circular tourism destinations management - The documents in this group focus on evaluating the best circular strategies to be applied at the tourism destination level for the promotion of more sustainable approaches. They provide guidelines, actions, and strategies useful to policy makers, local authorities and tourism organizations for planning and managing resources at the urban level to contain tourism flows and preserve the surrounding cultural and natural environment. Waste management, water supply, energy use are considered holistically. Studies on holistic management that considers the destination as a set of elements to be managed simultaneously stems from the understanding of huge pressure on resources (energy, water, soil and materials such as fossil fuels, minerals metals and biomass), food waste that led to congestion, loss of biodiversity, $CO2$ emissions and pollution. Therefore, the study of tourism impacts in the destination is a priority. Coastal and island destinations are frequent research topics focused on defining effective approaches for waste management, water and energy supply that are suitable to cope with growing tourism demand and avoid negative impacts on the destination's environment. The development of rural tourism, agri-tourism and farm-tourism is a boost to the creation of circular synergies in the destination and the development and preservation of rural areas. The adaptive reuse of cultural heritage buildings and traditional settlements is a core issue in the implementation of a circular economy strategy, especially in remote areas. Circular economy through the lens of cultural heritage enables the implementation of the principles of restoration, rehabilitation, refurbish, repurpose, refuse. Adaptive reuse of cultural heritage buildings, upcycling and sharing economy strategies are identified as approaches that can enable circularity. Some authors highlight the need to align the interests of the various stakeholders involved in the destination including local government, destination management organizations, the resident population, tourism, and tourism operators.

CE principles among service users and providers - The various circular economy practices adopted in the production, distribution and utilization of tourism services have been explored by papers included in this category. Circular economy principles are mainly studied in accommodation, restaurants, cafes, and spa facilities to explore the circular practices adopted in terms of less waste production, restoration and reuse of their resources. The practices can be distinguished in relation to food, water, and energy management. Food waste can be avoided through the implementation of just-in-time strategies for food procurement as well as partnerships with local suppliers and by allowing guests to bring leftover food with them from restaurants. Donating leftover food, using no longer edible food for animal feed or energy production are other circular strategies applied by tourism enterprises. Concerning water management, strategies related to the reduction (e.g. reduction in laundry water and wastewater) and recycling and reuse of water through the implementation of wastewater treatment and storage systems (blackwater, greywater, rainwater, desalination) were highlighted. Finally, energy saving equipment, use of alternative energy sources, as well as waste management practices such as reducing the use of plastic, biodegradable products, less paper and separate waste management, and recycling practices are reported and assessed. Moreover, indicator systems and performance evaluation in line with environmental certifications emerge as an area of interest. Included in this category there are also studies that focus on tourist behaviors, emphasizing its important role in the effective implementation of more circular tourism practices. Indeed, as tourists are both producers and consumers of their experiences, they are called upon to implement circular practices in line with those performed by service providers. Green practices are more demanded by clients and are increasingly tied to the quality of the experience. Some scholars claim that sustainable and circular attributes moderate the relationship between service quality and customer satisfaction.

CONCLUSIONS

The purpose of the present study was to analyze the concepts of circular economy and sustainability in the tourism sector and explore their role in defining higher quality tourism experiences. In general, it can be stated that there is a general application of circular economy principles ranging from the useful application of materials, linked to recycling and recovery strategies, to extending lifespan of product and its parts with re-use and repurpose practices, and to the smarter use and manufacture of product with rethink and reduce strategies. The concept of circular economy is explored at destination level for the sustainable management of tourist flows and the design of appropriate waste, water, and energy management systems. Other studies focus on the identification of circular economy principles applied by service providers and tourists, concentrating on the identification of circularity indicators and best practices that enable the assessment of the sector's environmental and economic impacts.

The implementation of circular practices within tourism facilities and destination management as a whole becomes important for the definition of a higher quality tourism experience. It allows tourists to visit places where air quality, the preservation of natural and cultural heritage, and the presence of efficient waste management, water supply and energy systems have a positive impact on the definition and planning of the tourism experience. These factors influence the image of the destination and the possibility of developing a sustainable tourism flow that preserves the environment and leads to positive impacts on the community by enhancing the identity and authenticity as well as the economic development of the place. The systematic literature review identified the main areas of study, the key concepts of circularity that are explored and the different implications on the quality of experience in relation to environmental, social and economic aspects. Sustainability in the tourism sector is a widely explored topic in the industry; however, there are few studies of its aspects from the perspective of circular economy practices implementation. Indeed, there are still a limited number of studies in the literature compared to other manufacturing sectors. However, the last four years have seen an increase in studies. More studies of a conceptual and qualitative nature are highlighted, underlining the 'exploratory' nature of the topic and paving the way for multiple aspects of the circular economy to be investigated in order to define the best circular economy practices to be implemented by both service providers and tourists for the circular transition of the sector and the realization of sustainable destinations.

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Exploration of the Concept of Standardization: a Literature Overview

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STRUCTURED ABSTRACT

Purpose - The paper aims to study the concept of standardization and its key purposes for solving problems of different groups of stakeholders and discovers the importance of developing common terminology in standardization.

Design/methodology/approach - By conducting a literature overview of research articles and other sources of literature, the authors analyze the concept of standardization. Through the analysis, scoping review is applied to identify the key purposes of the concept. Following, qualitative content analysis is carried out, within the framework of which the categories of elements characterizing the importance of developing common terminology in standardization are identified.

Findings - The concept of standardization covers a wide range of areas ensuring an optimal level of orderliness and compliance with the requirements for quality, safety, and compatibility. It serves a different purpose for various groups of stakeholders in solving modern day problems such as sustainability, environmental protection, digitalization, innovation and industrial development. The concept of standardization envisages a unified approach for the creation and transfer of information and knowledge, thus the development of common terminology in the areas covered by standardization plays an important role to ensure common understanding among interested parties. The role of standardization for different stakeholder groups and its coverage in research reveals that it not only has practical purposes, for example in quality management, but is a topic that can be expanded by focusing on the theoretical aspects of the concept in academia as well.

Originality/value - Through the analysis, the authors describe what the concept of standardization means today for different groups of stakeholders in face of industrial development and global societal expectations. The elements that describe the importance of developing common terminology in standardization are also identified through the research. In addition, the study contributes to a deeper understanding of the level the topic of standardization has been covered in scientific research, illustrates the areas where standardization has increased its role as a research subject and identifies the possible gaps and opportunities for further research.

Keywords: Common terminology, Standardization, Standards, Terminology.

Paper type: Literature review

INTRODUCTION

The demand for high quality and safety of products and services, transparency of company processes, as well as the expectations of society for sustainable living conditions and interoperable infrastructure arising from the development of industry and digitalization have long created the need for a unified approach to solving complex issues. From simple units for measurement and comparison of quantities to the combining of knowledge, experience, and competence of experts all over the world to solve complex problems, the modern international standardization system has created a basis for common understanding of object characteristics, conformity assessment solutions and systemic frameworks. The areas, directions and topics covered by international standardization develop over time. In this regard, the understanding of the concept of standardization, its defining elements and purpose is changing and adapting to the needs of different stakeholders. The constantly evolving environment also puts increased pressure on the importance of creating and transferring knowledge to solve modern day problems and follow the advancements, e.g. in artificial intelligence, actions to address climate change, and to promote increased life expectancy (Skrzek-Lubasinska and Malik, 2023). For this purpose, the creation of common terminology plays an important role in standardization. The study aims to explore the answers to the research questions: *what is the concept of standardization and its purpose for different groups of stakeholders?* and *why is it important to develop common terminology in standardization?*

RESEARCH METHODOLOGY

The methodology is based on the analysis of research articles and other sources of literature that cover the topic of standardization. Systematic literature review methods such as overview, scoping review and qualitative content analysis are applied to achieve the aim of the paper. An initial mapping of research areas covering standardization issues is carried out through the analysis of the contents of the data bases SCOPUS and Web of Science. Through the search of the keyword "standardization" 49,865 research articles on SCOPUS and 69,469 articles on Web of Science are displayed for the period from 2001 to 2024. By reviewing the results, open-access articles in English that meet the research objectives are selected for further analysis. By conducting a literature overview of research articles and other sources (e.g. conference proceedings, book chapters, online resources), the authors analyze the development of the concept of standardization. Scoping review is applied to identify the categories of elements that characterize the concept of standardization and its key purposes for different stakeholder groups. Following, through the search of publications using the keywords "standardization" AND "common terminology" AND "terminology", twenty-one research articles, reviews and conference papers are selected to perform qualitative content analysis through the application of open coding, identifying the aspects that describe the importance of development of common terminology in standardization.

THE COVERAGE OF STANDARDIZATION IN RESEARCH

Previous studies on standardization reveal that the beginning of standardization research can be dated to 1980s with the start of issuing scientific standardization journals. The amount and type of research on standards and standardization has been previously analyzed approximately two decades ago by De Vries when it was identified that the number of scientists that cover standardization in research is growing. It was revealed that standardization research is generally focused on one technical topic, item or aspect of standardization, covering research areas in both fundamental and applied sciences. It was concluded that research on standardization in applied sciences may further require new additions, however, it was stated that standardization will only establish itself as an individual academic discipline when standardization professionals demonstrate that it is capable of developing its own theoretical foundations (De Vries, 2001).

To understand the amount and subject areas of available articles that cover the topic of standardization following the study period, an analysis of the library of two databases – SCOPUS and Web of Science – is performed, looking up the keyword "standardization" in open and limited access research articles that cover the period from 2001 to 2024. The total count of research articles identified in databases is as follows: SCOPUS: 49,865 research articles, Web of Science: 69,469 research articles. Table 1 illustrates the top 10 subject areas and categories covering standardization issues in these research articles.

Table 1 – Top 10 subject areas/categories covering standardization issues in research articles.

SCOPUS		Web of Science	
Subject area / Category	**Count of articles**	**Subject area / Category**	**Count of articles**
Medicine	28,131	Engineering Electrical Electronic	2,898
Biochemistry, Genetics and Molecular Biology	7,526	Radiology Nuclear Medicine Medical Imaging	2,691
Engineering	5,473	Pharmacology Pharmacy	2,674
Pharmacology, Toxicology and Pharmaceutics	4,051	Chemistry Analytical	2,502
Environmental Science	3,680	Surgery	2,391
Computer Science	3,219	Public Environmental Occupational Health	2,313
Social Sciences	2,868	Environmental Sciences	2,274
Chemistry	2,519	Telecommunications	2,181
Agricultural and Biological Sciences	2,466	Computer Science Information Systems	2,159
Health Professions	2,043	Biochemical Research Methods	2,082

It can be observed that within the selected databases standardization is still part of research covering a broad variety of research subjects, as areas that cover the concept differ from industrial to social sciences. Most articles refer to research on medicine, biochemistry, genetics and molecular biology related topics but it can also be observed that engineering, social, environmental topics and ones that focus on other industrial areas are also covered. To analyze the concept of standardization, further analysis is performed, defining its key characteristics and purposes.

THE CONCEPT OF STANDARDIZATION

According to the International Standardization Organization (ISO) and the International Electrotechnical Commission (IEC) standardization is the "activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context." The definition is complemented by the statements: "in particular, the activity consists of the processes of formulating, issuing and implementing standards" and "important benefits of standardization are improvement of the suitability of products, processes and services for their intended purposes, prevention of barriers to trade and facilitation of technological cooperation" (ISO/IEC, 2004). The definition is included in the ISO/IEC Guide 2:2004 "Standardization and related activities – General vocabulary" which was last reviewed and confirmed in 2016 and is planned to be refined in the near future to ensure the compliance to modern frameworks. It should be noted that, according to the guide, the expression “product, process or service” should be applied also for any materials, components, equipment, systems, interfaces, protocols, procedures, functions, methods, and activity as the subject of standardization can be encompassed in a broad sense (ISO/IEC, 2004). The American Society for Quality (ASQ) describes standardization as “when policies and common procedures are used to manage processes throughout the system. Also, English translation of the Japanese word *seiketsu*, one of the Japanese five S’s used for workplace organization” (*https://asq.org/quality-resources/quality-glossary*). As stated by Wiegmann et al. (2017), the key aim of standardization is “limiting the number of solutions when using many different options simultaneously is ineffective and inefficient”. An important aspect of international standardization is the consideration of the *state of the art* which refers to the present highest level of development, meaning that the current stage of technical capability based on the relevant consolidated scientific, technological findings and experience are considered in standards (Viardot et al., 2021). Standardization thus has an important role in supporting research and innovation activities, however, it may also introduce rigidity due to the specific nature of the concept (Gottinger et al., 2023; Rojas et al., 2021). An important part of standardization which supports the reliability and trust in the quality of standards is the cooperation of different experts representing a variety of stakeholder groups and the application of the principle of consensus in the standards development processes (Jäckel et al., 2021; Gottinger et al., 2023). In the case of international standardization, the knowledge and experience are gathered from representatives of different countries, thus creating a valuable basis for the development of the mutually understood concepts. Through these activities standardization enables repeatable actions, provides technical support and prevents the distortion of competition while also facilitating trade and providing support at macroeconomic and governmental levels (Jäckel et al., 2021).

Nowadays, standards are crucial for the transition to more sustainable production and consumption models as they facilitate the development of new markets for innovative products and services (Gottinger et al., 2023). Through globalization and the development of digital solutions, standardization simplifies the processes of product development, facilitates interoperability and creates an environment for the increase of competition (Viardot et al., 2021).

Standards play a key role in conformity assessment as they create the criteria and basis for product acceptance, testing, calibration, inspection, accreditation, and certification for products, personnel and systems. By following a unified approach to these activities, it is possible to ensure consistency, the application of uniform procedures, decision rules and risk analysis frameworks (Tojiyev et al., 2023; Philips and Krystek, 2014). For example, the legislative system of the European Union has established a system of harmonization of standards to create a framework for conformity assessment and governance mechanisms that ensure the safety of consumers, while also addressing the regulatory challenges introduced by digitalization and the development of artificial intelligence (Prifti and Fosch-Villaronga, 2024). Thereby, standards also support regulatory systems to adapt to product and service innovation, particularly in uncertain markets (Gottinger et al., 2023).

For companies, standardization serves to improve organizational productivity and reduce variability in processes (Rojas et al., 2021). It also improves the transparency of business operations by providing consistent quality to customers and impacting process outcomes, including cycle time and costs (Wurm and Mendling, 2020). Standards are a popular basis for implementing management systems which also promotes the maintaining of corporate social responsibility practices of companies (Pandey et al, 2019; Masud et al., 2019).

The role of standardization is increasing in modern society as standards, like ISO standards, enhance quality of life, e.g. by setting the requirements for quality management systems, inclusive living conditions, and ensuring food safety (Krykun, 2022). It also has a key impact on the improvement of occupational safety, productivity, quality, and employee engagement (Misiurek, 2022). Through the application of standards that address environmental issues it also possible to facilitate the implementation of practices and solutions to reduce the impact on the environment, e.g. by providing methodologies for the measurement and reduction of emissions resulting from the operations of companies (Gui et al., 2019).

It can be concluded that standardization brings multiple benefits to different groups of stakeholders, as it covers a wide set of interests. Based on the articles reviewed, a classification of groups of stakeholders is illustrated in Table 2, defining the key purposes of standardization for each of the groups.

Table 2 – Key purposes of standardization for different groups of stakeholders.

Stakeholder group	Key purposes of standardization	Key references
Industry (incl. SMEs)	- improved product service quality; - meeting regulatory requirements; - providing requirements and guidance for conformity assessment; - improved stakeholder satisfaction; - increased transparency of processes; - increased productivity, reduction of risks and costs; - promotion of innovation	Gottinger et al., 2023; Misiurek, 2022; Philips and Krystek, 2014; Rojas et al., 2021; Tojiyev et al., 2023; Wurm and Mendling, 2020

Stakeholder group	Key purposes of standardization	Key references
Environmental stakeholders	- solutions for reducing environmental impact; - introduction of methodologies for evaluation of environmental impact	Gui et al., 2019; Ransome et al., 2017
Societal stakeholders	- guidance for ensured occupational health and safety; - socially responsible operation of companies	Masud et al., 2019; Misiurek, 2022; Pandey et al, 2019
Consumer organizations	- ensured safety of consumers; - solutions for improvement of the quality of life of communities; - increased life expectancy	Krykun, 2022; Misiurek, 2022; Skrzek-Lubasinska and Malik, 2023
Governmental and public stakeholders	- ensured linkage between regulations and requirements for product and service safety; - the development of new markets, prevention of competition distortion; - support for regulatory framework and adequate conformity assessment procedures	Gottinger et al., 2023; Jäckel et al., 2021; Philips and Krystek, 2014; Prifti and Fosch-Villaronga, 2024; Tojiyev et al., 2023
Academia and research	- innovative solutions and new product development; - support for scientific developments and innovations, and vice versa	Gottinger et al., 2023; Viardot et al., 2021

By summarizing the results gathered in Tables 1 and 2 it can be observed that the topic of standardization has broad coverage in research, focusing on different subject areas. By the analysis of the selected sources of literature, it can be noticed that there is still a tendency for standards to be covered in research as practical tools for solutions of specific problems, however, standardization itself is also studied as the main object of analysis in the recent years. It can also be identified that the terms "standardization" and "standards" are interpreted differently in various research papers based on the research area and the topics covered in these papers. It has been detected that in current literature three modes of standardization are looked upon: committee-based standardization (*de-jure* standardization), market-based standardization (*de-facto* standardization) and government-based standardization (Wiegmann et al., 2017). Consideration of the multi-mode characteristic of the terms therefore is necessary to understand the correct use in different contexts and to ensure that the sources for future analysis apply to the specific area of research, e.g. the development or application of standards in separate entities, the standardization of processes as an internal activity of an organization or the operations of the international standardization system. Nevertheless, the analysis reveals that standardization helps to ensure uniformity of different concepts and contributes to different groups of stakeholders. Consequently, these considerations introduce the importance of developing common understanding of the concepts, quantities and systems covered by standardization to ensure that standards are equally understood and applicable among all parties involved.

THE IMPORTANCE OF COMMON TERMINOLOGY IN STANDARDIZATION

The development of standards brings together different stakeholders which promotes the transfer of knowledge to industrial practice and encourages research activities (Gottinger et al., 2023). The creation and transfer of knowledge is fundamentally based on the common understanding of terminology (Auksoriūtė, 2016; Ciobanu, 2012). As mentioned before, standardization covers a wide range of areas, setting certain requirements, defining methods and approaches to ensure a defined level of quality and safety worldwide. Standards work as tools for ensuring that the data, knowledge, experience and best practice of standards developers is accumulated, structured and reaches standards users. Therefore, the development of common terminology is key to ensure mutual understanding among the involved parties of this process (Garretson et al., 2016). This can be considered crucial in any field of standardization as terminology provides clear explanations of the concepts applied in various industries and systems. Keeping in mind that the implementation of standards results in products, processes and systems that are intended to be compliant with specific requirements and principles, ensuring common understanding of the concepts covered in standards is highly important to achieve the desired results.

Given the previous considerations, the authors identify the aspects that characterize the importance of developing common terminology in standardization by conducting qualitative content analysis to answer the research question – *why is it important to develop common terminology in standardization?* For this purpose, twenty-one open access research articles, reviews and conference papers are analyzed to determine the main elements that describe the importance of developing common terminology in standardization (see Figure 1). The sources of literature are selected from the databases – SCOPUS and Web of Science. The articles are selected based on the defined criteria*:

- the paper addresses terminology issues in the standards directly; and/or
- the paper addresses terminology issues in areas that are covered in international standardization.

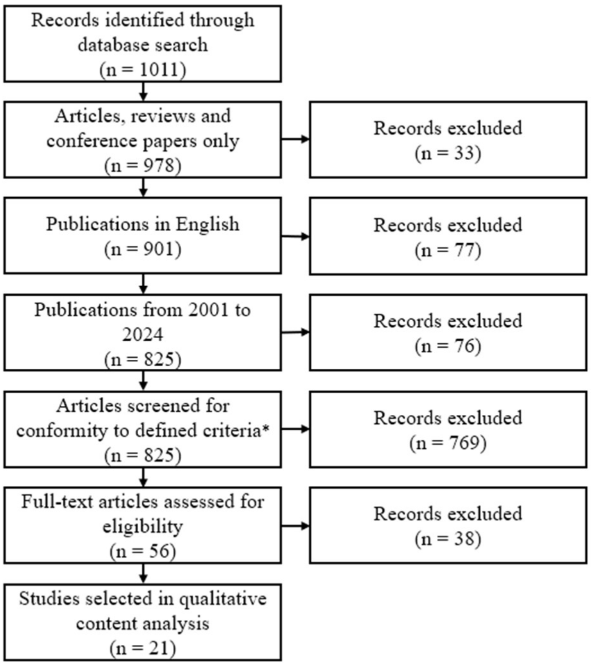

Figure 1 – PRISMA diagram for the selection of sources used in the qualitative content analysis.

In the application of open coding eleven categories characterizing the aspects of the importance of developing common terminology in standardization are created. Through the analysis of terms included in the ISO Online Browsing Platform (OBP) the definitions of the categories are developed (see Table 3). Where the terms are directly applicable to the specific technical standardized area and the relation to the identified categories is indirect, in addition the online Cambridge Advanced Learner's Dictionary & Thesaurus is used.

Table 3 – Definitions of categories developed through the content analysis.

Category	Definition	Source **
To create knowledge	To develop a set of facts, information, truths, principles or understanding acquired through experience or education.	ISO/IEC TS 17027:2014
To communicate knowledge	To convey or exchange information of a set of facts, information, truths, principles or understanding acquired through experience or education.	ISO/TR 19358:2002, ISO/IEC TS 17027:2014
To order knowledge	To place a set of facts, information, truths, principles or understanding acquired through experience or education in an arrangement in accordance with specified rules.	ISO/IEC 2382:2015, ISO/IEC TS 17027:2014
To facilitate exchange of knowledge	To make the storing, accessing, transferring, and archiving of a set of facts, information, truths, principles or understanding acquired through experience or education possible or easier.	ISO/TS 13399-50:2013, ISO/IEC TS 17027:2014, Cambridge Advanced Learner's Dictionary & Thesaurus

Category	Definition	Source **
To eliminate variability	To reduce or completely remove the differences and likeliness to be changed often.	ISO 22442-1:2020, ISO 14617-2:2002, Cambridge Advanced Learner's Dictionary & Thesaurus
To eliminate differential use	To reduce or completely remove the possibility of the application of different purpose for which something is used.	ISO 22442-1:2020, Cambridge Advanced Learner's Dictionary & Thesaurus
To eliminate confusion	To reduce or completely remove a situation where something is interpreted differently, or people do not understand what something is.	ISO 22442-1:2020, ISO 24620-3:2021, Cambridge Advanced Learner's Dictionary & Thesaurus.
To ensure common understanding	To guarantee that the knowledge about a subject is same for a lot of people.	ISO/IEC 18045:2022, Cambridge Advanced Learner's Dictionary & Thesaurus
To ensure uniqueness	To guarantee being the only existing one of its type or, more generally, unusual, or special in some way.	ISO/IEC 18045:2022, Cambridge Advanced Learner's Dictionary & Thesaurus
To ensure adaptability	To guarantee the ability to be changed or modified to make suitable for a particular purpose.	ISO 6707-1:2020, ISO/IEC 18045:2022
To ensure correct interpretation	To guarantee that determining the nature or forming an opinion of an indication based on objective data is performed without error.	ISO 15463:2003, ISO/IEC 18045:2022, ISO 14708-1:2014

** The references to standards are retrieved from: ISO Online Browsing Platform (OBP), available at: *https://www.iso.org/obp/ui*

By examining the terms included in the OBP, it is possible to conclude that the definitions and the meaning of the terms in different areas of standardization differ and are applicable for certain purposes of the subject area. Again, this indicates that it is essential to define the terms and their definitions in different standardization subjects to ensure common understanding and prevent misunderstandings in the application of standards. In order to discover the answer to the research question, the content analysis of the selected articles is carried out and the frequency of the identified categories is recorded. In Figure 2, the results of the frequency of the identified categories are visualized.

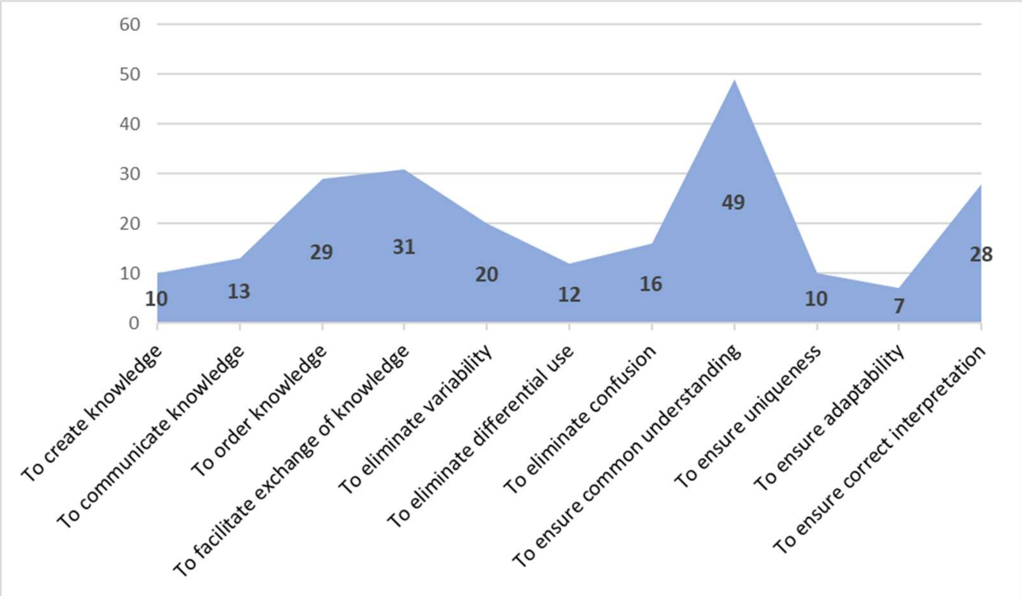

Figure 2 – The frequency of aspects characterizing the importance of the development of common terminology in standardization: the results of qualitative content analysis.

In Table 4, the frequency of appearance of the categories with references to the analyzed publications is summarized.

Table 4 – The frequency of aspects characterizing the importance of the development of common terminology in standardization with references to the sources of literature.

Category	Frequency	Sources
To ensure common understanding	49	Athu, 2012; Bessa et al., 2017; Buhmanna et al., 2019; Bylka and Mroz, 2019; Christensen et al., 2003; Ciobanu, 2012; De Groot et al., 2020; Fujino et al., 2006; Garretson et al., 2016; Gernant et al., 2020; Kim et al., 2010; Kosanke and de Meer, 2001; McClaran et al., 2020; Spink et al., 2019
To facilitate exchange of knowledge	31	Athu, 2012; Auksoriūtė, 2016; Bug et al., 2008; Ciobanu, 2012; De Groot et al., 2020; Gernant et al., 2020; Guerra et al., 2019; Kim et al., 2010; Kosanke and de Meer, 2001; Moss et al., 2003; Spink et al., 2019
To order knowledge	29	Athu, 2012; Auksoriūtė, 2016; Buhmanna et al., 2019; Ciobanu, 2012; De Groot et al., 2020; Fonseca et al., 2020; Kim et al., 2010; Kosanke and de Meer, 2001; Moss et al., 2003; Narayanan et al., 2015; Spink et al., 2019
To ensure correct interpretation	28	Athu, 2012; Ciobanu, 2012; De Groot et al., 2020; Garretson et al., 2016; Gernant et al., 2020; Kim et al., 2010; Kosanke and de Meer, 2001; Spink et al., 2019
To eliminate variability	20	Athu, 2012; Buhmanna et al., 2019; Ciobanu, 2012; Fonseca et al., 2020; Fujino et al., 2006; Garretson et al., 2016; Gernant et al., 2020; Kim et al., 2010; McClaran et al., 2020; Spink et al., 2019
To eliminate confusion	16	Bessa et al., 2017; Buhmanna et al., 2019; Christensen et al., 2003; Ciobanu, 2012; De Groot et al., 2020; Fonseca et al., 2020; Gernant et al., 2020; Kosanke and de Meer, 2001; Moss et al., 2003; Spink et al., 2019
To communicate knowledge	13	Athu, 2012; Auksoriūtė, 2016; Bug et al., 2008; Ciobanu, 2012; De Groot et al., 2020; Fonseca et al., 2020; Garretson et al., 2016;

Category	Frequency	Sources
		Guerra et al., 2019; McClaran et al., 2020; Moss et al., 2003; Spink et al., 2019
To eliminate differential use	12	Athu, 2012; Bug et al., 2008; Buhmanna et al., 2019; Christensen et al., 2003; Ciobanu, 2012; Fonseca et al., 2020; Garretson et al., 2016; Guerra et al., 2019; Kosanke and de Meer, 2001; Spink et al., 2019
To ensure uniqueness	10	Athu, 2012; Buhmanna et al., 2019; Ciobanu, 2012; De Groot et al., 2020; Gernant et al., 2020; Guerra et al., 2019; Fujino et al., 2006
To create knowledge	10	Athu, 2012; Auksoriūtė, 2016; Ciobanu, 2012; Garretson et al., 2016; Kim et al., 2010; Moss et al., 2003; Spink et al., 2019
To ensure adaptability	7	Athu, 2012; Bug et al., 2008; Gernant et al., 2020; Moss et al., 2003

As seen in Figure 2 and Table 4, the aspect that appears the most often when characterizing the importance of developing common terminology in standardization is the necessity to ensure common understanding (frequency: 49), which can be explained by the need for the involved parties in standardization activities to communicate and ensure the development and exchange of information on the basis of mutual understanding of the terms used in the specific field. Here, the importance to facilitate the exchange of knowledge (frequency: 31) is introduced, which can be explained based on the activities of standardization that envisage the exchange of knowledge within the specific area among industry experts all over the world, thus indicating that common terminology can facilitate this exchange by providing a common framework for communicating. The importance of developing common terminology can also be characterized by the necessity to order knowledge (frequency: 29), meaning that a clear set of terms and definitions introduces a definite framework for characterization of aspects within the specific standardization field. Also, the importance of ensuring correct interpretation of the terms used (frequency: 28) is identified to guarantee that the content of standards is based on objective data, thereby promoting accurate development, usage and exchange of data. Other aspects characterizing the importance of developing common terminology in standardization include the elimination of variability (frequency: 20), confusion (frequency: 16) and differential use (frequency: 12) to ensure that the terms used by the involved parties in standardization activities remain as specified, ensure clear understanding of their meaning and are used appropriately within the specific area covered. The importance of the development of common terminology is also associated with communicating knowledge (frequency: 13), meaning that the knowledge can be distributed to parties both within the inner circle of the field of standardization activities in question and for other parties that can obtain the knowledge through the framework of clear, definite terminology of the standardization field. It is stated that "there is no knowledge without terminology"

(Spink et al., 2019) as the importance of developing common terminology in standardization is associated with the creation of knowledge (frequency: 10). Defining new terms and concepts can relate to the development of industries, practices and the changing order within the field in question, therefore the development of knowledge is an integral part of the standards setting process, which requires the use of appropriate terminology. Also, ensuring uniqueness (frequency: 10) can be observed as one of the aspects characterizing the importance of developing common terminology in standardization as distinct, sector-specific terminology ensures a precise framework for communicating in the field. Finally, the ensuring of adaptability (frequency:7) is also correlated with the importance of developing common terminology in standardization as with the constantly evolving industries and the development of new technologies the need to ensure interoperability of systems through adapting terminology to the specific needs of the area in question is introduced.

It can be observed that the importance of developing common terminology is reflected in research of various fields covered by standardization activities as the ongoing development of science and technology and the amount of knowledge acquired introduce the necessity to create mutually understood terms and definitions. A variety of aspects are identified to characterize the importance of common terminology, including the facilitation of mutual understanding, creating a clear framework for information exchange, and ensuring clarity of terms within the field. The aspect of ensuring common understanding is identified as the most pronounced for the development of common terminology, although the study revealed an additional set of aspects that indicate that a strong focus on the definition of terms to be used within the specific standardization field should be put throughout standardization activities to ensure that both the developers and users of standards are able to develop, communicate and understand the terms of the industry correctly.

Although no similar studies that address the importance of common terminology in standardization in general were found during the research process, some authors have identified the importance of standardized terminology within the industries covered in the studies. For example, Törnvall and Jansson (2015) have analyzed the usefulness of standardized nursing terminologies in different fields of application identifying that "the studies included in the analysis described evidence for usefulness rather than effect" which in some cases could also be observed in the course of this study. This indicates that studies on the relevance and effect of developing and applying common terminology in standardization could be expanded through the involvement of standardization experts (standards developers) and standards users, e.g. by the application of expert evaluation method. Also, to evaluate the development of terminology within a set of standards in a specific field, it is possible to conduct an expert survey on the comprehensibility and compliance of the terms included in the standards with the needs of the industry, thereby consequently identifying and defining the necessary improvement measures for addressing terminology development issues in standards development processes in general. This could lead to a more in-depth exploration of the impacts of common terminology in standardization on the operations of different industrial sectors and conformity assessment systems.

CONCLUSIONS

Standardization creates a unified system and understanding of objects, processes, and systems, ensuring the fulfillment of set of purposes among various stakeholders through the following and supporting of modern development trends and innovations, societal expectations and environmental protection, and is an essential basis for conformity assessment, quality, and safety. The concept of standardization and standards are part of research in a wide range of areas covering industrial and social issues. The tendencies of research on standardization identify the growing topicality of this research area, however, standardization is mainly connected to separate subject matters like product and process conformity, assessment methods, management systems and others. The complexity of standardization issues and its diverse coverage in research articles introduces an opportunity for further studies where standardization is the main, general object of analysis, especially as there is an opportunity to develop theoretical foundations for the concept on its own. The study reveals that standardization can be viewed not only from the perspective of its practical contribution to various stakeholders, including quality managers, executors of conformity assessment procedures, representatives of the governmental and nongovernmental sectors, but also has a significant theoretical potential for the academic environment, where, by continuing and expanding the analysis of the concept in theoretical frameworks, it would be possible to create a basis for the development of the practical aspects of the concept. Through the expansion of the analysis of the concept of standardization, it would be possible to view it from a chronological point of view, analyzing what issues standardization has solved historically, how it has developed today and what is the future of standardization. In addition, by analyzing the purpose of standardization for different groups of stakeholders, it would be possible to conduct a comprehensive analysis of measurable indicators of the contribution of standardization, including company efficiency indicators, macroeconomic indicators, environmental impact, and other aspects as studies that cover these issues individually have been conducted before.

The development of common terminology in standardization is important as it ensures common understanding, facilitates the exchange of knowledge, orders knowledge and ensures correct interpretation of terms among the involved parties operating in the areas covered by standardization activities. The aspects characterizing the importance of developing common terminology in standardization also include the elimination of variability, confusion and differential use of terms, the creation and communication of knowledge, as well as ensuring uniqueness and adaptability among terms used in the specific fields. Within the framework of this study, the issue of developing common terminology is considered in a conceptual way, thus it could be a matter of further research, focusing not only on the importance of the development of common terminology in specific standardization sectors, but also on the practical considerations of these activities. The studies could determine the challenges and best practice of terminology development by involving standardization experts of specific industries where standards are crucial for operation. This could lead to a clearer understanding of the broader impact of common terminology on the operation of different industries and the issues of compliance covered by standardization.

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Conditions for Continuous Improvement in the Operation of Manufacturing Enterprises

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STRUCTURED ABSTRACT

Purpose - The article endeavors to achieve the following objectives: 1) delineate the current role and significance of continuous improvement in the operations of manufacturing enterprises, considering an evaluation of the extent to which this concept is implemented; 2) determine how CI is understood and what activities CI is aimed at; 3) ascertain the degree of utilization of improvement methods and techniques; 4) indication of factors hindering the use of CI in manufacturing enterprises in Poland.

Design/methodology/approach - The research comprised two distinct phases. The initial phase involved a comprehensive literature analysis, facilitating the formulation of a structured questionnaire. The subsequent segment employed a quantitative approach, employing the telephone interview technique. A total of 70 manufacturing companies based in Poland actively participated in this research endeavor.

Findings – The undertaken research underscores that continuous improvement (CI) in manufacturing enterprises is primarily used as a principle within quality management and as a management philosophy, while its role in perfecting methods and techniques is less significant. Definitions of CI are mainly understood as actions aimed at fulfilling customer requirements, changing production processes, and implementing pro-ecological changes. The most frequently used CI methods are standardized quality management systems, whereas lean manufacturing and Six Sigma are the least used and considered least effective. Factors hindering CI include ambiguous decision-making and a lack of integration with company strategy, emphasizing the need for strong management leadership.

Research limitations – An inherent limitation of the conducted research pertains to its sample size, which comprised 70 companies exclusively operating within the geographical confines of Poland.

Originality/value - The issues presented in this study represent a novel exploration, as empirical research on these aspects among manufacturing companies in Poland has not been previously

undertaken. This contributes to delineating the present state and developmental trajectory of this approach within the specified context

Keywords: Continuous Improvement (CI), Quality Management, Continuous Improvement Techniques

Paper type: Research paper

INTRODUCTION

The last years of the development of production companies are associated with the search for ways to improve the efficiency of operations as well as the development, aimed to meet customer's expectations. According to Fryer and Ogden (2014) numerous researchers argue that a contemporary organization cannot attain a high level of performance without a fundamental component, namely Continuous Improvement (CI). For example, the analyses conducted in Morocco indicate that companies implementing Six Sigma and Lean Manufacturing have seen improvements in their financial and operational performance. This has resulted in enhanced quality, productivity, waste reduction, and increased revenue compared to firms that do not employ either Six Sigma or Lean Manufacturing (Achibat *et al.*, 2023). Jurburg *et al.* (2019) stresses that companies ought to pursue excellence in both their products and their processes by developing sustainable CI processes. Research on the evolution of this approach indicates both its Japanese and Western roots, related to the principles of Total Quality Management (TQM) (Bhuiyan and Baghel, 2005; Dahlgaard-Park *et al.*, 2013; Sanchez and Blanco, 2014; Suárez-Barraza and Ablanedo-Rosas, 2014). Currently, the term Kaizen, that derives from the Japanese variant of the concept, is alternatively used with CI as a western variant, of not only one of the management principles, but its independent concept (Aoki, 2008). Research conducted by Suárez-Barraza et al. (2011) based on analysis of the various definitions of Kaizen in the academic literature allowed to identify and describe Kaizen from three perspectives:

- Kaizen as a "management philosophy",
- Kaizen as a component of TQM,
- Kaizen as a theoretical principle for improvement methodologies and techniques.

Analyzing the proposed prospects and scientific research conducted in this management area, it can be concluded that the development paths of CI/Kaizen and TQM are very close. According to Marin-Garcia *et al.*, (2008) and Sunder & Prashar (2020), many authors have considered CI as one of the basic tools for implanting production systems based on TQM, Lean Management or Lean, Lean

Production, Six Sigma and the hybrid Lean Six Sigma or World Class Manufacturing. Suárez-Barraza and Ablanedo-Rosas (2014) point out that quality practice is a significant driver towards a CI philosophy. Pérez-Rave *et al.* (2023) highlight that CI, understood today as: philosophy, management style, process and method, requires the use of a combination of both soft and hard factors. However, research carried out by (Dahlgaard-Park, 2011) confirms that CI is recognized as one of the five core principles of TQM, which is consistent with the second perspective proposed by (Suárez-Barraza *et al.*, 2011). According to Singh and Singh (2015) TQM and Kaizen are interdependent. Kaizen is included among Deming's principles, so this makes it a subset of TQM.

Because of the expansive nature of the CI domain, various interpretations of the concept exist in academic literature. Although they share similarities, each emphasizes different aspects (Sanchez-Ruiz *et al.*, 2020). CI can be defined as improvement initiatives that increase successes and reduce failures or progressive amendment involving all company's employees (Sanchez and Blanco, 2014). CI is also referred to as pervasive and continuous efforts, beyond the standard defined participants' roles in order to identify and achieve results, which contribute to the achievement of organizational goals (Brunet and New, 2003). Bhuiyan and Baghel (2005) studying the history of CI presented a range of definitions from other leading authors. Singh and Singh (2015) made an overview of the history and existential research on CI, but they cover the period before 2012. Swinehart and Green (1995) describe CI as the final ultimatum for building an organisation belonging to the 'a World-Class' group, while research on the application of the concept of CI in countries such as Japan, Australia, Sweden, Great Britain, Spain, Belgium or China confirm that it is implemented in enterprises worldwide (Boer and Gertsen, 2003; Dabhilkar *et al.*, 2007; Marin-Garcia *et al.*, 2008). As indicated above, CI is also seen as a component of TQM (Dahlgaard-Park, 2011; Suárez-Barraza *et al.*, 2011). Research also indicates different approaches to the classification of CI methods (Ehie and Sheu, 2005; McLean and Antony, 2014; McLean *et al.*, 2017; Singh and Singh, 2015; Suárez-Barraza *et al.*, 2011). According to this research, the basic methodologies (also called CI programs) include: TQM, Lean manufacturing, Six Sigma, the Balanced Scorecard, Lean Six Sigma, Theory of constraints, standardization and process management and the basic techniques which are presented in section 2 (*Measurement and data analysis*).

Approaching CI from such perspectives prompts reflection on the application of the theory among practitioners who introduce and use this approach in business management. Although CI is not a new concept, research on it is state-of-the-art and is still insufficient. According to Carnerud *et al.* (2018) there is a need to strengthen and clarify Kaizen's theoretical basis and its relationship to CI. The results from their study highlight the need to address and clarify epistemological, terminological and theoretical issues. Researchers point out that this is not just an academic problem. Clarifying the theoretical basis of the concept is necessary to successfully implement the concept in enterprises. All the more, that various methodologies and techniques were identified in the literature for applying Kaizen in companies. These included Kaizen Blitz, Gemba-Kaizen workshops, Kaizen Office, Lean-Kaizen Six Sigma right through to those based on staff suggestion schemes such as Kaizen Teian or broader approaches such as TQM. Research, conducted in Mexican organization's, demonstrates that quality practice is a significant driver towards a CI philosophy. So in depth study is still needed to clarify the nature and scope of Kaizen (Suárez-Barraza *et al.*, 2011). If Kaizen and CI are to take advantage of what appears to be an increasing interest in this topic, increased theorization is required (Carnerud *et al.*, 2018).

Studies on the evolution of CI (Sanchez and Blanco, 2014) show the existence of regional differences in research on CI, the predominance of the case study and the survey as research methodologies, and the positioning of Total Quality Management and Business Excellence as the leading scientific publication in continuous improvement areas. Research on various aspects of the application of the CI concept was conducted among enterprises operating in Italy (Corso *et al.*, 2007) , in the Netherlands (Middel *et al.*, 2007), Spain (Jaca *et al.*, 2012; Jurburg *et al.*, 2017; Sanchez-Ruiz *et al.*, 2020), Ireland (McDermott *et al.*, 2022), UK (Fannon *et al.*, 2022), in Australia (Terziovski and Power, 2007), Brazil (Oprime *et al.*, 2011), in Mexico and Ecuador (Alvarado-Ramírez *et al.*, 2018). A comparative study on the critical failure factors was conducted in the USA, UK, China and India (Sunder and Prashar, 2020). Researchers analyzed primarily on issues relating to critical failure factors (McLean and Antony, 2014; Sanchez-Ruiz *et al.*, 2020), employee motivation in CI activity CI (Jurburg *et al.*, 2017), CI tools (Corso *et al.*, 2007; Middel *et al.*, 2007) and enablers of CI programmes (Jaca *et al.*, 2012).

To the best of the author's knowledge, however, the development of CI was not researched in manufacturing companies operating in Poland, no analyzes have been carried out so far to show the role and level of application of CI methods and techniques. The conducted research allows to fill in the indicated research gap. The results indicate the level of the principles application, methods and techniques of CI in the surveyed production companies.

Therefore, taking into account the presented research context, the aim of the article is to indicate the current role and importance of CI in the operation of Polish production enterprises and the assessment of the degree of application of improvement methods and techniques. Identification of the research gap prompted the authors to raise the following research questions:

- RQ1. What are the current role of CI in Polish manufacturing enterprises and to what extent is it implemented?
- RQ2. How is CI understood by representatives of manufacturing enterprises in Poland?
- RQ3. What CI methods and techniques are used and what is their level of effectiveness in Polish manufacturing enterprises?
- RQ4. What factors hinder the application of the CI approach in Polish production organizations?

The remainder of this paper is organized as follows: section 2 describes the research methodology (research model, data collection, measurement and data analysis), section 3 contains research results in relation to the research questions and lastly section 4 contains conclusions resulting from the conducted research.

RESEARCH METHODOLOGY

Research model

The research employed a quantitative methodology, employing the Computer-Aided Telephone Interview (CATI) technique, during the data collection phase in November 2020. This approach was chosen due to its efficacy in conducting supra-regional investigations, facilitating access to a sizable and geographically diverse respondent pool while ensuring a swift implementation timeframe. The survey was structured in a cascade format, commencing with a pilot study involving representatives from manufacturing companies. The primary objective of this preliminary phase was to validate the appropriateness of the research instrument, including its structure and the comprehensibility of the questions embedded within the survey questionnaire. The standardized interview questionnaire utilized in the study comprised four substantive questions, formatted as closed queries (with predetermined response options) or constructed on a scale basis. Additionally, the questionnaire incorporated five metric questions designed to characterize both the surveyed individuals and the enterprises they represented. The Cronbach's alpha reliability coefficient, a metric assessing the internal consistency of the questionnaire used in the study, yielded a highly reliable result of 0.981 on a scale ranging from 0 to 1. A higher coefficient value signifies greater questionnaire reliability.

The formulation of the inquiry pertaining to the role of CI, along with the suggested response options, was derived from the three Kaizen perspectives proposed by Suárez-Barraza *et al.* (2011), as previously presented. The articulation of possible responses to the query assessing comprehension of CI was crafted through an examination of the CI definition as expounded by Sanchez and Blanco (2014). Furthermore, the formulation of potential responses to queries addressing the principles, values, as well as improvement methods and techniques associated with CI as well as factors hindering the application of CI was meticulously developed through a comprehensive analysis of relevant literature (McLean and Antony, 2014). The full scheme of the conducted study showed in Figure 1.

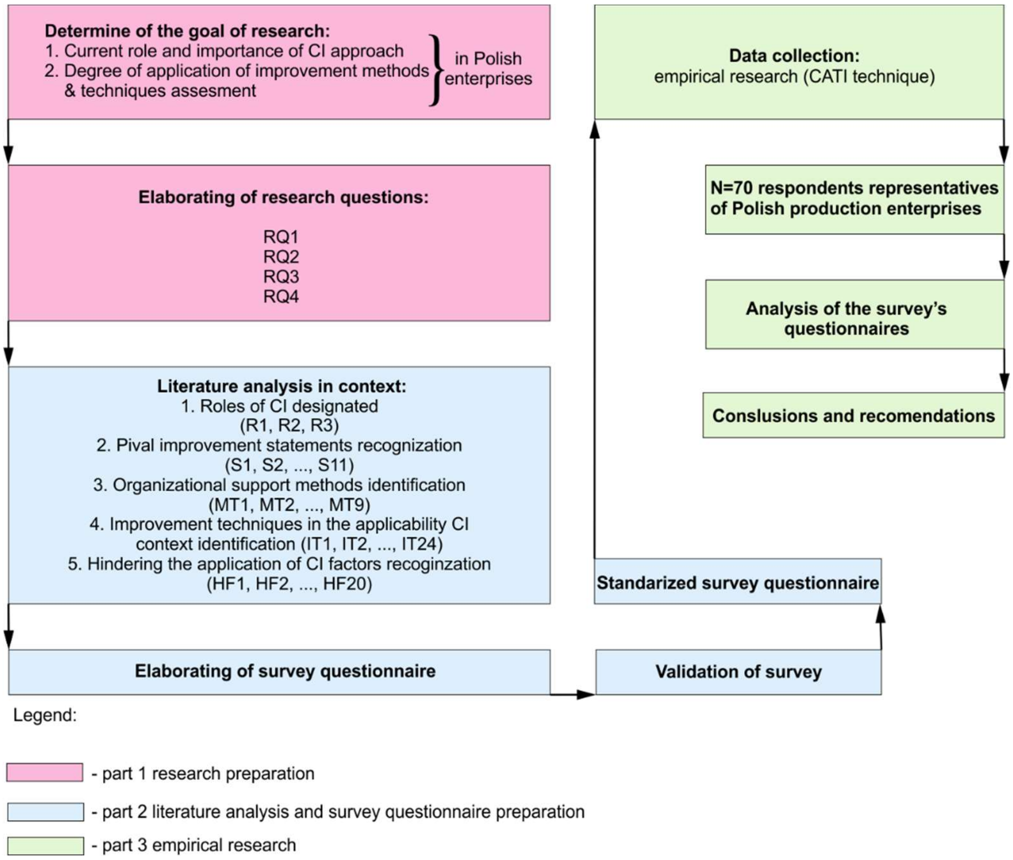

Figure 1 – Scheme of conducted research.

Source: own elaboration

Data collection and research sample characteristics

A total of 70 individuals participated in the survey, representing Polish production enterprises with responsibilities in quality management, the implementation of CI methods, organizational management. The survey aimed to fulfill the objective outlined in the article's introduction. The criterion for selection was the engagement of the enterprise in production activities, with particular emphasis on the significance of the respondent's indicated role. Among the respondents, representatives specializing in quality management constituted the majority, comprising 37.1% of the total. Individuals in senior management positions accounted for a quarter of the participants (25.7%), with leaders, coordinators, and quality management specialists making up an equivalent percentage

(25.7%). Additionally, participants included plenipotentiaries for the integrated management system (8.6%) and members of the management board (2.9%).

The preponderance of surveyed enterprises, specifically over 84%, falls within the category of medium-sized enterprises, characterized by a workforce ranging from 50 to 249 employees. Small enterprises, employing 10 to 49 individuals, constitute one-tenth of the surveyed entities. Large-scale corporations with over 249 employees represent a modest share, comprising less than 6% of the research sample. Within the respondent pool, the electromechanical industry, encompassing sectors such as metal, machinery, precision, transportation, electrical engineering, and electronics, demonstrated dominance, accounting for 40% of the surveyed enterprises. Other notable sectors included the wood and paper industry, representing 30% of the surveyed companies, the food industry comprising 20%, and the cosmetics industry, accounting for every tenth surveyed enterprise.

Measurement and data analysis

The authors utilized a comprehensive literature review to formulate the inquiries for the survey employed in their empirical investigation, with the primary focus on assessing enhancement initiatives within manufacturing enterprises. The resultant survey was meticulously structured into four distinct sections, each dedicated to the scrutiny of pertinent aspects, namely: the roles ascribed to CI, assertions encapsulating the CI domain, the methodologies and techniques applied within the CI framework, including enhancement methodologies within the purview of CI, as well as factors hindering the application of CI.

In the pursuit of comprehending the designated roles of CI, conceivable answers to inquiries concerning these roles encompass:

- the philosophy of managing the entire enterprise (R1),
- the principle implemented as part of quality management (R2),
- the principle underlying the application of improvement methods and techniques such as Kaizen, Lean, Six Sigma (R3).

The respondents evaluated each principle using a 6-point scale (ranging from 0 for non-applicable to 5 for very high) to gauge both the extent of implementation and the level of significance.

The survey's second section delved into statements encompassing the realm of CI. An examination of the literature facilitated the recognition of pivotal improvement statements integral to the establishment and sustenance of enterprises' CI systems. These elements encompass:

- initiates the introduction of radical innovations in processes (S1),
- focused on pro-ecological changes in processes (S2),
- focused on pro-ecological changes in products (S3),

- focused on changes mainly in the production processes (S4),
- first and foremost a sustainable improvement culture that's aims to eliminate process losses (S5),
- aimed at reducing the amount of waste (S6),
- aimed at identifying new areas of improvement (S7),
- set of procedures to help improvement implementation (S8),
- focused on changes in meeting the requirements of internal customers (S9),
- focused on changes in meeting the requirements of external customers (S10),
- part of the organization's strategy (S11).

To gauge the degree to which fundamental improvement practices are employed within the organization, a 6-point scale was employed. Here, 0 signifies non-applicability, 1 denotes minimal implementation, 2 indicates selective usage in specific company areas, 3 represents widespread adoption within the company albeit with varying levels of commitment, 4 implies substantial utilization with active participation of employees across all company tiers, and 5 underscores comprehensive adoption with highly engaged employee involvement at all organizational levels.

In the examination of the organizational structure concerning the improvement activities undertaken, as addressed in the third section of the survey, the analysis was grounded in the recognition that endeavors associated with CI within an enterprise necessitate explicite organizational support. This support may encompass the following methods:

- Lean Manufacturing (MT1),
- Six Sigma (MT2),
- Lean Six Sigma (MT3),
- Quality Management (MT4),
- Standards QMS (MT5),
- Integrated Management System (MT6),
- Balanced Scorecard (MT7),
- Process Management (MT8),
- Theory of Constraints (MT9).

In addition, in the context of examining the organizational structure of the improvement activities undertaken, an important issue seems to be the use of appropriate improvement techniques in the context of the applicability of the CI approach, which include:

- CI office (IT1),
- Coaching (IT2),
- Benchmarking (IT3),

- Self-evaluation (IT4),
- Cooperation with suppliers (IT5),
- Process mapping (IT6),
- Value Stream Mapping (VSM) (IT7),
- 8D (IT8),
- Control chats (IT9),
- Statistical Process Control (SPC) (IT10),
- Design of Experiment (DoE) (IT11),
- CI workshops (IT12),
- Failure Mode and Effect Analysis (FMEA) (IT13),
- Plan Do Check Act (PDCA) (IT14),
- Hoshin Kanri (IT15),
- Visual Management (IT16),
- 5S (IT17),
- Cross Functional Management (IT18),
- Total Flow Management (IT19),
- Just in Time (JIT) (IT20),
- Kanban (IT21),
- Single Minute Exchange of Die (SMED) (IT22),
- Jidoka (IT23),
- Total Productive Maintenance (TPM) (IT24).

Concerning the two aforementioned research areas, the authors utilized a 5-point scale, wherein respondents were instructed to assign values ranging from 1 denoting "to a very small extent," 2 indicating "to a small extent", 3 signifying "to an average extent," 4 representing "to a large extent," and 5 corresponding to "to a very large extent." This scale facilitated a nuanced evaluation of the extent to which respondents perceived or experienced the elements under consideration.

An important issue in the context of the application of selected approaches, i.e. CI, is the analysis of factors that prevent its application or theses that contribute to its ineffectiveness. Therefore, based on a thorough analysis of the literature, factors hindering the application of CI were defined, which may include:

- lack of time (HF1),
- lack of knowledge or experience on CI (HF2),
- lack of training on CI (HF3),

- lack of a proper management system (HF4),
- lack of commitment from managers (HF5),
- lack of employee involvement (HF6),
- different levels of employee involvement (HF7),
- lack of employee motivation system (HF8),
- lack of a system to monitor proposed improvements (HF9),
- lack of proper resources (HF10),
- employees resistance to change (HF11),
- lack of income from the application of CI (HF12),
- lack of adequate measurements in processes (HF13),
- focus on the number of improvements rather their effects (HF14),
- lack of integration of CI goals and company strategy (HF15),
- lack of learning from mistakes approach (a culture that is intolerant of errors) (HF16),
- lack of information about problems or incorrect analysis of information (HF17),
- lack of information about improvement goals or ambiguity of goals (HF18),
- ambiguity of decisions (it isn't understood why the change is needed) (HF19),
- lack of formal problem-solving procedures/processes (HF20).

Respondents assessed the degree of influence of the above-mentioned CI hindering factors on operations in the enterprise. In this regard, the authors used a 5-degree scale, in which respectively: 0 means no impact, 1 to a very low degree, 2 to a low degree, 3 to a medium degree, 4 to a high degree, 5 to a very high degree.

RESULTS

The role and definition of CI

The initial segment of the study focused on aspects pertaining to the role of CI within the scrutinized organizations. Participants were prompted to articulate their comprehension of this process and assess the extent of its integration into their enterprises through various methodologies and enhancement techniques. CI within the respondents' enterprises was assessed within the framework of three distinct dimensions: as a foundational philosophy guiding enterprise management, as a principle integrated into quality management practices, and as a fundamental principle guiding the application of improvement methodologies and techniques (following the approach delineated by (Suárez-Barraza *et al.*, 2011)). The data revealed that, predominantly, respondents indicated a minimal or negligible role for CI as the guiding principle underpinning the application of improvement methodologies and techniques (64.2%; combining the answers „0” and „1”). Conversely, the respondents commonly identified CI as playing a significant or highly significant role when implemented within quality management practices (44.3%; combining the answers „4” and „5”) (Figure 2).

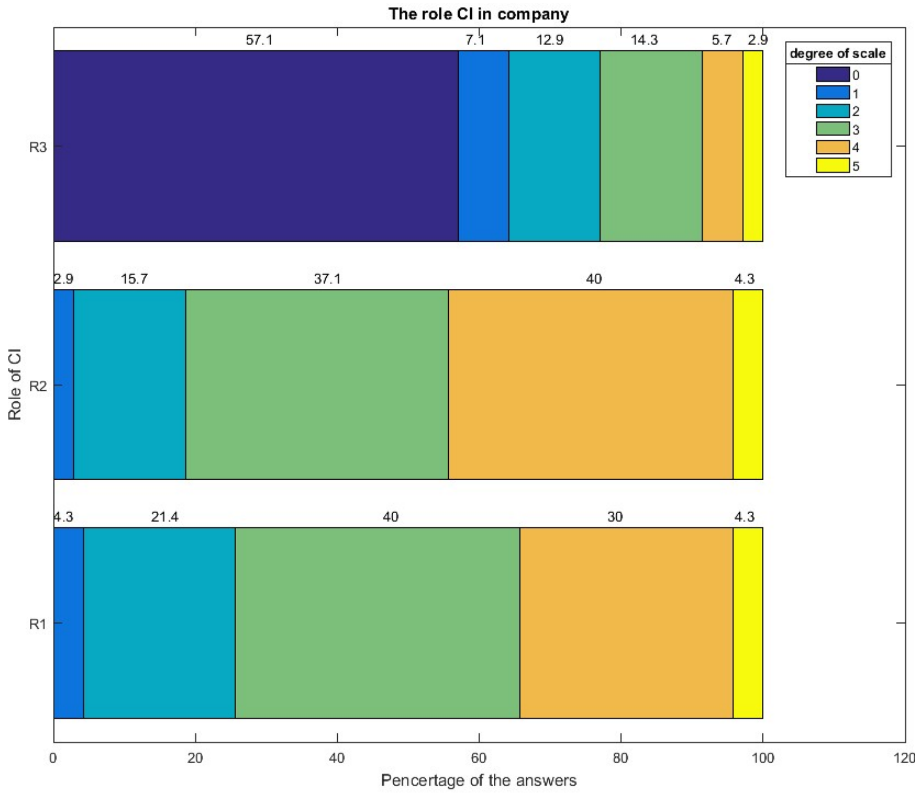

Figure 2 – The role of CI in the enterprise, scale $< 0; 5 >$; $n = 70$.

Source: own elaboration

A parallel trend emerges concerning the implementation of continuous improvement across the aforementioned three dimensions. The data indicates that a notable absence or minimal implementation predominantly occurs when continuous improvement serves as the guiding principle for the application of improvement methodologies and techniques (62.9%; combining the answers „0” and „1”). Conversely, continuous improvement as a management philosophy permeating the entire enterprise and as a principle within quality management are implemented with similar frequency (44.3% and 41.4% respectively; combining the answers „4” and „5”) (Figure 3).

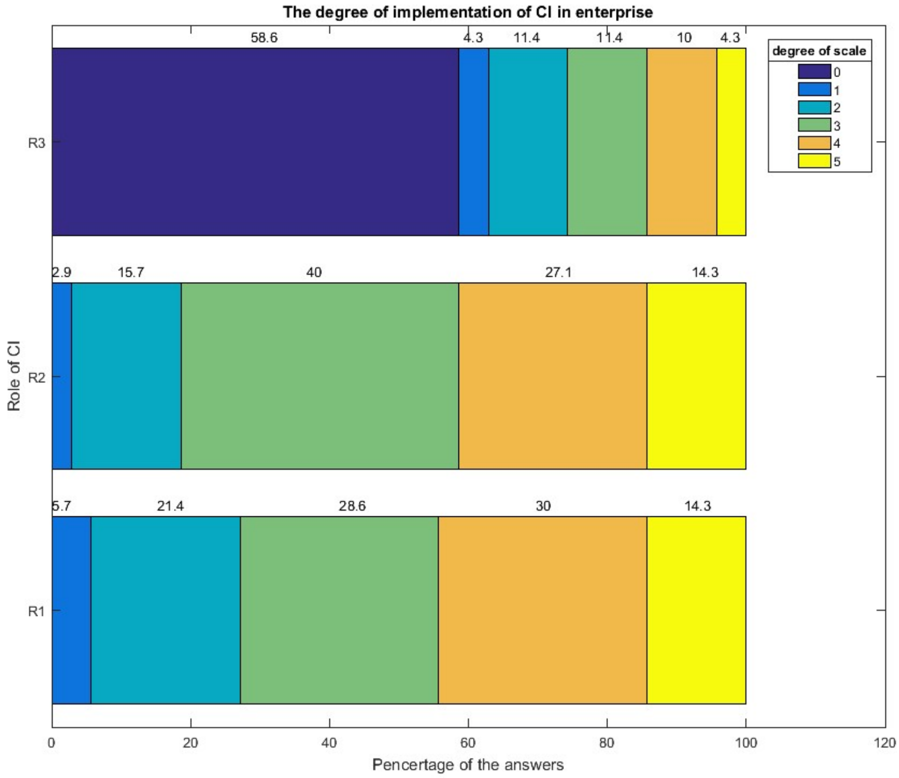

Figure 3 – The degree of implementation of continuous improvement in the enterprise; scale $< 0; 5 >; n = 70$.

Source: own elaboration

It is pertinent to comprehensively assess all responses garnered in this inquiry. To facilitate this, the arithmetic mean measure (m) can be employed, offering an estimate of the mean rating concerning the role and implementation of CI within the company across various approaches. According to the respondents, CI is primarily perceived as a principle integrated within quality management practices ($m = 3.27$), followed by its role as a foundational philosophy guiding the management of the entire enterprise ($m = 3.09$). Conversely, the least significant role attributed to CI pertains to its function as the basis for the application of improvement methodologies and techniques ($m = 1.13$).

The degree of implementation of CI within specific areas of the surveyed enterprises was also evaluated using a six-point scale, where 0 denoted "not implemented" and 5 signified "implemented to a very large extent". The distribution of responses mirrored the assessment of CI's role in companies: the highest level of implementation was observed in its application as a principle integrated within quality management practices ($m = 3.34$). Conversely, to a slightly lesser extent ($m = 3.26$), CI was implemented as the overarching management philosophy of the enterprise. Additionally, respondents were queried regarding their understanding of continuous improvement. A majority of respondents concurred with statements asserting that continuous improvement primarily focuses on changes in the production process (64.2%; combining the answers „strongly agree” and „rather agree”), as well as on pro-environmental alterations in products (55.7%; as above). Conversely, the assertion that CI is an integral element of the organization's strategy garnered the least agreement from respondents (21.5%; combining the answers „strongly disagree” and „rather disagree”). The definitions provided elicited nearly equivalent levels of accuracy from respondents, with the mean agreement level ranging from $m = 3.36$ (stating that CI initiates the introduction of radical innovations in processes) to $m = 3.61$ (asserting that CI is directed towards fulfilling external clients’ requirements). Factors such as meeting the expectations of external customers, enhancing production processes, and implementing pro-ecological changes in products were most frequently cited by respondents as determinants of continuous improvement within a company. However, respondents' responses varied between a median of 3 ("I don't have an opinion") and 4 ("rather agree"). Respondents displayed a lack of clear consensus when defining CI as a culture of perpetual improvement aimed at eliminating losses in processes, activities targeting pro-ecological changes in processes, and initiating the introduction of radical innovations in processes

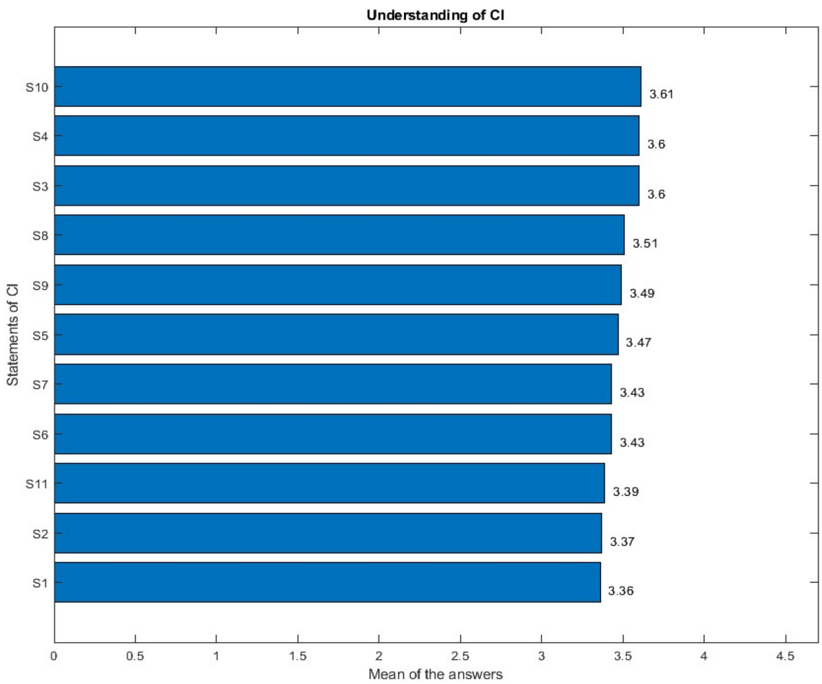

Figure 4 – Understanding of the continuous improvement; scale $< 1; 5 >$; $n = 70$.

Source: own elaboration

The CI methods and techniques

The conducted survey revealed that respondents predominantly indicate the standardized quality management system (such as ISO 9001 and industry standards) as the most frequently utilized method of CI in the surveyed organizations (97.1%), followed by quality management practices (81.4%). Furthermore, these methods garnered the highest level of positive ratings, with 52.8% and 48.6% of respondents respectively rating them as "4" or "5" on a five-point scale. Conversely, methods receiving the lowest ratings (combining answers "1" and "2") in terms of utilization levels include the balanced scorecard (25.7%) and the theory of constraints, process management, and integrated management systems (quality, environment, safety), each receiving ratings of 24.3%. Standardized quality management systems and quality management practices emerge as the most frequently utilized and highest-rated methods of CI in terms of effectiveness. Approximately 54.2% and 50.0% of respondents respectively awarded ratings of "4" or "5" for these methods. Conversely, the strategic scorecard received the lowest scores, with 27.2% of respondents providing positive ratings, followed by the theory of constraints at 22.9%. Additionally, the least frequently used methods include the Lean Manufacturing concept and quality management according to the Six Sigma methodology. The respondents' statements regarding the effectiveness of individual methods exhibit a similar degradation: quality management in general ($m = 3.39$) and quality management in accordance with standardized systems ($m = 3.51$) are rated the highest. Conversely, respondents deem Lean Manufacturing, Six Sigma, and Lean Six Sigma to be the least effective (Figure 5).

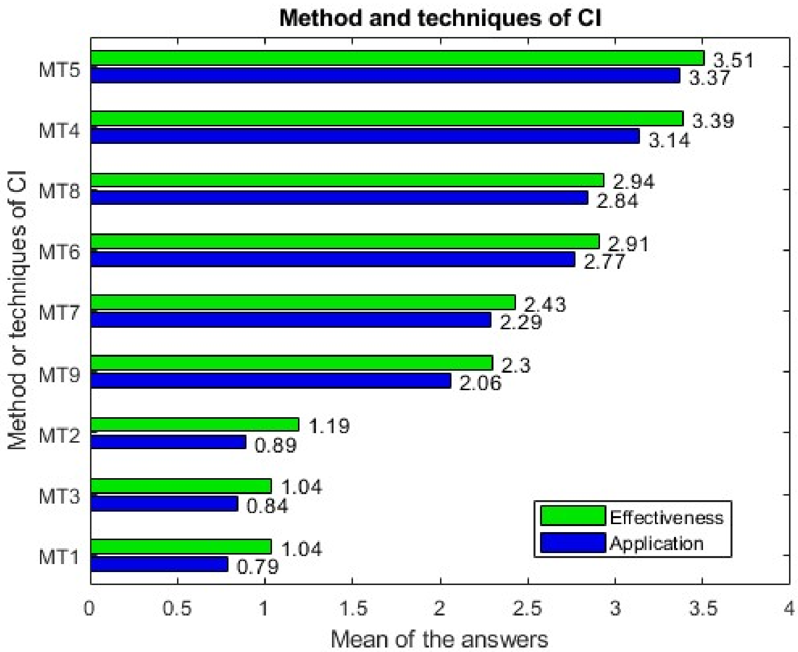

Figure 5 – Degree of application and effectiveness of continuous improvement methods; scale $< 0; 5 >$; $n = 70$

Source: own elaboration

The frequency of applying improvement techniques in the surveyed companies was another topic of discussion. The degree of application of specific techniques was delineated using a six-point scale, like in to previous questions (Figure 6). It was observed that the frequency of employing particular, specific techniques related to CI within the enterprise was slightly lower compared to methods. The most frequently utilized improvement techniques include the activity of a CI unit or office (30.0%) and CI workshops (25.7%; combining answers „4” and „5”). Conversely, techniques least applied in surveyed companies include the 8D Report (30.0%) and Jidoka - autonomization (25.7%). The majority of techniques, when considering the mean grade, were found to be applied to a very small or small extent. Notably, systematic self-assessment ($m = 3.03$) and cooperation with suppliers ($m = 2.99$) were employed to a mean extent. Classical quality management methods, such as FMEA ($m = 2.36$), experimental design ($m = 2.26$), SPC ($m = 2.31$), and Shewart control charts ($m = 1.91$), were utilized to a limited extent. Additionally, it was found that surveyed companies moderately often have departments or units responsible for CI ($m = 2.94$). Conversely, techniques such as the Hoshin Kanri strategic planning process ($m = 1.50$) and the PDCA matrix are infrequently used in surveyed enterprises. Production management techniques, like the Kanban system ($m = 1.73$) or inventory reduction through Just in Time production ($m = 1.76$), are also rarely employed.

The analysis of the results indicates that the surveyed enterprises understand the role of CI primarily as the principle implemented as part of quality management and the philosophy of managing the entire enterprise. Therefore, the standardized quality management system was indicated as the basic continuous improvement program. The next ones are Quality Management and Process Management. The focus on these programs may result in low levels of application of methods such as Lean Manufacturing, Six Sigma, and Lean Six Sigma. This also applies to CI techniques, for example: Hoshin Kanri, PDCA, Kanban, 8D, Jidoka or TPM. Research results Kucińska-Landwójtowicz and Czabak-Górska, (2022) indicate that both the application of the principles and values of CI and the key CI practices are areas that require support and development. The consequence of this may be a low level of use of CI methods and techniques. It is worth emphasizing that the research was conducted primarily (84%) in medium-sized enterprises, which may also influence organizational behavior regarding continuous improvement and difficulties associated with its implementation. Similarly, Antony and Gupta (2019) point out that the impact of such initiatives as Lean, Six Sigma and Lean Six Sigma on business performance is skewed towards either untimely termination or ultimate failure.

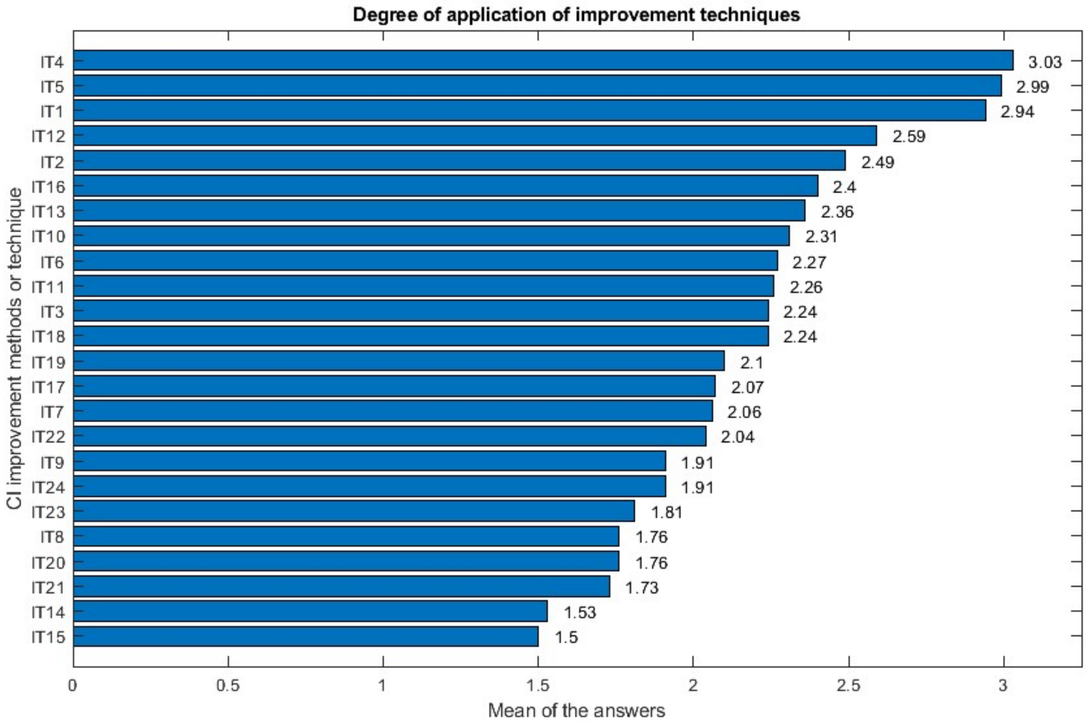

Figure 6 – Degree of application of improvement techniques; scale $< 0; 5 >$; $n = 70$.

Source: own elaboration

The hindering factors application of CI

The factors most often indicated as most hindering an enterprise's CI process were (Figure 7): lack of time (20.0% with a combination of responses "4" and "5") and lack of information about improvement goals or ambiguity of goals (17.1%). The least hindering factors with the least negative impact on the CI process at the enterprise were, respectively: lack of knowledge or experience of CI (64.3% when combining responses "1" and "2") and focus on the number of improvements rather their effects (58.6%).

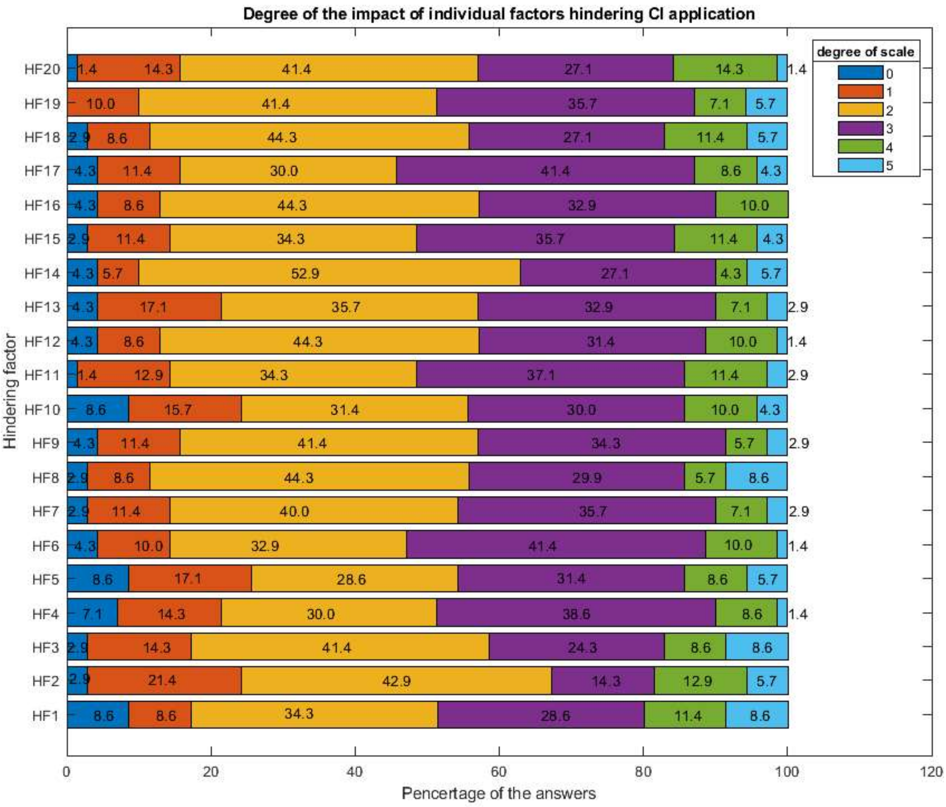

Figure 7 – Impact of individual hindering factors on CI application at the enterprise; scale $< 0; 5 >$; $n = 70$.

Source: own elaboration

In the case of the analysis of barriers to CI process applicability, ratings were even, ranking between low and medium degrees of influence. Analyzing the respondents' answers (Figure 8), it can be pointed out that the three factors hindering continuous improvement had the relatively lowest impact ($m = 2.30$), i.e.: lack of CI knowledge or experience, lack of adequate resources in the company, and insufficient measurements in the company's processes. In contrast, the factors considered to have the most hindering effect on CI included: the lack of integration of continuous improvement goals with the company's strategy ($m = 2.54$), as well as ambiguity in decision-making and lack of understanding of the need for change among employees ($m = 2.57$).

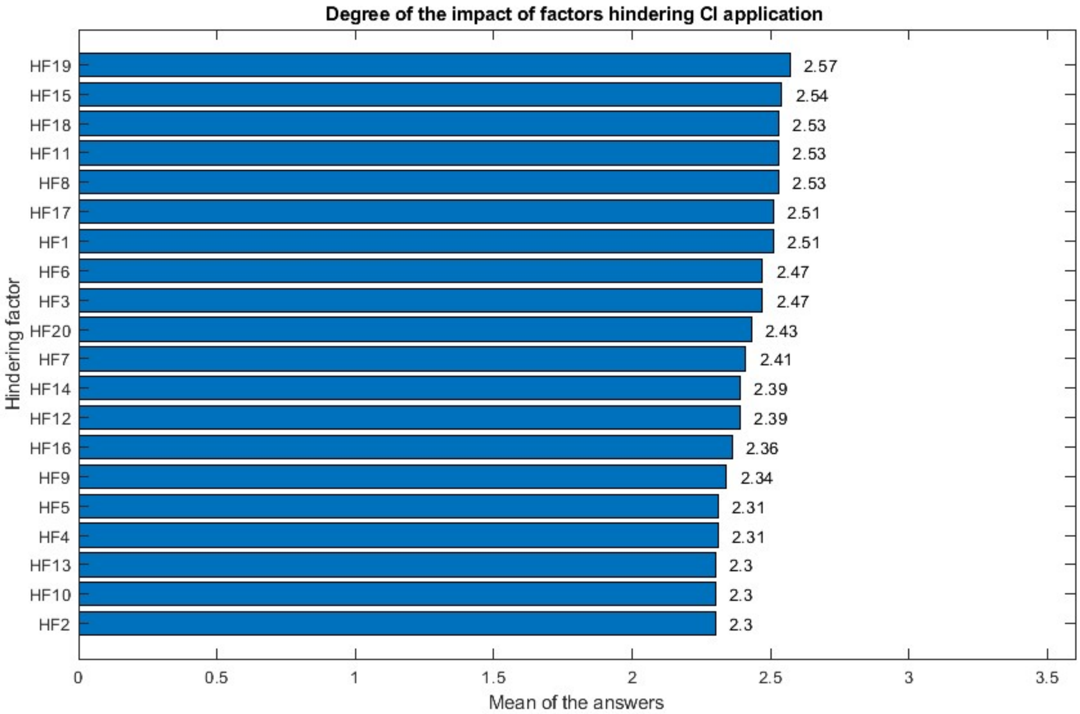

Figure 8 – Assessment of the impact of factors hindering CI application on enterprise operations; scale $< 0; 5 >$; $n = 70$.

Source: own elaboration

CONCLUSIONS

The first part of the study to determine the current role and significance of continuous improvement in the operations of manufacturing enterprises indicates that, CI is primarily a principle implemented as a part of the quality management, and secondly, a philosophy of the management of the entire enterprise. The least important role of continuous improvement is, on the other hand, providing the basis for the application of perfecting methods and techniques. The distribution of responses regarding the degree of the individual CI areas' implementation in the surveyed enterprises was similar to the assessment of the role of continuous improvement: the highest level of implementation concerned its application as a principle implemented within quality management, and to a slightly lesser extent it was implemented as a philosophy of enterprise management. This refers to the second and first perspectives proposed by the approach represented by Suárez-Barraza et al. (2011) as well as to research of Bhuiyan and Baghel (2005), Dahlgaard-Park et al. (2013), Sanchez and Blanco (2014) and Suárez-Barraza and Ablanedo-Rosas (2014).

The presented definitions of CI turned out to be almost equally accurate for the respondents, while CI is primarily understood as an action aimed at: changes in fulfilling the requirements of external customers, changes mainly in the production process, pro-ecological changes in products.

The conducted survey showed that the respondents indicated that the most frequently used methods of continuous improvement in the surveyed organizations are the standardized quality management system and quality management. The standardized quality management system and quality management are also the most frequently used and the highest rated methods of continuous improvement in terms of the level of effectiveness. The least frequently used in the surveyed companies are the concept of Lean Manufacturing, Six Sigma and Lean Six Sigma. They were also identified as the least effective. The research regarding the application of improvement techniques showed that, according to the respondents, the most frequently used improvement techniques are: the activity of a unit or bureau of a continuous improvement as well as the continuous improvement workshops. Enterprises use systematic self-assessment and cooperation with suppliers to an average extent. Classic methods of quality management, i.e: FMEA, experimental design, SPC and Shewart control charts are applied to a small extent. The techniques that most often are not applied at all in the surveyed companies are: the 8D Report and Jidoka. The Hoshin Kanri strategic planning process and the Plan-Do-Check-Act (PDCA) matrix are the least frequently used in the surveyed enterprises. Techniques related to production management, such as the Kanban system or the inventory reduction through the Just in Time approach, are also rarely used.

Analysis of the impact of the indicated factors hindering CI activities indicates that their level of impact is equal. However, attention should be paid to two areas strongly related to management activities in the company. The ambiguity of the decisions made, which results in a lack of understanding of the need to introduce changes, means that the management staff is not prepared to implement the CI approach. This is also indicated by the second factor with a higher rating, which is the lack of integration of continuous improvement goals with the company's strategy. This refers to the McLean and Antony (2014) approach, which indicates management leadership as one of the areas of influence on the success of CI. Identifying factors hindering the implementation of CI provides company managers with insights on what to avoid, thereby reducing the risk of failure in CI implementation.

The findings of this study have several important implications for both practice and theory. Implications for practice: enhanced focus on quality management, management training and leadership and method selection and application. Manufacturing enterprises should prioritize the implementation of CI as a core principle within their quality management systems. This focus can lead to improved customer satisfaction, more efficient production processes, and greater environmental sustainability. Given the identified barriers to CI, such as ambiguous decision-making and poor integration with company strategy, it is crucial for companies to invest in management training programs. Strengthening leadership skills and aligning CI goals with strategic objectives can enhance the effectiveness of CI initiatives. Enterprises should critically assess the effectiveness of various CI methods. Emphasizing the use of proven methods like standardized quality management systems and considering the selective application of techniques like lean manufacturing and Six Sigma, based on specific organizational needs and contexts, can optimize CI efforts.

On the other hand, the following implications for the theory can be pointed out: integration with strategic management and barriers identification to CI implementation. The findings highlight the critical intersection between CI and strategic management. Future theoretical models should incorporate factors related to decision-making clarity and strategic alignment to better predict CI success. The identification of specific barriers to CI offers a valuable contribution to the theoretical discourse on CI. By understanding these obstacles, researchers can develop more robust models and frameworks that address the challenges faced by manufacturing enterprises.

The limitation of the conducted research is the fact that it was conducted on a sample of 70 companies. However, they allowed us to outline the situation regarding the use of CI in manufacturing enterprises in Poland. They also provide the basis for expanding research on a larger number of enterprises, which will allow in the future to present a full diagnosis in the area of CI application.

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Unlocking the potential of Control Charts for patient injected doses in Nuclear Medicine procedures

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STRUCTURED ABSTRACT

Purpose – To showcase the importance of Statistical Process Control (SPC) in detecting and preventing errors in radiopharmaceutical dose dispensing in Nuclear Medicine imaging techniques, such as Positron Emission Tomography with Computed Tomography (PET/CT).

Design/methodology/approach - Retrospective analysis was conducted on anonymized data from 3003 patients who underwent [18F]fluoro-2-desoxy-D-glucose (2-[^{18}F]FDG) PET/CT procedures between January 3, 2020, to December 30, 2021, at a Portuguese hospital. Control Charts were utilized to monitor the administered activity of 2-[^{18}F]FDG between patients, and to monitor the 2-[^{18}F]FDG PET/CT examination days.

Findings – Contrary to initial belief, the dose dispensing system is not the sole source of dose dispensing errors. Errors related to communication, as well as administering the dose to the patient before or after the scheduled time also contribute to this unwanted event. It was also found that the technologists sometimes request a dose to the system that is different than the recommended one, also resulting in dispensing errors. Through the control charts application, it was found that the process lacks capability to meet technical specifications.

Research limitations/implications – The findings of this study are limited as they are predicated on the research of a single case study.

Originality/value – SPC in Nuclear Medicine departments allows for an early detection of the dose dispensing errors, preventing its occurrence, and thus improving the dose dispensing process performance. To the best of our knowledge, no other study demonstrated how Control Charts can be a valuable tool in Nuclear Medicine Departments (much less in the dose preparation process).

Keywords: Statistical Process Control, Control Charts, Positron emission tomography/computed tomography; Radiation protection.

Paper type: Research paper.

INTRODUCTION

Considered one of the scourges of the 21st century, cancer is the second leading cause of death in the world, responsible for approximately 10 million deaths in 2020 (World Health Organization, 2022). On the other hand, the increasing use of imaging techniques involving ionizing radiation has led to a rise in population exposure to radiation. Nowadays, medical exposure is the largest source of artificial radiation, contributing to 20% of the total population's exposure. Annually, more than 4 billion medical imaging exams using ionizing radiation are performed worldwide, among which 37 million are Nuclear Medicine procedures (World Health Organization, 2016).

In diagnostic applications, Nuclear Medicine (NM) imaging techniques aim to investigate the *in vivo* functioning of suspected organs or tissues (Caramelo et al., 2008). In these techniques, the patient is administered, typically intravenously, with a radiopharmaceutical to study a specific biochemical, biophysical, or pharmacological process. This distinguishing characteristic of Nuclear Medicine imaging techniques is particularly crucial in oncology, as the initial expressions of pathology occur at the cellular level, preceding morphological changes. The imaging technique Positron Emission Tomography with Computed Tomography imaging technique (PET/CT) with the radiopharmaceutical 2-[^{18}F]fluoro-2-desoxi-D-glucose (2-[^{18}F]FDG) has been revolutionizing oncological diagnosis, due to its contribution in meeting the needs of early diagnosis, staging and management of a variety of tumor types (Almuhaideb et al., 2011).

In PET/CT, being a hybrid technique, both components contribute to the exposure of patients and professionals to radiation. While in CT acquisition, radiation is applied externally by the equipment, in PET acquisition, radiation is emitted by the patient's body. Errors in the preparation of the radiopharmaceutical for PET acquisition can result in incidents or unintentional exposure of patients and/or professionals (Larcos et al., 2014; Marengo et al., 2022). One of the errors that can occur is the administration of the patient with an incorrect radioactive activity, i.e., with an activity different from the recommended one. According to the International Commission on Radiological Protection, the administered dose should be as low as reasonably achievable, but not so low as to compromise the quality of the medical image (ALARA principle) (International Commission on Radiological Protection, 2007).

In this regard, monitoring sequential data activity to ascertain differences between observed and expected values can be a powerful tool in preventing such errors (Duncan, 2017). Control Charts, the core tool of Statistical Process Control (SPC), enable the detection of significant deviations from expected values or a non-random sequence of minor deviations, thereby signaling the need to investigate their underlying causes. SPC, derived from statistical techniques pioneered by Walter Shewhart in the 1920s, is a methodology for continuously improving process quality through statistical control of variation.

Sibley et al. (2020) implemented a quality improvement system to reduce hospital stays for patients undergoing a specific Nuclear Medicine imaging examination, known as myocardial perfusion imaging. In this study, the authors utilized control charts solely to assess the success of the intervention, rather than in the intervention itself. Larcos et al. (2015) employed Shewhart control charts to identify the root causes of variation in Australian monthly reporting rates of administration errors, with no intervention in a real process.

Therefore, the purpose of this paper is to demonstrate the importance of integrating SPC in Nuclear Medicine departments based on a case study, acting as a powerful weapon in the identification, control and prevention of the causes that lead to errors in administered activity. To achieve the overall objective, control charts were applied to (1) monitor the administered activity of 2-[^{18}F]FDG (approach entitled "Interpatient Control") and (2) the 2-[^{18}F]FDG PET/CT examination days (approach entitled "Interday Control").

RESEARCH METODOLOGHY

The research methodology is schematized in Figure 1. The first step in implementing SPC is identifying the process quality characteristic to be controlled. The next step involves defining a data collection plan for the characteristic (sample size, sampling frequency, etc.) and collecting the data itself. If data collection is not possible, a historical data sample should be requested. In either case, it is crucial to conduct a proper analysis of the dataset obtained before proceeding to construct control charts. Exploratory data analysis (EDA) is a data analysis approach that utilizes a variety of techniques (both graphical and non-graphical) with the primary goal of maximizing understanding about a given dataset. EDA stands out for the freedom it offers in data analysis, unlike classical statistical approaches. In classical analysis, after data collection, a model is immediately imposed, and all subsequent analyses and conclusions are based on the parameters of that model. In EDA, data collection is not followed by model imposition; instead, an analysis is conducted to infer the most appropriate model for the dataset. Graphical representations, combined with some quantitative techniques and the natural pattern recognition abilities inherent in all humans, replace reliance on model assumptions with an approach where the data "reveal" their behavior and underlying model. Thus, EDA is an approach/philosophy aiding natural pattern recognition abilities, trends, or outliers, constituting a fundamental step after data collection (Komorowski et al., 2016; NIST/SEMATECH, 2012).

For our study, the percentage change between the administered activity and the recommended activity (MBq) was chosen as the quality characteristic of interest (Δ_{FDG}). A dataset was obtained containing information of 4322 patients who underwent PET/CT procedures at the Nuclear Medicine Department of a public Portuguese hospital, over the period of March 2019 to December 2021.

According to hospital's clinical protocol for whole-body PET/CT procedures, patients receive a weight-based injection of 2-[^{18}F]FDG activity (3.7 MBq per kg). In this study, the "dose dispensing process" is defined as the entire process of dispensing the 2-[^{18}F]FDG single-dose. This process begins with the patient's weight being recorded in the nuclear medicine information system and verbally communicated by the operational assistant to the nuclear medicine technologist, who is responsible for dispensing the dose. It ends with the syringe being handed over to the nurse for intravenous administration to the patient. The dose dispensing is facilitated by an automated dispensing system. The technologist inputs the activity and scheduled administration time, and the system dispenses the single dose accordingly. For 2-[^{18}F]FDG PET/CT procedures, daily doses are ordered based on estimates derived from the weights of patients scheduled for the next day and their scheduled administration times. On the day of the examination, the daily dose is transported from the production site to the hospital in a multiple-dose container. One of the technologists then begins the process of dispensing each single dose at the scheduled time with the aid of the aforementioned system.

In Interpatient Control, monitoring the activity of individual doses administered to patients over days is proposed. Individuals and Moving Range (I-MR) charts are well suitable for this approach (Montgomery, 2009; Quesenberry, 1997). The control limits are given by

$$\text{I chart}\begin{cases} UCL_I = \bar{I} + \dfrac{3}{d_2}\overline{MR} \\ CL_I = \bar{I} \\ LCL_I = \bar{I} - \dfrac{3}{d_2}\overline{MR} \end{cases} \tag{1}$$

$$\text{MR chart}\begin{cases} UCL_{MR} = D_4\overline{MR} \\ CL_{MR} = \overline{MR} \\ LCL_{MR} = D_3\overline{MR} \end{cases} \tag{2}$$

In Equation 1 and Equation 2, $\bar{I}$ represents the mean value of the N observations of Δ_{FDG}, $\overline{MR}$ is the mean value of $N-1$ of MR (moving rages with two observations were consider), and d_2, D_3 and D_4 are control chart constants.

Regarding Interday Control, the aim is to meet the internal audit needs of the hospital department, and help planning the orders of daily doses. Monitoring daily behavior will also allow the identification of trends not visible in Interpatient Control, thus becoming a complement to it. In this case, since the total daily number of patients undergoing PET/CT examinations varies, the values of the statistics of the Mean and Standard Deviation charts ($\bar{X}$-S) were normalized, so that the centerlines are equal to zero and the upper and lower control limits are +3 and – 3, respectively (Pereira & Requeijo, 2008). At time *t*, the normalized sample mean, and the sample standard deviation are given by

$$Z_{\bar{X}_t} = \frac{\bar{X}_t - \bar{\bar{X}}_p}{\hat{\sigma}_0 / n_t} \tag{3}$$

$$Z_{S_t} = \frac{S_t - \bar{S}_p}{\hat{\sigma}_0 / \sqrt{1 - c_4^2}} \tag{4}$$

where $\bar{\bar{X}}_p$ and $\bar{S}_p$ correspond, respectively, to the weighted overall mean and the weighted average standard deviation of the *m* variable-sized samples.

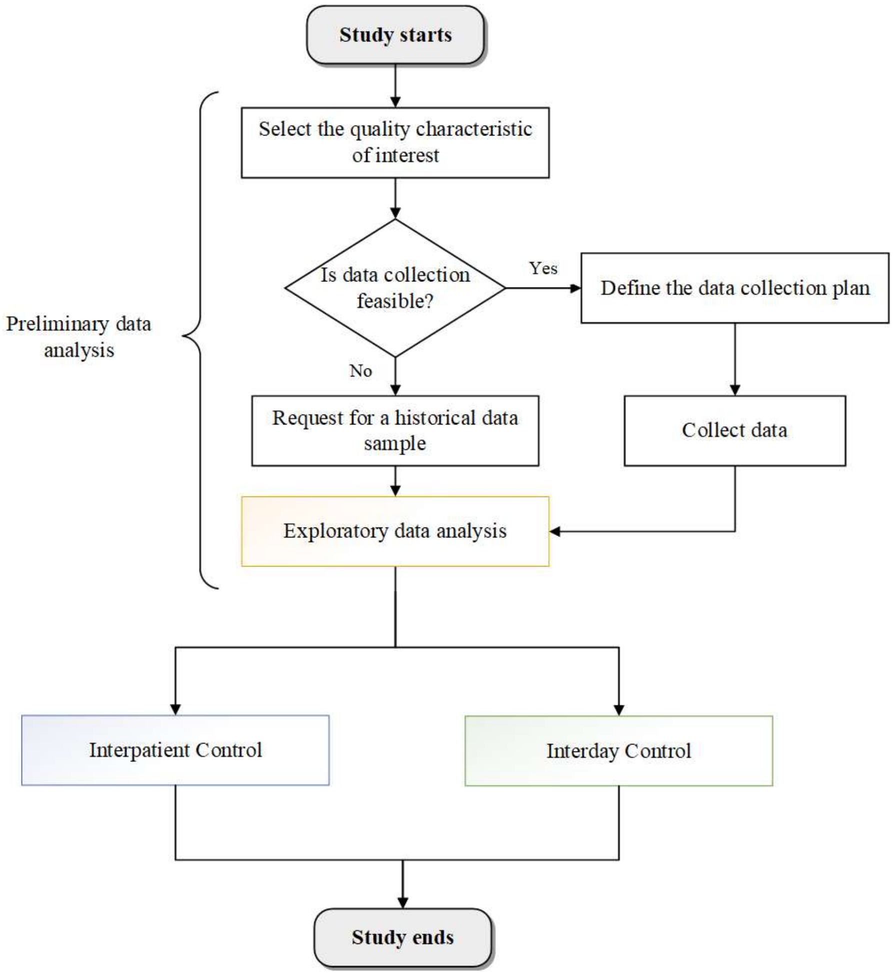


Figure 1 – Research methodology

RESULTS

Data Sample

The historical dataset obtained consists of anonymized data from 4322 patients, including anthropometric data, administration date, administration time, and the type of radiopharmaceutical administered. The temporal window of the initial data sample spans from March 19, 2019, to December 30, 2021. To obtain the data sample for this study, all data related to PET/CT examinations with the administration of other radiopharmaceuticals and data corresponding to 2-[^{18}F]FDG brain studies were excluded.

We immediately observed that the year 2019 exhibited a distinct behavior compared to the other years. Therefore, it was necessary to investigate the reason behind this behavior. According to the information gathered, an upgrade of the dose partition system was carried out at the end of 2019.

Consequently, it was concluded that including the data from 2019 would not be meaningful, as it is not considered representative of the current process.

Therefore, the resulting dataset consists of information from 3003 patients. Among all the information at hand, only the following data will be considered: Administration Date (dd/mm/yyyy), Administration Time (hh:mm:ss), Weight (kg), and Administered Activity (MBq). From the last two, one can obtain the values of the quality characteristic (Δ_{FDG}), and thus obtain the data sample under study.

Identification and Treatment of Outliers

To identify the outliers of the data sample, a boxplot was constructed. Once outliers are identified, the treatment of these values should be undertaken. This decision is somewhat subjective and can prove to be a complex task. Rejecting the entire set of identified outliers is undoubtedly the simplest choice. However, there is a risk of disregarding important information about the quality characteristic under study. It is thus essential to seek to understand the origin of the identified values and their practical significance, which may eventually lead to alternative treatment options.

In Table 1, the causes behind the values identified as outliers and their respective relative frequencies, f_i, in percentage, are presented.

Table 1 – Causes behind the identified outliers, and respective relative frequencies.

Causes	f_i **(%)**
Type 1: Dose partitioning system	54,2
Type 2: Data entry	15,1
Type 3: Communication	16,3
Type 4: Dose administration before/after the scheduled time	14,4

The cause identified as “Type 1” is related to errors in the dose partitioning system which include, amongst others, the occasional dispensing of higher doses at the beginning of the day (which were already of the knowledge of the Service team), occurrences in which the system dispenses a dose much higher or much lower than requested (excluding situations where the error arises in the doses of the first patients of the day), and complete system failure, requiring manual dose dispensing.

When analyzing the values identified by the boxplot, it was possible to ascertain that in some paper records, the percentage change given by the system did not correspond to the calculated Δ_{FDG} value.

From this analysis, it was concluded that sometimes technologists request a dose to the system that is different from the recommended one (3.7 MBq per kg). However, it was not possible to justify the outliers with this occurrence since technologists rarely record the requested dose. Therefore, regarding occurrences where the system dispenses a dose higher or lower than the recommended value (or theoretical, if you will), it is unknown how many of these values the technologists requested a different activity from the recommended one. The respective values were eliminated.

As for the type 2 cause, it does not result in an administered activity to the patient that is higher or lower than recommended, as it is related to errors in recording weight or activity after the dose is dispensed. The respective values were corrected.

The type 3 cause relates to occurrences where there was a failure in weight communication between the operational assistant and the technologist. The corresponding values were eliminated.

The last cause, the type 4 cause, corresponds to situations where the patient is administered before or after the scheduled time. At time *t*, the activity of a radioactive sample can be obtained by

$$A(t) = A_0 e^{-\lambda t} \tag{5}$$

Where A_0 is the initial activity of the radioactive sample. The constant λ is called the decay constant (Glascock, 2014).

Hence, if a patient is administered before the scheduled time, they will receive a higher activity; likewise, if the administration occurs after the scheduled time, the patient receives a lower activity than recommended for their weight. The respective values were eliminated.

By observing the relative frequency presented in Table 1, it is noted that the dose partitioning system was the cause that resulted in the most outliers, with a relative frequency of 54.2% (type 1 cause). On the other hand, errors related dose administration before or after the scheduled time have the lowest frequency, 14.4% (type 4 cause).

Verification of Data Normality

Based on some EDA techniques, it is possible to formulate the hypothesis of the distribution that best describes the data behavior. As a first step, after all outliers were identified, analyzed, and treated, some basic sample statistics of Δ_{FDG} were calculated, which are presented in Table 2.

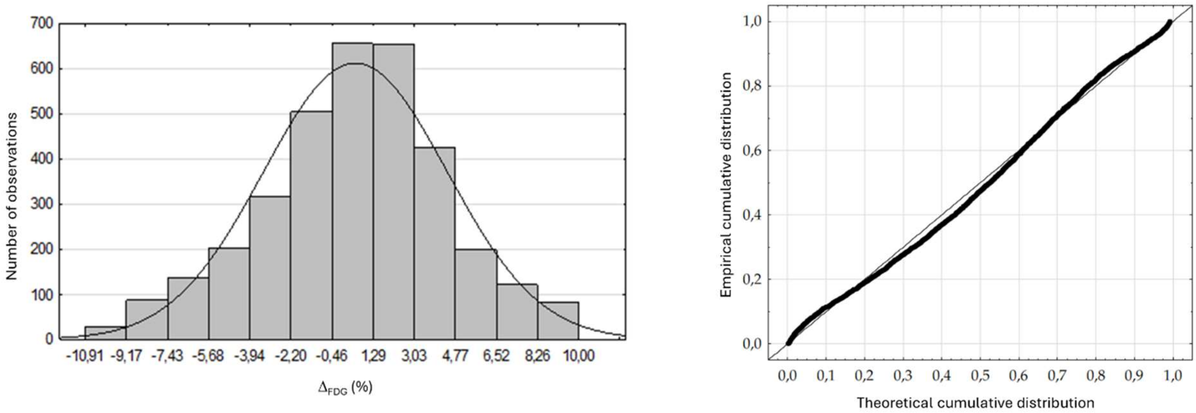
Table 2 – Summary of basic statistics for the variable percentage change of 2-[^{18}F]FDG.

Sample statistic	**Value**
Number of observations	2798
Minimum (%)	-10.91
3rd Percentile (%)	-7.72
25th Percentile (%)	-1.93
Mean (%)	0.50
Standard deviation (%)	3.93
Median (%)	0.86
75th Percentile (%)	3.06
97th Percentile (%)	7.97
Maximum (%)	10.00
Coefficient of skewness (γ_1)	-0.24
Coefficient of kurtosis (γ_2)	-0.04

An analysis of Table 2 allows us to infer that the data sample under study exhibits a negative coefficient of skewness (γ_1) – albeit very close to zero – and a coefficient of kurtosis (γ_2) of, approximately, 3. Taking into account the values of γ_1 and γ_2 for the Normal distribution, namely 0 and 3, considering that the data follows a Normal distribution appears to be a quite plausible hypothesis at this point.

It can also be observed that 50% of the values lie between -1.93% and 3.06%. Similarly, 95% of the data falls within the range of -7.72% and 7.97%. The minimum and maximum values are, respectively, -10.91% and 10.00%.

The frequency histogram with a fitting Normal distribution, as well as the probability-probability plot (P-P plot), are presented in Figure 2.



(a) (b)

Figure 2 – (a) Histogram with a fitting Normal distribution, (b) P-P plot.

By observing Figure 2a, the slight skewness of the dataset can be noted, however, it can be affirmed that the curve of the Normal distribution resembles the shape of the histogram. In Figure 2b, one can observe that the line drawn on the P-P plot slightly deviates from the line $y = x$, however, with no apparent substantial deviation.

In summary, based on the results presented in Table 2 (sample statistics), Figure 2a (frequency histogram), and Figure 2b (P-P plot), considering that the data of the quality characteristic follow a Normal distribution seems to be a highly plausible hypothesis, as the behavior of the data sample closely resembles that of the Normal distribution.

Interpatient Control

In this section, the aim is to apply I-MR charts to the historical data sample, where the percentage variation of the administered dose of 2-[^{18}F]FDG will be monitored (i.e., Δ_{FDG}).

As such, the first step should be to calculate the MR statistic. When this step is concluded, one should calculate the control limits (see Equation 1 and Equation 2). For our study, regarding I chart, the obtained control limits (UCL_I, CL_I, LCL_I) are (11.13, 0.50, -10.13)%. As for the MR chart, the control limits (UCL_{MR}, CL_{MR}, LCL_{MR}) take on the values (13.06, 4.00, 0)%.

For visual clarity, we divided the representation of I-MR chart in four temporal windows. The control chart corresponding to the first temporal window is presented in Figure 3. The graphical representations for the remaining three temporal windows can be found in Appendix A, specifically in Figure A.1 (2nd temporal window), Figure A.2 (3rd temporal window), and Figure A.3 (4th temporal window).

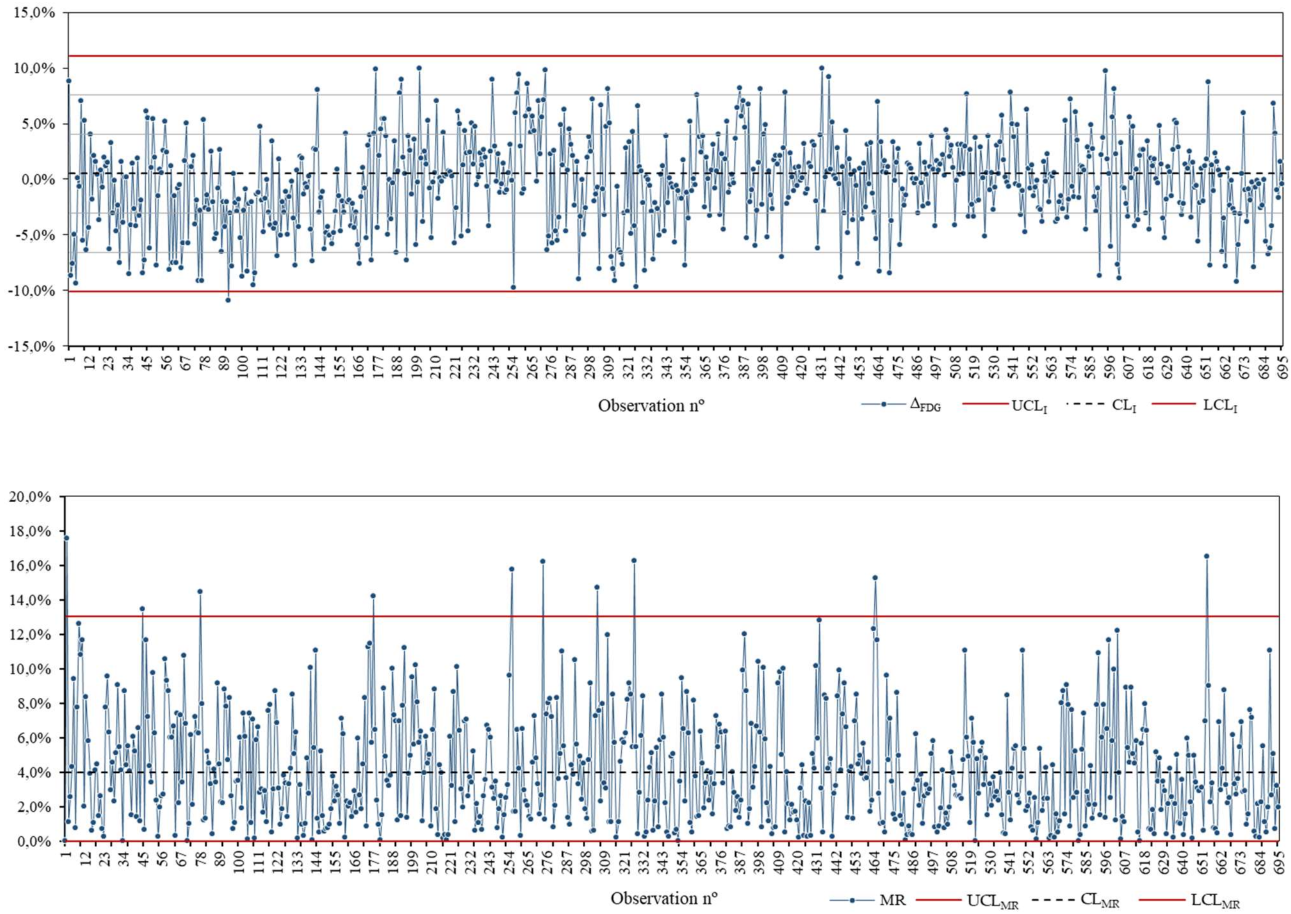


Figure 3 – Individuals and Moving Range chart (1st temporal window)

In the I chart, the eight control rules contained in ISO 7870-2:2013 were applied. As for the MR chart, only Rule 1 was applied – any point outside the upper or lower control limits.

When detecting a non-random pattern, the decision of which points to eliminate requires careful consideration. At this stage, the aim is to estimate the process parameters, so all decisions made at this stage will have implications on the estimates obtained. For example, upon detecting a Rule 2 violation (9 consecutive points on the same side of the centerline), the following questions arise: considering the process under study, would it be prudent to eliminate *all* observations? If not, which ones?

Therefore, the following strategy was adopted: for each non-random pattern, the day(s) and administration hours corresponding to the identified points are investigated in parallel. If it is found that one or more days were the cause of this non-random pattern, only the corresponding observations are eliminated. Consider, for example, the hypothetical situation where Rule 7 (15 consecutive points in zone C above and below the centerline) is detected on Days 1, 2, 3, and 4 (generic notation), with the following distribution: one observation on Day 1, five observations on Day 2, seven observations on Day 3, and two observations on Day 4. In this example, if it is not considered that any problem occurred on Days 1 and 4, only Days 2 and 3 would be eliminated, totaling 13 eliminated observations. Another example would be the detection of Rule 3 (six consecutive points in the ascending and descending direction) on Day 7 (generic notation), a day on which, hypothetically, seven exams occurred, but only the first six observations of the day resulted in a non-random pattern – the seven observations of Day 7 are eliminated, considering that Day 7 is not representative of the process; it would not make sense, from the study's perspective, to include the last observation if it is evident that there was a problem in the process on that day.

In the adopted strategy, the following rules are exceptions: Rule 1, Rule 5 (two out of three consecutive points in zone A, on the same side of the centerline), and Rule 6 (four out of five consecutive points in zone B or A, on the same side of the centerline). In the I chart, when Rule 1 is detected, the identified point is eliminated; regarding Rules 5 and 6, the highest absolute value of Δ_{FDG} is eliminated. As for the MR chart, if any point outside the control limits is identified, the two observations that led to the statistic exceeding the limits are checked, and the highest value of $|\Delta_{FDG}|$ is eliminated. This way, the observations furthest from the centerline, LC_I, are eliminated.

It is advisable, as a first step, to observe and eliminate occurrences of Rule 1 on the MR chart, which will eliminate some occurrences of control rules on the I chart.

Table 3 presents a summary of the observations removed from the initially identified non-random patterns on the I chart of the first temporal window.

Similarly, in Table 4, a summary of the rules identified on the MR chart and the respective justification for the initially eliminated points from the 1st temporal window are presented.

Table 3 – Summary of the rules identified on the I chart and justification for the eliminated points (1st temporal window).

Rule I Chart	Detected observations	Eliminated observations	Justification
Rule 6	1-5	2; 5	Higher values of $\|\Delta_{FDG}\|$
Rule 4	17-34	17-34	Days 13/01, 17/01 and 20/01/20
Rule 5	42-44	*Resolved by identifying Rule 1 on the MR chart*	
Rule 5	58-60	58	Higher values of $\|\Delta_{FDG}\|$
Rule 5	60-62	62	Higher values of $\|\Delta_{FDG}\|$
Rule 5	75-77	*Resolved by identifying Rule 1 on the MR chart*	
Rule 1	92	92	Observation outside of the control limits
Rule 2	88-109	88-111	Days 21/02 and 02/03/20
Rule 6	116-120	120	Higher value of $\|\Delta_{FDG}\|$
Rule 2	122-130	122-127	Day 09/03/20
Rule 2	144-153	148-151	Day 18/03/20
Rule 2	160-168	161-166	Days 24/03 and 25/03/20
Rule 6	178-182	180	Higher value of $\|\Delta_{FDG}\|$
Rule 5	189-191	191	Higher value of $\|\Delta_{FDG}\|$
Rule 5	256-258	258	Higher value of $\|\Delta_{FDG}\|$
Rule 6	261-267	263; 264	Higher values of $\|\Delta_{FDG}\|$
Rule 6	277-281	277	Higher value of $\|\Delta_{FDG}\|$
Rule 6	312-316	314	Higher value of $\|\Delta_{FDG}\|$
Rule 2	330-340	331-341	Days 26/05 and 27/05/20
Rule 2	344-352	348-353	Day 01/06/20
Rule 6	383-387	385	Higher value of $\|\Delta_{FDG}\|$
Rule 7	412-429	412-422	Day 22/06/20
Rule 7	478-496	482-492	Day 03/07/20
Rule 5	600-602	602	Higher value of $\|\Delta_{FDG}\|$
Rule 2	674-689	676-689	Days 07/09 and 08/09/20

The detection and elimination of values is an iterative process, so the control limits will inevitably vary as points are eliminated. The occurrence of other control rules after the elimination of the initially identified rules is resolved by applying the same strategy adopted thus far. The process is repeated until the point where it is no longer possible to identify the occurrence of any control rules in the four temporal windows considered.

Table 4 – Summary of the rules identified on the MR chart and justification for the eliminated points (1st temporal window).

Rule MR Chart	Detected MR observations	Eliminated $\|\Delta_{FDG}\|$ observations	Justification
Rule 1	2 45 78 177 256 274 305 327 465 654	1 44 77 176 255 273 304 326 465 653	Higher value of $\|\Delta_{FDG}\|$

With all control rules eliminated, one can concluded that the data sample is only subject to common causes of variation, which means that the conditions are met to proceed with the estimation of process parameters.

The estimates for the mean and standard deviation obtained are $\hat{\mu}$ = 0.67% and $\hat{\sigma}$ = 3.37%, respectively.

At the Nuclear Medicine department under study, it is considered that a percentage change in the administered dose of the radiopharmaceutical 2-[^{18}F]FDG is acceptable if it falls within [-10; 10]%. That is, the administered activity of 2-[^{18}F]FDG should not exceed 10% or fall below -10% of the value of the recommended activity calculated for the patient's weight (3.7×Weight [MBq]). This information allows for the calculation of process capability indices, considering a bilateral specification.

The process potential capability index has a value of C_p = 0.99. It is observed that the obtained potential capability index is lower than the reference value of 1.33 for existing bilateral process specifications – the process does not have the potential to be capable. This value indicates that the process exhibits a natural dispersion much higher than the tolerance of the technical specification.

Another index that can be calculated is the process capability index C_{pk}, which considers both the natural dispersion of the data and the location of the mean. To calculate this index, it is necessary to first obtain the lower and upper capability indices, $(C_{pk})_I$ and $(C_{pk})_S$ (Montgomery, 2009).

Taking into account the estimates of the process parameters, $(C_{pk})_I$ = 1.058 and $(C_{pk})_S$ = 0.923.

Since the process capability index Cpk is the minimum of the values of the indices $(C_{pk})_I$ and $(C_{pk})_S$, $C_{pk} \approx 0.92$. It is concluded that the process is not capable since $C_{pk} < 1.33$. Furthermore, it is observed that the process is not centered on its nominal value.

In summary, the results obtained indicate that in order to correct the process, it is necessary to act towards reducing both the dispersion and the mean.

Interday Control

In Interday Control, the aim is to monitor 2-[^{18}F]FDG PET/CT examination days using Normalized Mean and Normalized Standard Deviation control chart ($Z_{\bar{X}} - Z_S$). Unlike Interpatient Control, in this approach, samples will be formed based on the same data set.

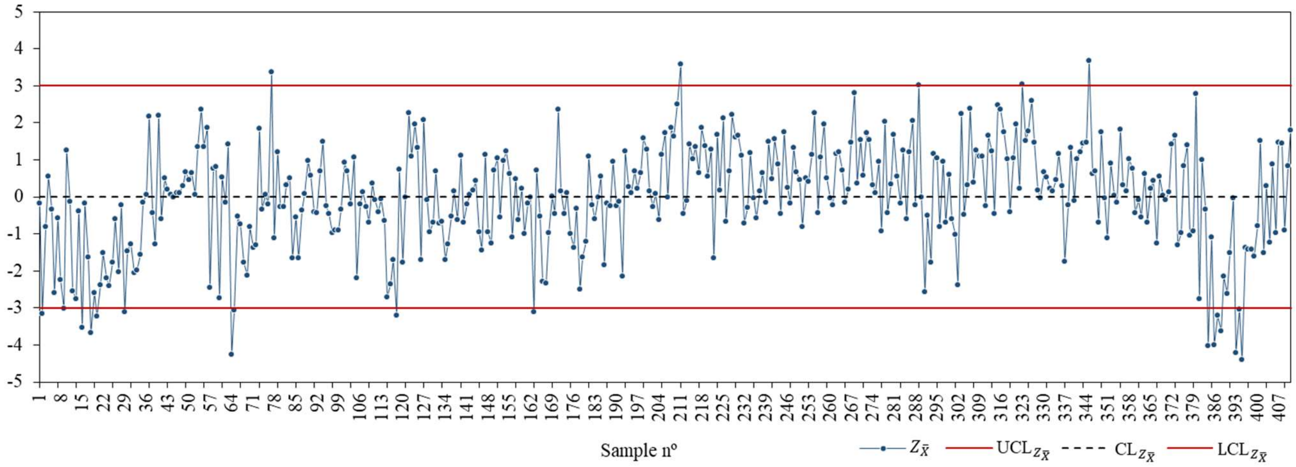
Out of the created samples (examination days), approximately 85% have a size between n = 5 and n = 8, inclusive, with n = 7 being the most frequent size.

The values of the weighted mean, the weighted average standard deviation, and the initial process standard deviation estimate are given by $\bar{\bar{X}}_p$ = 0.497%, $\bar{S}_p$ = 3.699% and $\hat{\sigma}$ = 3.544%, respectively.

As mentioned, since the statistics $Z_{\bar{X}}$ and Z_S are the result of normalizing the values of the statistics $\bar{X}$ and S, the centerlines of the control chart $Z_{\bar{X}} - Z_S$ are equal to zero, and the upper and lower control limits have values of +3 and -3, respectively.

Once the values of the statistics for each sample and the control limits are obtained, the conditions are met to proceed with the construction of the control chart.

The obtained $Z_{\bar{X}} - Z_S$ control chart is presented in Figure 5.9. In this chart, only Rule 1 is considered – any point outside the control limits.



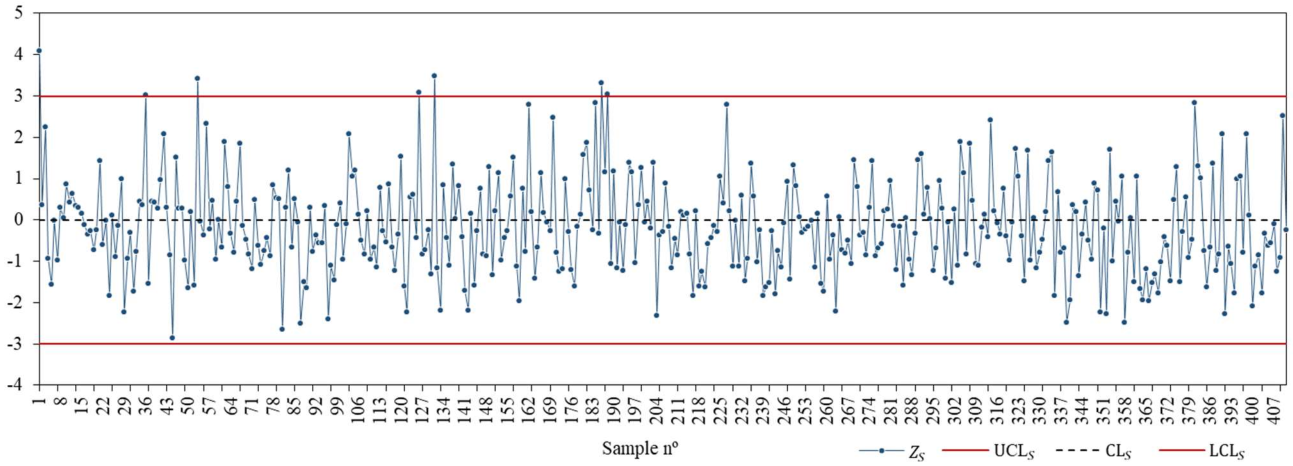


Figure 4 – Normalized Mean and Normalized Standard Deviation control chart

In Table 5, a summary of the out-of-control occurrences identified on the Normalized Mean control chart ($Z_{\bar{X}}$) is presented. All identified samples were eliminated.

Table 5 – Summary of rules identified in the Normalized Mean chart and justification for the eliminated samples.

Rule $Z_{\bar{X}}$ Chart	**Detected samples**		**Justification**
	Nº	**Day**	
Rule 1	2	07/01/2020	All detected samples were eliminated. Justification: Points outside the control limits.
	9	03/02/2020	
	15	17/02/2020	
	18	21/02/2020	
	20	28/02/2020	
	29	18/03/2020	

Table 5 – Summary of rules identified in the Normalized Mean chart and justification for the eliminated samples (continuation).

Rule $Z_{\overline{X}}$ Chart	Detected samples Nº	Day	Justification
Rule 1	64	19/05/2020	All detected samples were eliminated. Justification: Points outside the control limits.
	65	20/05/2020	
	77	12/06/2020	
	118	08/09/2020	
	163	30/11/2020	
	211	02/03/2021	
	289	29/06/2021	
	323	16/08/2021	
	345	16/09/2021	
	384	15/11/2021	
	386	17/11/2021	
	387	18/11/2021	
	388	19/11/2021	
	393	26/11/2021	
	394	29/11/2021	
	395	30/11/2021	

Similarly, Table 6 summarizes the out-of-control occurrences identified on the Normalized Standard Deviation control chart (Z_S).

Table 6 – Summary of the rules identified on the Normalized Standard Deviation control chart and justification for the eliminated samples.

Rule Z_S Chart	Detected samples Nº	Day	Justification
Rule 1	1	03/11/2020	All detected samples were eliminated. Justification: Points outside the control limits.
	36	30/03/2020	
	53	28/04/2020	
	126	25/09/2020	
	131	06/10/2020	
	186	18/01/2021	
	188	20/01/2021	

With all samples corresponding to out-of-control situations eliminated, it means that the data set is only subject to common causes of variation. Therefore, the conditions are met to proceed with the estimation of the process parameters.

The estimated parameters for the mean and standard deviation are, respectively, $\hat{\mu}$ = 0.67% and $\hat{\sigma}$ = 3.52%.

Similarly, the process capability can be calculated, considering an upper specification limit of 10% and a lower specification limit of -10%. The obtained potential capability index has a value of C_p = 0.95. It can be observed that the potential capability index is lower than the reference value of 1.33 for existing bilateral process specifications. Therefore, it is concluded that the process does not have the potential to be capable. The lower and upper capability indices, $(C_{pk})_I$ and $(C_{pk})_S$, have values of 1.012 and 0.884, respectively. Thus, the capability index is $C_{pk} \approx 0.88$. The process is not centered on its nominal value and is not capable.

CONCLUSIONS

In Nuclear Medicine imaging techniques, the patient is administered, typically intravenously, with a radiopharmaceutical to study a specific biochemical, biophysical, or pharmacological process. 2-[^{18}F]FDG PET/CT has been revolutionizing oncological diagnosis, due to its contribution in meeting the needs of early diagnosis, staging and management of a variety of tumor types.

Nonetheless, in PET/CT procedures, errors related to the dispensing of the radiopharmaceutical unit dose can result is an incorrect activity being administered to the patient, i.e., different than the recommended dose. Following the guidelines of the International Commission on Radiological Protection, it is imperative to keep the dose as low as reasonably achievable (ALARA principle).

Hence, this study demonstrated the applicability of Statistical Process Control (SPC) in Nuclear Medicine departments to monitor patient dosage, thereby providing early detection of causes contributing to such unwanted event. In literature, we did not encounter any other studies that applied SPC to intervene in the dose dispensing process. Therefore, regrettably, we were unable to make comparisons with our findings.

According to Duncan (2017), "...one can ask why these tools (control charts) are not yet routinely used to analyze clinical data such as vital signs, labs symptoms, or radiation exposure." It is believed that the answer to this question may partly lie in professionals' lack of familiarity with the principles necessary for their construction and interpretation.

A data sample from the Nuclear Medicine Department of a public Portuguese hospital was retrospectively analyzed.

The identification and treatment of outliers' stage corroborated the suspicion that the dispensing system is not the sole source of the problem (contrary to the hospital team's belief). The error, expressed in the study as the percentage change between the administered activity and the prescribed activity, is the sum of various sources of variation, including the variation introduced by the dispensing system. However, since there is typically no record of the activity requested by the technologist, it was not possible to study each cause individually. For this reason, errors in the administered activity were studied as a whole.

Interpatient Control (between patients) and Interday Control (between PET/CT examination days) are proposed control chart approaches that, although with distinct purposes, can complement each other.

An example is the trend observed in the $Z_{\bar{X}}$ chart (Figure 4) for samples 18 to 54 (from February 21, 2020, to April 29, 2020). These samples correspond to observations 88 to 264 on the I chart, as shown in Figure 3. A single observation from Figure 3 may not reveal the trend mentioned on the I chart. In a real-life scenario, Interday Control would retrospectively identify the occurrence.

Interpatient Control translates to a prospective control, meaning, after dispensing the dose, the technologist must verify if the percentage change of 2-[^{18}F]FDG between the dispensed activity and the recommended activity (calculated based on the patient's weight) exceeds the control limits or if there is any non-random pattern within the limits; in either of these situations, immediate action should be taken, which will prevent the occurrence of special causes of variation in subsequent dose dispensing.

Interday Control, on the other hand, is a retrospective monitoring: each day is recorded as a single point on the Control Chart, which allows for investigating discrepancies between PET/CT examination days. Interday Control also has the advantage of assessing whether the ordered doses are acceptable, considering the behavior of previous days.

After ensuring that the data sample was only subject to common causes of variation, the process parameters (mean and standard deviation) were estimated, and a process capability analysis was conducted. It was found that, in both approaches, the process lacks the capability to meet technical specifications, and it was concluded that efforts should be made to reduce both the process mean and the process standard deviation. The fact that the mean is greater than zero indicates that, on average, patients are receiving a dose with a radioactive activity higher than necessary for their weight.

Besides, the process exhibits a natural dispersion far exceeding the tolerance of the technical specification. To improve the process, a change in work procedures is suggested, such as the way the operational assistant communicates weight and the recording of all activities requested by the technologists, with each one's name. Implementing these improvements will allow for equipment and technician studies to be conducted individually. It is also advisable to study each technologist separately to understand if there is any professional with a behavior that is distinct from the rest.

As a future step, a Graphical User Interface (GUI) will be developed to allow the professionals of the Nuclear Medicine Department to automatically generate control charts and identify the presence of non-random patterns.

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APPENDIX A

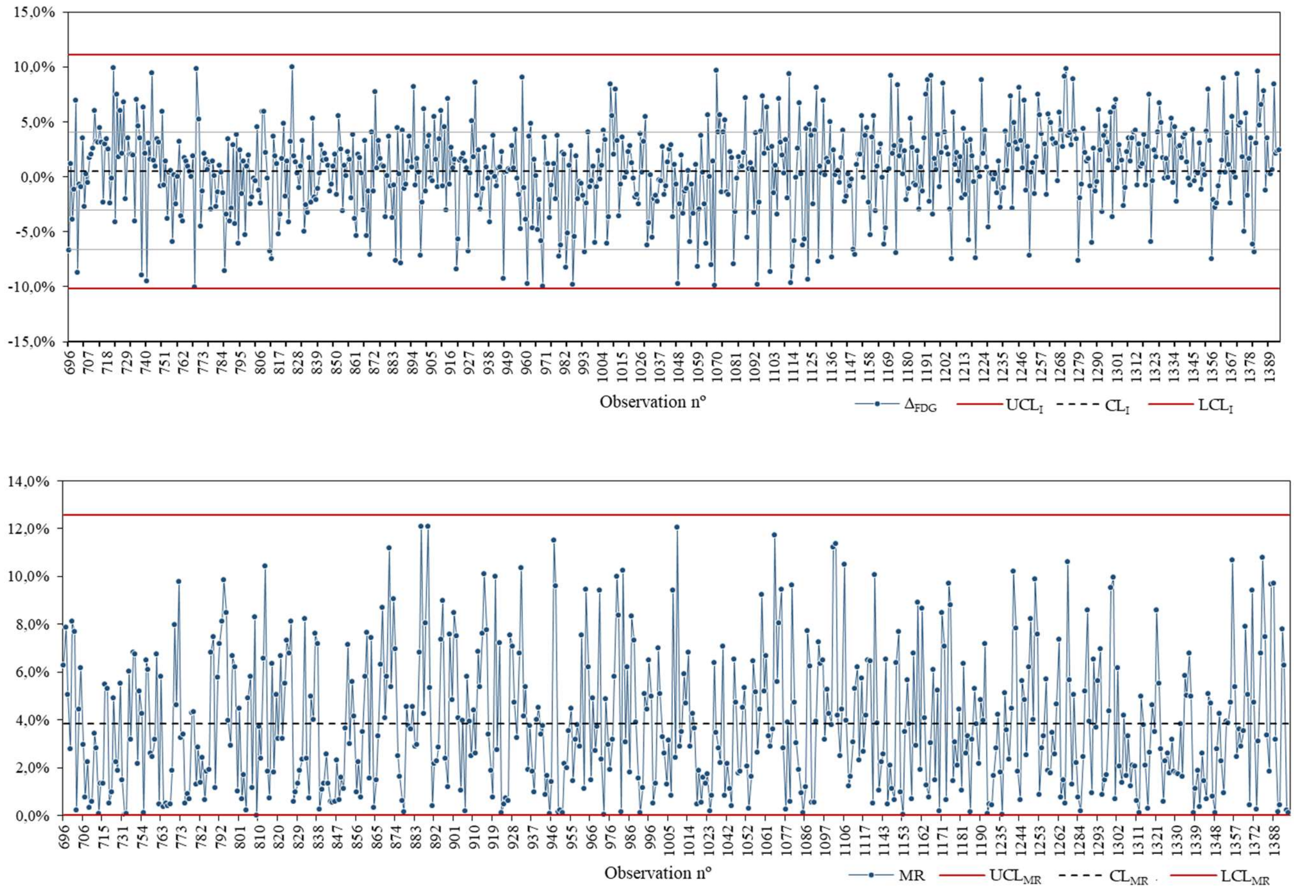
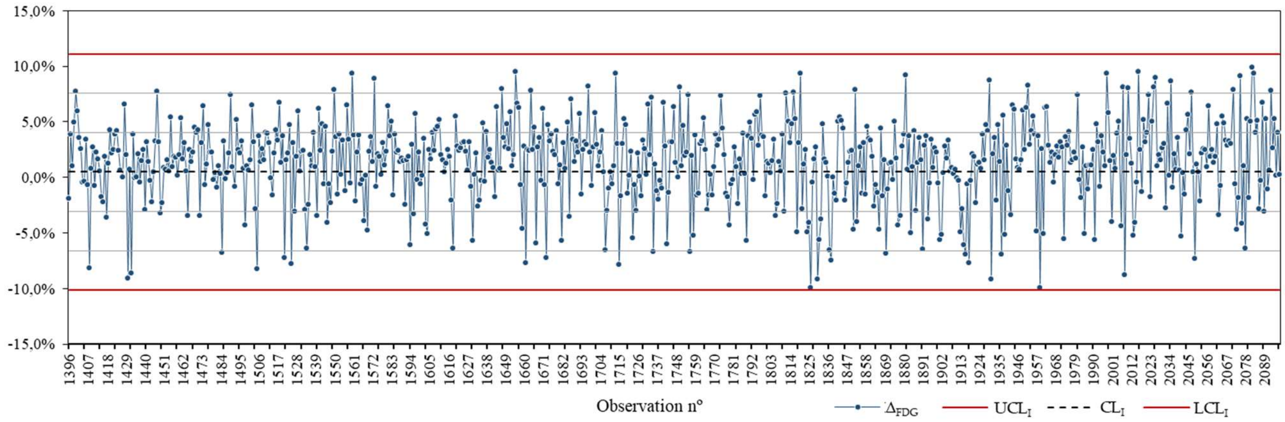


Figure A.1 – Individuals and Moving Range chart (2nd temporal window)



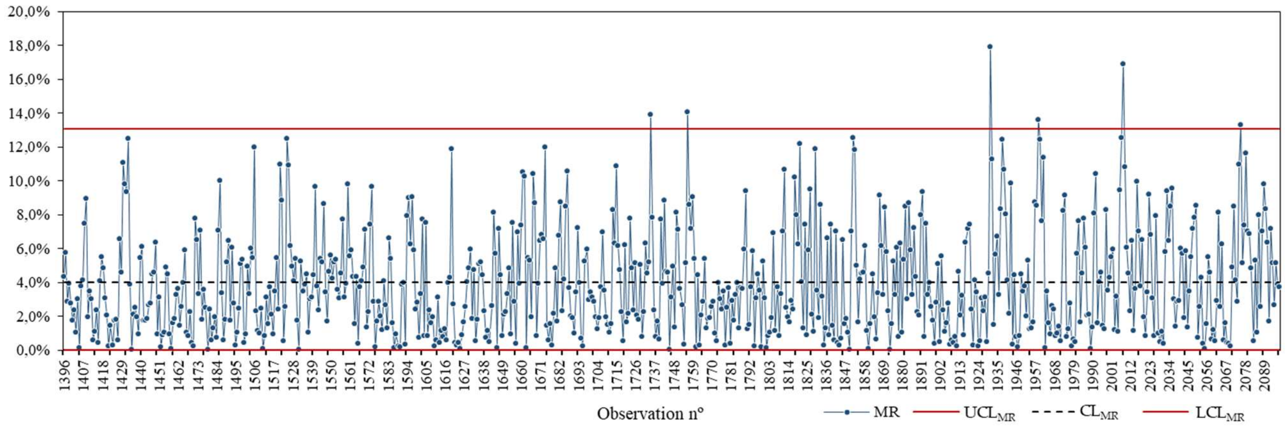
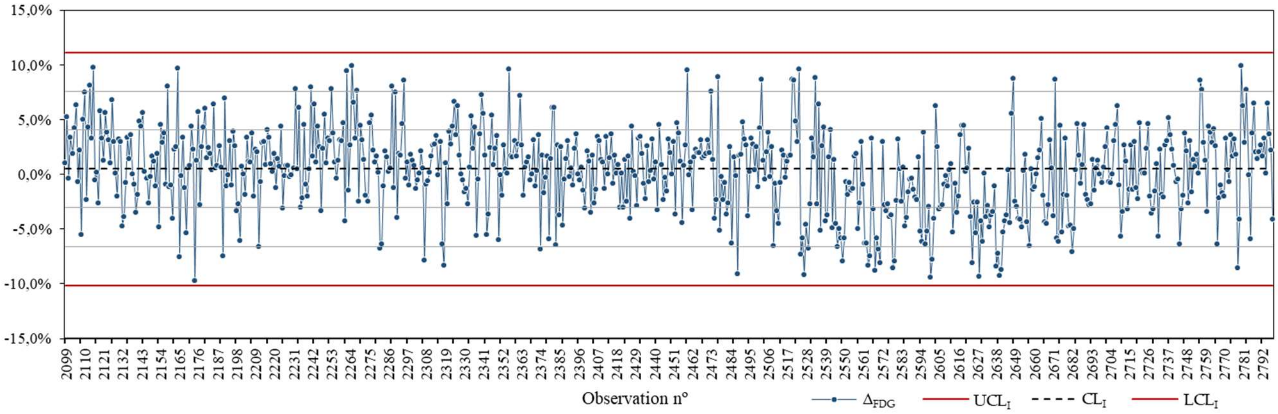


Figure A.2 – Individuals and Moving Range chart (3rd temporal window)



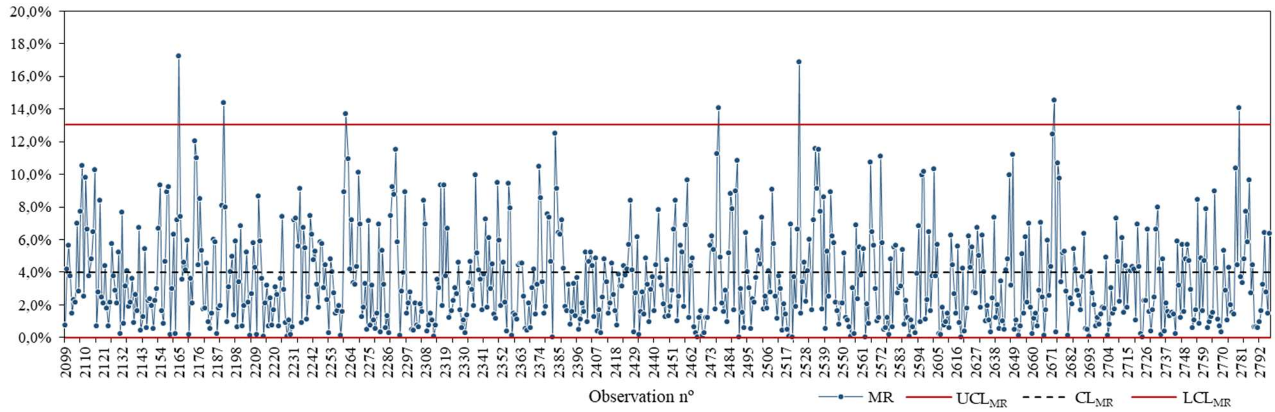


Figure A.3 – Individuals and Moving Range chart (4th temporal window)

Use of Control Charts to Define Diagnostic and Activities Reference Levels for PET/CT Studies in adults: a local study

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STRUCTURED ABSTRACT

Purpose – This article proposes a methodology, based on Statistical Process Control (SPC), to define reference values of levels and activities (DRL and ARL_{18FDG}, respectively) used in PET/CT (Positron Emission Tomography with Computed Tomography) studies, as well as to build a monitoring tool to control the patients' radiological activity at the Nuclear Medicine Department of Hospital Garcia de Orta (HGO).

Design/methodology/approach – In the first phase, the aim is to obtain the reference values for CTDIvol and DLP (for CT component) and administered activities (for PET component) (respectively DRL and ARL18FDG) for the standard patient (70 ± 10kg) and to estimate the parameters needed to construct the control chart later. In the second phase, the control chart for monitoring shall be implemented, using the ratio administered activity of 2-[18F]fluoro-2-desoxi-D-glucose (2-[18F]FDG) per patient weight.

Findings – Determining the values of DRL and ARL_{18FDG} for auditing purposes, which shall be used as guides at the HGO Nuclear Medicine Department.

Social implications – In Portugal, the regulator has not yet defined diagnostic reference levels for nuclear medicine procedures. As such, SPC, through Control Charts, can be a useful tool for achieving this at the institutional level, since they make it possible to detect situations in which the administered activity is lower, or higher than that proposed for the standard patient. It may also be used to establish internal reference dose levels and to compare them with those reported in international scientific articles, leading to greater control of the institution, patient protection and, ultimately, functioning as an internal auditing tool.

Originality/value – With this study, it will be possible to establish reference values for for PET/CT scans in adults, both in terms of radiopharmaceutical administration of 2-[^{18}F]FDG and use of ionizing radiation, respectively ARL_{18FDG} and DRL,, at the HGO Nuclear Medicine Department in Portugal.

Keywords – Positron Emission Tomography, Computed Tomography, Nuclear Medicine, Statistical Process Control and Control Charts

Paper type – Research paper

INTRODUCTION

There is increasing evidence that exposure to elements that are harmful to health is leading to a higher incidence of cancer problems in the population, particularly at younger ages. Currently, for 20-year-old males and females, the risk of cancer due to radiation-emitting components is 0.323% and 0.514% respectively. It is therefore becoming more important to have greater control over the procedures carried out and the necessary substances administered, particularly those using ionising radiation, due to the risks associated with excessive radiation (Alkhybari et al., 2018; Thomas, 2022; Verfaillie et al., 2023).

It is imperative to implement processes to optimise and control the administered doses, especially in the field of Nuclear Medicine, where there is not much reliable information to demonstrate the risks associated with low doses of radiopharmaceuticals, which include the majority of examinations in Nuclear Medicine (Alkhybari et al., 2018; Thomas, 2022; Verfaillie et al., 2023).

To establish this control, the terms DRL and ARL_{18FDG}, Dose Reference Levels and Activity Reference Levels of 2-[^{18}F]FDG, respectively, have emerged. These terms appear as an optimization tool for imaging procedures using ionising radiation, with the DRL associated with CT and the ARL_{18FDG} with PET for the case study.

The DRL and ARL_{18FDG} values both indicate the expected level of radiological exposure received by an individual per type of examination. They also serve as a basis for comparison within the institution itself and between institutions, as well as being an audit tool, an opportunity to improve and optimize processes.

The origin of the dose reference level was due to the International Commission on Radiological Protection (ICRP), which was responsible for creating it in the 1990s. Its use was recommended in 1996, but it was not until 1997 that the European Medical Exposure, through a directive, defined DRLs for certain types of exams and for different types of "standard" patients.

Currently, the ICRP recommends that the DRL and ARL_{18FDG} be established at the 75th percentile of the distribution, i.e. the established value comes from the value which, after sorting the values in ascending order, occupies the position where, from a cumulative perspective, it contains 75 percent of the data.

In addition to the above, the ICRP warns institutions below the 25th percentile to ensure that when administering lower doses, they still ensure the quality of the images, while the Royal College of Australian and New Zealand Radiologists (RANZCR,) has set up an audit to assess the quality of the images (Thomas, 2022).

When setting the DRL and ARL_{18FDG}, it is important to remember that these are always established from a monitoring and recommendation perspective, not as a dose limit, and therefore mainly serve to alert patients to the problem of radiation protection and safety, always trying to reduce dosages.

The values established for the reference levels can be exceeded, justifiably, due to various variables, namely the characteristics of the patient and the disease factors associated with them, and this must be duly documented in the patient's file, as proof may be requested by the regulatory authorities (Salvatori et al., 2019).

The DRL and ARL_{18FDG}, once established, must be constantly kept up to date. This is due to the constant advance of technologies and the consequent increase in equipment efficiency, allowing procedures to have a more efficient benefit/risk ratio, always following the ALARA (As Low As Reasonably Achievable) principle, since reducing injected levels cannot result in compromised image quality (Verfaillie et al., 2023).

There is a high degree of variability in DRL values between different countries, mainly due to the type of equipment used, given it is more or less up-to-date technologically and given its resolution capacity (Deevband et al., 2021; Hosono, sem data; Perić et al., 2021; Pimenta et al., 2023).

Although DRL and ARL_{18FDG} have not been established at the national level for the PET/CT modality, it is that Diagnostic and Activities Reference Levels (DRL and ARL_{18FDG}) will be established and monitored at local level, by each institution that carries out diagnostic medical activity with ionising radiation.

If the institution's DRL and ARL_{18FDG} values are above the national reference value, measures must be taken to reduce them. Thus, the facility should investigate the image collection procedure in order to reduce the levels to an acceptable value, without compromising image quality (Thomas, 2022).

The use of Statistical Process Control (SPC) in the health context could be a good methodology for establishing process parameters by identifying and eliminating possible special causes, as well as for monitoring DRL and ARL_{18FDG} values.

SPC makes it possible to monitor the behaviour of the process using statistical Control Charts, which will allow to reduce variability and calculate estimates of the process parameters. A process is a set of interrelated and inter-acting activities that transform inputs, in this case data, into outputs with added value, in this case the possibility of representing the current situation in relation to the problem.

The main causes of variation in the process under study can be, for example, causes related to metrology, such as measurement errors, incorrect use of equipment, or inadequate measuring equipment. In addition, the conditions of reproducibility and repeatability are not guaranteed, as is the way in which the daily schedule is organized. This factor is perhaps the most important, as patients with higher weights are usually placed first, based on the weight reported when the examination is booked, which may not correspond to the weight on the day of the examination, sometimes leading to an excess of radiopharmaceutical or the last patient being missed.

Something that is necessary for a complete clarification of the causes of variation is to understand that they are divided into two groups: common causes of variation; and special causes of variation. On the one hand, common causes of variation affect a process that is under statistical control, in which the values of a given characteristic are different, but all of them follow a certain pattern that can be modelled by a statistical distribution. These types of causes are still responsible for 80 to 85 percent of problems. On the other hand, special causes of variation are sporadic causes that do not fall within the distribution followed by a characteristic, when the process is under statistical control, and are responsible for 15 to 20 percent of problems. Statistical Control Charts make it easy to identify special causes (Do Rêgo et al., 2023).

The charts assume that the observations are independent and normally distributed. They are made up of a central line (LC=μ) which corresponds to the mean and an upper (LSC) and lower control limit (LIC), which are defined by LC +- 3 standard deviations (3σ). These control limits determine the expected variability of a set of observations. The process is under statistical control when the values of the observations are between the control limits (Requeijo & Pereira, 2008).

Something important to pay attention to is the selection of control limits, which implies that two types of errors can be made: Type I (alpha) and Type II (beta). A Type I error usually means that a point is outside the limits and there is no special cause, while a Type II error means that the points are within the given limits, but in reality there are special causes of variation present (Seland, 2024).

In Control Charts, the occurrence of special causes of variation is verified when one or more observations fall outside the control limits or when a systematic or non-random pattern is identified. To identify special causes of variation, the chart is divided into 3 distinct zones (Zone A, Zone B and Zone C), defined according to the control limits: LC ± $n\sigma$, with $n \in \{1, 2, 3\}$ (Ajadi et al., 2024).

As a result of the work carried out, it became clear the total lack or complexity of the statistical control used, as many of the studies are limited to carrying out a study based on calculating the value of the averages and standard deviations of the data, with a clear lack of validation.

It is therefore necessary to carry out a more robust study of statistical control, to try to eliminate at least the special causes of variation, which in this case may refer to, for example, values that are much higher or lower than the values of the analysed sample, or to establish a monitoring plan based on the application of Control Charts. This will make it possible to increase the robustness of the analysed data , since without the outliers present in the data to be worked on to define the DRL, a more optimized and robust value will be obtained (Deevband et al., 2021; Lima et al., 2018).

This article aims to analyse the use of Control Charts for definition of diagnostic and activities reference levels in hybrid PET/CT examinations, a diagnostic methodology in the field of Nuclear Medicine, addressing how this control is already being carried out and how statistical control can be a tool for estimating process parameters.

RESEARCH METODOLOGHY

This study is divided into two basic parts:

Phase I - Developing the methodology for monitoring, based on SPC, the administrated activity of 2-[18]FDG and the activity associated with the CT component, in patients who have undergone PET/CT studies, in order to define the local diagnostic reference levels of the Institution.

Phase II – Develop and implement Control Charts to monitor the CTDIvol and dose administered, as a tool for monitoring the service.

General objectives:

The overarching aim is to devise a methodology grounded in SPC for establishing diagnostic reference levels in PET/CT scans. Additionally, another goal is to devise a methodology utilizing

Control Charts for real-time monitoring of administrated doses of 2-[18F]FDG in PET/CT scans, aimed at enhancing patient radiological protection. The objective further entails comparing the outcomes derived from determining reference dose levels with those documented in international literature.

Phase I methodology:

To carry out the first phase of the proposed work, it was first important to choose the population to be analyzed so that it would be possible to establish a methodology that could later be used for the different types of examinations using ionising radiation at the Nuclear Medicine Department.

To establish a valid phase I methodology, only whole-body PET/CT scans using the radiopharmaceutical 18-fluorodeoxyglucose (18F-FDG) were analyzed for each year. In addition, only for patients whose body weight was between 70 ± 10kg, without any gender restriction since the dosages are independent of this factor.

It's important to say that the weight range adopted comes from the recommendation of the health professionals at the Nuclear Medicine Department of Hospital Garcia de Orta (HGO), who consider the Portuguese standard patient to be an adult weighing between 70 ± 10kg.

The characterization of the sample is extremely important as it will be the factor that allows different institutions to carry out a study like the one proposed for a similar sample of patients. In this way, different institutions will be able to arrive at their DRL and ARL_{18FDG} values in the future and compare them, thus allowing for greater communication and continuous improvement on the values determined.

As previously mentioned, in this phase of the study we will determine the 75^{th} and 25^{th} percentiles for the CTDIvol values in order to establish the DRL and those for the dose administered to obtain the ARL_{18FDG} values. In addition, at the request of the HGO, the 50th percentile was also determined, since they want to be more ambitious and work with tighter warning limits in order to promote greater radiological protection.

Firstly, a study will be carried out on the filtered data sample to see if it is close to a normal distribution so that a chart can be selected without the need to normalize the data. The criterion for determining normality will be the Sturges criterion, i.e. the number of classes (k) is the smallest integer such that k= 1+3.322Log$_{10}$(n), where n is the number of observations.

Next, in order to carry out the percentile studies mentioned above, it is important to study the presence of possible outliers, so that the value obtained is not affected by erroneous values or other possible special causes.

It is therefore important to select a methodology that is efficient and easy for technicians to use. As a first suggestion, we propose studying the use of BOX-Whiskers charts, due to the ease with which values outside the established limits can be visualized.

The second methodology proposed, in order to eliminate special causes, is to use charts of individual observations and moving ranges (X-MR).

To determine the moving ranges, two consecutive values of the variable X are used, given by the equation (1.1).

$$MR_i = |X_i - X_{i-1}| \tag{1.1}$$

In order to determine the upper, central and lower control limits of the X and MR chart, the following equations are used. For the case under study, the values d_2, D_4 and D_3 are determined on the basis of the factors for constructing variable Control Charts of Requeijo and Pereira (2008), for n = 2.

$$LSC_X = \bar{X} + 3\frac{\overline{MR}}{d_2} \quad (1.2) \qquad LSC_{MR} = D_4\overline{MR} \quad (1.3)$$

$$LC_X = \bar{X} = \frac{\sum_{i=1}^{m} X_i}{m} \quad (1.4) \qquad LC_{MR} = \overline{MR} = \frac{\sum_{i=k+1}^{m} MR_i}{N-k} \quad (1.5)$$

$$LIC_X = \bar{X} - 3\frac{\overline{MR}}{d_2} \quad (1.6) \qquad C_{MR} = D_3\overline{MR} \quad (1.7)$$

After constructing the chart, any value above the upper control limit or below the lower control limit will be eliminated and the respective percentiles calculated.

<u>Phase II methodology:</u>

For the second phase, it was again important to select the population to be analyzed. The data used to build the monitoring model was therefore only for the year 2023, considering all days with more than 5 records and all types of exams, with the exception of brain PET/CT, which uses much higher radiation values.

The aim of this second phase is to build a tool that allows professionals to monitor the levels and activity administered to patients daily. In order to achieve this goal, the proposed methodology will be Short Run Control Charts, since in each day a low patient's volume (5 to 10 patients) is examined, and the estimation of the Control Charts' parameters (mean and standard deviation) can be seriously compromised. These charts allow us to monitor a reduced number of observations, where the parameters are updated whenever we have new data, which makes this type of chart very appealing.

For phase II, Charles Quesenberry's proposal, the Q-charts, will be used. According to this proposal, the quality characteristic to be analyzed, with independent and identically distributed values following a normal distribution, is transformed into a Q variable with a Reduced Normal Distribution. (Quesenberry, 1997; Requeijo & Pereira, 2008).

To be able to control the process mean using the variable, the following transformation described by the equation must be carried out (1.8).

$$Q_r(X_r) = \Phi^{-1}\left(T_{r-2}\left(\sqrt{\frac{r-1}{r}}\left(\frac{X_r - \bar{X}_{r-1}}{S_{r-1}}\right)\right)\right), \text{with } r \geq 3 \qquad (1.8)$$

X_r – Observation r

$\bar{X}_{r-1}$ – average of r-1 observations;

T_{r-2} - T-Student Distribution with r-2 degrees of freedom

Φ^{-1} – Function of inverse Reduced Normal Distribution

Regarding the process variability, the Q statistic, as a function of the MR statistic, is defined for instant r by:

$$Q_r(MR_r) = \Phi^{-1}\left(F_{1,v}\left(\frac{v(MR)_r^2}{(MR)_2^2+(MR)_4^2+\cdots+(MR)_{r-2}^2}\right)\right), \text{com r par} \geq 4 \qquad (1.9)$$

$$v = \frac{r}{2} - 1 \qquad (1.10)$$

v – Degrees of freedom

MR_r – Moving range

$F_{v1,v2}$ –Fisher Distribuition

v_1 e v_2- Degrees of freedom

Due to the transformation of the values to a reduced normal, for both Q(X) and Q(MR) the control limits applied are LSC=3, LC=0 and LIC=-3. In addition, one of the biggest advantages of the Short Run charts is that there are no phases, since phase I and II are applied simultaneously, making them easier for employees without SPC knowledge to apply.

RESULTS

The data provided was first filtered to obtain the CTDIvol, DLP and Dose Administered values for the Standard patient (70 ± 10kg), for Whole Body PET/CT, so that ARL_{18FDG} and DRL could be determined according to ICRP standards.

As mentioned above, we first checked whether the CTDIvol and Dose administered data followed normal distributions and obtained the following graphs (Figure 1).

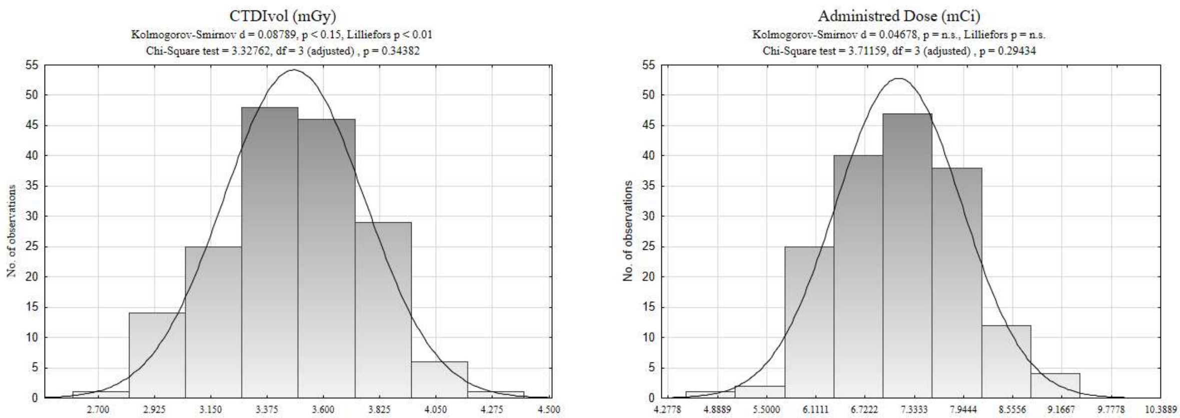


Figure 1: Normal Distribution test

As can be concluded, since the p-value for both distributions is greater than 5%, it can be confirmed that the data follows a normal distribution and can therefore proceed with the proposed methodology.

Tables 1, 2 and 3 show a summary table of the data provided by the local health Department for the years 2021, 2022 and 2023.

Table 1 – Data from 2023

2023								
	n	mean	median	min	max	P-25	P-75	sd
Weight (kg)	171	69.60	70.00	60.00	80.00	64.00	74.00	6.02
CTDIvol (mGy)	171	3.48	3.47	2.47	4.20	3.31	3.68	0.29
Total DLP (mGy.cm)	171	624.56	618.40	415.13	2398.40	572.07	655.08	147.76

Administered Activity (mCi)	171	7.16	7.11	2.14	16.37	6.51	7.70	1.12

Table 2 – Data from 2022

2022								
	n	**mean**	**median**	**min**	**max**	**P-25**	**P-75**	**sd**
Weight (kg)	145	70.13	70.00	60.00	80.00	66.00	75.00	5.66
CTDIvol (mGy)	145	3.51	3.47	2.84	4.31	3.31	3.73	0.30
Total DLP (mGy.cm)	145	615.01	618.60	353.12	757.30	573.67	655.53	60.15
Administered Activity (mCi)	145	7.12	7.08	5.25	9.72	6.58	7.56	0.71

Table 3 – Data from 2021

2021								
	n	**mean**	**median**	**min**	**max**	**P-25**	**P-75**	**sd**
Weight (kg)	75	69.35	70.00	60.00	80.00	64.00	76.00	6.37
CTDIvol (mGy)	75	3.46	3.47	2.78	4.15	3.26	3.63	0.27
Total DLP (mGy.cm)	75	608.57	600.43	499.00	712.20	572.14	662.38	55.24
Administered Activity (mCi)	75	6.95	7.00	5.23	8.75	6.44	7.46	0.77

To be able to determine DRL and ARL_{18FDG} from the 75^{th} percentile of CTDIvol and Dose Administered, respectively, it was necessary to develop a methodology that would easily identify the presence of outliers that could compromise the value obtained.

In this way, two possible graphical approaches could be used and easily lead to the identification and elimination of outliers, first a Box-Whisker graph, and then X-MR Control Charts.

As can be seen from Figure 2 and Figure 3, although the Box-Whisker graphs are very easy to apply, they do indicate the presence of the outlier, but do not allow us to identify its location with any insight. On the other hand, looking at the X-MR control chart, we can see that identifying the outlier and its location is easier, and it is also possible to assess the magnitude of the outlier, something that is not so noticeable with Box-Whisker.

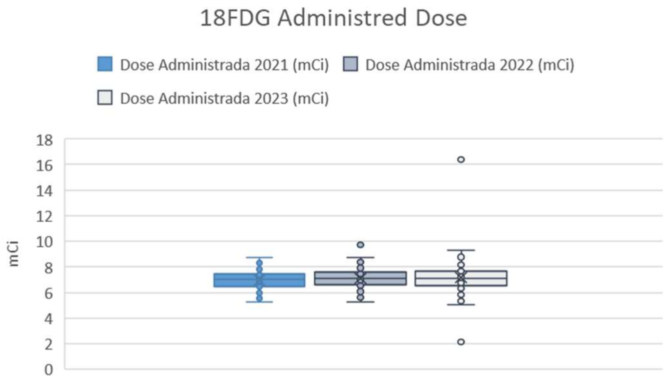


Figure 2: Box-Whisker Plot for the Administered Activity

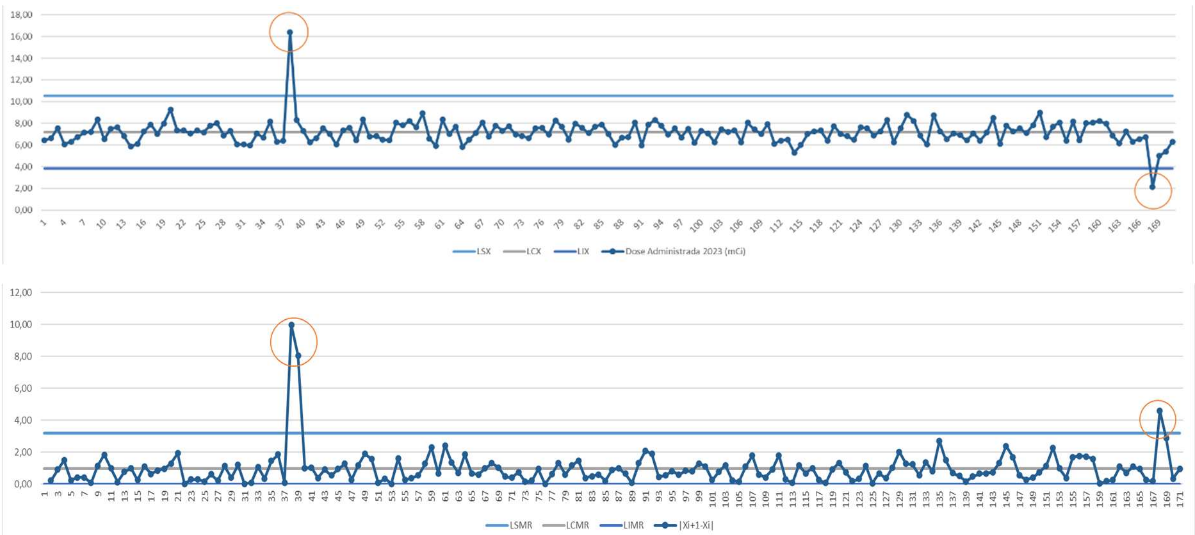


Figure 3: Moving Average Chart for the Administered Activity

Of the various types of Control Charts that can be applied, it was decided at this stage to apply the X-MR Chart, as it is the most appropriate since the data obtained is exclusive to the collection of just one observation.

The X-MR Chart makes it possible to control the dispersion of values, which is very beneficial for the case study carried out, since the main objective is to optimize the radiation levels and activities to which patients are subjected. Thus, for each year and for the standard patient, the respective X-MR Charts were constructed, where it was possible to identify the outliers present for each annual period of data.

After eliminating the outliers identified, it was possible to construct new summary tables where it was found that the average cannot be used to carry out a good analysis, as it is very sensitive to the presence of outliers given the variability seen from Tables 1, 2 and 3 to Tables 4, 5 and 6, especially those referring to 2022 and 2023.

Table 4 – 2023 data resume without outliers

2023 without outliers								
	n	mean	median	min	max	P-25	P-75	sd
Weight (kg)	171	69.60	70.00	60.00	80.00	64.00	74.00	6.02
CTDIvol (mGy)	170	3.48	3.47	2.78	4.20	3.31	3.68	0.28
Total DLP (mGy.cm)	170	614.13	618.31	415.13	771.45	572.07	653.70	56.86
Administered Activity (mCi)	169	7.14	7.11	5.02	9.28	6.51	7.70	0.78

Table 5 – 2022 data resume without outliers

2022 - without outliers								
	N	mean	median	min	max	P-25	P-75	sd
Weight (kg)	145	70.13	70.00	60.00	80.00	66.00	75.00	5.66
CTDIvol (mGy)	145	3.51	3.47	2.84	4.31	3.31	3.73	0.30
Total DLP (mGy.cm)	144	616.82	618.60	491.02	757.30	573.73	655.54	56.22
Administered Activity (mCi)	144	7.10	7.07	5.25	8.71	6.58	7.54	0.68

Table 6 – 2021 data resume without outliers

2021								
	n	mean	median	min	max	P-25	P-75	sd
Weight (kg)	75	69.35	70.00	60.00	80.00	64.00	76.00	6.37
CTDIvol (mGy)	75	3.46	3.47	2.78	4.15	3.26	3.63	0.27
Total DLP (mGy.cm)	75	608.57	600.43	499.00	712.20	572.14	662.38	55.24
Administered Activity (mCi)	75	6.95	7.00	5.23	8.75	6.44	7.46	0.77

On the other hand, the median is more robust to the presence of outliers, since after removing the outliers, its value varies little. It can therefore be concluded that the percentiles are more relevant for measuring DRL and ARL_{18FDG} values.

After eliminating the outliers, as shown in the tables above, the 75th, 50th and 25th percentiles were determined. According to the International Commission on Radiological Protection (ICRP) standards, the DRL for the CT component and the ARL_{18FDG} for the activity administered are determined from the 75th percentile of the data distribution for each indicator.

The 50th percentile was also determined since the local health department, where the study is being carried out, intends to use this percentile as an internal alert value, in order to minimize the patient's exposure to radiation.

On the other hand, the 25th percentile was also determined based on ICRP recommendations, as it is crucial to establish a minimum limit for the level of administered activity to ensure image quality is not compromised.

It is therefore possible to establish the DRL and ARL_{18FDG} values for the local health department according to the 75th percentile. As can be seen from Table 7, for the DRL value associated with the CT component of the hybrid PET/CT scan, CTDIvol, we can see a slight increase in the value from 2021 to 2022, which may be associated with the increase in the size of significant samples.

On the other hand, for the same value we see a slight decrease from 2022 to 2023, however we can deduce that the values from year to year observe little variability. A similar analysis for the 50th and 25th percentiles, shown in Tables 8 and 9, evidence that there is less variability in the values obtained.

Table 7 - 75th Percentile Resume

75th percentile	2021	2022	2023
DRL (mGy)	3.63	3.73	3.68
ARL_{18FDG} (mCi)	7.46	7.54	7.70

Table 8 - 50th Percentile Resume

50th percentile	2021	2022	2023
DRL (mGy)	3.47	3.47	3.47
ARL_{18FDG} (mCi)	7.00	7.07	7.11

Table 9 -25th Percentile Resume

25th percentile	2021	2022	2023
DRL (mGy)	3.26	3.31	3.31
ARL_{18FDG} (mCi)	6.44	6.58	6.51

For the second phase of the proposed methodology, short-run charts were constructed for the data collected on CTDIvol and Dose administered. To build the CTDIvol short-run control chart, equations (1.8) and (1.9) were used to obtain $Q_r(X)$ and $Q_r(MR)$, respectively, where *r* represents the obtained value in each day. Control Charts are presented in Figure 4 and Figure 5.

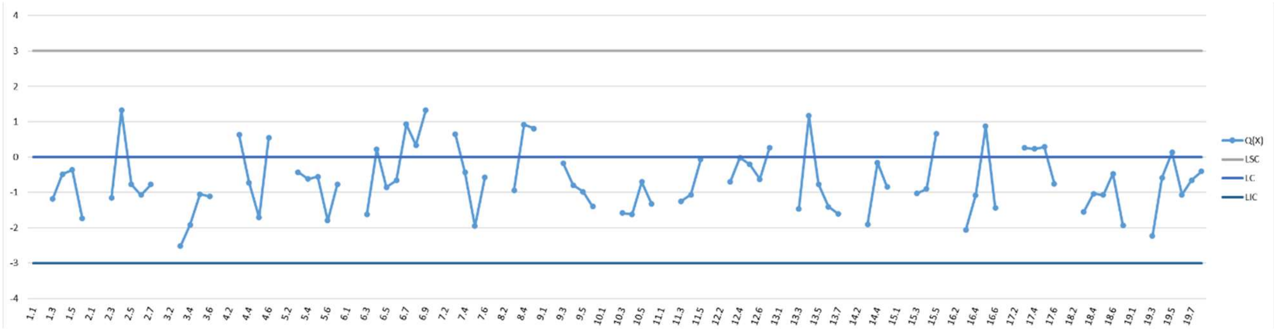


Figure 4: Short-run Q(X) for CTDIvol

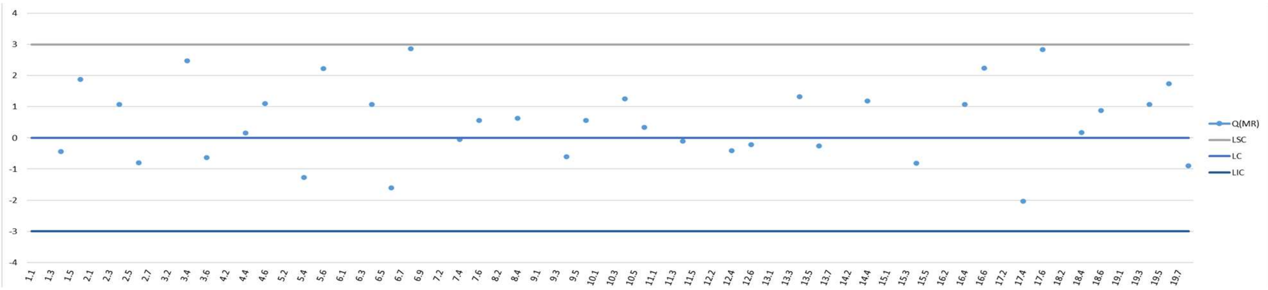


Figure 5: Short-run Q(MR) for CTDIvol

Since the CTDIvol parameter corresponds to the radiation emitted by the equipment per "slice" (i.e., per image), it will depend significantly on the patient's physiognomy. Thus, a number of physiognomic factors are always present, such as body mass index and bone density, which prevent from drawing any kind of conclusion.

In addition, the CTDIvol value is obtained based on what the equipment, through iterations carried out by the software, indicates is necessary to acquire the desired image. Furthermore, the order of magnitude used makes this type of chart less reactive to point values above the 75th percentile or below the 25th percentile.

Therefore, the chart presented on the figure 4 and 5 above would only be relevant if there are values within the same day that are significantly higher or lower, which could alter the weighted average. To address this issue, Capacity indices were used for the short-run control charts, (Qs)r and (QI)r, as defined by the following equations.

$$(Q_S)_r = \frac{USL - \mu_r}{k.\sigma_r} \tag{1.11}$$

$$(Q_I)_r = \frac{LSL - \mu_r}{k.\sigma_r} \tag{1.12}$$

For the study to be conducted, the USL (Upper Specification Limit) and LSL (Lower Specification Limit) were considered to be the 75th and 25th percentiles, respectively. It should be noted that the purpose of these two indices is not to assess the process capability, but rather to add a reference that allows understanding between which percentiles of the data distribution the CTDVol values fall. For this reason, the considered value of *k* is equal to one.

This decision is based on the fact that, initially, only 50% of the points will be within the determined specification limits, making it incompatible to accept a 6σ level. The resulting chart is shown in Figure 6.

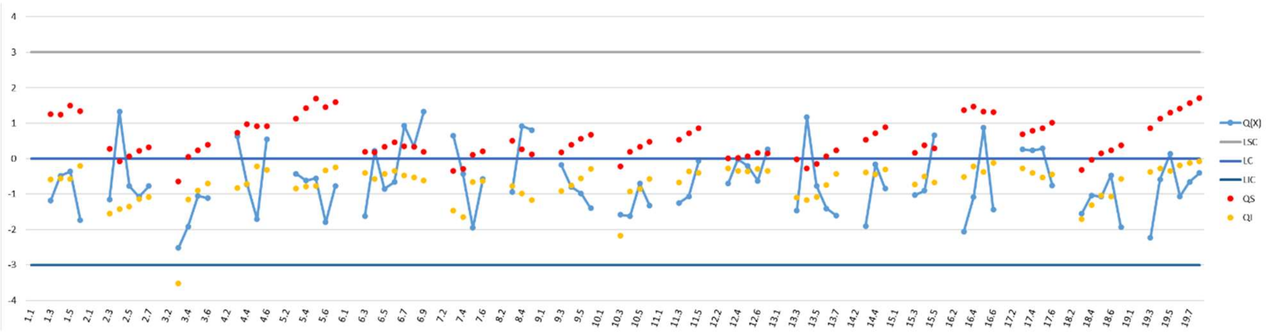
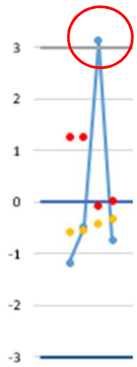


Figure 6: Short-run Q(X) for CTDIvol with $(Q_s)_r$ and $(Q_I)_r$

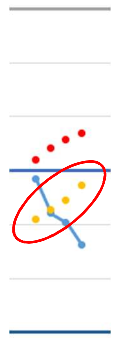
Therefore, for the proposed chart, the technicians will need to be alert to the situations listed in Table 9.

Table 10 -Short-run CTDIvol Patterns

<table>
<tr>
<td>Observations outside the control limits
Indication that there is a very high or very low level of radiation.</td>
<td>
<table>
<tr><th>Obs</th><th>CTDIvol</th></tr>
<tr><td>1</td><td>4,26</td></tr>
<tr><td>2</td><td>3,89</td></tr>
<tr><td>3</td><td>3,26</td></tr>
<tr><td>4</td><td>3,47</td></tr>
<tr><td>5</td><td>9</td></tr>
<tr><td>6</td><td>2,68</td></tr>
</table>
<table>
<tr><th></th><th>CTDIvol</th></tr>
<tr><td>75th percentile</td><td>4,52</td></tr>
<tr><td>25th percentile</td><td>3,36</td></tr>
</table>
</td>
</tr>
<tr>
<td>Ever-increasing $(Q_I)_r$ values</td>
<td></td>
</tr>
</table>

It indicates that radiation levels are decreasing consecutively.

The closer to, or above the central axis the $(Q_I)_r$ points are it indicates that we are below the 25th percentile



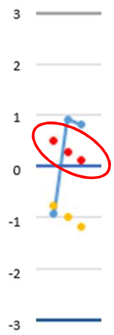
Obs	CTDIvol
1	5,1
2	3,73
3	4,15
4	3,52
5	3,21
6	2,57

	CTDIvol
75th percentile	4,52
25th percentile	3,36

Ever-decreasing $(Qs)_r$ values

It indicates that radiation levels are increasing consecutively.

The closer to or below the central axis the (Qs)r points are indicating that we are above the 75th percentile

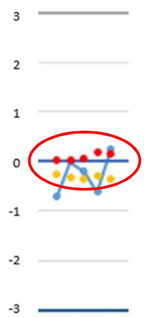


Obs	CTDIvol
1	4,68
2	4,05
3	3,47
4	4,89
5	4,94

	CTDIvol
75th percentile	4,52
25th percentile	3,36

Values of $(Qs)_r$ and $(Q_I)_r$ near central limit

Indicates a wide dispersion of values, with values above the 75th percentile and below the 25th percentile.



Obs	CTDIvol
1	7,46
2	3,73
3	2,21
4	4,41
5	3,89
6	2,89
7	4,63

	CTDIvol
75th percentile	4,52
25th percentile	3,36

The proposed methodology is based on the fact that the administered radiopharmaceutical dose depends exclusively on weight, making it necessary to use the transformed variable, the ratio between the administered activity and the patient's weight.

In addition, the values have a lower order of magnitude, which makes this type of chart more reactive. This way, the Q(X) and Q(MR) charts were constructed with the ratio, which are shown below in Figure 7 and Figure 8, respectively.

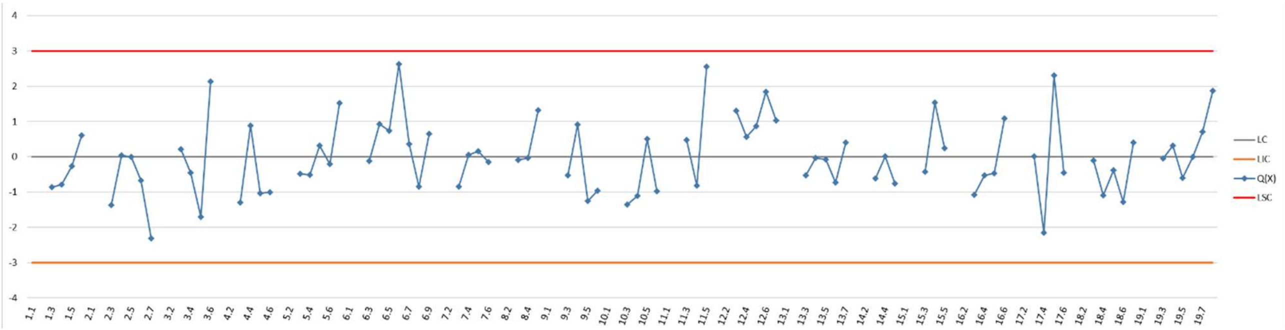


Figure 7: Short-run Q(X) for Ratio Administered

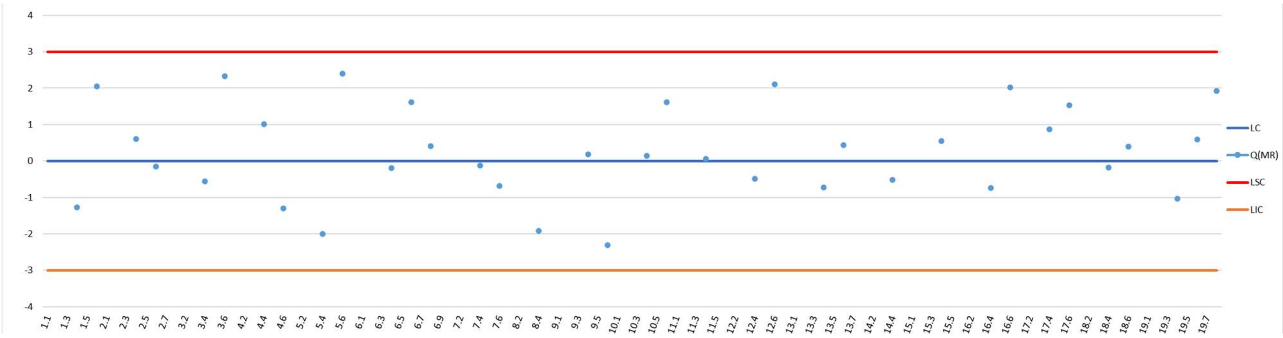


Figure 8: Short-run Q(MR) for Ratio Administered

Given the guidelines recommended by the ICRP, the internal upper and lower alert limits should be established using the information regarding the 75th and 25th percentiles, respectively. Thus, the use of the traditionally established limits of 3 and -3 for the inverse normal are only useful for indicating outliers.

As a result, the respective warning limits were established by transforming the aforementioned percentiles into inverse normal values, as shown in the equations (1.11) e (1.12).

$$\mathrm{IUL} = 3 - \Phi^{-1}(0{,}75) = 2{,}325 \tag{1.11}$$

$$\mathrm{ILL} = -3 - \Phi^{-1}(0{,}25) = -2{,}325 \tag{1.12}$$

IUL – Internal Upper Limit ILL– Internal Lower Limit

After determining the limits and applying them to the charts, we obtain the following charts shown in Figure 9 and Figure 10.

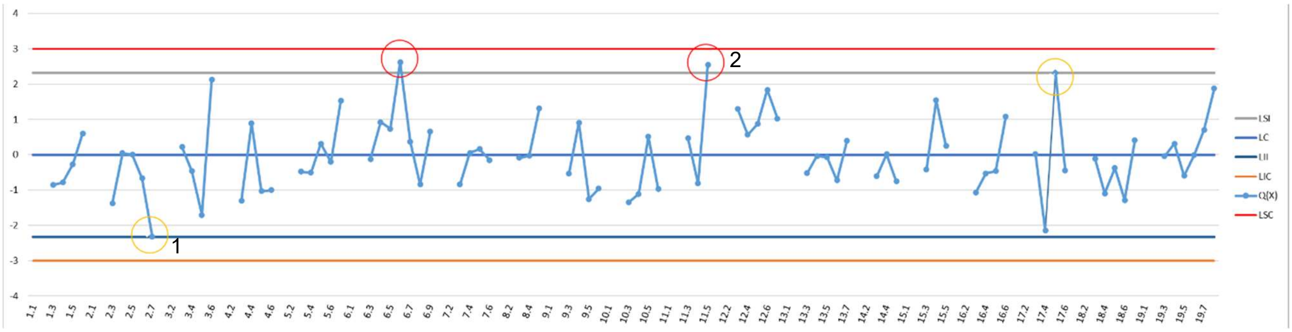


Figure 9: Short-run Q(X) for Ratio Administered with LSI and LII

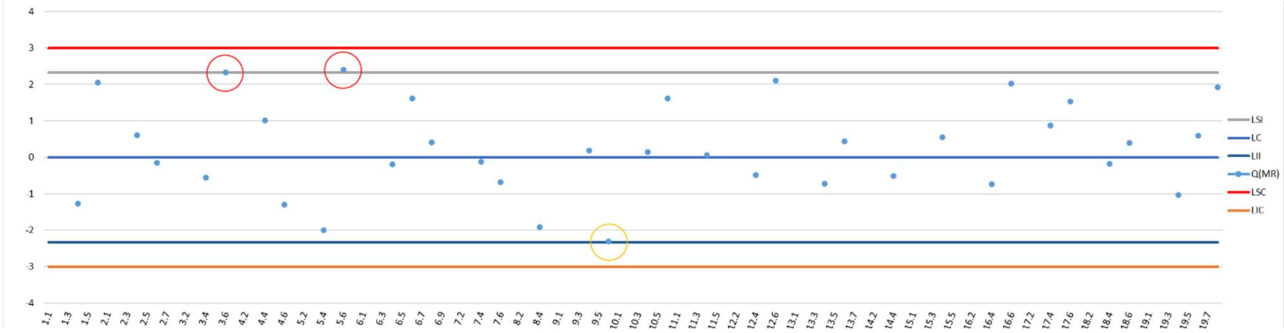


Figure 10: Short-run Q(MR) for Ratio Administered with LSI and LII

For the same dataset, several points on the chart exceeded our internal alert threshold, corresponding to cases where patients received higher than recommended dosages. One of the primary causes of such events is related to the patient's scheduling.

Prior to the test, an appointment is scheduled, during which the patient's weight is recorded to determine the appropriate radiopharmaceutical dose. However, significant fluctuations in the patient's weight can occur between the appointment and the day of the examination.

Thus, as indicated by points "1" and "2" in Figure 9, we are addressing the aforementioned cause. On day "1," the total weight of the patients was higher than expected, resulting in the last patient receiving a lower dosage. Conversely, on day "2," the opposite situation occurred.

Additionally, it is crucial to examine the Q(MR) chart, as the presence of special causes in the moving ranges can indicate dosages that are either higher or lower than recommended.

CONCLUSIONS

It is quite clear how important it is to carry out a control associated with exposure doses in patients, in order to allow the best diagnosis with the least possible risk. In addition, it is very important that the DRL and ARL_{18FDG} are established based on an As Low as Reasonably Achievable (ALARA) principle, since it is necessary to reduce exposure doses as much as possible, without compromising image quality.

It is also clear that there is a great opportunity to reduce variability through SPC, since an analysis of the studies already carried out in the area shows that there is a lack of a good theoretical and practical basis for suggesting DRL values, given that, often, they are limited to "static" statistical models that do not follow the evolution of the data. However, by using Control Charts we can monitor the data and constantly update the parameters used.

The Control Charts will make it possible to create alerts and adjust automatically to the data that is being collected by the institutions, thus ensuring that patients have an optimised level of exposure.

For future studies, we also recommend carrying out an isolated study of the technologists, since to date, and based on the research carried out, there are no studies on the variability of the administered dosages, determined by the performance of the technologist in charge.

It should be noted, however, that this study is merely illustrative of the topic in question and that investment should continue in studying this problem, as to minimize the risk for patients undergoing this type of examination.

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A PROPOSAL FOR ACTIONS TO IMPROVE URBAN SOLID WASTE MANAGEMENT BASED ON CIRCULAR ECONOMY CONCEPTS

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STRUCTURED ABSTRACT

Purpose: The goal of this study was to develop a proposal for actions to improve the management of urban solid waste, based on the concepts of Circular Economy.

Methodology: Qualitative research based on a bibliographical study with the application of a questionnaire as a data collection instrument, which was submitted to the appreciation of experts in the area of Urban Solid Waste Management, using method Delphi.

Findings: The results proposed to cover waste management programs, formation of a sustainable mentality in the population, recognition of experts, transfer of practical knowledge for technological development and integration of the system.

Research limitations/implications: The possibility of omissions and errors in interpreting questions by interviewees, even after validation by the pre-test and unavailability of some respondents due to the functions performed.

Practical implications: The results contribute to academic research and can be used as a basis for future studies, aiming to quickly achieve global Sustainable Development goals.

Originality/value: The formulation of the research theme arose from the need to investigate which bottlenecks are making it difficult to comply with Sustainable Development guidelines and goals, established worldwide, aimed at the management of urban solid waste, towards a Circular Economy.

Keywords: Sustainable development, Waste Management, Circular Economy, Integrated Solid Waste Management.

Paper type: Research Article

INTRODUCTION

The Circular Economy model addresses not only a reduction in the negative impacts caused by the Linear Economy but aims to achieve systemic change in the long term, which can generate economic and business opportunities, providing social and environmental benefits in a more complex and broader vision, from the redesign of processes and products (from their source), to creating new business models that long to optimize the use of resources (Esquível et al., 2019). According to (Lemos, 2018), recycling is an end-of-line solution aiming to limit the linear model impacts such as extraction, production, consumption, and disposal.

The Circular Economy is a fundamental economic model to face the sustainable development challenge, in which global efforts aim to transform waste into resources that will be reintroduced into the economic system through proper management (Avilés Palacios et al., 2021; Sharma et al., 2021). According to (Batista, 2019), in order to manage the disposal of solid waste in a sustainable manner, it is necessary to understand the concepts of digital transformation and manufacturing 4.0 applied to the management of municipal solid waste.

The problem situation of this research is the need to align existing USW management models with the concepts of Circular Economy, counting on the contribution of experts in the area, who were selected based on the information obtained in the literature review, with the aim of to speed up the actions taken, in addition to proposing new actions based on experience with the subject. Therefore, for the reasons explained, the research is related to the following question: **"What obstacles hinder the implementation of a sustainable model of Urban Solid Waste Management based on the concepts of the Circular Economy?"**.

Finally, the participation of social actors is fundamental to consolidating sustainability assessment instruments, where the key actor involvement throughout the entire process of formulation, implementation, and evaluation increases the legitimacy and the relevance of the tool, improving the quality of decisions, as it provides extended information (Certulo, 2020). The main goal of the research was to develop a proposal for actions to improve urban solid waste management based on the concepts of Circular Economy.

LITERATURE REVIEW

Sustainable Development

Most authors define sustainability as a process to achieve a level of development capable of meeting the needs of the current generation without compromising the ability to meet the needs of future generations, preserving nature's resources in a balanced way, as they are finite. This concept, even written in a simplified way, forces human beings to rethink the global economic paradigm to propose better ways to promote sustainable development (Soliani et AL., 2019).

It is worth highlighting that the reduction, reuse, collection, and recovery of recyclable materials are sustainable behaviors and people's awareness of them plays an important role in implementing strategies and policies in this field. Thus, a quantitative analysis carried out on a group of students from the Polytechnic University of Timisoara (Romania) aimed to find answers to main environmental concerns and observe the students' behaviors of reuse and selective collection of waste resulting from various recyclable materials.

Faced with the current reality, Environmental Education is the tool that aims to mitigate, contain, and even reverse this process of environmental degradation, which is determined by habits that are not conscious of the population as a whole, raising awareness and transmitting information on how is the correct way to proceed in the face of these factors, and EE is envisioned by warning about the damage already caused to the environment that we live, of which we are part of and depend on to survive (De Queiroz, 2013; Mateus et al., 2020; Nunes e Lucas, 2014; Quinta et al., 2019).

Therefore, according to the historical approach to Urban Solid Waste Management (GRSU), there is a growing increase in the production of solid waste in societies, showing in research that economic interests, in most cases, stand out to the interest of environmental preservation. The waste management hierarchy is a key to waste management policy worldwide. In the European Union, this hierarchy is enshrined in several strategic documents and reflected in article four of Directive

2008/98/EC, transposed into national law by Decree-Law nº 73/2011 from June 17th. (Paes et al., 2021; Lemos, 2018).

Waste management

The Integrated USW Management seeks to find a balance between three dimensions of waste management: environmental effectiveness, social acceptability, and economic accessibility. It incorporates stakeholder perspectives and needs, local context, and the optimal combination of available appropriate prevention, reduction, recovery, and disposal methods. Its presupposition is the implementation of policies aimed at reducing, reusing, and recycling USW and, therefore, reducing the quantity for final disposal. The key elements for the success of these programs are public participation and empowerment, transparency in decisions, networking, cooperation and collective action, communication, and accessibility of information (Marshall e Farahbakhsh, 2013).

The research by (Sakamoto, 2021) addressed how much inclusive and supportive selective garbage (waste) collection costs, based on the statement that waste management and recycling need to be more inclusive, integrating informal agents, such as Collectors, discovering in their search that, in many countries in the Global South, these organizations have their work recognized at country level, while, despite the achievements of Brazilian policies, cooperatives still face many challenges, mainly in financial sustainability. It is a fact that sorting and recycling associations are fundamental parts of strengthening selective collection, which is why joint articulations between municipalities are necessary for a process of regional development, demanding relationships that go beyond municipal territories. (Almeida et al., 2020; Berticelli et al., 2020).

From all the information presented, we understand that Waste Collectors Organizations are the fundamental link in the integrated management of urban solid waste and play a fundamental social, economic, and environmental role. As a result, the main activity carried out by Waste Picker Organizations is to insert materials into the production cycle, promoting a circular economy. Therefore, due to the financial dependence on the public sector as the economic source and the difficulties of self-management, these organizations do not achieve a competitive position in the recycling market (Romeiro, 2021; Tong et al, 2021).

It is crucial to emphasize that the challenges encountered in implementing sustainability to mitigate USW problems require correct planning and management that seeks to reduce, reuse, and recycle solid waste correctly, and the appropriate measures involve educational actions environment, which, in addition to guiding the population on the correct disposal of this waste, can make them aware of the practice of excessive consumption. Consequently, there is a need to establish responsibilities and partnerships with the government, public institutions, and private companies, in addition to regulating the rights and protection of collectors of recyclable materials and disseminating information on ways of disposing of recyclables and co-responsibility of society, in a transparent and easy-to-understand manner (Costa e Dias, 2020; Cristina, 2021; Felisardo, 2021).

Circular Economy

The Circular Economy is considered a fundamental economic model to face the challenge of sustainable development and, for that reason, the global efforts focused on transforming waste into resources are reintroduced into the economic system through appropriate management. In this way, linear and waste-producing value chain problems get fixed, making circular and more sustainable solutions in these chains that already benefit from circular processes, reducing waste generation in contrast to the inefficient consumption of resources. Following this reasoning, it's known that CE is a more holistic approach that advocates extracting value from waste and achieving sustainability goals (Avilés e Rodrogues, 2021; Sharma et al., 2021).

According to (Korhonen, 2018), the CE restricts the production flow to a level that nature tolerates and utilizes ecosystem cycles in economic cycles, respecting their natural reproduction rates. The mentioned concept originates from various schools and lines of thought that underpin discussions on Sustainable Development, one of them being Life Cycle Management. Furthermore, the CE transforms goods at the end of their life cycle into resources for others, minimizing waste. That represents a shift in economic logic because it replaces production with sufficiency: "Reuse what you can, recycle what cannot be reused, repair what's broken, and rebuild what can't be fixed" (Stahel, 2016).

The results of the study by (Tiossi and Simos, 2021) showed that Sustainability and Circular Economy share the common goal of addressing environmental, economic, and social issues, emerging as a new supportive strategy for sustainable development. It is also a tool that has come to strengthen sustainable practices and assist companies in achieving the globally proposed sustainable development goals.

Achieving environmental sustainability and transitioning from a linear economy to an Environmental Conservation model heavily depends on the effective management of waste and how waste is treated as a potential resource for the future. However, socioeconomic disadvantages, insufficient specialized knowledge, and a lack of information posed challenges to its adaptation and implementation in low and middle-income countries. Therefore, one of the primary strategies to overcome these issues is to use waste as a resource, in other words, transitioning towards an Environmental Conservation model (Ezeah e Roberts, 2012; Huysman et al., 2017; Ranjbari et al., 2021).

It's worth noting that most developing countries are facing significant challenges in managing the growing amount of waste generated in rapidly expanding urban areas. (Ferrari's, 2016) study addresses the topic of international partnerships for sustainable development in urban solid waste management in developing countries, focusing on the Italian private initiative responsible for the technical transfer of knowledge and expertise. This initiative is supported by an international association that acts as a cultural bridge to ensure the translation of innovative knowledge into viable local solutions for Guinea-Bissau in West Africa (Ezeudu, 2019; Ferrari et al., 2016; Ferronato, 2021).

According to (Batista, 2019), to manage solid waste disposal sustainably, it is essential to understand the concepts of digital transformation and Industry 4.0 applied to municipal solid waste management. Thus, the automated execution of public services for the collection, transportation, reduction of weight, and volume of urban waste (residue) to the final disposal can be structured based on the effectiveness of successful business models. In addition, (Deka and Goswami, 2018) emphasize real-time monitoring and management of the garbage (waste) collection system, thereby eliminating the collection of partially filled bins. They also question the mapping and status of waste in a city, contributing to a more systematic and cost-effective ecological garbage (waste) collection. In conclusion, authors Xue et al. (2019) point to Internet and Communication Technologies in waste management to create a new collection model: smart collection.

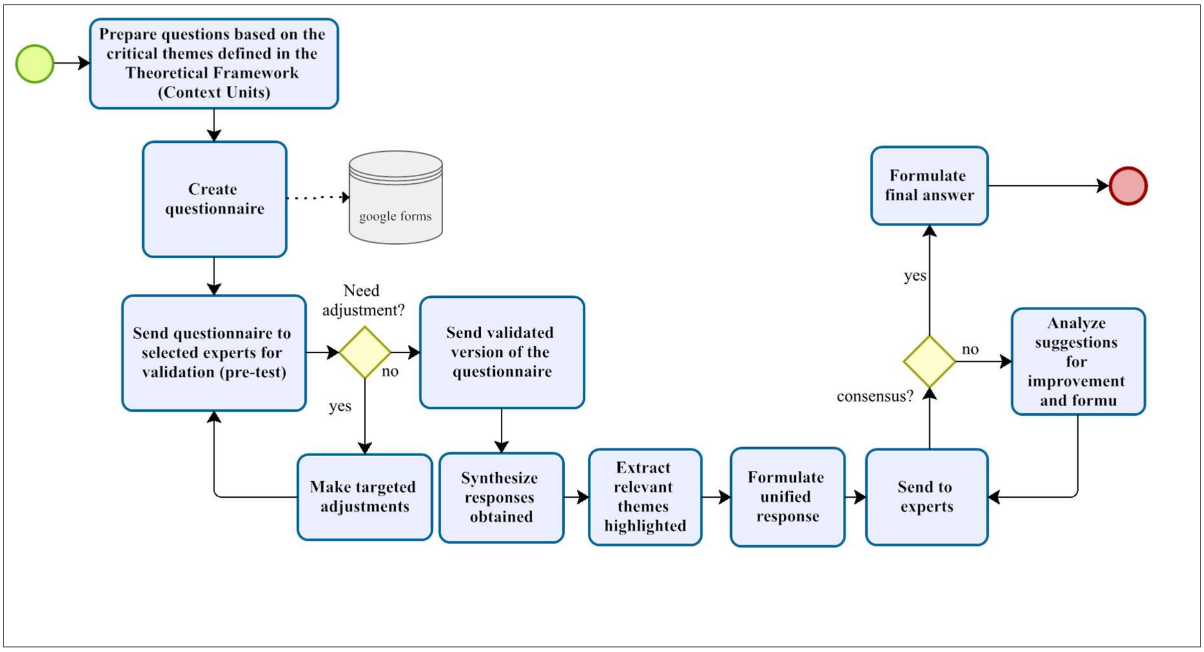
RESEARCH METODOLOGHY

The data collection instruments used in the current research were a bibliometric survey (for secondary data) conducted to academically support the research and a research questionnaire (for primary data) developed based on the theoretical foundation. This questionnaire was administered to a group of experts via a Google Forms survey to gather primary data on the subject, aiming to utilize their specialized knowledge in the field of Urban Solid Waste Management to identify gaps that can be addressed with suggestions found in the literature or arising from the experience of the interviewed experts.

To manage the research questionnaire, the Delphi technique was employed. This technique represents a qualitative interpretative paradigm based on the participant's expertise. Furthermore, the Delphi technique, used in content validation processes, involves the consensus-building of a group of experts conducted in successive rounds. Its purpose is to evaluate a specific problem or proposed intervention while preserving the anonymity of participants and their responses. This technique allows for the interaction of responses through feedback in each round, summarizing the technical and scientific content, both practical and theoretical, expressed in the opinions provided by the interviewed experts (professors, urban cleaning company managers, recycling cooperative managers, professionals in the solid waste area, non-governmental organization for the defense of the environment in the state of Rio de Janeiro**).**

Figure 1 illustrates the complete process for data collection, from the formulation of the questionnaire, pre-testing, application, to the feedback of responses from the experts.

Figure 1 - Primary data search process



Source: prepared by the authors (2024)

RESULTS

As shown, the questionnaires were sent as a tool to gather input from experts in Urban Solid Waste Management from various fields of expertise in Rio de Janeiro. The data was collected from the forms distributed via Google Forms. Out of the 25 experts invited to whom the questionnaires were sent, 10 of them were returned and filled out randomly based on the availability and interest of the respondents. Thus, a return rate of 40% was achieved, which is considered an acceptable average for the return of applied questionnaires. Studies indicate that an optimal number of respondents for the Delphi technique should not be less than 10, and in most cases, panels have at most a few dozen experts (Grisham, 2009; Osborne et al., 2003). The research was conducted from August to November 2022.

Table 1 provides a summary of the results from the first and second rounds, considering the criteria set by the Delphi technique as presented in the methodology. It is acknowledged that the level of agreement with the unified responses of the interviewed experts presented in the 2nd round was high, achieving consensus among the participants.

Table 1 - Results obtained after applying the delphi technique

Context Units	Results %			Quantitative data collected		
	I fully agree	Partially agree	I do not agree	Nº 1st round registration units	Nº 2nd round suggestions	Nº of suggestions included
1 Sustainability	90%	10%	0%	5	2	0
2 Integrated Urban Solid Waste Management	80%	20%	0%	5	2	0
3 Selective Collection, economic development and social inclusion	80%	20%	0%	5	3	0
4 Sustainable initiatives	90%	10%	0%	5	1	0
5 Sustainable models	90%	10%	0%	5	2	1
6 Participatory methodologies	90%	10%	0%	5	1	0

Source: prepared by the authors (2024)

DISCUSSION

The research was composed of 6 (six) questions, formulated based on the context units contained in the theoretical framework, all inserted into one of the 3 major themes of the research that delimit the subjects covered in the theoretical foundation.

The first question is included in the theme of Sustainable Development and, according to the answers presented, the first difficulty in accelerating the process of popular awareness regarding GRSU lies in the still timid communication regarding the topic. In this way, publicizing in the mass media the environmental education programs contained in the approved waste management plans and the solutions available for operationalizing waste in each location are actions that can be taken immediately, given that many municipalities already have active waste management initiatives, but partially.

In general, authors and respondents reinforce that quality environmental education is the first step towards sustainable development. Thus, (Quinta et al, 2019), they argue that environmental education should begin from the first school years, so that citizens understand the importance of preserving the planet where they live in everyday practices. In addition, (De Queiróz, 2013; Mateus et al, 2020 and Nunes and Lucas, 2014), argued in their studies that Environmental Education is the tool that aims to mitigate, contain and even reverse this process of environmental degradation, which is determined by unconscious habits of the population as a whole, always raising awareness and transmitting information about the correct way to proceed in the face of these factors.

The second question is part of the topic of waste management. Respondents first highlighted the need to provide the necessary training and autonomy for solid waste managers to work in multidisciplinary areas, without forgetting to train specialists working in recycling cooperatives, including them as instructors in environmental education programs.

Corroborating this position, (Certrulo, 2020) highlighted that the participation of social actors is fundamental to consolidate sustainability assessment instruments, where the involvement of key actors throughout the entire process of formulation, implementation and evaluation increases legitimacy and relevance of the tool, improving the quality of decisions, as it provides more complete information. In this context, participants highlighted that the contribution of experts is the key to multiplying the concepts necessary for sustainable solid waste management, in addition to valuing the knowledge acquired over years of experience.

Also included in the theme of solid waste management, the third question is perhaps the most emblematic of the questionnaire, as it focuses on one of the most important themes in the research, selective collection, as it is undoubtedly the most challenging activity to achieve a sustainable development. According to the experts participating in the research, for materials to effectively reach the recycling chain, it is necessary to effectively regularize the integration between recycling cooperatives and industry, objectively defining the processes so that these cycles occur naturally.

In this context, survey respondents warned of the need to effectively regularize the integration between recycling cooperatives and the industry, as in agreement with (Almeida et al, 2020 and Berticelli et al. 2020), selective collection, in addition to contributing significantly to urban sustainability, has gradually incorporated a profile of social inclusion for the most needy sectors and those excluded from access to formal labor markets, as it promotes recycling efficiently, increasing the percentage of material returned to industry, fueling the Circular Economy.

The fourth question is inserted in the theme of Circular Economy, which, as already presented, is a popular concept promoted by companies, countries and the European Union, and represents a rationality of greater efficiency in the use of resources, as opposed to the linear rationality of extracting resources. produce-consume-discard.

In order to achieve the global targets for urban solid waste management, it is necessary to join forces so that the most developed locations in this area can help the less favored ones, both with the transfer of knowledge acquired through experiences, and with the signing of formal cooperation agreements, aiming for a greater objective, which is sustainable development towards a Circular Economy in a globalized way.

In line with the theme, the study by (Ferrari, 2016) addressed the subject of international partnerships for the sustainable development of urban solid waste management in developing countries. In agreement with the authors (Ezeudu and Ezeudu, 2019), survey respondents pointed out the importance of promoting events aimed at transferring technologies in waste management and exchanging good practices in conscious consumption and solid waste management, disseminating (with a strategic dissemination) in the mass media.

The fifth question, also included in the Circular Economy theme, focuses on the improved efficiency of urban solid waste management, based on investments in technologies capable of accelerating the processes necessary for sustainable urban waste management. It is worth noting that, most of the time, investing in technology is expensive, however, with the evolution of the internet of things, many low-cost solutions are being implemented through the use of applications and the MSRM area has been using some of these solutions. The experts participating in the research indicated that the first action was to identify the appropriate technologies for each situation.

According to (Batista, 2019), in order to manage the disposal of solid waste in a sustainable manner, it is necessary to understand the concepts of digital transformation and manufacturing 4.0 applied to the management of municipal solid waste. In line with the author, the experts focused on the need for investments in systems that provide the automated execution of public services for collection, transportation, weight reduction and volume of urban waste until final disposal, which can be structured based on effectiveness of business success models.

The sixth and final question is also included in the EC theme and focuses on the need for private companies to participate in this transition process, as they are important actors in driving sustainable development, being largely responsible for generating jobs and wealth in civilized society.

In agreement with the authors (Ezeah, 2012; Huysman et al., 2017; and Ranjabar et al., 2021), the need for better state performance was highlighted in order to expand tax benefits and incentives to companies that contribute to -ra a circular economy; demand more energetically compliance with environmental targets imposed on companies; and establish performance indicators to measure the efficiency of waste management by companies, aiming for the transition to a Circular Economy.

Finally, not only the experts consulted, but also the authors researched in the literature review argued that the main activity carried out by Waste Collector Organizations is to insert materials into the production cycle, promoting a circular economy, however, due to dependence of the public sector as the main economic source and the difficulties of self-management, these organizations do not achieve a competitive position in the recycling market.

Based on the results presented in this research, a proposal for improvement actions in the urban solid waste management models was developed to achieve the overall research objective: "to create a proposal for improvement actions in urban solid waste management based on the concepts of Circular Economy."

Frame 1 - Proposal for actions to improve SWM models based on the concepts of CE.

Proposed Theme 1: *Sustainability*	What can immediately be done to make the environmental education programs offered more comprehensive in order to accelerate the process of popular awareness about GRSU?
Required Action	**Desired Outcomes**
1- Spread in the mass media the environmental education programs contained in the approved waste management plans.	Wider Coverage of Waste Management Programs.
2-Expand the Implementation of Environmental Education Actions/Programs proposed in approved plans and monitor the results achieved.	Formation of a sustainable mindset in the population.

3- Provide training to potential information multipliers (representatives of residents' associations, condominium cleaning teams, representatives of basic education institutions, and businesses with significant waste generation).	Utilization of existing structures to properly dispose of a larger quantity of waste.
4- Promote through mass media the available solutions for waste management in each locality.	Contribution of waste generators to the proper disposal of waste.
5- Include environmental education as a subject in all basic education curriculum.	Raising awareness about environmental responsibility from early childhood.
Proposed Theme 2: ***Integrated Management of Urban Solid Waste***	What is the best way to leverage the expertise of a specialist to expand integrated solid waste management initiatives?
Required Action	**Desired Outcomes**
1-Provide the necessary training and autonomy for waste management professionals to work in multidisciplinary areas.	Technical training
2-Recruit interested waste managers to provide paid instruction in the environmental education projects outlined in approved waste management plans.	Recognition of experts
3-Efficiently monitor the environmental education projects outlined in approved waste management plans.	Project Control
4-Provide training to experts stationed at recycling cooperatives, including them as instructors in environmental education programs.	Technical training and social inclusion
5-Utilize the knowledge of waste managers to develop interactive platforms aimed at engaging audiences of all ages with approved environmental education programs.	Transfer of practical knowledge for technological development
Proposed Theme 3: ***Selective Waste Collection, Economic Development, and Social Inclusion***	To ensure that materials effectively reach the recycling chain, how could recycling cooperatives be formally included in municipal SWM processes, given their role in returning Urban Solid Waste to the industry?
Required Action	**Desired Outcomes**
1-Formalize the integration between recycling cooperatives and the industry effectively.	Integration of the SWM system
2-Conduct a waste gravimetric study in areas not covered by selective collection programs.	Identification of priorities for the implementation of new SWM programs
3-Regularize the hiring of labor for cooperatives.	Social Inclusion
4- Regularize the fiscal and corporate status of cooperatives.	Social Inclusion
5-Develop bidding documents for contracting services provided by cooperatives	Social Inclusion

Proposed Theme 4: *Sustainable Initiatives*	What would be the ways to expand cooperation between countries, states and municipalities that cover SWM's global goals?
Required Action	**Desired Outcomes**
1-Develop technical cooperation agreements that result in benefits and/or fiscal incentives for the participating entities.	Integration of stakeholders towards the Circular Economy
2-Promote events aimed at technology transfer in waste management.	Transfer of practical knowledge for technological development
3-Promote course exchanges in SWM with academic institutions in environmentally advanced countries.	Technical training
4-Promote exchanges of best practices in conscious consumption and waste management, disseminating them through mass media.	Transfer of practical knowledge
5-Expand cooperation agreements between government entities and companies to enhance waste management actions.	Integration of stakeholders towards the Circular Economy
Proposed Theme 5: *Sustainable Models*	What measures could be taken at the public and private levels to increase investments in technologies in order to improve SWM efficiency?
Required Action	**Desired Outcomes**
1-Envision tax incentives upon proof of investment in technologies for proper waste disposal.	Integration of stakeholders towards the Circular Economy
2-Increase investment in computerized waste management systems.	Sustainable development
3- Form or expand partnerships with companies to invest in educational institutions for the development of waste management Technologies.	Integration of stakeholders towards the Circular Economy
4- Identify the appropriate technologies for each situation.	Sustainable development
5-Regulate the use of these waste management technologies with the appropriate sanctions in case of non-compliance.	Control of implemented programs
6- Promote contests for practical and feasible solutions.	Attracting talent and knowledge in favor of viable technological solutions.
Proposed Theme 6: *Participatory Methodologies*	What is the best way to encourage the participation of private companies in SWM with the aim of transitioning to a CE?
Required Action	**Desired Outcomes**
1- Disseminate the environmental management rules outlined in Solid Waste Management Plans.	Dissemination of waste management programs
2-Enforce compliance with environmental targets imposed on companies more vigorously.	Control of implemented programs
3-Expand tax benefits and incentives for companies contributing to a circular economy.	Integration of stakeholders towards the Circular Economy

4-Implement or expand the process of circularizing the production chain of waste-generating companies.	Circularization of supply chains
5- Establish performance indicators to measure the efficiency of waste management by companies.	Control of implemented programs

Source: developed by the authors (2024)

CONCLUSION

After concluding the literature review, it was possible to identify the primary critical themes related to Urban Solid Waste Management, thereby addressing the research question. Through the collection of this data, the necessary content was obtained to underpin the three main subjects addressed in this research, which were Sustainable Development, Waste Management, and Circular Economy. These themes served as the foundation for defining the context units that guided primary data collection.

An example highlighting the existing gaps in Urban Solid Waste Management that impact the transition to a Circular Economy is the compilation of individual research studies on the state of municipal selective waste collection in various regions of Brazil. Furthermore, the registration units extracted from the contributions of the interviewed experts pointed out various gaps in Urban Solid Waste Management systems, complementing the data collected from the literature.

The results contribute to academic research by providing content that can be used as a foundation for future studies, with the aim of more expeditiously achieving global Sustainable Development goals. According to the experts who participated in this research, achieving this requires the concerted efforts of more developed societies in the field of Urban Solid Waste Management to assist less developed ones. This assistance can involve the transfer of knowledge gained from their experiences and the establishment of formal cooperation agreements, all with the overarching goal of sustainable development towards a globalized Circular Economy.

Among the desired outcomes with the actions proposed by the interviewed experts, notable results include greater coverage of solid waste management programs, the cultivation of a sustainable mindset within the population, increased contribution of waste generators to proper disposal, technical training, the transfer of practical knowledge for technological development, and the attraction of talent and expertise for viable technological solutions. All of the results can be implemented through the collective efforts of all participants in the extensive process of Urban Solid

Waste Management, which begins with raising awareness among the population regarding the responsible care of the environment in which they live, using resources correctly to ensure the survival of future generations.

In conclusion, it is essential to motivate the population to fulfill the Sustainable Development Goals, especially SDG 11 (making cities and human settlements inclusive, safe, resilient, and sustainable) and SDG 12 (ensuring production and consumption sustainable patterns). Indeed, the 17 Sustainable Development Goals (SDGs) are interconnected, as effective waste management depends on a decent quality of life for all citizens, providing the conditions for everyone to contribute to the pursuit of a Circular Economy.

Therefore, it is hoped that this work contributes to society, businesses, researchers, and managers in adopting or maintaining Urban Solid Waste Management for the success and continuous improvement of existing and developing processes using Circular Economy concepts toward Sustainable Development.

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On Key Factors of e-Learning Quality for Senior Citizens

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STRUCTURED ABSTRACT

Purpose: The purpose of this study is to investigate the key factors of the quality of e-learning from the perspectives of the senior citizens.

Design/methodology/approach: This research surveys the senior citizens that over 50 years old and uses technology acceptance model as a theory basis to design a research model. A total of 300 questionnaires from the senior citizen are collected. The research model is examined using partial least squares (PLS) analysis.

Findings: The research results show that perceived ease of use (PEOU) and perceived usefulness (PU) are paramount in shaping seniors' attitudes towards their intention to adopt e-learning where technology anxiety emerged as a significant barrier.

Practical implications: The findings of this work could be used as a reference when designing the e-learning program.

Originality/value: There is a trend that the average age of the society has become older in many countries. The development of e-learning is becoming a great alternative, compared to traditional classroom, especially during the pandemic period. It is expected that even for senior citizens, they are also looking for the use of e-learning due to the readiness of modern information infrastructure. This work presents a practical investigation to explore the key factors to be successful for this domain.

Keywords: e-Learning, Technology Acceptance Model, elderly education, technology anxiety, COVID-19

Paper type: Research paper

INTRODUCTION

The swift progression of technological innovation alongside the significant evolution of the Internet has elevated e-Learning to a key educational paradigm for the future. This development is particularly pertinent to the global aging phenomenon, with many countries experiencing a notable increase in its aging population. This demographic shift and a heightened focus on adult education underscores the critical need to promote e-Learning within the elderly demographic.

Historically, the intricate operational commands of conventional computers and the necessity for keyboard proficiency have represented substantial obstacles for the elderly, exacerbating the digital divide between them and their younger cohorts (Lam & Lee, 2005). However, the recent ubiquity of personal computing devices and the transition from wired to wireless internet connectivity have made the internet a staple of everyday life. This transformation has spotlighted the digital divide as a significant issue, with the acceptance and eagerness of the elderly to engage with computer and internet technologies drawing considerable attention. Prompted by these societal observations, this work explores the aging trend, the rapid pace of technological advancement contributing to an expanding digital divide, and the increasing focus on adult education. It also addresses the dearth of domestic research in this area, thereby defining the motivation of this investigation.

The aging of the global population is occurring at an unparalleled rate, with life expectancy on the rise due to medical advancements and continuous improvements in public health, nutrition, and safety. This phenomenon is not confined to developed nations; developing countries are also grappling with the advent of an aging society. The escalating proportion of the aging population presents a formidable challenge worldwide.

The convergence of aging demographics with the rapid development of technology and the Internet has forged a significant generational digital divide. Whereas younger individuals have grown up immersed in digital environments, the elderly have not, making adapting to technology-laden lifestyles particularly challenging. For those among the elderly who are novices to technological products, mastering new technologies demands considerable effort and time (Hanson, 2009). The advent of tablets, characterized by their touchscreen functionality and user-friendly interfaces, has mitigated the need for keyboard use, significantly lowering the entry barrier for the elderly to engage with computer and internet technologies. This shift heralds the arrival of an era where e-Learning via computers or mobile devices is becoming the mainstream.

Recently, the COVID-19 pandemic has profoundly affected various sectors worldwide, including higher education. In this realm, the imperative to avoid infection has expedited the shift from conventional classroom instruction to e-Learning modalities (Mertens et al., 2021). Although this transition has been instrumental in containing the virus's spread, it has introduced numerous challenges, especially for older learners who may struggle to adapt to new technological tools and e-Learning platforms. Older adults, particularly those with limited technological savvy, unreliable internet access, or lacking digital devices, may experience technology anxiety and resistance to adopting e-Learning (Ngafeeson et al., 2024). These challenges are exacerbated for older learners by factors such as resistance to change, lower technological literacy, privacy concerns in e-Learning contexts (Zhang et al., 2014), and physical or cognitive impairments that complicate navigation of e-Learning environments. Additionally, psychological distresses like stress, anxiety, and depression, amplified by the pandemic and the absence of conducive learning environments at home, intensify the difficulties older learners face in transitioning to e-Learning (Mseleku, 2020).

Despite extensive research on e-Learning and the elderly, scant attention has been paid to e-Learning among this demographic during the COVID-19 pandemic. Previous studies on computer-based e-Learning have primarily concentrated on the acceptance of e-Learning platforms among industry personnel, students' acceptance of e-Learning platforms, and the efficacy of e-Learning systems, employing the technology acceptance model for e-Learning analysis. Conversely, most research on technology acceptance among the elderly has focused on their use of mobile devices, willingness to utilize smartphones, mobile device interface design for the elderly, and factors influencing their acceptance of new technologies. Yet, there is a notable gap in research exploring the elderly's acceptance and behavioral intentions toward e-Learning.

Identifying the factors influencing the elderly's acceptance of e-Learning is crucial for promoting e-Learning and facilitating their adoption of this educational approach. This endeavor is anticipated to improve the classroom learning efficiency of the elderly demographic significantly. Furthermore, it promises to narrow the generational digital divide, enhance the elderly's ability to access digital networks and empower them to acquire valuable information or skills via e-Learning. The elders could broaden their social networks and improve their overall life satisfaction.

Accordingly, this study examines the behavioral intentions of elderly population toward e-Learning amidst and after the COVID-19 pandemic. It aims to augment the technology acceptance model framework by integrating privacy concerns and technology anxiety, thereby investigating the elderly's willingness to participate in e-Learning activities.

LITERATURE REVIEW AND RESEARCH CONSTRUCT

Elderly e-Learning (during and after COVID-19)

The sudden onset of the COVID-19 pandemic necessitated a swift transition to e-Learning modalities across educational sectors worldwide. This shift was not without its challenges, particularly for elderly learners who, despite possessing a wealth of knowledge and experience, often face barriers to accessing and engaging with e-Learning platforms. The pandemic exacerbated these challenges, highlighting the digital divide and the need for pedagogical approaches that cater to the unique needs of older learners (Chung et al., 2020; Crawford et al., 2020).

E-learning for the elderly must consider cognitive abilities, technological proficiency, and the social aspects of learning. Adaptive learning environments that offer support for varying cognitive skills and provide straightforward, user-friendly interfaces can enhance the e-Learning experience for older adults. Moreover, incorporating interactive materials and fostering a collaborative learning atmosphere are crucial for engaging elderly learners and promoting community and belonging, which is especially important during social isolation for the fear of COVID-19 (**COV**) (Oliveira & Pasqualotti, 2023).

The transition to e-Learning during the COVID-19 pandemic has underscored the importance of flexible, inclusive, and accessible educational practices. For elderly learners, this means creating e-Learning environments that are not only technically accessible but also pedagogically supportive of their unique learning needs. The findings from the reviewed literature suggest that while there are challenges, there are opportunities to enhance the e-Learning experience for older adults, ensuring that education remains a lifelong pursuit accessible to all, regardless of age or technology anxiety. Therefore, this study has the following hypothesis. The question items have been proposed based on the review.

H_1: The fear of COVID-19 (COV) positively influences attitude toward e-Learning.

Technology Acceptance Model and Privacy Concerns

The Technology Acceptance Model (TAM) has been widely applied to understand the adoption of various technologies, including e-Learning, especially during the unprecedented COVID-19 pandemic. The model posits that Perceived Usefulness (PU) and Perceived Ease of

Use (PEOU) are fundamental determinants of technology adoption intentions and behaviors (Davis, 1989).

Table 1. Question items of Fear of COVID-19

ID	Question Items	Sources
COV1	I was worried about getting infected during COVID-19.	Oliveira Jr & Pasqualotti, 2023
COV2	I was worried about the number of COVID-19 cases in Taiwan would surge during COVID-19.	
COV3	I was worried about getting infected because of my friends during COVID-19.	
COV4	I was worried about getting infected to the point of insomnia during COVID-19.	
COV5	I often followed the pandemic situation through social media (LINE or Facebook) during COVID-19.	

Perceived Usefulness (PU) is the extent to which a person believes that using a particular system would enhance their job performance, while Perceived Ease of Use (PEOU) refers to the degree to which a person believes that using a particular system would be free of effort (Davis, 1989). Integrating these constructs into the TAM provides a robust framework for predicting and understanding the acceptance of e-Learning technologies. Based on the reviews, this paper provided the following hypotheses:

H_2: PEOU positively influences PU of e-Learning technologies.

H_3: PU positively influences the attitude toward e-Learning.

H_4: PEOU positively influences the attitude toward e-Learning.

H_5: Attitude towards e-Learning (ATT) positively influences the Intention to use e-Learning (INT).

Table 2. Question items of TAM

ID	Question Items	Sources
Perceived Usefulness		
PU1	I believe that e-Learning can improve my learning outcomes.	
PU2	I believe that e-Learning can enhance my learning efficiency.	
PU3	I think that e-Learning is useful for me to learn new knowledge.	
PU4	I was worried about getting infected to the point of insomnia during COVID-19.	
PU5	I believe that e-Learning will make it easier for me to prepare for learning new knowledge.	
PU6	I believe that e-Learning will make it easier for me to acquire knowledge.	Davis, 1989; Zhang et al., 2014; Chung et al., 2020
Perceived Ease of Use		
PEOU1	I believe that learning to use e-Learning to learn new knowledge is not difficult for me.	
PEOU2	I can easily master the skills of using e-Learning to learn new knowledge.	
PEOU3	I can easily get started with e-Learning.	
PEOU4	I believe that the process of using e-Learning to learn new knowledge is clear and easy to understand.	
PEOU5	I believe that it is not difficult to become proficient in using e-Learning to learn new knowledge.	
PEOU6	I believe that e-Learning is easy to use.	
Attitude towards E-learning		

ATT1	I believe that using e-Learning to learn new knowledge is a good idea.	
ATT2	I believe that using e-Learning to learn new knowledge is a wise choice.	
ATT3	I like the suggestion of using e-Learning.	
ATT4	I believe that using e-Learning to learn new knowledge should be enjoyable.	
Intention to Use E-learning (INT)		
INT1	I plan to use e-Learning to learn new knowledge.	
INT2	I think I will use e-Learning to learn new knowledge.	
INT3	I plan to use e-Learning in the future.	

In addition to the classical TAM constructs, privacy concerns emerge as a critical factor in the context of e-Learning, affecting both PU and Attitude towards technology. Privacy concerns (PC) pertain to users' worries about unauthorized access, use, and potential misuse of their personal information (Smith et al., 1996).

H6: Privacy concerns negatively influence PU of e-Learning technologies.

H7: Privacy concerns negatively influence attitudes toward e-Learning.

These hypotheses are grounded in the literature examining the interplay between technology acceptance and privacy concerns, especially in health-related contexts where personalization and privacy form a complex paradox influencing user acceptance (Zhang et al., 2014). The role of attitude, acting as a mediator between PU and the intention to use, underscores the multi-dimensional nature of technology acceptance models, suggesting that cognitive assessments of technology and affective reactions to technology (e.g., privacy concerns) are vital in understanding user acceptance and usage behavior.

Technology Anxiety

The rapid shift to e-Learning environments, necessitated by the COVID-19 pandemic, has brought the interplay between technology anxiety and perceived ease of use into sharp focus. The

Technology Acceptance Model posits that PEOU and perceived usefulness are key determinants of technology adoption and use (Davis, 1989). However, the unique circumstances of the pandemic and the forced migration to e-Learning platforms have underscored the importance of examining how technology anxiety impacts PEOU, especially among elderly learners and those less familiar with digital learning tools.

Table 3. Question items of Privacy Concern

ID	Question Items	Sources
PC1	I am worried that using e-Learning may leak my privacy.	Zhang et al., 2014
PC2	I am worried that my personal data may be misused by vendors when I log in to use the e-Learning system.	
PC3	I am worried that my personal data may be used by others because I use the e-Learning system.	

Technology anxiety, defined as an individual's apprehension or fear regarding the use of technology, can significantly deter the adoption and effective use of e-Learning platforms (Ngafeeson, 2024). Studies have shown that this form of anxiety can lead to a lower PEOU, affecting learners' confidence in their ability to engage with e-Learning technologies (Alshammari et al., 2020). This is particularly relevant in the context of the elderly population, who may face additional challenges such as reduced cognitive and motor skills, making the ease of use a critical factor in e-Learning adoption (Chung et al., 2020; Lin, 2021).

Empirical evidence suggests that interventions aimed at reducing technology anxiety could improve PEOU, thereby enhancing the willingness to engage with e-Learning platforms (Zhang et al., 2014). For instance, providing comprehensive support and training can alleviate fears and build confidence among users, making the technology seem more approachable and easier to use (Oliveira Jr & Pasqualotti, 2023). Based on the literature, the following hypotheses are proposed to investigate further the relationship between e-Learning Anxiety and Perceived Ease of Use (PEOU):

H_8: E-learning anxiety negatively influences the perceived ease of use of e-Learning platforms.

Table 4. Question items of E-learning anxiety

ID	Question Items	Sources
ANX1	I am worried about encountering setbacks in the process of e-Learning.	Ngafeeson, 2024
ANX2	I would hesitate to use e-Learning because of the fear of making mistakes.	
ANX3	I believe that e-Learning will discourage me.	

RESEARCH MODEL

To examine the influence of e-Learning Anxiety (ANX) on the Perceived Ease of Use (PEOU) and subsequent effects on Perceived Usefulness (PU), Attitude towards e-Learning (ATT) (Davis, 1989), and Intention to use e-Learning platforms among the elderly population (INT) during the COVID-19 pandemic. Additionally, the study aims to investigate the impact of Privacy Concerns (PC) on PU and ATT towards e-Learning. This study proposed the research model as below (see Figure 1).

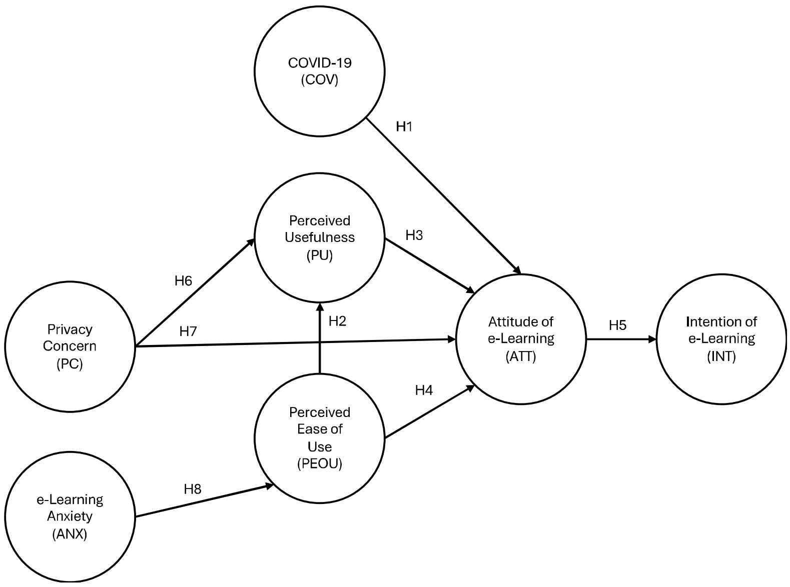

Fig. 1 Proposed Research Model

A questionnaire has been developed based on validated items from existing literature, tailored to measure the constructs of interest: COV, ANX, PEOU, PU, ATT, INT, and PC as shown in the previous section. The questionnaire has been pilot-tested to ensure reliability and validity.

In this study, the target population will be elderly individuals with experience or interest in e-Learning platforms. A stratified random sampling technique will be used to ensure a representative sample. Data will be collected through online surveys distributed via face-to-face surveys and social media platforms. The reflective measurement models have been used for all constructs based on TAM. Items will be measured on a Likert scale ranging from strongly disagree (1) to strongly agree (7). Given the applied nature of studying elders' e-Learning amidst COVID-19, the research might prioritize the model's predictive accuracy over the theoretical fit. PLS-SEM emphasizes prediction and the explanation of variance in dependent variables, aligning with the practical goal of identifying key factors that enhance or inhibit e-Learning adoption among the elderly, thus offering actionable insights for educational policy and program design. Thus, PLS-SEM has been employed (Hair et al., 2016; Henseler et al., 2009). The analysis involved two stages: assessing the measurement model (for reliability and validity) and the structural model (for hypothesis testing). The model's goodness of fit has been evaluated using SRMR (Standardized Root Mean Square Residual) and other fit indices appropriate for PLS-SEM.

RESULTS

Questionnaires were administered through face-to-face surveys targeting individuals aged 55 and above, yielding 300 valid responses. The analysis revealed that 53.33% of the respondents were women, with ages ranging from 55 to 76 years. Moreover, 14.87% of the participants were aged 65 years or older.

Items with factor loadings below 0.5 were excluded from the analysis to ensure the reliability and validity of the constructs. The identified factors exhibited satisfactory reliability, as evidenced by Cronbach's α, ρ_A, and composite reliability indices, all exceeding the threshold of 0.7 (Fornell & Larcker, 1981). Furthermore, the average variance extracted (AVE) for each construct surpassed the benchmark of 0.5, affirming convergent validity (Fornell & Larcker, 1981). Discriminant validity of the constructs was also confirmed based on the analysis (Fornell & Larcker, 1981). The model's fit was assessed using the standardized root mean square residual (SRMR), the unweighted least squares discrepancy (d_{ULS}), and the geodesic discrepancy (d_G), with acceptable thresholds determined by the 95% bootstrap quantile (Dijkstra et al., 2015). The SRMR value was 0.059, below the recommended maximum of 0.08 and its 95% bootstrap quantile of 0.087, indicating an acceptable fit (Dijkstra et al., 2015). The d_{ULS} and d_G values were 0.804 and 0.436, respectively, both lower than their 95% bootstrap quantile thresholds (HI95 of 1.740 for d_{ULS} and 0.647 for d_G), further validating the model's adequacy. The results are detailed in Figure 2 and Table 5.

In a refined examination of the analytical results by age group, a noteworthy distinction emerges between participants over the age of 65 and those younger. Specifically, the causal relationship between Attitude towards e-Learning (ATT) and Intention to use e-Learning (INT) demonstrates a stronger effect among older adults (Coefficient = 0.888) compared to their counterparts under 65 years of age (Coefficient = 0.649, *p*-value = 0.021<0.05). Similarly, the influence of Perceived Ease of Use (PEOU) on INT is more pronounced in the older cohort (Coefficient = 0.652) than in the younger group (Coefficient = 0.391, *p*-value = 0.032<0.05). These findings suggest that individuals aged 65 and above prioritize the usability of an e-Learning system to a greater extent than younger (aging between 55-64) users. Consequently, ease of use significantly impacts their intention to engage with e-Learning platforms. This differential response underscores the necessity of tailoring e-Learning environments to meet the specific usability requirements of older adults, thereby enhancing their engagement and learning outcomes.

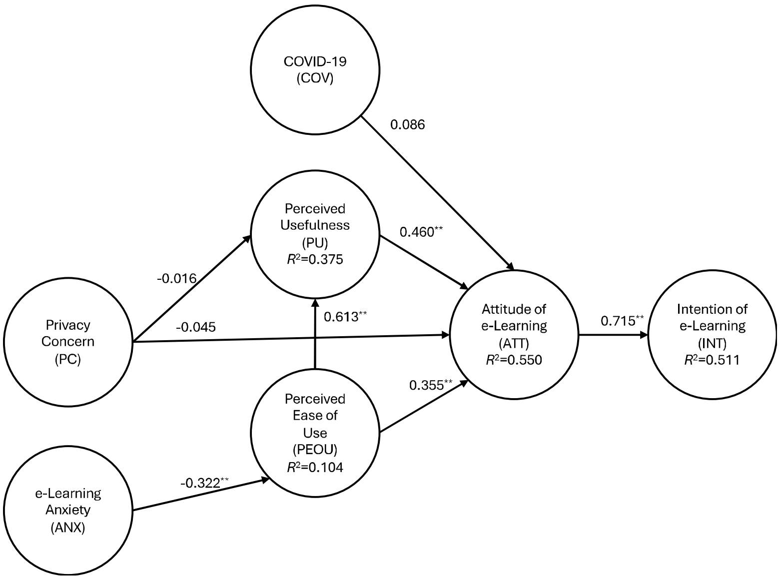

Fig. 2 Analytical Results

Table 5 Causality Relationship

Relation	Coef.	p-Value	Test
COV→ATT	0.086	0.391	H1 is unsupported
PEOU→PU	0.613	<0.001	H2 is supported
PU→ATT	0.460	0.001	H3 is supported
PEOU→ATT	0.355	0.009	H4 is supported
ATT→INT	0.715	<0.001	H5 is supported
PC→PU	0.016	0.960	H6 is unsupported
PC→ATT	-0.045	0.631	H7 is unsupported
ANX→PEOU	-0.322	0.018	H8 is supported

CONCLUSIONS

This study has contributed to general understanding of the factors influencing the adoption of e-Learning among senior citizens, especially during and after the disruptive period of the COVID-19 pandemic. By leveraging an extended Technology Acceptance Model (TAM) that incorporates privacy concerns and technology anxiety, our research provides comprehensive insights into the behavioral intentions towards e-Learning within this demographic.

Findings indicate that perceived ease of use (PEOU) and perceived usefulness (PU) are paramount in shaping seniors' attitudes towards e-Learning, which subsequently influences their intention to use such platforms. Interestingly, contrary to initial assumptions, privacy concerns did not markedly deter e-Learning adoption among older adults, suggesting that the perceived benefits of e-Learning may override privacy apprehensions. Moreover, technology anxiety emerged as a significant barrier, underscoring the need for supportive measures to facilitate e-Learning engagement among the elderly.

For future research, several paths are recommended to deepen and extend the findings of this study. One can explore the adoption of e-Learning across different cultures and geographic locations and provide a comparative perspective on how contextual factors influence technology acceptance among the elderly. Additionally, designing and evaluating interventions aimed at reducing technology anxiety and enhancing usability could directly address some of the key barriers identified in this study. This could include user-friendly design innovations, personalized learning paths, and comprehensive support systems. Employing qualitative methodologies to capture the nuanced experiences, motivations, and challenges senior citizens face in adopting e-Learning would enrich quantitative findings and provide deeper insights into how e-Learning platforms can better cater to this demographic. Future studies should integrate additional theoretical perspectives beyond TAM, such as the Unified Theory of Acceptance and Use of Technology (UTAUT) or models focusing on social influence and community building, which could offer a more nuanced understanding of the factors driving e-Learning adoption among seniors.

By addressing these areas for further development, subsequent research can continue to build upon the foundation laid by this study, enhancing the inclusivity, accessibility, and effectiveness of e-Learning platforms for senior citizens. As societies continue to age and technology evolves, understanding and supporting the lifelong learning needs of older adults will become increasingly important, not just for individual well-being but also for the social and economic health of communities worldwide. This study marks an important step in recognizing and addressing the unique e-Learning needs and challenges faced by senior citizens, paving the way for more inclusive and effective digital education strategies in the future.

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Assuring quality in higher education: defining dimensions in e-assessment

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STRUCTURED ABSTRACT

Purpose - Amidst the COVID-19 pandemic, higher education has shifted significantly towards online learning, prompting widespread use of digital tools in teaching. However, ensuring quality student assessment in online environments remains a challenge. This research, part of the REMOTE project (ref: 2022-1-ES01-KA220-HED-000085829) funded by the European Union, aims to tackle this challenge. Collaborating with multiple Higher Education Institutions (HEIs) and External Quality Assurance Agencies (EQAAs) across Europe, the study focuses on investigating the efficacy and quality of e-assessment methods.

Design/methodology/approach - In the previous review by Casadesús et al. (2024), it was noted that e-assessment has not been extensively studied, possibly due to its novelty. This article contributes an additional exploratory step in this research. Specifically, it discusses the results of interviews with 33 experts globally in the field, including researchers, HEIs' administrators, and EQAAs' representatives. These interviews, centered around three specific questions about the quality of the e-assessment, have been fully documented and publicly available for further scrutiny.

Findings - This research undertakes a qualitative analysis, leveraging insights from the previous interviews. Employing a structured data analysis methodology pioneered by Goia (1998), this article discerns critical dimensions for defining an effective e-assessment system that upholds quality standards.

Originality/value - This paper contributes to the ongoing discourse on online education by offering preliminary insights into the development of a comprehensive quality assurance framework. By delineating key dimensions for e-assessment quality, the presented findings serve as a foundational step towards fostering excellence in online education environments.

Keywords: e-assessment, quality in higher education, virtual learning

Paper type: Research paper

INTRODUCTION

The COVID-19 pandemic brought about a significant upheaval in the realm of education globally, prompting educational institutions to swiftly adopt remote learning models. This transition has sparked crucial inquiries into the effectiveness of assessing students in online environments, commonly referred to as e-assessment. E-assessment presents distinctive challenges such as the absence of adequate technologies, issues concerning credibility and authenticity, and the imperative to ensure fairness and security in online testing environments. Recognizing and understanding these challenges is paramount as e-assessment becomes an integral component of the educational landscape.

With the aim of addressing the challenges inherent in e-assessment and offering practical solutions for universities and evaluation agencies, the REMOTE project "Assessing and evaluating e-assessment practices in STEM (REMOTE)" (ref: 2022-1-ES01-KA220-HED-000085829) was launched. This initiative, funded by the European Union under the "Cooperation partnerships in higher education" action of the Erasmus+ program, involves collaboration among several Higher Education Institutions (HEIs) and External Quality Assurance Agencies (EQAA). The primary objective of the project is to define a framework of action that will enhance the quality of student learning outcomes through improved e-assessment practices.

This article presents the initial insights of the REMOTE project, specifically focusing on the crucial task of defining the dimensions that will significantly impact the enhancement of student learning in online environments. In other words, what dimensions should HEIs and EQAAs consider to ensure that e-assessment is carried out with the utmost quality possible? As described in Casadesús et al. (2024), literature on this topic is scarce and seldom specifically focused on the challenge of e-assessment, hence lacking a clear response to the posed question.

This article seeks to address this gap. Therefore, the primary objective of this article is to develop a framework, based on specific dimensions, for quality assurance in e-assessment in higher education.

The structure of this paper is as follows: the subsequent section outlines the literature review. Following that, the research methodology, based on interviews with experts and following the methodology developed by Gioia (1998), is presented. Subsequently, the main framework is introduced. Finally, the last section discusses and concludes upon the proposed framework for HEIs and EQAAs to enhance the quality of e-assessment practices and, consequently, the overall student learning experience in online environments.

LITERATURE REVIEW

Casadesus et al. (2024) is the sole reference detected upon analyzing academic contributions in the field of e-assessment. The authors identified a total of 47 contributions, many of which diverge significantly from the focus of the current article. However, the authors categorized these contributions into four main areas: students, teaching methodologies, teaching staff, and technologies, as depicted in Figure 1.

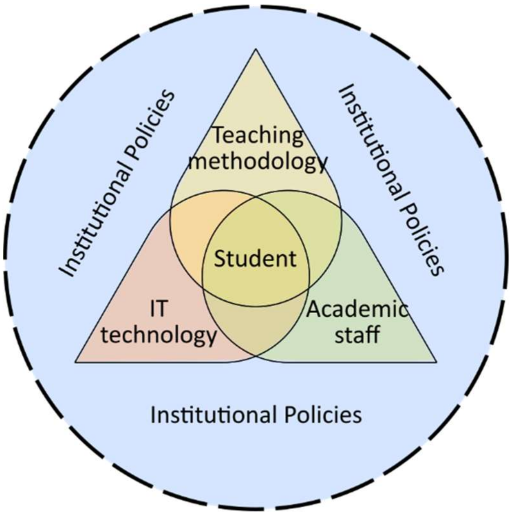

Figure 1 - Categorization of articles published in assessing and evaluating remote learning practices. Source: Casadesus et al. (2024)

The key characteristics of these entities, as outlined in the literature compiled by Casadesus et al. (2024), are summarized below:

- Student: In online education, students are encouraged to take an active role in their learning journey. This includes engaging with course materials, participating in virtual discussions, and seeking clarification when needed. They benefit from the flexibility to learn at their own pace and access a wide range of resources to support their studies. Many studies highlight the pivotal role of students in shaping their learning experiences in this context. Additionally, online assessment methods, such as quizzes, essays, and multimedia presentations, not only assess academic progress but also enhance digital literacy and proficiency in virtual communication. However, there is a noticeable lack of research specifically dedicated to online assessment.

- Teaching Methodology: Despite the significant shift to virtual teaching, literature suggests that this area remains relatively underexplored. Effective teaching methodologies in online programs prioritize engagement, interaction, flexibility, and personalized learning experiences. Analyzing and implementing these methodologies pose intricate challenges. Furthermore, the goal is to create inclusive learning environments that cater to students from diverse backgrounds and locations. While some studies focus on specific regions, the analysis has managed to transcend geographical boundaries.
- Academic Staff: Within the realm of online learning, academic staff members play multifaceted roles as instructors, facilitators, and mentors. They are instrumental in guiding and supporting students throughout their educational journey. These educators meticulously design and develop online course materials to ensure they are engaging, relevant, and aligned with learning objectives. Employing effective pedagogical strategies, they promote active learning and engagement in the virtual classroom. Moreover, they facilitate discussions, provide timely feedback on assignments, and address student queries to foster a supportive and interactive learning community. Academic staff also undertake the responsibility of assessing student performance and upholding academic integrity in online courses. Additionally, considering that many instructors also teach face-to-face classes, numerous comparative studies analyzing both practices have been identified.
- Information Technology: Information technologies (IT) are the backbone of online programs, enabling effective teaching and learning experiences. These technologies create seamless and interactive virtual environments where students can access course materials, engage in discussions, collaborate with peers, and submit assignments. Learning Management Systems (LMS) serve as the foundation of online courses, providing centralized platforms for content delivery, communication, and assessment. Moreover, these technologies facilitate data collection and analysis, empowering instructors to personalize learning experiences, identify

areas for improvement, and monitor student progress. Despite the considerable focus on the impact of IT in online education, there remains a research gap in connecting these technologies with teaching methodologies beyond their technical aspects.

The majority of the aforementioned studies only tangentially analyze e-assessment, such as Chen et al.'s (2018) work on student perception and engagement in online STEM classes or Usher and Barak's (2018) comparison of learning in physical campus versus online settings. Only the study provided by Guangul et al. (2020) delves into e-assessment within the framework of academic dishonesty in more detail. For instance, it concludes that combining various assessment methods, such as report submission with online presentations, aids in minimizing academic dishonesty since examiners have the opportunity to verify the authenticity of submitted work.

Thus, while various studies on e-assessment are identified, they could be deemed punctual in nature. In other words, no literature has been detected that establishes a framework, specifically a set of dimensions, for quality assurance in e-assessment within higher education. This constitutes the precise objective of the present study.

PROJECT AND METODOLOGHY

The REMOTE project: Assessing and evaluating remote learning practices in STEM

The research developed in this article is part of the REMOTE project. The REMOTE project aims to assess and evaluate remote learning practices in the field of STEM. The project is focused on addressing the challenges posed by online learning and the use of disruptive technologies in education. The project has a collaborative partnership between Higher Education Institutions (HEIs) and External Quality Assurance Agencies (EQAAs) to ensure the development of effective assessment and learning methodologies, namely: Universitat de Girona, Universitat Internacional de Catalunya (Barcelona), Politecnico di Torino and Universidade do Minho (Braga) as HEIs, and Agencia per la Qualitat del Sistema Universitari de Catalunya (Catalonia), Agenzia Nazionale di Valuazione del Sistema Universitario e della Ricerca (Italy) and Agencia de Avaliaçao e Acreditaçao do Ensino Superior (Portugal) as EQAAS.

The project has three main objectives. The first objective is to understand current assessment and remote learning practices in STEM disciplines and provide guidelines for efficient and effective assessment and remote learning particularly in emergency situations. The second objective is to provide guidelines and benchmarks for implementing and evaluating successful remote assessment methodologies, with a focus on gender issues and the needs of different HEIs. The third objective is to develop a roadmap and sustainability plan for implementing the assessment guidelines and ensuring their effective use by HEIs. In consequence this is a multifaceted research project that combines quantitative and qualitative methods as desk research, crowdsourcing screening, students and teacher questionnaire, in-depth interviews, etc. The development of the present research focuses just on the first of these three objectives.

Research methodology

In order to define the dimensions that should be part of the model for quality assurance of e-assessment in higher education proposed to be designed, a well-established approach in organizational identity research has been chosen: The “Gioia Methodology” for conducting inductive qualitative analysis (see Gioia, 1988). This methodology, used in many exploratory qualitative studies like the present one, allows for the development of a grounded model based on experts' interpretations. Gioia et al. (2012) provides relevant insights into this methodology, as well as a summary of studies using this methodology or variations of it. Thus, grounded theory building is used to generate an interpretative framework that relates the different aspects involved in the analysis object from the perspective of recognized experts. In the present research, this process has been designed in four main stages.

Firstly, and based on the literature review and exploration of relevant entities for the study's object, 33 experts were selected to provide their insights, including researchers, HEI’s and EQAA’s representatives, etc.

In a second phase, all experts were interviewed, specifically with three completely exploratory common questions designed based on the conclusions of the reviewed literature. The aim of all questions was to allow experts to construct their own narrative freely, and in this sense, following the indications of the "Gioia methodology" they all began with a "How." The first and third questions were complemented with sub questions that allowed, once the expert had expressed their main narrative, to focus on the most specific aspects related to teaching methodologies and, in this framework, e-assessment in particular. The questions designed are exactly as follows:

1. How do you imagine the university of the future?
    a. What teaching methodologies do you mostly imagine?
    b. Which learning technologies do you think will prevail?

2. How will the students of the future differ from those of today?

3. How do you think the remote learning practices will change in this future University?

   a. Do you think that remote learning practices can affect differently depending on the gender?

   b. Do you think that STEM studies require remote learning practices different from the rest of fields of study?

It is noted that in this exploratory work, no question explicitly referred to e-assessment in particular, precisely to give maximum freedom to the expert. In any case, it is obvious that all experts ended up giving their opinion on it, with the advantage of being able to determine the relevance they gave to this dimension of education.

All interviews were conducted by researchers of the team, so that once the three general questions were finished, a new debate often arose. The interviews concluded in October 2023, and all of them were recorded and are available at: https://diobma.udg.edu/handle/10256.1/7109?locale-attribute=en, classified by expert and question. Obviously, the criteria of the UdG Ethics Committee have been scrupulously followed, and the corresponding agreements have been signed so that all contributions of the experts can be publicly disseminated.

In a third phase, all interviews were transcribed. From these, the researchers selected and coded all those aspects that were considered most relevant to ensure their identification and management. In this way, for each of the different questions of each interview, a summarized and coded file was generated. Two levels were used for coding: (1) using a lexicon of concrete terms grounded in the data (e.g., hybrid, e-assessment, etc.) and (2) using a lexicon of more abstract terms arising from the a priori specification of constructs as proposed by Eisenhardt (1989) found in the literature (e.g., teaching methodology, assessment methodology, staff education, etc.). It is worth noting that in this coding process, the researchers were very careful to differentiate key aspects that could lead to confusion, such as the impact of new technologies on education versus new methodologies.

Finally, the last phase consists of analyzing all the collected information in order to cluster the theoretical categories that are defined into a few aggregated key dimensions, as proposed by the "Gioia methodology". This is an iterative analysis, as patterns are detected, "*moving among data, emerging patterns, and existing theory and research until the patterns were refined into adequate conceptual categories (Eisenhardt, 1989)"*. In this way, a classification is obtained, formulated from the experts' opinions, which provides answers to the questions posed and aligns with existing literature.

RESULTS

Figure 2 shows the data structure obtained, strictly following Gioia's methodology (1988), organized into three levels. At the first level, "first-order concept", those literal statements, coded individually, detected in interviews with experts are grouped together, considered relevant to the study's object. It should be noted that the figure does not include, nor is it the objective of the methodology, to determine the relevance of these statements. That is to say, the figure does not show the quantity of experts who agree on each of them, an aspect that could be analyzed in later stages but not in the exploratory analysis. Based on this coding, they are classified into the so-called "second-order themes" according to the dimensions defined previously in the literature. And finally, the aforementioned categories are aggregated into "Aggregate dimensions" that define the major decisions that need to be made to ensure the quality of e-assessment.

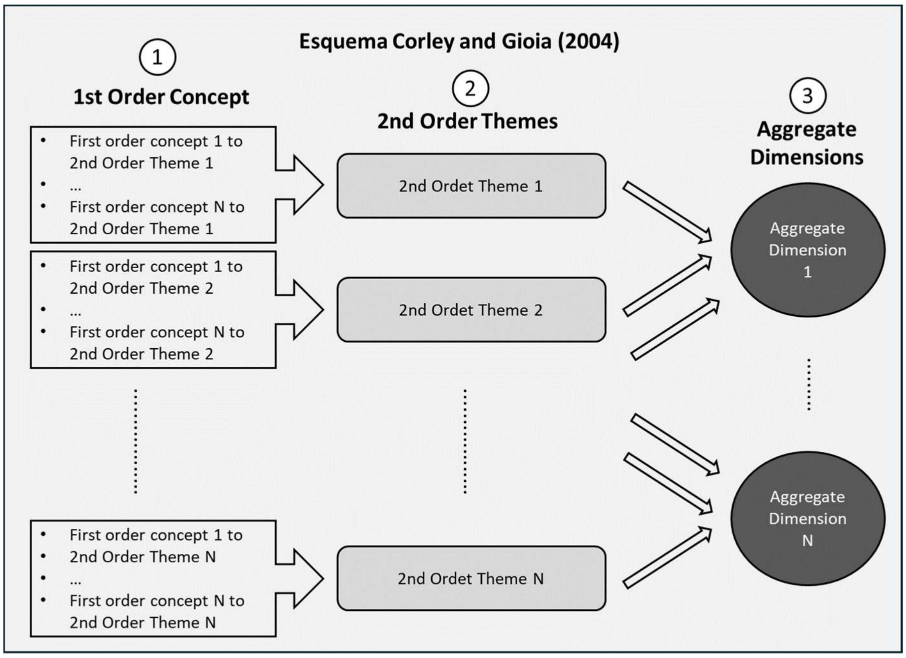

Figure 2 – Generic data structure for Gioia's methodology

In this specific case, the implementation of the Gioia methodology in our study serves to systematically explore the nuanced dimensions of quality assurance in distance assessment within higher education STEM disciplines. Traditionally, the Gioia methodology has been instrumental in organizing qualitative data to elucidate key themes and underlying concepts. However, to capture a more holistic view of the phenomena under investigation, we propose an innovative application of this methodology, termed the double-sided Gioia approach (Figure3).

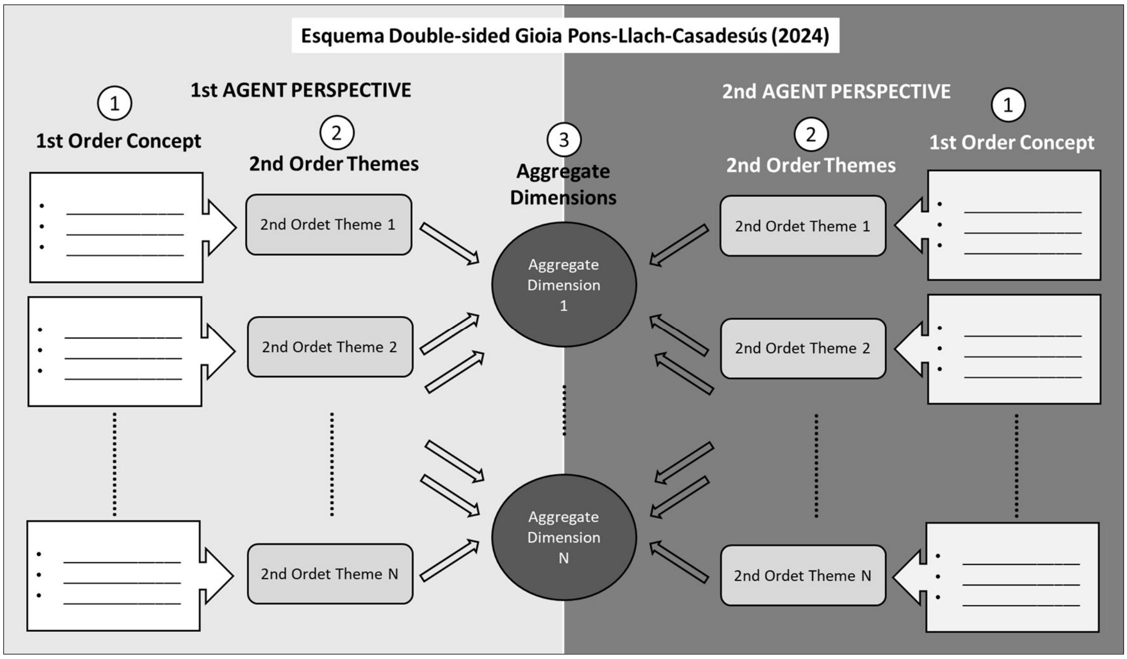

Figure 3 – Generic data structure for Double-sided Gioia's methodology

The double-sided Gioia methodology involves analyzing the data from two distinct yet complementary perspectives: that of the professors and higher education institutions (HEIs), and that of the students. This dual perspective is crucial for several reasons.

By incorporating both the viewpoints of educators and institutions as well as those of the students, the double-sided Gioia methodology allows for a more comprehensive understanding of the quality assurance landscape. Educators and HEIs bring insights into the design, implementation, and administrative challenges of distance assessment, whereas students provide firsthand accounts of their learning experiences, accessibility issues, and motivational factors. Combining these perspectives ensures that our analysis captures the full spectrum of factors influencing quality assurance.

Despite the differing viewpoints of the two groups, the double-sided Gioia analysis led us to identify the same overarching aggregate dimensions: Tools and Assessment Methodologies. This convergence underscores the robustness and reliability of these dimensions in explaining the core aspects of quality assurance in distance assessment. Tools encompass the technological infrastructure, equity considerations, and diversity aspects essential for effective online learning environments. Assessment Methodologies highlight the need for balanced, human-centric, and motivating evaluation strategies that cater to both online and offline settings.

The originality of the double-sided Gioia approach lies in its ability to cross-validate findings across different stakeholder groups. By demonstrating that both educators and students perceive similar aggregate dimensions, we enhance the validity of our conclusions. This methodological innovation not only strengthens our findings but also provides a novel framework that can be applied in future research to explore complex educational phenomena from multiple perspectives.

Understanding the shared and divergent views of professors, HEIs, and students has practical implications for policy and practice. It enables the development of more inclusive and effective quality assurance policies that address the needs and concerns of all stakeholders. For instance, ensuring equitable access to technology and promoting diverse and inclusive learning environments can be more effectively achieved when both the administrative and experiential aspects are considered.

The results of the double-sided Gioia's methodology are presented in Figure 4.

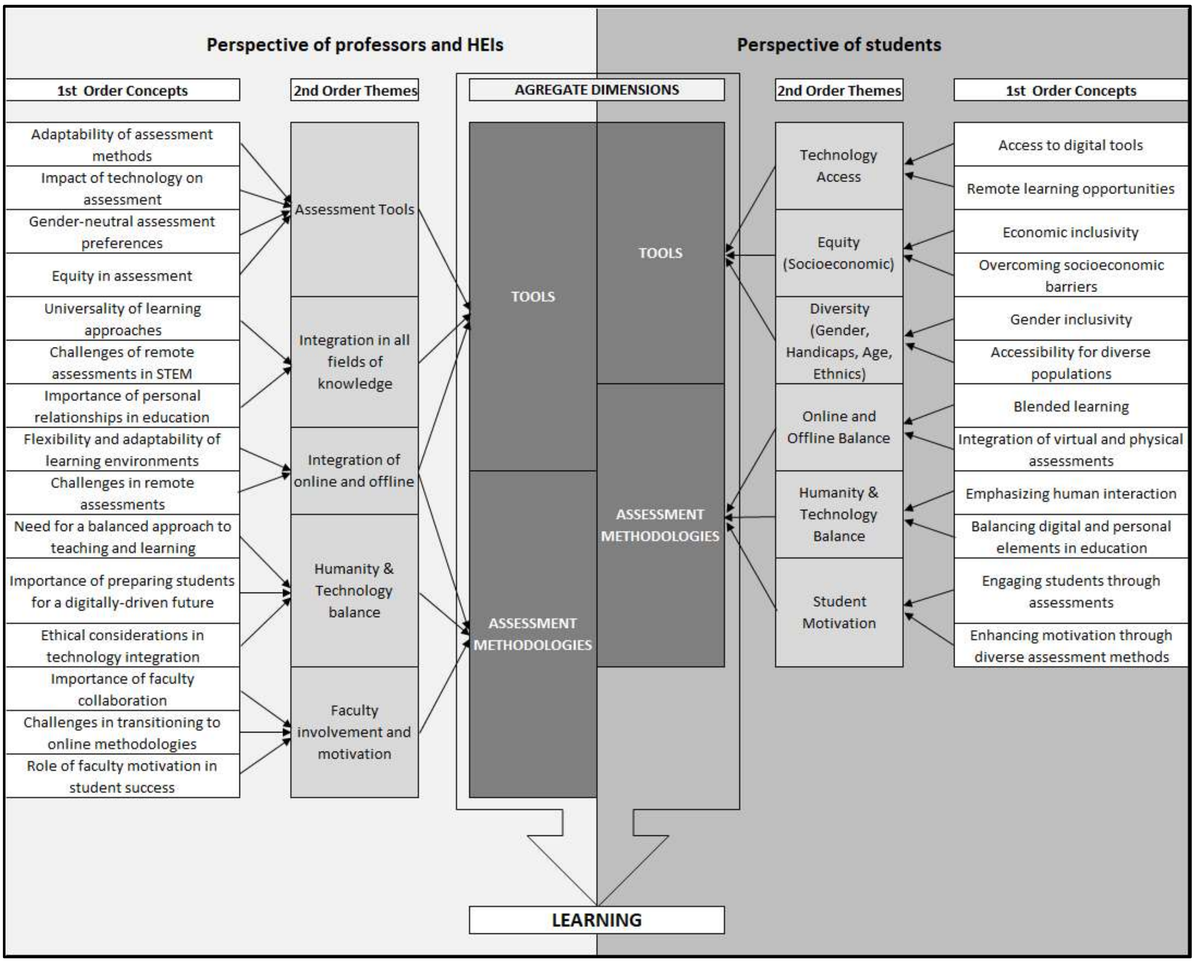

Figure 4 – Results of Double-sided Gioia's from the perspective of professors and HEIs and from students.

Results of the Analysis from the Perspective of Professors and Higher Education Institutions

Tools from the Perspective of Professors and HEIs

The first dimension, **Tools**, underscores the critical role that various technological tools play in the educational process. One key aspect within this dimension is the implementation of assessment tools. Professors emphasize that effective assessment tools are indispensable for enhancing learning and motivating students. As highlighted by one participant, "An assessment has to be one of these tools for learning much better" (Sangrà, 2023), and another who asserts, "Assessment is one important part of students' motivation" (Mesquita, 2023). These statements reflect a consensus on the necessity of robust assessment tools to foster continuous engagement and provide meaningful feedback throughout the learning journey.

Another significant theme within **Tools** is the integration in all fields of knowledge. Digitalization is reshaping educational practices, yet it is crucial to maintain the core essence of education. One respondent noted, "Digitalization will change the way we learn and the way we teach, but it will not fundamentally alter the meaning of education" (Onița, 2023). Additionally, there is recognition that different disciplines require tailored approaches, as stated: "Each field of learning will have its unique set of tools and methodologies for evaluation" (Karakhanyan, 2023). This highlights the need for adaptable and interdisciplinary digital tools that cater to the specific needs of various fields of study.

The final theme under **Tools** is the integration of online and offline learning methods. Professors advocate for a blended approach that leverages the strengths of both online and face-to-face interactions. One participant expressed a forward-looking vision: "In 20 years, I hope to see the boundaries between online and face-to-face are blurred" (Karakhanyan, 2023). Another supported this by mentioning, "We are learning, which is a different approach with teaching methods, blending direct lectures and online methods" (Rafele, 2023). These insights suggest that a cohesive integration of online and offline methods can enrich the educational experience, offering flexibility and enhancing the overall learning process.

Assessment Methodologies from the Perspective of Professors and HEIs

The second aggregate dimension, **Assessment Methodologies**, focuses on the strategies employed to evaluate student performance. A pivotal theme here is the integration of online and offline assessments. Effective learning and assessment benefit from the strengths of both online and face-to-face methods. As one participant noted, "Both learning and assessment have stronger data, stronger evidence, and also stronger effects when it can be done face to face" (Canals, 2023). Another echoed this by expressing a hope for a seamless blend between these modes in the future. This comprehensive approach ensures a thorough evaluation of students' knowledge and skills.

Another crucial theme is the balance between humanity and technology. While technological advancements are integral to modern education, maintaining the human element is essential. One professor emphasized, "It's very important for all of us and for our educators to teach students and younger generation how to remain the human being" (Llavori, 2023). Another reminded us, "We should not underestimate that we are relational beings" (Canals, 2023). These statements underline the importance of preserving social connectivity and emotional engagement in education, even as we integrate more technology into the learning environment.

Lastly, faculty involvement and motivation play a critical role in the effective implementation of assessment methodologies. Collaboration among educators and continuous professional development are vital for adapting to new educational challenges. As one participant mentioned, "Teachers need to collaborate even more and in a more effective way" (Gabriel, 2023). Another highlighted the necessity of ongoing development, stating, "The essential problem is that new fields and especially new contents even in established fields have to be able to develop in a continuous, consolidated way to meet up with new challenges" (Merisalo, 2023). These insights emphasize that motivated and engaged faculty are key to ensuring the success of evolving teaching practices.

Results of the Analysis from the Perspective of Students

Tools from the Perspective of Students

The first dimension, **Tools**, underscores the critical importance of various technological tools in facilitating equitable and effective learning experiences. One crucial aspect within this dimension is technology access. Experts highlight the significance of having reliable access to digital tools to participate fully in their education. As one expert noted, "Accessibility is giving students the opportunity to learn remotely from wherever they may be, and then bringing them together in a setting that utilizes the STEM technology in a laboratory, and then assess how they have achieved their learning outcomes in that STEM culture" (Matthews, 2023). Another emphasized the potential impact of digital inclusion, stating, "E-learning can benefit economically disadvantaged individuals and those with disabilities, but in STEM, access to good facilities and labs remains crucial" (Micari, 2023). These statements underscore the need for ensuring that all students have access to the necessary technology to engage in online learning and assessments effectively.

Another significant theme within **Tools** is equity (socioeconomic). The ability of online learning to bridge gaps and provide opportunities for diverse student populations is a recurring theme. As one participant observed, "I can see changes for the good because of this broader movement, which is also happening to, sort of a democratizing effect for higher education as well because of the access that online and remote learning provide" (Adair, 2023). This is further supported by another statement: "Online training allows women who, at the time, have not been able to have training when they were young, then they can, by means of the online studies, they can get the information or the studies when they are adults" (Salán, 2023). These insights indicate that online learning can significantly enhance access to education for students from various socioeconomic backgrounds, promoting greater inclusivity and opportunity.

The final theme under **Tools** is diversity (gender, handicaps, age, ethnics). Interviewed experts recognize the potential of online education to support diverse learning needs and promote inclusivity. As one participant pointed out, "Online assessments can provide a more inclusive and equitable environment for female students in STEM" (Rocha, 2023). Another commented on the broader societal implications, noting, "In some cultures women have been joining careers that historically belong to men for years and many of them, they are already the majority, but in other cultures where religious factors are very conservative values and intersect on this issue" (Strah, 2023). These perspectives highlight the role of online learning in fostering diversity and supporting students from various backgrounds and identities.

Assessment Methodologies from the Perspective of Students

The second aggregate dimension, **Assessment Methodologies**, focuses on the strategies used to evaluate student performance in a balanced and motivating manner. One pivotal theme is the balance between online and offline assessments. Students appreciate the flexibility and accessibility of online assessments but also recognize the value of in-person evaluations. As one specialist noted, "Online assessments can provide flexibility, enabling continuous assessment throughout the course, rather than just at the end" (Antonelli, 2023). Another echoed this by emphasizing the importance of a blended approach: "We are learning, which is a different approach with teaching methods, blending direct lectures and online methods" (Rafele, 2023). These statements suggest that a balanced integration of online and offline assessment methods can enhance the learning experience and provide comprehensive evaluations of student performance.

Another crucial theme is the balance between humanity and technology. While technology is integral to modern education, maintaining a human connection is essential. As one expert expressed, "It's very important for all of us and for our educators to teach students and younger generation how to remain the human being" (Lee, 2023). Another emphasized the relational aspect of learning, stating, "We should not underestimate that we are relational beings" (Canals, 2023). These insights underline the importance of preserving social interactions and emotional engagement in education, even in a technologically-driven environment.

Lastly, student motivation is a critical factor in effective assessment methodologies. Continuous assessment and active engagement are seen as key motivators for students. As one expert pointed out, "Assessment is one important part of students' motivation" (Mesquita, 2023). Another highlighted the role of continuous feedback, noting, "Continuous assessment, including frequent testing and class participation, supported by professors, can play a crucial role in the future of education" (Rattalino, 2023). These perspectives emphasize the need for assessment methods that keep students motivated and engaged throughout their educational journey.

CONCLUSIONS

The project will utilize a collaborative approach between HEIs and EQAAs to strengthen the understanding of current practices and develop relevant assessment guidelines.

The perspectives of professors and higher education institutions on the quality assurance of distance assessment in STEM disciplines highlight the importance of integrating effective tools and methodologies. The critical role of assessment tools and the need for cross-disciplinary integration of digital technologies are clear. Furthermore, a balanced approach that combines online and offline methods, while maintaining a human-centric focus, is essential for providing a holistic educational experience. Active faculty engagement and continuous professional development are crucial for adapting to the dynamic educational landscape. These insights underscore the necessity for strategic implementation and continuous improvement to ensure quality assurance in distance education.

From the perspective of students, the quality assurance of distance assessment in STEM disciplines hinges on the effective use of tools and assessment methodologies. Ensuring technology access and promoting equity and diversity are essential for providing inclusive and equitable learning experiences. A balanced approach that integrates online and offline methods while maintaining a human-centric focus is crucial for comprehensive and engaging assessments. Finally, fostering student motivation through continuous assessment and feedback is vital for maintaining engagement and ensuring successful learning outcomes. These insights highlight the need for strategic implementation and continuous improvement to ensure quality assurance in distance education from the students' viewpoint.

The double-sided Gioia methodology represents an original and robust approach to qualitative analysis in educational research. By integrating the perspectives of both educators and students, we can derive comprehensive and validated insights that inform more effective and inclusive quality assurance practices in distance assessment for STEM disciplines. This methodological innovation promises to enhance the depth and applicability of our findings, setting a precedent for future studies in the field.

AKNOWLEDGEMENTS

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Control charts for monitoring process with time trend: using monitoring random source, profile monitoring and modified location chart

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STRUCTURED ABSTRACT

Purpose - Statistical process monitoring has been a relevant practice incorporated into quality management systems. In a controlled process, the variabilities of statistical parameter estimates are expected to fluctuate within a pattern over time. Whenever this pattern is not identified, the root causes must be identified, and the necessary actions should be taken. However, there are situations where special causes are present but not practically significant. Recent studies on profile monitoring have tailored solutions for efficiently detecting trends and seasonality in high-capability processes. This paper proposes using profile curves and statistical modelling based on the location control chart approach.

Design/methodology/approach - Our research was carried out using decision-prescriptive models and Design Science Research approach to identify solutions for real and complex problems. Additionally, the modeling and simulation method was utilized to assist in developing, analyzing, and testing the model, which was classified as an artifact.

Findings - The modeling results clearly demonstrate that utilizing location control charts and modified graphs is essential in defining equipment adjustments. This approach guarantees the minimum acceptable capacity and maximizes the use of productive resources.

Originality - This study provides novel opportunities for developing and implementing control charts in systems that do not conform to the principles of randomness but rather display intricate temporal patterns. This is particularly relevant in the context of Quality 4.0, where real-time data collection is pervasive.

Keywords: Statistical Process Monitoring, Location Control Charts, Profile Monitoring, Quality 4.0.

Paper type: Research paper.

INTRODUCTION

Statistical Process Monitoring (SPM) has been a practice incorporated into quality management systems for many years. First developed by Shewhart in the 1920s, statistical process control brought innovation to the way processes are managed. The statistical identification of two different types of variability causes—random and special—at that time was groundbreaking and revolutionary, earning it a place as one of the key techniques in Total Quality Management (TQM). Its statistical principles are based on extracting random samples in subgroups at intervals. The assumption is that only random causes are present within the subgroups, and special causes are present between subgroups. In a controlled process, the variabilities of statistical parameter estimates are expected to fluctuate within a pattern over time. When a pattern is not identified at some point, causes must be identified, and actions should be taken to reestablish the pattern (Montgomery, 2019).

Despite the numerous published works, practical issues have more recently gained attention. There are situations where special causes are present but not practically significant. This is easily observed in processes with high capability indices, Cp and Cpk. The literature has solutions for this type of problem, known as acceptance charts or modified charts. Other recent solutions have been presented, incorporating Cp and Cpk indices into traditional Shewhart charts and introducing the concept of practical significance in statistical modeling in CUSUM and Weighted Moving Average charts. Woodall (1985) asserts that small changes in the process perceived over time may have little or no practical importance. Similarly, Mohammadian and Amari (2013), and Oprime and Mendes (2017), suggest that in highly capable processes, where natural variation is much smaller than specification limits, control limits should be relaxed, allowing the mean to vary within a certain range of values.

The pioneer in this area was Freund, who introduced acceptance charts in 1957, as the author himself indicated, suitable for high-capability processes (Mhatre et al. 1981; Holmes and Mergen, 2000; Mohammadian and Amiri, 2013; Woodall and Faltin, 2019). These authors contributed to the development and practical use of modified and acceptance control charts. However, a practical issue mentioned in the literature is the non-random behaviour of process measurements over time, the time trend, which could be seasonality, trend, or any other non-random profile. Understanding process profiles, when they exist, including the concept of practical significance, is an aspect that deserves attention from theorists and users of the technique. For this reason, new methods and types of control charts must be developed. According to Shper and Adler (2018), there is a potential existence of unknown (implicit) patterns in any given process. These patterns can either influence or not influence the process outcomes, but the challenge lies in the uncertainty of their presence.

To overcome these limitations, more recent approaches, such as Profile Monitoring and specific techniques for location and variation control, offer more tailored solutions for efficiently detecting trends and seasonality in high-capability processes. Including these advanced methodologies allows for a more robust and sensitive understanding of changes in process behavior promoting a proactive response to non-random alterations. Kang and Albin (2000) pioneeringly argue that there are situations in which the quality of the process or product can best be characterized by a functional relationship between the response variable, corresponding to the quality characteristic of interest, and one or more explanatory variables.

Linear temporal trends arise in the presence of uncontrolled factors and invalidate the assumption of independence among different values of the response variable. The effects of linear trends have already been studied in experimental design by Draper and Stoneman (1968), Cheng and Jacroux (1988), and Hilow (2013), for example. This way of considering the effects of linear trends in DoE changes the traditional proposal of randomization. We present this subject here to draw an analogy with control charts. Therefore, we can also mention here that a systematic order of sampling the process on a control chart should be considered in practice.

Our motivation for addressing this issue stems from the challenges faced by engineers and production supervisors in effectively analyzing critical process characteristics using traditional Shewhart charts and capability calculations. The aim of this research is to utilize decision-prescriptive models to identify solutions to novel problems or compare the efficacy of strategies to address a given issue. In addition, the study proposes the use of profile curves and statistical modeling based on the location control chart approach and residues to monitor processes with time trends. To achieve this goal, the paper will employ Design Science Research (DSR) methodology to solve practical problems through mathematical modeling. This approach emphasizes the importance of creating practical and effective solutions, as well as contributing to the advancement of knowledge in statistical process monitoring.

This paper has the following structure, in addition to the introduction: Section 2 presents what we understand as processes with linear trends, adjustments of a polynomial model, and analysis and monitoring of their residuals. Section 3 presents the research method and introduces the monitoring model based on the profile and location control chart. Section 4 exploring theoretical and practical implications of the developed study. Finally, Section 5 provides the final considerations and conclusions regarding the proposed approach.

EFFECTS OF LINEAR TRENDS AND RESIDUAL MONITORING

Contextualization of the problem of Linear Trend Effects

Shper and Hard (2018) bring an interesting discussion about the importance of temporal order as an aspect to be considered in Phase I. According to these authors, this aspect is often overlooked in the literature because there are situations where processes exhibit intrinsic trends or seasonality. From a practical standpoint, such temporal trends may be acceptable. In Phase I analysis, data is used retrospectively to assess process stability and establish limits that will later be used in Phase II for prospective monitoring. In Shewhart charts, any non-random behavior indicates the presence of special causes. Shper and Hard (2018) argue that patterns exist in all real-world processes, but sometimes, their influence may be small enough to ignore. However, in practice, there are cases where non-random trends are relevant and easily identified or known beforehand.

We often find situations where engineers attempt to apply the traditional control chart to processes with linear trends, *i.e.,* without randomness. When this happens, capability studies are compromised. The method of estimating the process standard deviation must be considered from the perspective of the analyzed phenomenon. There are many practical constraints and considerations when applying control charts in the presence of temporal trends or non-random events. The practical sense and the impact of linear trends are crucial for practitioners. Woodall (1985) mentioned that small changes in the process, observed over time, may have little or no practical significance.

Mohammadian and Amari (2013) suggest that in highly capable processes, where natural variation is much smaller than specification limits, the control limits should be relaxed, allowing the mean to vary within a certain range of values. Similar arguments are found in Kuiper and Goedhart (2023) for CUSUM and EWMA charts. Practical considerations must be considered when using control charts. In the words of Woodall and Faltin (2019), a slight deviation should not always be considered an out-of-control situation. From a practical standpoint, even the presence of linear trend effects, if they do not produce significant impacts, can be deemed acceptable if they are monitored.

Linear temporal trends arise in the presence of uncontrolled factors and invalidate the assumption of independence among different values of the response variable (while the independence of control variables is guaranteed by the orthogonality of design matrices). The effects of linear trends have been studied in experimental design (Cheng and Jacroux, 1988). Such practice alters the traditional randomization approach. We present this topic here to draw an analogy with control charts.

Modeling of control charts for residuals

As a tangible illustration of this real-world problem, we present a comprehensive study of a machining process, where the manufactured product at this machining center is designed to meet specifications of 65.6 + 0.2 millimeters. This case illustrates the significant impact of trends, as depicted in Figure 1. From the perspective of the classical approach, this is an unstable process, therefore out of control, as it does not exhibit random behavior. However, from a practical standpoint, it is a highly capable and in-control process. Despite having a systematic trend over time, due to the presence of a known source of variation, this process can be considered stable if this trend reproduces over time. Another important point, which aligns with the assertions of Shper and Adler (2018), is that statistical monitoring and capability studies cannot be determined by the classical approach, as the sample is not random.

The data plotted on the Y-axis, as indicated in Figure 1, represents the measurements of the piece in millimeters obtained as a function of the production order indicated on the X-axis. The first piece produced (x=1) had a Y-value of 65.737, and the 115th piece had a Y-value of 65.666. Processes with the characteristics shown in Figure 1 should have a different treatment from the approach of Shewhart charts. Monitoring for these cases can consider three measures: i) monitoring of residuals due to unidentified random causes; ii) monitoring of the adjusted polynomial profile; and finally; iii) monitoring of the angular coefficient derived from the rate of variation of Y with respect to production sequence X $(\lim_{x \to x_0} \frac{f(x)-f(x_0)}{x-x_0})$.

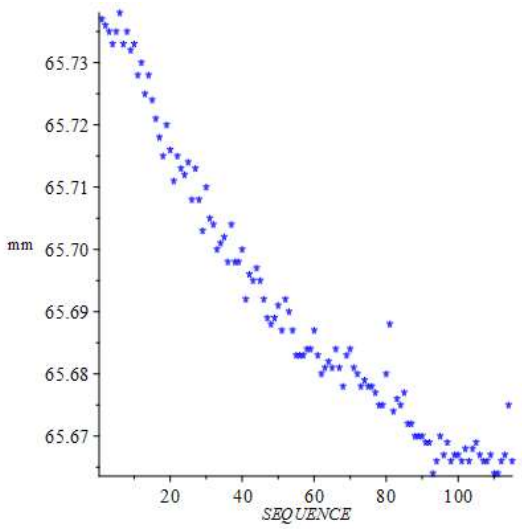

Figure 1 - Samples of 115 parts extracted sequentially.

Control charts with linear trends are acceptable from a practical standpoint for the following reasons: a) they exhibit high capability, which can be easily visualized by the relationship between engineering tolerance and process variation. Capability can be numerically verified by estimating the residual standard deviation, which is the standard deviation caused by unknown and uncontrolled factors. This estimation can be easily performed through knowledge of linear regression and calculation of residuals; b) The main cause of variability is known and manageable. In this case, it is the wear of the tool set that integrates the manufacturing system. Operational personnel can easily adjust the tools to the same starting point of production, and the curve reproduces until the tool changeover. Therefore, the process is controlled, but improvements can be made to increase the durability or lifespan of the tools.

The first step is to develop a mathematical model that can be used to infer the response from a given combination of factor values. If X_i are known quantities for each experimental run, models with p parameters are generally represented by a multiple regression model. For the case of Figure 1, we can consider that the independent variable is associated with time t, due to the sequential order of process sampling. Fitted to data similar to that in Figure 1, a statistical model would be a polynomial of the form:

$$\hat{\mu}_{(Y|x_0)} = \beta_0 + \beta_1 X_0 + B_{11} X_0^2, \quad (1)$$

Considering X as an integer ranging $1 \leq X \leq m$ (where m represents the total number of measured pieces), the production sequence would act as an auxiliary predictor variable of the inspected quality characteristic. We should consider that the adjustment of the mathematical model will be suitable to establish the relationship between the dependent variable Y (the quality characteristic) and the independent variable X (which is the manufacturing order of the pieces). In this case, the error (or residual) represents the variability due to unknown causes, with a Gaussian (normal) probability distribution, with zero mean and standard deviation σ_E. As already known, the random error is obtained by the difference between the observed value of Y for a given value of X minus the predicted value, $\hat{\mu}_{(Y|x_0)}$. Thus, the estimated standard deviation of the variability due to random causes is easily calculated by:

$$\hat{\sigma}_e^2 = \frac{\sum_{i=1}^{n}(Y_i - \hat{Y}_i)^2}{m-p} \quad (2)$$

Where $\hat{Y}_i = \hat{\mu}_{(Y|x_0)}$ is the expected mean value predicted by the model, p is the number of estimated parameters of the regression model. In the example, there are three estimated parameters. We can then apply the classical approach of Shewhart charts for the upper and lower control limits of the residuals using variance control chart, obtained respectively by: $LCL = \frac{\varphi^2_{m-1,1-\alpha/2}}{m-1}\hat{\sigma}_e^2$ and $UCL = \frac{\varphi^2_{m-1,\alpha/2}}{m-1}\hat{\sigma}_e^2$, where φ^2_{m-1} is a constant from the chi-square distribution with $m-1$ degrees of freedom, LCL is Lower Control Limits, UCL is Upper Control Limits, α is significance level. Generally, for a Type I error of α =0.0027 (0.27%). The distribution of residuals is random and independent. In Phase II, any change in one of the parameters of the model from Equation 1 adjusted to the data in Phase I would be detected in the residual plot. Considering that the random error $e_i = (Y_i - \hat{Y}_i)$ has a normal distribution with zero mean and standard deviation $\sigma_e, N\sim(0, \sigma_E)$ and they are independent, where i = 1, 2, ..., m. Assuming that the mean is known and zero and σ_e is estimated by equation 2, the process is under control when the residual is within the control limits. However, in practice, we estimate the mean error using Equation 6, $\bar{e} = \frac{1}{m}\sum_{i=1}^{m} e_i$, and the variance of the residuals using Equation 2, so that the estimated control limits are obtained by $\left(\bar{e} - K\frac{\sigma_e}{m}; \bar{e} + K\frac{\sigma_e}{m}\right) = (\widehat{LCL}; \widehat{UCL})$, as shown in Figure 2, which indicates that one point falls outside the control limits suggests the presence of some special cause that needs to be investigated. Another point to highlight is that the mean residual is shifted by 0.002 from the mean ($\bar{e} = 0.002$).

We normalize the data by dividing $\frac{e_i}{\sigma_e}$, so that the control limits are calculated by the standard normal distribution: Center Line, $CL = \frac{\bar{e}}{\hat{\sigma}_e}$ $UCL = \frac{\bar{e}}{\hat{\sigma}_e} + \hat{\sigma}_r$ and $LCL = \frac{\bar{e}}{\hat{\sigma}_e} - \hat{\sigma}_r$, where $\hat{\sigma}_r$ is the estimated standard deviation of the residual, which is approximately 1. For the case, $CL = -0.59, UCL = 1.75, UCL = 2.94$, $\hat{\sigma}_r = 0.9943$.

To adjust an empirical model to the data in the graph of Figure 1, the Maple program was used with the $PolynomialFit(2, X, Y, v)$ function, which resulted in the following equation 3.

$$y = 65.74 + 0.001339v + 6.252 * 10^{-6}v^2 \tag{3}$$

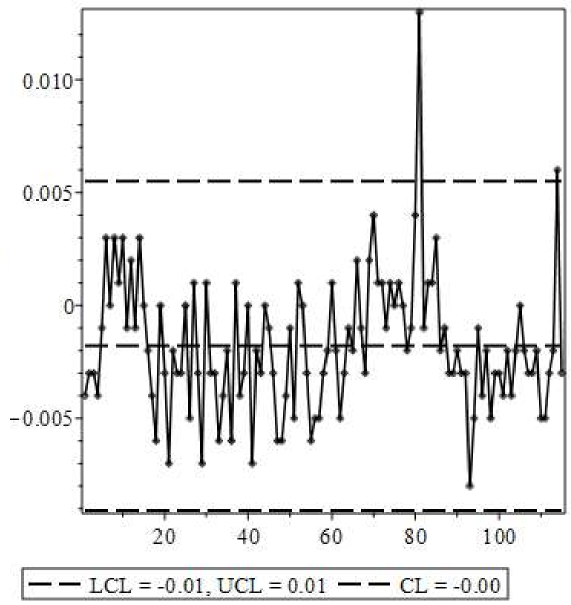

Figure 2 - Scores Residual Control Chart from Figure 1.

Table 1 presents the outcomes of significance tests conducted on the model parameters, affirming their statistical significance. The coefficient of determination (R-squared) for the model is 0.9815, signifying a robust explanatory power. Additionally, the estimated residual standard deviation stands at 0.00301, underscoring the model's accuracy in predicting observed data points. Furthermore, the standard errors of the model parameters were determined $[0.000856963;\ 0.0000341;\ 2.8481\ 10^{-7}]$.

Table 1 - Coefficients of the model

	Estimate	Std. Error	t-value	P(>|t|)
Parameter 1	65.7402	0.0008569	76713.0	0.0000
Parameter 2	-0.0013	0.0000341	-37.1482	0.0000
Parameter 3	$\mathbf{6.3 * 10^{-6}}$	$\mathbf{2.848\ 10^{-7}}$	19.2603	0.0000

These findings collectively indicate the efficacy and reliability of the empirical model. The performance of these charts can be assessed using the Average Run Length (ARL), as indicated by Equation 4 presented below:

$$ARL = \frac{1}{1-\emptyset(K-\delta\sqrt{n})\sqrt{n}+\emptyset(-K-\delta\sqrt{n})} \tag{4}$$

Where $\emptyset$ represents the cumulative distribution of the standard normal, K is the number of standard deviations, n is the sample size, and δ is the shift in the mean of the residuals when the process exhibits a new source of variability, altering the regression function profile. Additionally, we can develop new equations for the ARL considering the estimation errors of the mean of Y, $\hat{\mu}_{(Y|x_0)}$, for a given value of X, and the estimation error of the residual variance. Equation 5 refers to the second case, as follows:

$$ARL = \int_{-\infty}^{\infty} \frac{1}{[1-\Phi([\frac{W}{\sqrt{m}}+\delta\sqrt{n}+K])+\Phi([\frac{W}{\sqrt{m}}-\delta\sqrt{n}-K])]}\varphi(w)dw \quad (5)$$

Where φ(w) is the probability density distribution of the standard normal, m is the number of samples of size n. In this case, the control limits are determined, and a process will be under control when $e_i \in \left(\bar{e} - K\frac{\sigma_e}{m}; \bar{e} + K\frac{\sigma_e}{m}\right) = (\widehat{LCL}; \widehat{UCL})$ where $\bar{e}$ is the mean of the residuals obtained by:

$$\bar{e} = \frac{1}{m}\sum_{i=1}^{m} e_i \quad (6)$$

Given that m is the number of samples of size n. Considering that σ_e is estimated in the calculation of the control limits of the residuals, we can arrive at the following equation for the ARL, assuming that $e_i \sim N(0, \sigma_e)$:

$$ARL = \int_{0}^{\infty} \frac{1}{1-\emptyset(\boldsymbol{KU-\delta\sqrt{m}})+\emptyset(\boldsymbol{-KU-\delta\sqrt{m}})} f(u)du \quad (7)$$

Where $f(u) = (m-p)f_{X^2}(m-p)u)$ represents the unconditional average run length, and f_{X^2} denotes the probability density function of the Chi-Squared distribution with $m(n-p)$ degrees of freedom. Finally, considering that estimates of the mean of Y and the standard deviation of the residuals are also estimated, we have the following equations for the ARL in this case: $P\left(-\frac{W}{\sqrt{m}} - KU - \delta\sqrt{n} \leq Z \leq \frac{W}{\sqrt{m}} + KU - \delta\sqrt{n}\right)$, where $W = \frac{\sqrt{m}(\bar{e}-\mu_0)}{\sigma_e}$, it follows a n (0,1) normal distribution, and the probability function of U is $f(u) = m(n-p)f_{X^2}m(n-p)u)$. The unconditional average run length is geometric with the probability $p(W, U, K, \delta, m)$, it can be stated that the average run length ARL is given by equation 8:

$$ARL = \int_{-\infty}^{\infty}\int_{0}^{\infty} \frac{1}{1-\emptyset(\frac{W}{\sqrt{m}}+KU-\delta\sqrt{n})+\emptyset(-\frac{W}{\sqrt{m}}-KU-\delta\sqrt{n})} f(u)\varphi(w)dudw \quad (8)$$

Where φ denotes the pdf of a n(0,1) random variable and f_{X^2} is the density function of a chi-square distribution with $m(n-1)$ degrees of freedom. Equation 8 provides a means to assess the effectiveness of residual control chart performance across varying parameters, including the number of curves derived from experimental data (m), the sample size (n), and δ, which represents the number of standard deviations from the mean of the residual. While theoretically, the average residual is expected to be zero with a standard deviation of sigma, the polynomial curve serves as an estimation, suggesting that the average residual will approximate zero if the model is appropriately adjusted.

Analysis of Table 2 reveals the Average Run Length (ARL) results, which offer insights into the performance of the residual control chart. The table showcases the ARL values under different parameter settings, demonstrating the impact of m, n, and δ on the chart's sensitivity to detecting process deviations. Notably, higher ARL values suggest a reduced likelihood of signaling an out-of-control condition, while lower ARL values indicate a heightened probability of detection. For instance, when m=1, n=50, and δ=0, the ARL is 16610, indicating that it would, on average, require 16610 samples to identify a process change with a standard deviation of zero. As δ increases, the ARL decreases, underscoring the enhanced sensitivity of the control chart to process variations. These findings emphasize the importance of parameter selection in optimizing the performance of residual control charts for effective process monitoring and quality control.

Table 2 - ARL for residual control chart with K=3.

m	n	$\delta = 0$	$\delta = 0.25$	$\delta = 0.5$	$\delta = 0.75$	$\delta = 1.0$
1	50	16610	3972.	62.10	1.208	1.006
1	100	694.9	52.62	1.203	1.001	1.000
1	150	334.6	9.167	1.017	1.000	1.000
2	50	1137.	112.9	1.056	1.000	1.000
2	100	355.8	9.495	1.078	1.000	1.000
2	150	274.7	3.292	1.007	1.000	1.000
3	150	276.3	2.605	1.004	1.000	1.000
4	150	283.2	2.380	1.003	1.000	1.000
8	150	308.5	2.125	1.002	1.000	1.000
10	150	317.4	2.083	1.002	1.000	1.000

PROFILE MONITORING AND MODIFIED LOCATION CONTROL CHART

Profile Monitoring

The profile model in Figure 1 illustrates how the peculiarities of each process must be considered when designing a monitoring method. In the previous section, we used residuals to analyze and monitor sources of variation. We also proposed equations to assess the performance of residual control charts, adapting them from existing literature. Monitoring residuals has been presented in the literature for profile cases and, therefore, validated. An analysis and discussion on this matter were presented by Noorossana, Saghaei, and Amiri (2011). Colosimo and Pacella (2010) expanded the range of profile monitoring options. These authors demonstrate that most approaches to profile monitoring proposed in the literature share a typical structure, consisting of: i) identifying a parametric model of functional data; ii) estimating the model parameters; and iii) designing a multivariate control chart for the estimated parameters and a univariate control chart for residual variance. The proposed approaches can then be classified according to the type of application faced (i.e., calibration study, process signal, or monitoring of geometric specifications) or the modeling approach considered (mainly linear regression or approaches for reducing multivariate data, such as principal/independent component analysis).

Given that $E\left(\hat{\mu}_{(y|x)}\right) = \mu_{(y|x)}$ and the estimator for σ_e is $\hat{\sigma}_e = \sqrt{\frac{\sum_{i=1}^{n}(Y_i - \hat{Y}_i)^2}{n-p}}$ we can estimate for each point of X the estimated control limits for Y as follows:

$$\widehat{LSC}_{(y|x_0)} = \hat{\mu}_{(y|X_0)} + K\hat{\sigma}_e \tag{9}$$

$$\widehat{LIC}_{(y|x_0)} = \hat{\mu}_{(y|X_0)} - K\hat{\sigma}_e \tag{10}$$

Since there are m points in X for which control limits are estimated for Y, theoretically, there is a heightened probability of a point falling randomly outside the control limits, increasing the risk of Type I error. This suggests that the percentile of the standardized normal distribution used to calculate K should be adjusted. When multiple hypotheses are tested, the likelihood of observing a rare event increases, thereby elevating the probability of erroneously rejecting a null hypothesis (i.e., Type I error). To address this concern, the Bonferroni correction rule for dependent events is utilized to establish an actual false alarm rate that does not surpass a predefined threshold value.

In obtaining Bonferroni intervals, it is not necessary for all separate confidence coefficients $[100(1-\alpha_i)\%, i = 1,2,..,m\,]$ to be equal, but rather that $\alpha = \sum_{i=1}^{m} \alpha_i$. Thus, $\alpha' = \frac{\alpha}{m}$, recalling that m is the number of points in the regression, α is the Type I error of the control chart, and α' is the corrected value of the Type I error for each Y point estimated by the regression, which corresponds to the new K' of the standard normal distribution percentile. And the ARL can be calculated by extending Equation 8:

$$\mathrm{ARL} = \int_{-\infty}^{\infty}\int_{0}^{\infty} \frac{1}{1-\left(\emptyset_i\left(\frac{W}{\sqrt{m}}+K'U-\delta\sqrt{n}\right)-\emptyset_i\left(-\frac{W}{\sqrt{m}}-K'U-\delta\sqrt{n}\right)\right)^m} f(u)\varphi(w)\,du\,dw \tag{11}$$

Figure 3 illustrates how the profile chart would appear when adopting the Location Control Chart method for the data from Figure 1.

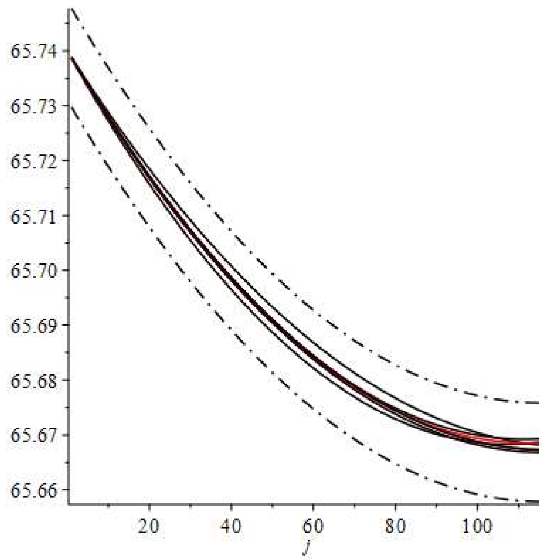

Figure 3 - Profile Monitoring Control Chart.

Table 3 displays the performance of the proposed control chart by equation 11. The calculations depict the Average Run Length (ARL) varying with the number of samples (m=[1,2]), sample size n=[50,100,150, and 115], and δ=[0.0,0.25,0.50,1.0, and 1.50]. The results in Table 1 were obtained considering that the statistical parameters were estimated and calculated by equation 11, where the average values of each Y were estimated as a function of the variable X, along with the standard deviation of the residual. When extracting a single curve from the sample data, the number of points (sampled pieces) for residual estimation must exceed 150 to detect a mean deviation δ=0.5. When m=2, meaning two curves plotted or two points in Y for each X, the detection capability of small deviations in the mean improves, indicating better process control detection power.

Table 3 - ARL of Profile Control Chart.

m	n	k	$\delta = 0$	$\delta = 0.25$	$\delta = 0.5$	$\delta = 1.0$
1	50	3	11144	2478.3	4.302	1.000
	100		587.59	19.408	1.667	1.000
	150		307.11	4.3390	1.000	1.000
	115		440.61	10.601	1.012	1.000
2	50		798.52	50.609	1.827	1.000
	100		315.52	5.8914	1.011	1.000
	150		255.10	2.5412	1.000	1.000
	115		289.24	4.2842	1.000	1.000

The curve of tool wear rate

Monitoring and controlling the variability of unidentified sources is recommended in control charts. In the case of Figure 1, we propose the control of standardized or non-standardized residuals together with monitoring the profile whose curve was fitted to the data by a second-order polynomial. However, it should be added that another characteristic related to the process efficiency is the tool wear rate, whose effect is measured by the first derivative of the fitted model. The derivative is given by the limit ($\lim_{x \to x_0} \frac{f(x)-f(x_0)}{x-x_0}$) , where the equation 12 is as follows:

$$-0.126689 * 10^{-2} + 0.19971 * 10^{-4} j \tag{12}$$

where j indicates the production sequence. Figure 4 shows the consumption rate (in mm) and the limits determined from the standard deviation of the random error. It is observed that the tool wear rate is decreasing, with a higher rate in the production of the first piece. The purpose of this chart is to monitor process wear and establish a reference standard for resource, equipment, and machinery usage improvement projects.

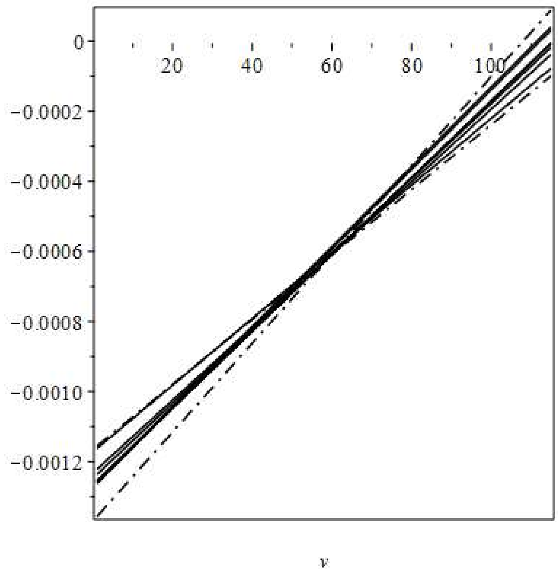

Figure 4: Curve of tools wear rate (millimeter by piece).

In order to determine the stability, point of the fitted function, we derived the function and set it equal to zero, finding the minimum point at 115, which is the number of sampled pieces, indicating the need to stop the machine for adjustments. Considering the estimation errors of the polynomial parameters, the machine adjustment moment could occur between 108 to 126 pieces, as shown in Figure 4. These results were obtained from the standard errors of the parameter estimates for a 99% confidence interval. The functions fit the curves data from figure 4 are:

1. $Center\ Line = -0.0012669 + 0.000011 * j$
2. $Lower\ Line = -0.001165 + 0.00000093 * j$
3. $Upper\ Line = -0.001369 + 0.000013 * j$

where j represents the production sequence of pieces. In Figure 4, we have shown the simulation for curves with different parameter estimates of the mathematical model fitted by tool wear rate. The change in rate could indicate the presence of a special cause in the process. Therefore, we could use these tools to monitor the process along with residual and profile control charts.

Modified Control Chart applied in Profile

According to Montgomery (2019) and Holmes and Mergen (2000), there is processes that, due to their nature, exhibit inevitable changes in the mean value of the quality characteristic of interest but still are capable of meeting the established specifications. This situation occurs when the process standard deviation is very small compared to the width of the tolerance (i.e., the difference between the upper and lower specification limits). In terms of standard statistical process control, this process, although not necessarily in control, can produce acceptable products that must be protected against rejection. Montgomery (2019) argues that, in achieving a high level of process capability, it is sometimes useful to relax the level of surveillance provided by standard control chart.

By observing Figures 1 and 3 and comparing the measurements with the specification (Ø65.60+0.2), whose tolerance is 0.2 tenths of a millimeter, the process is highly capable. In this case, the estimated standard deviation of the residual was $\hat{\sigma}_e = 0.003\ mm$. With the aim of maximizing the use of tools, given that their wear occurs over time, the operational procedure is to adjust the machining process equipment close to the upper engineering specification limit. The proposal is to include acceptance control limits in the profile chart to parameterize the cyclical process adjustments. The basic concept behind the first approach, the modified ¯X chart, is to allow the process mean to shift in such a way that the fraction of nonconforming pieces produced does not exceed a specified value δ. Hill (1956) and Freund (1957) provide a general discussion of this technique. Montgomery (2019) also provides an extensive reference on this technique from the statistical theory perspective.

As mentioned earlier, it is considered that in the present case the quality characteristic is normally distributed with a mean $\mu_{(y|x)}$ and a variance of σ_e^2. For a process with bilateral specification limits, in order to produce pieces with a nonconforming fraction lower than δ, the process mean μ can only shift within de μ_L and μ_U, as shown in Figure 5.

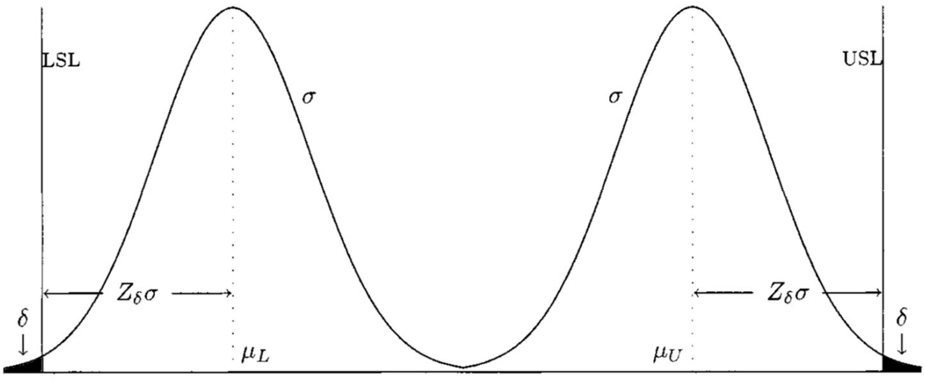

Figure 5 - Distribution of normal quality characteristic. Source: Chang and Gan (1999).

Thus, the control limits are obtained by:

$$LCL = LSL + \left(Z_\delta - \frac{Z_{\alpha/2}}{\sqrt{n}}\right)\sigma_e \quad (13)$$

$$UCL = USL - \left(Z_\delta - \frac{Z_{\alpha/2}}{\sqrt{n}}\right)\sigma_e \quad (14)$$

Where δ represents a fraction of nonconforming items, α the Type I error, n is the sample size for the mean estimation, Z the standard normal percentile, LSL lower specification limit, and USL upper specification limit. Given that the machine is adjusted from the upper specification limit, and for a minimum Cpk, as a customer requirement, it is suggested that the process be adjusted by the value given in equation 15. How $Cpk = min\left(\frac{USL-\mu(y|x)}{3\sigma_e}, \frac{\mu(y|x)-LSE}{3\sigma_e}\right)$, we have obtained following equations:

$$\mu_{(y|x)} = LSE + Cpk.(3\sigma_e) \quad (15)$$

$$\mu_{(y|x)} = USE - Cpk.(3\sigma_e) \quad (16)$$

For case, taking $Cpk = 1.67$ we have δ of 0.27 ppm (parts per million) with $Z_\delta = 5.0$, $\hat{\sigma}_e = 0.003$, and USL=65.80 and LSL=65.60, using of equation 14 and 15 we have the minimum and maximum limits value to $\mu_{(y|x)}$: $LCL = 65{,}62$, $UCL = 65{,}78$. The adjustment and regulation mechanism for this specific process is based on the UCL and LCL. Figure 6 shows how the proposed chart would look with the modified control limits in some simulated cases.

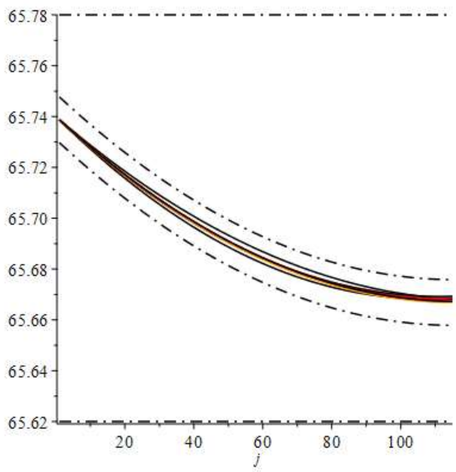

Figure 6: Control limits for modified and profile control char.

CONCLUSION

The artifacts developed from a real-world problem, which involved the application, modeling, and performance evaluation of control charts in processes with linear trend effects, aimed to contribute to the development of the field of knowledge in statistical monitoring, focusing on practical issues. We innovated in this work by fully applying widely known methods, consolidating a comprehensive approach to the problem that included the use of profile control charts, monitoring of regression model parameters, application of the location control chart approach, acceptance charts, and capability calculations in profiles. We analytically assessed the performance of these charts through ARL, and through these analyses, we indicated the effects of sample sizes used in Phase I to estimate the parameters of the regression model on performance in Phase II.

This article proposes an innovative approach to monitoring processes with temporal trends, using profile curves and statistical modeling based on location and residual control charts. By using prescriptive decision models and the DSR approach, we sought to solve practical problems and contribute to the advancement of knowledge in statistical process monitoring. The results have demonstrated that processes with linear trends can be adequately monitored and controlled, even when exhibiting non-random behavior over time. The study also offers a theoretical and practical framework for the implementation of these techniques. This artifact contributes with a more effective approach to identifying and managing changes in industrial processes. Finally, the concluding remarks emphasize the importance of integrated and adaptable approaches to process monitoring, with an emphasis on the application of advanced statistical methods and a detailed understanding of the characteristics of the process at hand.

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Getting an Insight into Quality 4.0 Reality: Design of a questionnaire

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STRUCTURED ABSTRACT

Purpose - In this era of digital transformation, Quality 4.0 stands out as a fundamental step in quality management. However, implementing Quality 4.0 goes beyond mere technological investments, demanding a profound cultural and managerial shift within organizations. Despite the relevance of Quality 4.0, research on its implementation is still limited. This paper addresses the development and preliminary testing of a questionnaire intended as a diagnostic instrument to assess the implementation of Quality 4.0 within Portuguese companies.

Methodology - The questionnaire design was based on: a systematic literature review on Quality 4.0, the findings from a pilot study in a ceramics company embracing Industry 4.0, and a collection of articles using questionnaires to explore Quality 4.0 implementation in diverse organizational contexts.

Findings - The questionnaire comprises sixteen closed questions grouped into four categories: i) the company's context regarding Industry 4.0; ii) quality management under an Industry 4.0 approach; iii) the Quality 4.0 professionals and iv) the motivations, critical success factors and challenges towards the implementation of Quality 4.0. Validation was achieved through a pre-test.

Research implications- The future application of the questionnaire to Portuguese companies will allow to shed light on the extent of Quality 4.0 implementation, diagnose adopted tools and methodologies, assess current quality management approaches, identify motivational drivers, integration challenges, and delineate competencies required for professionals.

Originality/value - The study's value lies in the development of a versatile diagnostic tool applicable across various organizational contexts worldwide, supporting the assessment of quality management within the Quality 4.0 paradigm.

Keywords: Quality 4.0; Industry 4.0; Portuguese Industry; Questionnaire Design

Paper type Research paper

INTRODUCTION

Considering the rapid technological advancements and escalating market competition, organizations are compelled to adopt new production strategies to meet the evolving demands, needs, and feedback from their stakeholders. Thus, in 2011, the concept of Industry 4.0 (I4.0) emerged, quietly initiating a profound transformation of conventional factories into smart factories (Lee et al., 2022). This Fourth Industrial Revolution (4IR) brings with it various technologies such as the Internet of Things (IoT), Machine Learning (ML), Artificial Intelligence (AI), Virtual Reality (VR), Augmented Reality (AR), among others (Maganga & Taifa, 2022). The era of digital transformation has been extensively discussed, highlighting how this technological revolution impacts organizational structures, management practices, and the roles of employees within companies (Maganga & Taifa, 2022; Souza et al., 2022).

It is expected that the I4.0 revolution will also imply a transformation in the way quality is managed, leading to the emergence of what has been coined as Quality 4.0 (Maganga & Taifa, 2022; Souza et al., 2022). In the era of Quality 4.0, digitalization and smart techniques are crucial to achieving the balance between quality and productivity (Antony et al., 2022). As such, this emerging era of quality signifies a fundamental restructuring of conventional quality management practices, integrating a diverse array of new technologies like Big Data, AI, ML, and AR, alongside traditional quality frameworks such as Six Sigma, statistical process control, ISO 9001, and TQM (Oliveira et al, 2024). Quality is evolving into a data-driven discipline, using various data analysis methods to develop increasingly reliable, efficient, and impactful digital quality management systems (Oliveira et al, 2024). According to the literature, its adoption improves quality standards, increases customer satisfaction and provides a competitive advantage, leading to cost reduction, revenue growth and improved product compliance (Antony et al., 2022).

The implementation of Quality 4.0 goes beyond mere technological investments, requiring a profound cultural and managerial change in organizations. Companies must equip their workforce with the necessary skills to effectively use these emerging technologies and promote a culture of continuous improvement throughout the organization (Maganga & Taifa, 2022). While the concept of Quality 4.0 has been increasingly discussed, accompanied by a growing number of empirical studies in the field, most of these studies explore theoretical aspects, or address the presence of a favourable environment for Quality 4.0, as well as the barriers to its implementation. According to Antony et al. (2022), there is still a lack of evidence on the success of the implementation of Quality 4.0, as well as on the readiness factors necessary before its adoption. Therefore, it can be said that there remains a gap in practical investigations on Quality 4.0 implementation in the industrial environment. What practices, methodologies, and quality tools are used? What is the level of maturity regarding the digitalization of quality management systems? Who are the professionals responsible for quality management currently, and what are their skills? For these and other questions, the literature still does not provide enough answers, so there seems to be space and need for further empirical research in this area (Oliveira et al, 2024).

With the goal of addressing this gap, a study involving Portuguese companies is being carried out, aimed at understanding their current state regarding Quality 4.0 and developing a framework to help industries implementing Quality 4.0. As part of this work, the design and preliminary testing of a questionnaire, intended as a diagnostic tool for assessing the implementation of Quality 4.0 in Portuguese companies, have been undertaken and are detailed in this paper.

In the next section the research methodology used in this work is explained. Afterwards, results are described by addressing the sections of the questionnaire and their contents, as well as the justification for the different questions designed. The final section presents the main conclusions, along with some indications regarding the future implementation of the designed questionnaire.

RESEARCH METODOLOGHY

To design the questionnaire the six stages depicted in Figure 1 were followed.

Figure 1- Stages of the questionnaire design

Next, each of the referred stages is detailed.

1) Questionnaire goals' definition

The need to develop a questionnaire and, consequently, define its objective emerged within the scope of a doctoral project aimed at developing a framework for the implementation of Quality 4.0 in small and medium size enterprises. After conducting a systematic literature review and recognizing the lack of empirical studies addressing industrial companies' practices, the decision was made to create and implement a questionnaire tailored to these companies, in order to incorporate the main issues referred by them in the aforementioned framework.

The main objectives of the questionnaire were then defined as: (i) to evaluate the degree of implementation of Quality 4.0 in Portuguese companies; (ii) to understand the motivational factors that drive the companies and the challenges they face when adopting Quality 4; and (iii) to outline the skills and knowledge necessary for professionals who work within the scope of Quality 4.0.

2) Identification of the population to address

This questionnaire was specifically designed to address professionals occupying leadership and managerial positions within the Quality area of Portuguese companies, since the aim is to seek valuable insights from individuals who are pivotal in quality management, in order to gain a comprehensive understanding of the actions being undertaken, particularly in the context of implementing Quality 4.0 initiatives.

3) Sources of information for the questionnaire design

In the initial phase, three primary sources of information were used in designing this questionnaire: (i) the results of a systematic literature review on the concept of Quality 4.0 (Oliveira et al, 2024); (ii) the findings from a pilot study conducted within a ceramics company immersed in the Industry 4.0 paradigm, where some Quality 4.0 initiatives are already under implementation (Oliveira et al, 2023); and (iii) a collection of articles using questionnaires and interviews as the methodological tool to explore the degree of adherence to and implementation of Quality 4.0 in different organizational contexts. Concerning the latter, five papers were analysed. The study by Schumacher et al. (2016) is based on a maturity model that enables companies to carry out a comprehensive assessment of their maturity within Industry 4.0; the study by Maganga & Taifa (2022) involved the implementation of structured questionnaire, covering open and closed formats, to assess respondents' perceptions regarding their knowledge of Quality 4.0 and manufacturers' readiness for its implementation. Antony et al. (2022) employed a methodology focused mainly on collecting qualitative data through interviews, aiming at delving deeper into Quality 4.0, exploring its benefits, critical success factors, and skills required for successful implementation, seeking to investigate essential organizational challenges and readiness when embracing Quality 4.0; Sony et al. (2021), used a qualitative interview approach as a basis to understand the motivations, obstacles, and readiness levels involving the adoption of Quality 4.0; finally, the study by Zulqarnain et al. (2022) relied on a questionnaire as the main tool, to elucidate the need and feasibility of digitalization and connectivity in the field of quality management, particularly in developing countries.

4) Design of the questionnaire: main sections and their respective questions

In this phase, the essential topics to be included in the questionnaire were identified (main sections), as well as the different questions within each topic. The information collected in 3) was organized and synthetized with the aim of creating an instrument that covers the relevant issues to address in a clear way, so that respondents find it easy to answer. It was also taken into account the size of the questionnaire, since it is important that respondents do not feel it takes too much time.

5) Implementation of the questionnaire in an online platform

It was decided to implement the questionnaire online. Among the various platforms available, LimeSurvey was chosen for its user-friendly interface, versatility, and customizable features, ensuring a seamless experience for both participants and survey administrators.

6) Pre-test and questionnaire refinement

The final phase corresponded to the pre-test of the questionnaire by six quality experts (quality managers and directors, and university professors in the quality field). Their expertise ensured a thorough examination and refinement of the questionnaire's content and structure, assuring its content validity and effectiveness for subsequent application. An estimation of the time needed to complete the questionnaire was also conducted, leading to a duration between 10 and 15 minutes.

RESULTS

In this section, the designed questionnaire is presented, including its main sections and their respective questions, together with a brief explanation of how they were formulated. In its essence, the questionnaire encompasses sixteen closed questions, arranged around four main sections: (i) the company's context regarding Industry 4.0; (ii) quality management under an Industry 4.0 approach; (iii) Quality 4.0 professionals; and iv) motivations, critical success factors and challenges for implementing Quality 4.0. A Likert scale ranging from 1 to 5 was used to collect the answers. This scale was chosen for its effectiveness in capturing the varying degrees of the respondent's alignment with the topics addressed in the questionnaire across different organizational contexts.

The questionnaire also comprises an initial contextualization section designed to gather data for characterizing both the respondent and the company's context.

0) Company context

This section comprises six questions and seeks to characterise the companies involved in the questionnaire future application, namely their size, sector of activity and geographical area. Additionally, data is also collected on a few individual characteristics of the respondents (position in the company and academic background). The aim is to identify the professionals leading the Quality area within the companies, namely Quality 4.0 projects when they are being implemented, along with their respective areas of expertise.

The process of selecting these particular questions involved incorporating relevant ones from the research conducted by Zulqarnain et al. (2022). Each chosen question underwent necessary modifications to align with the Portuguese reality. For example, for Question 1, consideration was given to the utilization of the regions' official division (NUTS II) as the set of response hypothesis. Regarding Question 2, the Economic Activity Codes (CAE) for the manufacturing sector were employed. Table 1 provides an overview of the questions related to the company context.

Table 1 – Questions designed to collect data on the company' context

Questions – Company Context
Q1 - Region in which the company operates
Q2 - Activity sector
Q3 - Number of employees of the company
Q4 - Number of employees assigned to the Department / Quality Area
Q5 - Position held (e.g.: General Director, Quality Director, Quality Manager)
Q6 - Academic qualification (i) Basic education; (ii) High school; (iii) University education
Q7 - Area of academic training If you answered "university education" to the previous question, indicate the area of academic training: (i) Arts and Humanities; (ii) Social Sciences; (iii) Exact and natural sciences; (iv) Engineering

1) The company's situation regarding Industry 4.0

This is the first main section of the questionnaire and encompasses a set of three questions designed to ascertain the companies' stance on adopting a Industry 4.0 strategy (Table 2). The main objective is to assess how far the companies addressed by the future application of the questionnaire have implemented some of the basic strategies underlying Industry 4.0, thereby gauging the level of digitalization within the company and its subsequent adoption of Industry 4.0 technologies. In selecting these questions, attention was paid to include some considered pertinent from various authors including Antony et al. (2022), Maganga & Taifa (2022), and Schumacher et al. (2016). Each chosen question underwent essential adaptations to ensure its alignment with the Portuguese context.

Table 2 – Questions designed to collect data on the company's situation regarding Industry 4.0

Questions – Industry 4.0
Q8 - What is the level of implementation of an Industry 4.0 strategy in the company?
Q9 - What Industry 4.0 activities are planned/under implementation/implemented in the company? (i) Digitalization of processes through the implementation of information systems; (ii) Integration between systems and/or equipment using the Internet of Things (IoT); (iii) Implementation of systems that allow efficient control of processes, products and services; (iv) Analysis of the performance of processes, products and services in real time; (v) Allocation of human resources to support digital transformation.
Q10 – Please indicate, on a scale from 1 to 5, where 1 corresponds to "not at all used" and 5 to "very used", the degree of use of the following Industry 4.0 technologies in your organization. - (i) Sensors; (ii) Industrial robots; (iii) RFID - Radio Frequency Identification; (iv) Cloud technologies; (v) Connectivity with mobile devices (smartphones, tablets); (vi) Real-time location systems; (vii) Machine-to-machine communication (M2M); (viii) Internet of Things (IoT); (ix) Simulation; (x) Virtual and/or augmented reality technologies, (xi) Additive manufacturing (3D printing), (xii) Big data, (xiii) Collaborative robots, (xiv)Machine learning, (xv)Artificial intelligence, (xiv) Cybersecurity

2) Quality management under an Industry 4.0 approach

In this section a set of seven questions is presented, aiming at collecting data about the companies' situation regarding quality management in general terms (Table 3). The aim was to delve into the quality management approaches, tools, and methodologies employed to manage quality within the company, alongside understanding the data collection methods within this department. Moreover, this section tries to explore the degree of digitalization within the Quality Management System (QMS) and ascertain the existence of initiatives targeted towards Quality 4.0.

In the process of selecting questions, questionnaires developed by other authors, including Antony et al. (2022), Maganga & Taifa (2023), and Schumacher et al. (2016) were considered, along with the main conclusions drawn from a systematic literature review previously undertaken (Oliveira et al., 2024). Additionally, the main findings from a pilot study conducted within a ceramics company immersed in the Industry 4.0 paradigm, where some Quality 4.0 initiatives are already under implementation, have also been used to design the questions (Oliveira et al, 2023). Moreover, each question was also tailored to fit the specific Portuguese context.

Table 3 – Questions designed to collect data on the company's situation regarding quality management

Questions – Quality Management under an Industry 4.0 Approach
Q11- Which of the following approaches are used to manage quality in the company? (i) Inspection; (ii) Quality control (e.g. control charts); (iii) Quality assurance (e.g. Ishikawa diagram, histogram, standardization); (iv) Quality improvement (e.g.: TQM, lean, 6 sigma); (v) Quality 4.0 (e.g.: processes are digitalized and integrated, there is big data management, artificial intelligence, machine learning, IoT, etc.)
Q12 - Which of the following quality management methodologies are currently used in the company? (i) PDCA cycle; (ii) 5S; (iii) A3 Report; (iv) 8D; (v) FMEA - (Failure Mode and Effects Analysis); (iv) 6 Sigma (DMAIC)
Q13 - Which of the following quality management tools are currently used in the company? (i) Flowchart; (ii) Ishikawa Diagram; (iii) Histogram; (iv) Pareto Diagram; (v) Scatter diagram: (iv) Control charts; (v) 5 Whys; (vi) 5W2H
Q14 - The company's Quality department/area collects data: (i) Exclusively manually; (ii) Some digitally; (iii) Much of it digitally; (iv) All digitally
Q15 - Which of the following elements are present in the way the company manages quality? (i) Top management commitment to implementing Quality 4.0; (ii) Quality Management supported by information and communication technologies; (iii) Connectivity between Quality Management and smartphones/tablets; (iv) Collection, processing and analysis of data and information in real time; (v) Automatic Statistical Process Control; (vi) Real-time visualization of Quality indicators; (vii) Predictive maintenance; (viii) Automatic traceability system; (ix) Automation of customer data collection and analysis (e.g. sales, feedback, needs and expectations); (x) Automation of relationships with suppliers and the supply chain
Q16 - Are there projects currently underway regarding Quality 4.0?
Q17 - If so, which ones?

3) Quality 4.0 professionals

This section contains two sets of questions designed to better understand the companies' quality professionals experience, skills and knowledge regarding relevant topics for the implementation of a Quality 4.0 approach (Table 4). The questions were derived from a variety of sources, including the works by Antony et al. (2022) and Maganga & Taifa (2023). Additionally, the results of the systematic literature review conducted by the authors was incorporated into this selection process (Oliveira et al., 2'24). Again, each chosen question underwent a process of adaptation to ensure its alignment with the nuances of the Portuguese context.

Table 4 – Questions designed to collect data on the company's quality professionals' level of experience, knowledge and skills about relevant topics for the implementation of a Quality 4.0 approach

Questions – Quality 4.0 Professionals
Q18- Regarding the following set of items, indicate, on a scale of 1 to 5, what level of knowledge/skills the company's quality professionals have. (i) Quality 4.0 Concept; (ii) Information and Communication Technologies; (iii) Industry 4.0 Technologies; (iv) Structured problem solving; (v) Data-driven decision making; (vi) Big data analysis; (vii) Teamwork; (viii) Creative thinking; (ix) Leadership; (x) Communication; (xi) Cross-functional cooperation (ability to work together with different departments within the company); (xii) Ability to combine new technologies with good quality management practices; (xiii) Ability to adapt to change Q19 - Indicate on a scale of 1 to 5, where 1 is "not at all motivated" and 5 is "very motivated", what is the level of motivation of employees in the company's Quality department/area to implement Quality 4.0?

Subsequently, a specific question was created to evaluate the extent to which a quality 4.0 strategy has been integrated into the company's operations (Table 5). This question segments the questionnaire into two distinct paths. If the company has not yet embraced the implementation of a Quality 4.0 strategy, the questionnaire ends, with only a final closing question being presented, asking for comments and suggestions for improvement. If otherwise, the company is already implementing a Quality 4.0 strategy, the questionnaire continues with a subsequent set of questions addressing the motivations and challenges related with the implementation (section 4).

Table 5 – Questions designed to collect data on the company's level of implementation of a Quality 4.0 strategy

Questions – Quality 4.0 Strategy
Q20 - What do you consider to be the level of implementation of a Quality 4.0 strategy in the company? (i) There is no strategy; (ii) Some pilot initiatives were launched; (iii) The strategy is under development; (iv) The strategy is formulated; (v) The strategy is being implemented; (vi) The strategy is implemented.

4) Motivations, critical success factors and challenges for implementing Quality 4.0

This section presents three sets of questions designed to explore the motivations, critical success factors, and challenges encountered by companies aiming at implementing a Quality 4.0 approach (Table 6). These questions resulted from the information collected in various sources, including the works by Antony et al. (2022); Maganga & Taifa (2023) and Sony et al. (2021). Moreover, the results of the aforementioned systematic literature review conducted by the authors (Oliveira et al., 2024) and the insights gleaned from the pilot study regarding the implementation of Quality 4.0 were also taken into consideration. Through this procedure, a set of relevant items concerning challenges and motivations that companies face when moving towards Quality 4.0 were identified. Each selected question underwent adaptation to ensure its adequacy to the Portuguese context.

Table 6 – Questions designed to collect data on the company's motivations, critical success factors and challenges associated with the implementation of a Quality 4.0 approach

Questions – Motivations, Critical Success Factors and Challenges for Implementing Quality 4.0
Q21- To what extent did the following aspects motivate the adoption of Quality 4.0 in your company?
(i) Eliminate/reduce human inspection; (ii) Improve data management (Collection / Analysis / Automatic visualization(s)); (iii) Analyse big data; (iv) Use predictive data analysis techniques; (v) Monitor processes in real time; (vi) Improve synergy between Quality Management and Lean; (vii) Use smart quality; (viii) Support decision making; (ix) Improve customer satisfaction; (x) Increase productivity; (xi) Achieve long-term time and cost savings
Q22 – To what extent are the following factors important for the successful implementation of Quality 4.0 in your organization?
(i) Organizational culture; (ii) Vision and strategy for Quality 4.0; (iii) Change management; (iv) Top management involvement; (v) People involvement; (vi) Relationship management (suppliers, customers and other interested parties); (vii) Knowledge of Industry 4.0 technologies; (viii) Knowledge about Quality 4.0; (ix) Quality 4.0 Training; (x) Connectivity; (xi) Scalability; (xii) Data analysis technologies (analytics); (xiii) Application development
Q23- To what extent have the following factors hindered the adoption of Quality 4.0 in your organization?
(i) Organizational culture; (ii) Difficulty in articulating Quality 4.0 with the organization's strategy; (iii) Top management commitment; (iv) Resistance to change; (v) Initial costs; (vi) Lack of financial resources; (vii) Complexity of calculating ROI; (viii) Lack of knowledge about Industry 4.0 technologies; (ix) Need to adapt Industry 4.0 technologies to the company's reality; (x) Lack of knowledge about Quality 4.0; (xi) Lack of digital skills; (xii) Lack of data analysis skills; (xiii) Lack of ability to work in a team; (xiv) Lack of time; (xv) Security and privacy concerns

The twenty-fourth and final question of the questionnaire is optional and consists of an open question that gives the participant the opportunity to make comments and improvement suggestions.

CONCLUSIONS

The main objective of this paper is to present a diagnostic questionnaire to evaluate the current panorama of the industrial sector in Portugal with regard to the implementation of Quality 4.0. Through the analysis of different sources of information, and taking into account the Portuguese industrial context, the questionnaire was designed, implemented in an online platform and pre-tested to assure content validity. Its future application to a sample of Portuguese companies will provide comprehensive information on the status of Quality 4.0 implementation in Portugal. This effort is aimed at acquiring an understanding of the quality management tools, methodologies, and practices prevalent in these organizations. Additionally, the questionnaire will allow to identify the skills and competencies essential for professionals working within the Quality 4.0 paradigm. Moreover, the data collected will offer valuable insights into the motivating factors driving the adoption of Quality 4.0, as well as the main challenges companies face when implementing it. By examining these factors, a framework will be developed to help industries implementing Quality 4.0. The framework is intended to provide practical recommendations on how to overcome obstacles and increase the effectiveness of Quality 4.0 initiatives.

A potential limitation of this study is the likelihood of bias towards companies with a higher level of maturity in implementing Industry 4.0 technologies. Despite this caveat, the insights gleaned from the questionnaire will undoubtedly deepen our comprehension of the current state of Quality 4.0 implementation in Portuguese companies, paving the way for future research and interventions in this area.

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Holistic Quality Excellence: Being Best for the World

Ir. Willy Vandenbrande

Quality for Nature

STRUCTURED ABSTRACT

Purpose: The purpose of this paper is to show several inconsistencies in the current measurements of sustainability and to propose a thought leadership model (Holistic Quality Excellence) that offers a new route for our future, having care for Earth's biosphere at its core.

Methodology / approach: By examining the current sustainability measurement systems and their results, inconsistencies are observed between the measurement results and actual planetary status. By evaluating the causes for these inconsistencies, a new way of thinking emerges, putting doubt on our current definition of sustainable development.

Findings: The People, Planet, Profit thinking that is present in most sustainability systems, is unsustainable for Earth's biosphere and a recipe for ecosystem disaster. A new definition for sustainability is proposed in which long term (generational) and preventive thinking play a major part. Quality management offers an approach to create the needed change.

Research limitations: The number of systems that claim to evaluate the sustainability of an organization makes it near impossible to take them all into account. Focus has been on the best known systems.

Practical & Social Implications: The findings cast doubt on the validity of well-established systems. Economic growth, triple P and the United Nations Sustainability Development Goals (UN SDG) are not supporting environmental sustainability and even contribute to the rapid destruction of Earth's biosphere.

Originality/value: The contradiction between measurement and reality has been studied before, but we offer a possibility for action through quality management.

Keywords: Sustainability, Quality, Leadership, Holistic Thinking.

Paper type: Conceptual paper

RESEARCH METHODOLOGY

Introduction

Today there is a lot of attention to sustainable development, both within organizations and at a political level. Several systems have been developed to evaluate the sustainability of organizations and of countries and even of the planet as a whole. However, some of the most destructive problems, like loss of biodiversity and climate change, are getting worse, despite all the attention, reports and regulations. This paper evaluates the reasons for this, with special attention to the underlying philosophies that have led to our definition of sustainable development and that dominate most of the measurement systems. A holistic thinking approach is presented that uses a different philosophy to come to improvement actions based on quality.

A Myriad of measurements

As indicated in the introduction there is no lack of attention and consequently of measurement systems for sustainable development. Most of them start from the idea that sustainability consists of several aspects, with the best known being financial, social and environmental. This is very visible in John Elkington's triple bottom line system that is better known as triple P: People, Planet, Profit (Elkington, 2004). The United Nations (UN) Sustainable Development Goals (SDG) [I] build on that and created a 5P logic: People, Planet, Prosperity, Peace and Partnership. But many other evaluation schemes use a similar logic: ESG (Environment, Social, Governance) [II], B-Corps [III], GRI (Global Reporting initiative) [IV], the European Union (EU) Sustainable Development Reporting Directive (SDRD) [V] and many other local, national and sectorial reporting systems.

Recently the UN Research Institute for Social Development (RISD) added their measurement system called SDPI (Sustainable Development Performance Indicators) [VI], claiming to be an "authentic" system because it compares results to norms and thresholds, so targets are consistent with sustainability needs. This myriad of available systems does not make it easy for an organization to know how to measure and what to report. For the EU this confusion may end because the SDRD has been turned into a legal requirement and that could be a game changer for the reporting.

Apart from these balanced measurement systems, there are a couple of measurements that focus on the state of the planet and on the impact of humans on planet Earth. In this paper reference will be made to two of them: the planetary boundaries (Richardson et al. 2023) and Earth Overshoot Day [VII] . We will compare their results and findings to that from the UN SDG system. These systems offer a global view (world results) and Earth Overshoot Day allows a comparison by country to the UN SDG. For specific aspects of sustainability, like climate change, we will also use data from NOAA (National Oceanic and Atmospheric Administration) [VIII] and Our World in Data [IX].

Datasets used

The SDG results of 2022 were used as described in the 2023 report (Sachs et al. 2023). For the planetary boundaries (Richardson et al. 2023) and the World Overshoot Day [VII], the results of 2023 are referred to. In some cases (comparing ppm CO_2 in the atmosphere to World Gross Domestic Product (GDP)) data up to 2021 were used as these were the latest available data at the time of writing. However this slight offset in timing does not pose doubt on the conclusions, because of the slow evolution of the indicators used.

RESULTS

Observations from the data

Despite a lot of criticism (Zeng et al. 2020), it cannot be denied that the UN SDG system is the most used, widely distributed and referenced system when talking about sustainable development. The system started in 2015, following the UN Millenium Goals and with an end date - targets to be reached by – 2030. In this analysis some absolute values of individual SDG's in 2022 and the evolution between 2015 and 2022 will be evaluated.

The following data are shown: overall evolution of World SDG Average (figure 1); absolute world value by SDG (figure 2); change in world value by SDG between 2015 and 2022 (figure 3); contribution by P to the increase of World SDG between 2015 and 2022 (figure 4) – note that the Peace category had decreased and has been left out of the pie chart ; Top 5 SDG ranked countries with their associate world overshoot day and required planets to cover their consumption needs (table 1).

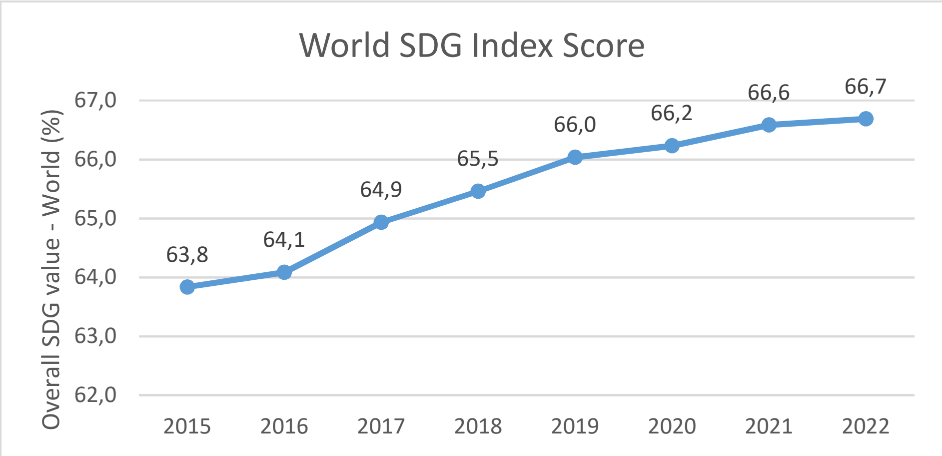

Fig.1: Evolution of World SDG (% points)

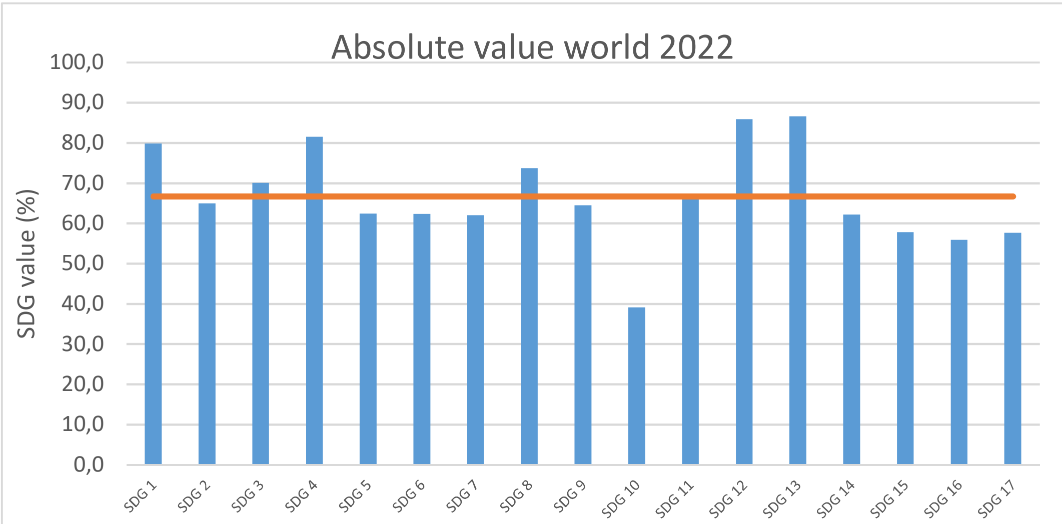

Fig. 2: World SDG score by SDG in 2022 (% points)

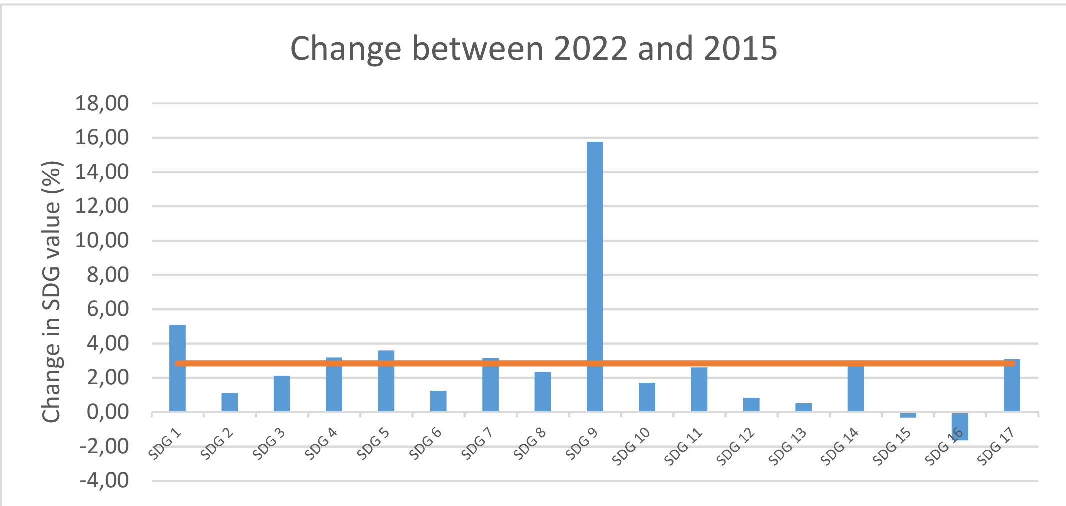

Fig 3: Change in SDG score by SDG between 2015 and 2022 (% points)

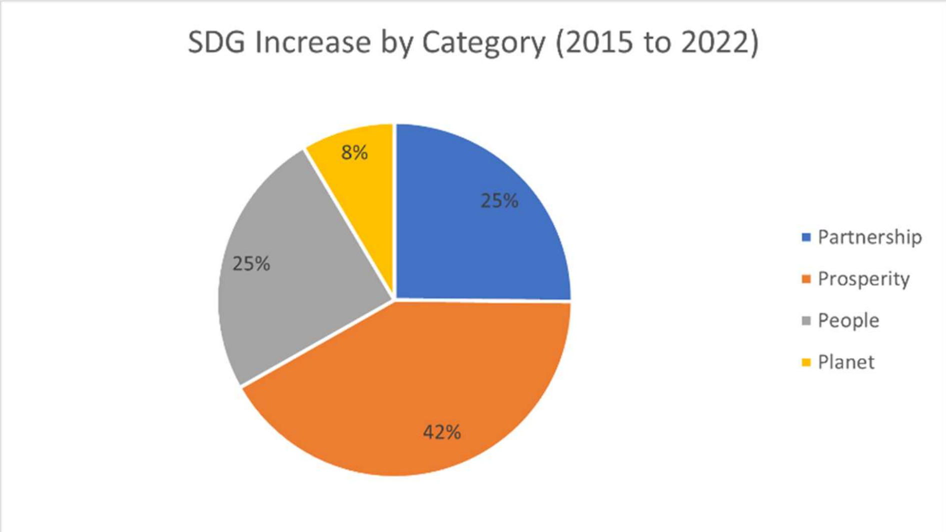

Fig. 4: Contribution by P to the SDG increase between 2015 and 2022

Table 1: top 5 SDG countries & Score (2022) and their 2023 Overshoot Day

Country	SDG score 2022	Overshoot Day 2023	Nr of Planets
Finland	86,8	31/03/2023	4,1
Sweden	86,0	3/04/2023	4
Denmark	85,7	28/03/2023	4,2
Germany	83,4	4/05/2023	3
Austria	82,3	6/04/2023	3,8

Some conclusions:

- The World SDG index is increasing but clearly not fast enough to result in any breakthrough by 2030 (fig.1).

- The two highest scoring goals are SDG 13: Climate Action and SDG 12: Sustainable Consumption and Production, with a respective score of 86,6 and 85,9 (fig.2). In fact, over the entire period these SDG's have had a very high value. Putting it differently: the problems these SDG's report on, have to be seen as almost solved. Apparently, we are – and have been for a long time – consuming and producing sustainably and we are taking successful action against climate change.

  As figure 5 shows, the latter is in total contradiction to reality with current Earth Surface Air Temperatures, showing an almost out-of-control behaviour.

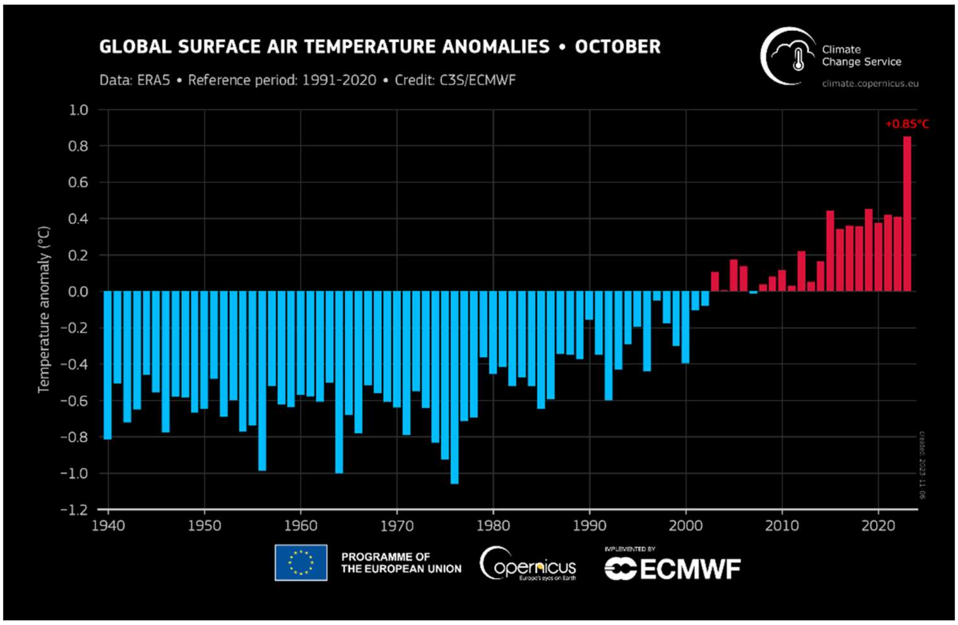

Fig. 5: World Average Surface temperatures. Note the result for 2023

As far as consuming sustainably is concerned, the overshoot data (table 1) clearly shows that not consuming sustainably may be the biggest threat to Earths Biosphere. The huge dump sites with fast fashion clothing is another proof of our detrimental consumptive behaviour [X]. If we had been producing and consuming sustainably there would probably not even be a sustainability crisis.

- The only SDG that has shown a real breakthrough is SDG 9: Industry, Innovation and Infrastructure, with an increase of 15,75 % points (fig.3), showing that over this 7 year period huge investments in the economic aspect of sustainability have been made.

- Consequently the contribution of Prosperity (economic sustainability) to the overall increase is high (42%). Unfortunately that goes hand in hand with a very small contribution of Planet (environmental sustainability) that only makes up for 8% of the increase (fg.4). One could almost say that according to the data, sustainability is about everything except environment. At the top of the SDG ranking you typically find rich countries with a well-established social system. These countries score very high on social and economic sustainability goals, but their impact on the planet is extremely high as shown by their overshoot day and corresponding number of planets needed (table 1). If the entire world population was to live like the most sustainably developed people live, 3 to 4 planets would be required to support their needs. And yet, they are praised for being highly sustainable.

Causes for the discrepancy between SDG measurement and state-of-the-planet reality

One of the most complete sets of data showing the overall state of the planet are the planetary boundaries. Figure 6 shows the state of the planet compared to the boundaries in 2023 (Richardson et al. 2023). As can be seen on the graph, the situation now is that 6 out 9 boundaries have been crossed and some have been crushed.

This is another proof that the SDG measurement is not representative for the environmental part of sustainability and creates a wrong view of progress. What are the causes for this?

- Some indicators used to come to an SDG score need to be evaluated (SDG 12 and 13). The disconnect between the obtained numbers and the observed facts is such, that the system loses its credibility. In relation to environmental sustainability, an evaluation logic comparing the actual status to a standard based on planet carrying capacity could offer a solution. Further investigation is needed, but the SDPI system of the UN RISD can be a reference.

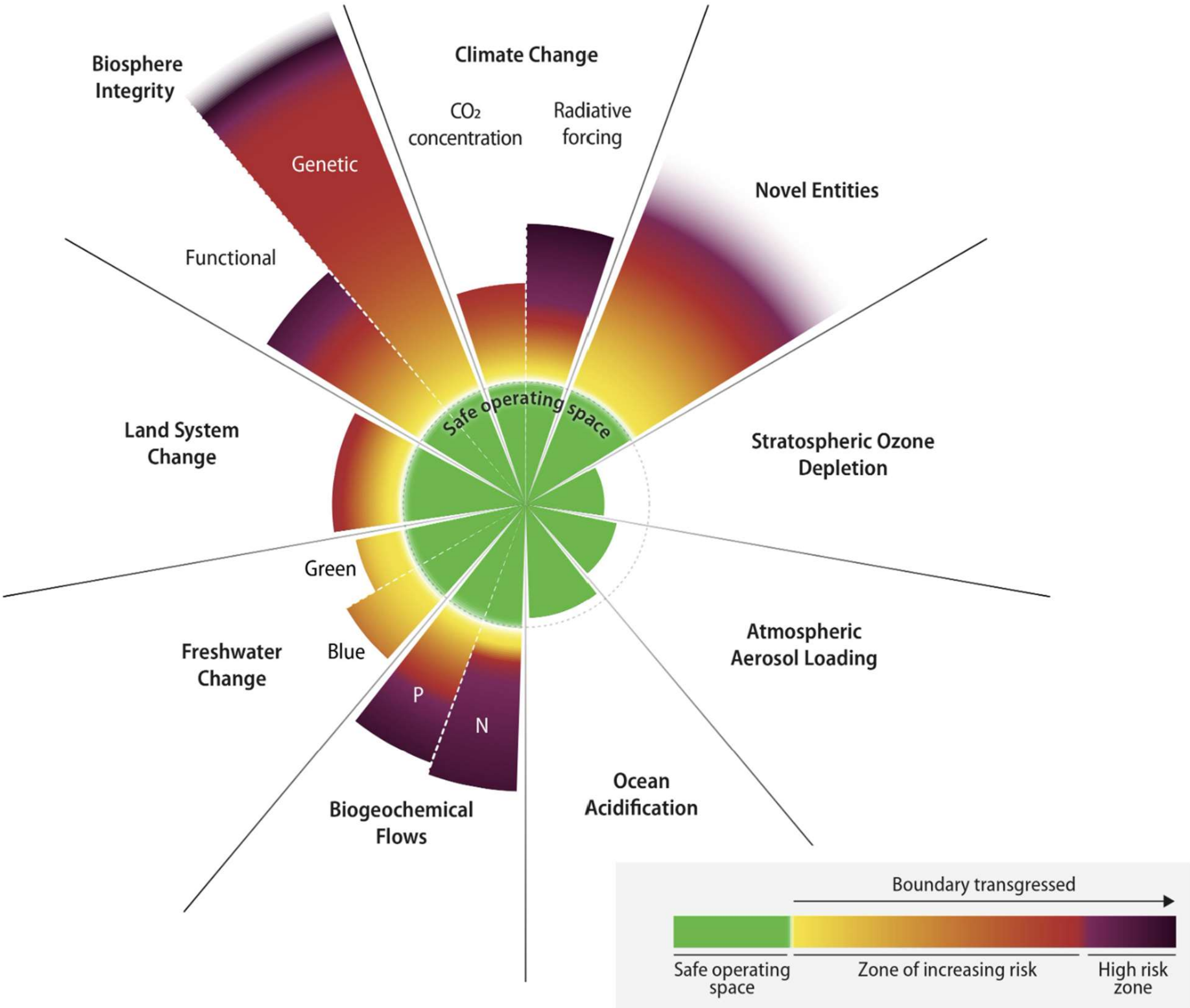

Fig. 6: The 2023 Planetary State in comparison to its boundaries

- Reporting on sustainable development as an average of various indicators representing different aspects, obscures the actual situation. Rich countries with a good social system score very high, even if their consumption pattern is environmentally destructive, generally in other parts of the world. This balancing act was one the main reasons for John Elkington to recall his triple P model in 2018 (Elkington 2018).
- SDG 8 calls for economic growth, but it is the growth model itself that has brought us in the dangerous state we are in right now. Figure 7 shows how the climate change driver of ppm CO2 in the atmosphere is directly linked to economic growth. Figure 8 shows that CO2 emissions closely follow the evolution of the economy.

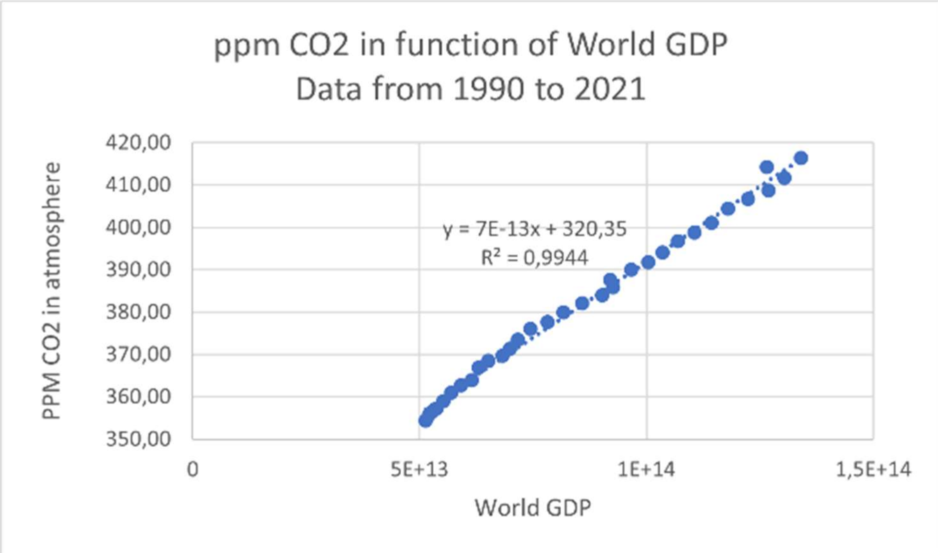

Fig. 7 Impact of economic growth on ppm CO2 in the atmosphere

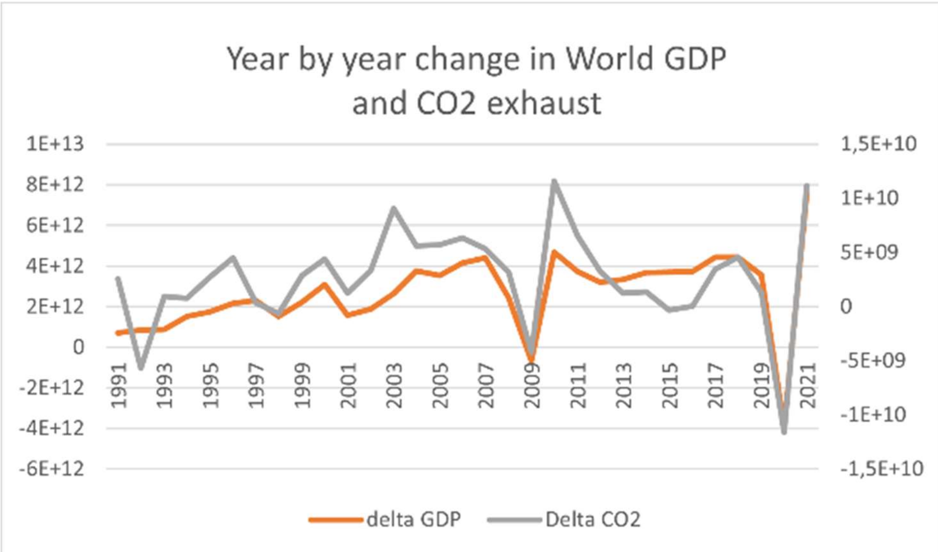

Fig. 8 Link between World GDP changes and CO2 Emissions

However, the foundation of the problem, what in quality is often called the root cause, lies in our definition of sustainable development and in the ethnocentric view expressed in it. The 1987 UN Brundtland commission came up with a definition of sustainable development as follows: "Sustainable development is development that meets the needs of the present generation without compromising the ability of future generations to meet their own needs." [XI]

This definition defines development as sustainable if one species thrives (Homo Sapiens Sapiens) and without limiting the needs this species might have. An economic growth model will fulfill this definition but does so at the expense of other species. That same logic can be found in the work of Hans Rosling (Rosling 2018). It shows how things have dramatically improved for (most) humans throughout history and specifically over the last fifty years. But at the same time wildlife populations, including mammals, birds, amphibians, reptiles, and fish, have experienced a devastating 69% decline on average since 1970, according to the World Wildlife Fund's (WWF) Living Planet Report 2022 [XII]. To change this human focused view, a more holistic approach is needed that must be expressed in a new definition, a different approach and an adapted measurement of sustainability.

A Proposal for change: Holistic Excellence

Given that Earth is the only known planet in the universe to hold life and that this life is present in a shallow ring around the globe called the biosphere, any credible definition of sustainability must focus on the protection of that biosphere. A proposal: "Sustainable development means that the present generation takes the necessary actions to pass on our unique biosphere to the next generation in a better state than it was received. And so on …" (Vandenbrande 2024).

This definition encompasses all life and is as such holistic by nature. It sets a clear target and can be measured by using indicators linked to the most critical problems like biodiversity loss and climate change and their corresponding drivers. This inevitably has to lead to a different approach to our economic system, away from growth and drastically reducing consumption (Murphy et al. 2021,Majdoub 2021). Even focusing heavily on a circular economy has its limits (Mayers et al. 2021). Several models have been described to create a more balanced and long term sustainable economy (Raworth 2018, Klomp 2021). This is an approach at the macro level, to be organized by politicians and international institutions. But how could an organization contribute?

Companies embracing business excellence aim to become the best in the world, holistic thinking aims for a long term thriving planet and all life on it. Holistic excellence combines the two. To make it happen, quality can play a major part and is introduced here as a working tool to achieve true sustainability. In previous publications (Vandenbrande 2019, Vandenbrande 2020) a triple A model was presented as a means to link quality to sustainability and to offer a path for organizations to gradually increase their efforts in sustainability at their pace and using quality tools to make it happen – see Table 2 for an overview.

When the concept for the model was thought out (2016) the idea was that triple P could function and that reducing harm to the environment would be good enough for some time to come. However, as shown in the observations form the data, that was an overly optimistic view. It is clear that reducing harm simply is not good enough anymore.

Table 2: Overview of the Triple A model

Sustainability Status	Financial sustainability	Environmental sustainability	Social sustainability	Quality methods and tools
AWARENESS **Operational sustainability** Remove false contradiction between sustainability and profitability.	Focal point and driving force	Start to reduce harm	Fulfil Local Legal Requirements	Add environmental goals Savings from improvements 7 tools PDCA Basic lean principles DMAIC problem solving
ADOPTION **Strategic sustainability** Sustainability incorporated in mission, vision and objectives.	Added benefit	Driving force Focus on reducing harm	Expand on Legal requirements using SDGs	Integrate systems fully Expand companywide Add DFSS Add TRIZ Expand Lean and TPM
ACHIEVEMENT **Holistic sustainability** Integrated sustainability as the driver and primary company value.	Logical consequence	Focus on improving the global ecosystem	SDGs as basis for full social responsibility	SDGs as basis for targets Ecosystem improvement Empowerment through values

This means that organizations must move towards holistic excellence and contribute to improving the global ecosystem. Further research is needed to come up with a set of rules and actions that can help organizations to change in the right direction. The assumption is that strategic sustainability has been achieved and that quality excellence is applied, leading to a sustainable production system with minimal (or zero) waste and inefficiency. To make the next step towards holistic sustainability and with quality in mind, actions to be taken can be:

- Take up "Future Generations" as an interested party in your quality management system (QMS), evaluating their needs and expectations and translate this throughout the organization. Do the same with "Earth Biosphere". Use this as a design input, so any new offerings will take that into account. Use in your risk analysis methods and in your design reviews and verifications.
- Use double materiality thinking to evaluate the risks and opportunities associated with current biosphere status. Do not only look at your impact on the environment, but also at the potential impact of the environment on your activities. The effect of climate change on business will be, and already is, more critical than generally thought. One of the key elements is water, both too much (flooding) and not enough (drought).

- Treat future generations and Earth's biosphere as a shareholder. One way of doing this is to reserve a number of shares for organizations that work on restoring ecosystems. That can be local or global but by doing this you relate the success of the organization (best in the world) to ecosystem restoration (best for the world).
- Many of our economic activities are about adapting nature. In the long term this leads to new problems. An example is the straightening of rivers leading to flooding problems. Rethink technology and development to be adaptive **to** nature, so natural processes go hand in hand with economic development. Low tech, low energy solutions are cost effective and much longer lasting.

CONCLUSIONS

The data shows that an approach to sustainability that is based on balancing economic, social and environmental aspects, is leading to a deterioration of ecosystems. When faced with a choice, satisfying human requirements always prevails over care for nature. Only by creating a holistic definition of sustainability, putting Earth's biosphere at the center, can an authentic sustainability be obtained. This will require a change in economic objectives and a focus on all aspects of life. Organizations need to be good in the world and best for the world. Using quality philosophy, methods and tools can bring us to a strategic sustainability, aiming to become best in the world. But holistic sustainability will be needed to think beyond reducing harm by investing in restoring ecosystems.

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Index for detecting techwashing level in Chilean technology startups

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STRUCTURED ABSTRACT

Purpose - Communication in technology is complex. The trend of companies exaggerating technology development, known as techwashing, creates mistrust and affects their reputation. This research aims to promote ethics and transparency by designing an index from a questionnaire for startups. This index will help stakeholders, including customers, users, and investors, in decision-making and evaluating technology companies.

Design/methodology/approach - The assessment identifies the potential absence of techwashing using five binary and depth indicators from existing literature. Companies are categorized based on their scores, ensuring a balanced, representative, clear, simple, granular, and easily interpretable selection of indicators and scoring framework.

Findings - Analysis of existing literature reveals that techwashing is widespread across various sectors and technologies. It involves promoting excessive optimism about technological solutions to divert attention from issues, enhance organizational and political images, attract investment, and gain credibility. Its ethical implications highlight the need for promoting ethical and transparent practices. Although research has explored various factors of techwashing, the lack of a tool to measure it directly underscores the necessity of its development.

Research limitations/implications - Accessing comprehensive information on techwashing is challenging, given the difficulties in obtaining detailed practices. Companies are unlikely to reveal information that could harm their reputation. Therefore, developing a tool that encourages organizations to publicly evaluate themselves is crucial.

Originality/value - The hypothesis proposes that it is possible to develop an index to detect the potential absence of techwashing in Chilean technology startups.

Keywords: Techwashing, Artificial Intelligence, Transparency, Startups.

Paper type: Research paper

INTRODUCTION

1. Problem

The problem of techwashing lies within communication. In the realm of technology and science, explaining and understanding phenomena, especially those related to advanced technology, can be challenging in a complex world [I]. Common examples include misrepresenting Machine Learning as artificial intelligence (AI) or promoting a future within the metaverse without the necessary infrastructure or experience (Massaro et al., 2023).

While AI has numerous positive applications, most people perceive it as a mysterious concept difficult to grasp in their everyday lives (Dwivedi et al., 2019). This leads to "AI Washing," where the mystery and lack of clarity about how artificial intelligence operates lends it an almost magical touch, even though it typically requires significant human power, often hidden, to function (Walker, 2022).

Techwashing is a trend spreading across various areas, whether political, business, economic, or even ethical, in both the private and public spheres. The term also implies organizational and political image laundering by promoting excessive optimism about technoscientific solutions as the sole solution, and by pushing megalomaniacal technological ideas to divert attention from real problems (Ribeiro and Soromenho-Marques, 2022).

Research has attempted to identify factors determining the gaps between discourse and reality regarding both the development and adoption of technology.

For instance, a study examined whether companies' perception or reputation as technological innovators corresponds to their actual innovative activity. Factors such as patent portfolio and advertising expenditure were used to examine their influences on reputation. The findings show that innovative performance is linked to the reputation of technological innovation, while marketing intensity has a negative influence on this reputation (Höflinger et al., 2018).

An article published in 2022 mapped conceptual properties and relationships to transfer knowledge from the known Greenwashing to the more recent AI Washing or "Machinewashing". It addresses structural analogies and the idiosyncrasies of Machinewashing, leading to an innovative model with a theoretical basis (Seele and Schultz, 2022).

Another piece of work contributes to the literature on business ethics and strategic corporate social responsibility in relation to AI ethics by proposing a normative viewpoint. It examines the phenomenon of ethical instrumentalization, which includes (1) symbolic hiring of ethical experts, (2) hiring policies that promote non-critical consensus, (3) the use of persuasion techniques to divert attention from ethical issues, and (4) the focus on the ethical design of specific technologies while ignoring or defunding other efforts to address system-level ethically unacceptable outcomes (Fioravante, 2024).

Another paper delves into the accountability challenges within the virtual reality of the metaverse. The research proposes that current metaverse creators may be "techwashing" their initiatives, painting an idealized picture of their virtual realms while sidestepping genuine challenges and complexities (Massaro et al., 2023).

On the other hand, the ability of certain countries to achieve their strategic AI plans was assessed through a factor analysis. Each country was scored based on its level of technology (computing power, AI research and AI investment) and its level of AI workforce in relation to the fulfillment of AI objectives. The screening process revealed the countries that are advancing towards AI fulfilment compared to those that have not yet initiated any actions in this direction, highlighting the disparity between their intentions and their actual progress (Fatima et al., 2022).

Research has also studied factors for AI development. The Latin American Artificial Intelligence Index (ILIA) identifies three dimensions: Key Enablers (Infrastructure, Data, and Talent Development), AI Ecosystem Maturity (Research, Innovation and Development, and Adoption), and Governance (Vision and institutionality, International Governance and Regulation). The index ranks countries based on these criteria but does not evaluate how they promote themselves regarding AI. It concludes that a lack of understanding of AI, combined with media coverage, can lead to misconceptions about its risks and benefits, potentially causing unfounded fears or exaggerated expectations of its capabilities (Kaura et al., 2023).

On the other side, there are also policies and frameworks for technology companies to actively demonstrate their reliability, through, for example, (1) the design of their applications, emphasizing its capabilities and limits, (2) the development of technological and moral skills, as well as practical wisdom in their employees, and (3) surpassing mere legal obligations (Keymolen, 2023).

There is currently no tool or framework to measure the level of techwashing as such. It is difficult to gain access to all the sources of information on the main factors of techwashing, so it is necessary to develop a tool that incentivizes organizations to assess themselves publicly.

2. Theoretical Framework and State of the Art

2.1 Techwashing

There are different ways in which technology manifests itself. Companies in the technology sector are usually divided between those that facilitate it and those that adopt it. Those that facilitate technology support the growth of other companies, while those that adopt technology do so to gain a competitive advantage. Therefore, some argue that the broad definition of what technology encompasses has contributed to the prevalence of techwashing in general [I].

Techwashing is the practice of applying a trendy, new label on legacy solutions. Examples like Greenwashing and Cloud washing are widely recognized. This phenomenon extends to different technologies such as artificial intelligence (AI) and software-defined networking (SDN), and it's gradually infiltrating regulatory technology (RegTech) (Alikhani, 2019).

Furthermore, techwashing can be expressed in different ways: first, incited by opinion leaders to divert attention or achieve economic, reputational, or power purposes. Second, to obtain financing by using and exploiting scientific concepts, methods, and research projects. Third, to turn science fiction into reality through marketing campaigns and communications. Fourth, to promote fear over reason, and fifth, to postpone the resolution of essential issues as a strategy of public entities and decision-makers (Ribeiro and Soromenho-Marques, 2022).

2.1.1 Artificial Intelligence and AI Washing

Media analysis reveals that the legitimization of AI accelerated from the mid-2010s, and its legitimacy has increased over time. Although generally well-evaluated, the study identifies three specific media frameworks - Regulation, Privacy and Security, and Ethical Challenges - utilized to delegitimize AI applications. This highlights the need to address societal concerns to build trust in technology and foster its acceptance and dissemination (Korneeva et al., 2023).

AI is shaped by its social context at all stages of its development and use. The interaction between technology and society is reflected in how we conceive and adopt technologies (Hagerty y Rubinov, 2019). Used correctly, artificial intelligence can be very powerful, as positive attitudes toward this technology can positively influence brand associations. In fact, a study on how AI drives branding developed a Framework to effectively address privacy issues, consumer fears, and ethical concerns towards the success of a brand, highlighting the importance of reputation and credibility for its acceptance (Deryl et al., 2023).

Strong AI refers to machines and AI as equivalent to humans, capable of solving any problem, while Weak AI is defined as considering AI as a device that solves specific problems with little transferability to new challenges. Weak AI is associated with the term "AI Washing," which is when software providers label algorithms with "AI" without justification (Medeiros et al., 2023).

For example, in the medical field, due to the growing interest in the application of artificial intelligence, various providers approach healthcare systems ensuring the use of AI in their products. This could be considered as AI Washing, by adding the AI label to any software platform, which could be simply a basic algorithm (Bini, 2018).

Intelligent robots and AI are emerging as driving forces that are reprogramming the traditional banking sector. In the FinTech industry, payment service solutions, blockchain technology, and robotic advisory services have become crucial. AI exaggeration is generating strong pressure from both investors and consumers on organizations to adopt this technology, making real value creation difficult (Prisznyák, 2023).

In systemic investment, investors fall into the "black box" trap, with claims from managers such as "We cannot disclose how the model works because it is proprietary information." In this case, an investment product claims to use "the latest artificial intelligence and machine learning tools," but these tools are misapplied or play a minimal role (Harvey, 2023).

Techwashing can also involve denying the real capabilities or consequences of technology. From a human rights perspective, some AI applications can contribute to ensuring rights, such as access to health and food. However, these benefits are offset by numerous risks and potential harms, many of which pose ethical dilemmas. Concerns arise about data protection, privacy, and hidden biases (Stahl et al., 2023).

One case is predictive policing, where the algorithms used can be presented as objective and unbiased solutions, but in reality, they are full of biases and racism. There is increasing evidence suggesting that human biases have been incorporated into these tools because machine learning models are trained on biased police data. Instead of counteracting racism, these algorithms could be more effective at concealing it. Many critics now consider these tools a form of techwashing by masking inequalities in society under the guise of objectivity (Heaven, 2020).

On the other hand, while it is important to focus on the details of AI legal systems to avoid structural biases, there is a risk of investing excessive time in small improvements, neglecting other interventions that could have a much more significant impact on strengthening essential legal values [II].

2.1.2 Other Technologies

In the field of the Internet of Things, marketing narratives produced by leading technology companies have been examined, and the results have shown how these companies resort to fundamental mythical archetypes and sociocultural narratives to try to legitimize emerging technology (Bonnin and Alfonso, 2019).

Exaggeration surrounding metaverses represents big business, with investments of billions of dollars, according to an analysis conducted on 32 startups selected from Crunchbase. Advertising suggests that retail investors have a "once-in-a-lifetime opportunity" to join this movement, presenting a utopian ideal of how these universes will look. However, the realities of these companies are obscured by the use of technological slang that few understand. Fear of Missing Out (FOMO) drives emotional and erratic investment behavior (Massaro et al., 2023).

Finally, the use of automation is growing in various aspects of our lives, and its capabilities are often exaggerated. Media descriptions and marketing about vehicle automation affect users' perceptions of the system's capabilities and subsequently their interaction with it. Therefore, the term

"Autonowashing" has been introduced to describe the practice of making something appear more autonomous than it really is. This is defined as the practice of making unverified or misleading claims that misrepresent the appropriate level of human supervision required for a product, service, or partial or semi-autonomous technology. The signs of autonowashing are detailed as: the use of vague language, unsubstantiated claims, false figures of influence or authority, idealized features in media, and hidden trade-offs (Dixon, 2020).

2.2 Private Sector

The private sector is often considered the engine of wealth creation and innovation, where shareholder value is perceived as the ultimate measure of a company's success (Mazzucato, 2022).

An analysis of 23 interviews conducted with AI entrepreneurs in the United States (Winecoff and Watkins, 2022) identified that, due to the difficulty of objectively verifying the value of startups, entrepreneurs rely on the legitimacy of AI to gain credibility. Investor pressure not to miss out on opportunities drives the cycle of exaggeration about AI. When facing stakeholders without technical knowledge, startups adopt exaggerated language about AI, thus turning it into a discursive tool to evade institutional pressures through a process of "window dressing”.

Artificial intelligence could constitute the fastest paradigm shift in the history of technology. In 2019, within a span of three years, it was expected that the proportion of companies undertaking AI-related initiatives would increase from one in twenty-five to one in three (Kelnar, 2019).

An individual review was conducted of the activities, focus, and funding of 2,830 purported artificial intelligence startups in 13 European Union countries (Kelnar, 2019). In approximately 60% of the cases, i.e., in 1,580 companies, evidence and support were found for artificial intelligence being an important element in the company's value proposition. This means that these companies actively promoted artificial intelligence as a fundamental part of what they offered to their customers or investors with compelling evidence. Therefore, it follows that the other 40% lacked evidence of this.

2.3 Public Sector

The public sector refers to the part of the economy and society controlled and managed by the government in liberal democracies or democratic capitalist societies. This sector includes political, governmental, and office institutions that operate with the purpose of promoting the public interest and addressing collective problems (Lane, 2010).

A recently studied practice in the public sector is called "Tech Diplomacy," which involves a nation strategically engaging with technological actors for diplomatic purposes and using it both from a national marketing perspective and for the professional field of public diplomacy. Nations can use four rhetorical tools to articulate and emphasize the image of technology as: (1) promoting key innovative concepts (technological buzzwords), (2) focusing on entities (high-tech companies), (3) recognizing individuals (technological entrepreneurs), and (4) showcasing high technology (technological products and services) (Mashiah, 2023).

On the other hand, by deciphering the gap between national AI plans and their concrete advancements, a study examined the AI strategies of different nations and compared them with their available AI resources (Seele and Schultz, 2022). The analysis showed that over 50% of the countries studied were labeled as "Aspirational," indicating that most are still in the initial phases of national AI development.

Another qualitative research analyzed 28 national AI strategies in the public sector (Hjaltalin and Sigurdarson, 2024), with the aim of understanding how governments define and position AI applications from a perspective of generating public value. It is highlighted that, although efficiency and service provision dominate the discourse, the implemented AI does not directly respond to citizen needs nor does it address democratic imperatives.

For example, the United Arab Emirates (UAE) has an ambitious vision for the future with its National AI Strategy for 2031, which aims to build an AI-based economy. This plan aligns with its long-term goal of becoming the "best country in the world" by 2071. However, this technological drive raises questions about potential social and political consequences. While the UAE is making significant investments in AI and technology to project an image of innovation and leadership, it is important to recognize that these initiatives may overshadow or minimize more urgent concerns, such as labor exploitation and restrictions on freedom of expression within the country (Al Khatib, 2024).

2.4 Ethics and Transparency

Ethics in the technology sphere is not merely an academic or intellectual activity; it is the practice of engaging in the technology sector in a morally acceptable manner (Grellette, 2022).

AI researchers often present and talk about AI in a way that can lead to misunderstandings. This is due to confusion about the autonomy of AI and the lack of recognition of the role of human actors in AI systems (Johnson and Verdicchio, 2017).

For better or for worse, ethics is used in AI. The increase in our dependence on intelligent machines has generated a growing demand for more transparent and interpretable models. Good practices such as explainable artificial intelligence (XAI) develop more understandable models that facilitate human users to understand, trust, and implement artificial intelligence systems (Dwivedi, 2022).

On the opposite pole, other practices emerge such as "Ethics Washing," where the susceptibility of AI ethics is evident. This logic leads to questioning the role that "ethics" play within the technology industry, where it is used to wash concerns raised by the behavior of a company or a technopolitical crisis. Ethics is strategically used to project an image of contributing to the common good while minimizing ethical constraints that could limit the company's actions (Van Maanen, 2022).

Transparency has gained relevance in current regulatory debates due to the agenda of major technology companies. Analyzing the latest transparency initiatives of IBM, Google, and Facebook, the concept of "Transparency Washing" emerges, where the focus on transparency acts as a distraction and diversion from more substantial and fundamental questions about the concentration of power, substantive policies, and actions of tech giants (Zalnieriute, 2021).

Ethics in the technology sector is not just theoretical; it's about actively engaging in morally acceptable practices. It's crucial to navigate these complexities, particularly in the context of techwashing, to ensure technology serves the common good and respects ethical boundaries.

RESEARCH METHODOLOGY

The divergences in how to apply ethics highlight the need to prevent the practice of techwashing through an evaluation of factors that help identify the potential absence of this practice for the peace of mind of stakeholders.

In 2021, Chile in particular launched its own artificial intelligence policy, addressing ethics and particularly transparency from various perspectives. In the document, the State emphasizes the importance of addressing the ethical implications of AI in the field of e-commerce, and how lack of transparency and accountability can lead to deceptive or discriminatory practices (Arancibia et al., 2021)

It is then that the idea of developing this initial tool is presented, whose objective is to promote ethics and transparency regarding the authentic application of technology. This tool will be designed for use by Chilean startups, enabling them to respond to the questionnaire, allowing the assessment of the extent to which techwashing is absent.

This initiative will empower stakeholders, including customers, users, investors, among others, enabling them to make more informed decisions and to evaluate technology companies and products more thoroughly and effectively.

1. Hypothesis and Testing Method

Hypothesis 1: It is possible to develop an index that allows the detection of the level of techwashing present in startups.

The variables of this research could be identified as follows:

1. Independent Variable: design of the proposed evaluation
2. Dependent Variable: absence of techwashing in startups

Validating this hypothesis involved the following methodical approach:

Firstly, a comprehensive review of existing literature was essential to grasp the concepts and methodologies related to techwashing and startup evaluation.

A set of profiling questions was created to obtain more information about the company the respondent is referring to.

Utilizing defined criteria and existing literature, indicators were selected to assess the absence of techwashing, rather than the extent of this phenomenon, due to challenges associated with acquiring comprehensive data on techwashing behaviors. This process included the development of binary and depth indicators, as well as the establishment of a scoring system.

The choice of having five indicators, each with a maximum score of 4 points, and a total maximum index score of 20 points was based on these factors:

1. Balance and representativeness: By having five indicators, a variety of relevant aspects is covered to comprehensively and equitably measure the absence of techwashing.

2. Clarity and simplicity: An index with five indicators and a maximum score of 4 points per indicator is easy to understand and apply for both startups and evaluators.
3. Granularity: With a maximum of 4 points per indicator, there is sufficient gradation and nuances to differentiate between levels of compliance.
4. Ease of interpretation: A total maximum score of 5 points makes it easy to interpret the overall level of absence of techwashing.

As a result, this analysis will allow the creation of a tool to assess the absence of techwashing.

2. Company's profile

For the identification of participants, the following profile questions will be asked:

Table 1 – Profiling questions.

Variable	Question	Answer
Company Name	What is the name of the company?	(Optional)
Respondent's Position	What is the respondent's job title?	(Optional)
Company Size	How many employees does your company have?	Less than 10 employees 10-50 employees 51-100 employees 101-500 employees 501-1000 employees More than 1000 employees
Revenue	Within what range are the company's annual sales?	Between 0.01 UF to 2,400 UF [III] Between 2,400.01 UF to 25,000 UF Between 25,000.01 UF to 100,000 UF
Company Age	How many years has the company been in operation?	Less than 1 year Between 1 and 5 years Between 5 and 10 years More than 10 years

Industry Sector	What is the primary industry sector of your company?	a. Agriculture, forestry, and fishing b. Mining c. Manufacturing industry d. Energy and water supply e. Construction f. Wholesale and retail trade; vehicle repair g. Transportation and storage h. Accommodation and food service activities i. Information and communication j. Financial and insurance activities k. Real estate activities l. Professional, scientific, and technical services m. Public administration and defense; social security n. Education o. Healthcare and social assistance p. Arts, entertainment, and recreation q. Other services
Type of Technology	In order of most to least importance, select a maximum of 3 technologies by which your company is characterized or promoted.	a. Artificial intelligence and machine learning b. Blockchain c. Big data and data analytics d. Robotics e. Augmented reality and virtual reality f. Software development g. Biometric technology h. Cloud computing i. Cybersecurity j. Internet of Things k. Other:

Type of Company	Is the company primarily a developer or adopter of the technologies it is characterized or promoted by?	a. b.	Developer Adopter

3. Indicators

The selection of indicators was based on the factors of techwashing identified in existing literature and also on the information that could feasibly be obtained from companies without compromising them to hide or lie. Thus, the indicators were designed to be practical and implementable, fostering transparency and encouraging honest responses. This approach aimed to create a balanced assessment tool that effectively captures the absence of techwashing while respecting the limitations and constraints of participating companies.

For the development of the tool, the following types of indicators, each with its own questions, types of responses, and scores were taken into account:

3.1 Binary Indicators

These indicators were chosen in order to take only one of two possible values, representing the presence or absence of a characteristic or event related to Techwashing. The two values were coded as 0 and 4, with 0 indicating the presence of a characteristic or event related to Techwashing and 4 indicating its absence.

Table 2 – Binary indicators.

Indicator	Question	Answer	Score
# 1 Ethics and transparency	Does the company have an ethics and transparency policy governing its technological activities?	a. Yes b. No	a) = 4 points b) = 0 points
# 2 Investment	Do the company's financial statements reflect an investment commensurate with the development or adoption of the technologies for which it is characterized or promoted?	a. Yes b. No	a) = 4 points b) = 0 points
# 3 Talent	Does the company have specialized talent within its team in the technologies for which it is characterized or promoted?	a. Yes b. No	a) = 4 points b) = 0 points

3.2 Indicators of depth

These indicators are organized into stages, each representing a level of intensity or severity related to the presence or absence of Techwashing. In this categorization, the lower the stage, the higher the potential presence of techwashing, as there is insufficient evidence to confirm its absence, resulting in a score of 0. Conversely, the higher the stage, the higher the score assigned, with a maximum score of 4, reflecting a greater absence of Techwashing. This staging system allows for a nuanced assessment, where higher scores indicate a more favorable outcome in terms of Techwashing mitigation or absence.

Indicator # 4: Transparency and explainability

Question: How is the type(s) of technology(ies) used in your company and its(their) technical background communicated?

Table 3 – Indicators of depth: Transparency and explainability.

Stage 0	**Stage 1**	**Stage 2**	**Stage 3**	**Stage 4**
Not publicly communicated	At a high level, without delving into complex technical details	Through graphical interpretations	Based on results, highlighting achievements and benefits attained	Aggregated summaries and statistics illustrating its impact or effectiveness clearly and concisely
Indicates that the company does not provide information about its technologies or the benefits they generate transparently, making it difficult to evaluate their operation and effectiveness.	Provides a general and concise description of the technologies used, avoiding complicated technical details to make it understandable to the general public.	In addition to the above, it uses graphics or other visual representations to communicate general information about the technologies clearly and visually.	Additionally, it focuses on highlighting specific achievements and benefits obtained through the technologies, offering concrete examples of tangible improvements.	Furthermore, in addition to highlighting achievements and benefits, it presents summaries and statistics that support them, allowing for a deeper and more quantitative understanding of their effectiveness.
0 points	1 point	2 points	3 points	4 points

Indicator # 5: Innovation

Question: Has the technology promoted as innovative been applied as a real innovation? In the context of "real innovation", it is understood as "the art of establishing something new or different in the real world that has a significant impact" (O'Connor, 2017).

Table 4 – Indicators of depth: Innovation.

Stage 0	Stage 1	Stage 2	Stage 3
No	Has potential for patenting	Is in the process of patenting	Yes, it has been patented
No attempt has been made or has not been successful in obtaining a patent for the technology promoted as innovative, suggesting that it has not been formally recognized as a unique innovation or that it has not been deemed necessary to legally protect it in this manner.	It is recognized that the technology has features or elements that could be eligible for patenting in the future, indicating that it is considered to have a degree of originality and innovation.	The technology is currently in the process of obtaining a patent, suggesting that it has been deemed potentially innovative and is being evaluated for legal protection.	The technology has been officially patented, indicating that it has undergone a rigorous evaluation process and has been recognized as a unique and original innovation.
0 points	1 point	2 points	4 points

4. Open-ended question

Additionally, an open-ended question was included at the end as an additional input for the characterization of the companies:

Question: What additional factors would you consider feasible and demonstrable for evaluating the potential absence of techwashing in your company?

5. Interpretation of results

Based on the accumulated scores from all indicators, companies will be categorized into distinct groups to better understand their potential absence of techwashing:

Table 5 – Interpretation of results.

Group 1	Group 2	Group 3	Group 4	Group 5

Between 0 to 3 points	Between 4 to 7 points	Between 8 to 11 points	Between 12 to 15 points	Between 16 to 20 points
Minimal evidence indicative of the absence of techwashing practices.	Initial indications of addressing and acknowledging the risks associated with techwashing.	Significant strides in actively mitigating the risks of techwashing.	Robust evidence of effectively controlling and managing the risks associated with techwashing.	Concrete and compelling evidence supporting the potential absence of techwashing..

Through this classification system, stakeholders can gain insights into the varying degrees of potential techwashing absence among companies, enabling informed decision-making and risk assessment in the context of technology-related investments and engagements.

RESULTS

The analysis of existing literature on techwashing reveals several key findings. Firstly, techwashing is pervasive across various sectors, encompassing political, economic, business, and ethical domains. It involves the promotion of excessive optimism about technological solutions, often to divert attention from underlying issues or to enhance organizational and political images.

Furthermore, the emergence of AI Washing has drawn attention to the misrepresentation of artificial intelligence and technology-driven solutions. Additionally, techwashing extends beyond AI to other emerging technologies such as the metaverse and automation, where exaggerated narratives and marketing tactics distort public perception and understanding.

In the private sector, startups and technology companies face pressure to adopt and promote AI solutions, often resorting to exaggerated language and claims to attract investment and gain credibility. Meanwhile, in the public sector, despite discrepancies between aspirations and implementation, nations strategically position themselves as leaders in technology and innovation, often prioritizing technological advancements over pressing societal issues.

The ethical implications of techwashing, such as Ethics Washing and Transparency Washing, underscore the importance of promoting ethical practices and transparency in the technology sector. Initiatives such as explainable artificial intelligence (XAI) aim to enhance transparency and accountability in AI systems, mitigating the risks associated with unethical practices and deceptive marketing. Lastly, research has explored the factors associated with techwashing, such as innovation, human resources, investment, ethics and marketing. Despite these efforts, there is currently no comprehensive tool or framework available to measure techwashing directly, highlighting the need for the development of such tools to incentivize organizations to assess and address techwashing practices transparently. Therefore, a comprehensive tool was successfully designed to measure the absence of techwashing based on the factors identified in the literature review.

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CONCLUSIONS

It is evident that preventing techwashing practices is paramount in ensuring ethical and transparent conduct in both facilitators and adopters of technology. Rather than solely measuring whether companies engage in techwashing, it is more effective to encourage an evaluation framework that incentivizes businesses to assess the potential for techwashing absence. This proactive approach not only promotes accountability but also fosters a culture of integrity and responsibility. Given the challenges associated with accessing detailed information on techwashing practices, such an evaluation model offers a pragmatic and forward-thinking solution to address this pressing issue. The developed tool suggests considering indicators such as ethics, transparency, investment, talent, explainability and innovation. By prioritizing these factors, companies can strive for genuine ethical practices and contribute to a more trustworthy technology-driven landscape.

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[I] https://www.charteredbanker.com/resource_listing/knowledge-hub-listing/dissecting-techwashing.html

[II] https://es.scribd.com/document/679924664/156-1

[III] The UF or "Unidad de Fomento" is a unit of account used in Chile, adjusted according to inflation.

Control Limits for Monitoring the Average of Correlated Streams

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STRUCTURED ABSTRACT

Purpose – An increasing number of manufacturing processes involve multiple streams where the same type of item is produced in a parallel fashion. Traditionally, streams need to be monitored using separate control charts. The number of charts becomes unrealistic as the number of streams increases. This research proposes modified limits for individual measurement group charts to control the average of multiple streams and account for the level of correlation between them.

Methodology – Results of simulation studies were used to develop a mathematical model representing the relationship between the in-control average run length (ARL_0), the number of streams, the level of correlation between them, and the half-width of the control limits. The fitted model was confirmed and used to generate tables of recommended values of the half-width to be used in constructing group control charts to achieve a specified level of the ARL_0. A similar approach was used to characterize the shift detection capability of the proposed charts.

Findings – The fitted model was confirmed and used to generate tables for modified values of the half-width factor based on the number of streams and the level of correlation between them.

Research limitations – Simulated measurements were generated from the normal distribution assuming that the process variability is in-control and that the streams are equally correlated.

Value – Research findings offer a solution for implementing group control charts to monitor the average of multiple stream processes.

Keywords: Multiple Stream Processes, Group Control Charts, Charts for Individual Measurements, Average Run Length.

Paper type: Research paper

INTRODUCTION

Following the pioneering work of Walter Shewhart (1931), many organizations applied control charts to achieve and maintain acceptable levels of performance. Designing a control chart requires the specification of three parameters. The subgroup size (n), the half-width factor (L), and the sampling interval (h). These three parameters set the level of two performance characteristics of the control chart. The average run length while the process is in-control (ARL_0) represents the expected number of points plotted within limits until a false alarm. Typically, the higher the value of the ARL_0, the better the chart design. On the other hand, the average run length (ARL_1) represents the expected number of points plotted within limits following a shift in the process average. Smaller values of the ARL_1 indicate higher shift detection capability of the control chart and are generally preferred. Over the last decade, the manufacturing environment has undergone significant transformations. An increasing number of manufacturing processes involve multiple streams where the same type of item is produced in a parallel fashion. These conditions represent challenges to applications of the Shewhart-type charts. Boyd (1950) proposed the use of group control charts (GCC) for monitoring multiple stream processes. However, the streams were assumed to be independent. Montgomery (2019) pointed out that if the streams are highly correlated, then only one stream needs to be monitored. In practice though, streams are neither perfectly correlated nor independent as was pointed out by Epprecht et al. (2015), Mortell and Runger (1995), and Nelson (1986).

In this research, modified limits for the individual measurement group charts are proposed for monitoring the average of multiple stream processes (MSPs). The following section presents a literature review of the fundamental aspects of the group control charts. This is followed by a detailed description of the research procedure, the simulation model used, and statistical analysis of simulated measurements. Conclusions and directions for future research are presented in the last section.

LITERATURE REVIEW

Boyd (1950) was the first to propose group control charts (GCC) for multiple head processes using the mean and sample ranges. This method remains the basic procedure for monitoring MSPs. Boyd's method is based on setting up a single pair of charts to monitor the performance of m streams using samples of n from each. One chart ($\bar{x}$ chart) is used to monitor the average across the streams, and another (R chart) to monitor variability between the streams. The charted statistics represent extreme values of the sample average and sample ranges. Ott and Snee (1973) presented a comparison between counting runs above and below the median (nonparametric method), use of residuals, and analysis of variance methods for analyzing multiple-head machines. They concluded that the appropriate method for a given application depends on the end-user of the information generated. Nelson (1986) was the first to express concern over the statistical performance of GCCs. He recommended adjusting the control limits so that the false-alarm probability does not exceed an acceptable level. He proposed a run test for GCCs to increase their ability to detect a shift in a single stream. Mortell and Runger (1995) proposed monitoring the MSPs using two charts: one for tracking the average across all streams and another to monitor the range. They compared the performance of these charts with Nelson's run test using simulated data and reported that the proposed charts are better than Boyd's GCC. They also pointed out that the lack of consideration for the correlation among the various streams can change the rate of false alarms (ARL_0) in a significant way.

Grimshaw et al. (1999), demonstrated that for a Shewhart-type chart with $L= \pm 3$, the ARL_0 decays with the number of streams (m) as shown in Figure 1. They assumed that the streams are independent and proposed corrections to the half-width (L) required to maintain the ARL_0 at 370.4 as shown in Table 1. Epprecht et al. (2011) proposed modified GCCs for residuals as an alternative scheme for monitoring MSP. They concluded that the residual charts are faster and more efficient at detecting shifts in the mean of one stream. Compared with other methods, they concluded that the gain in performance increases with the number of streams.

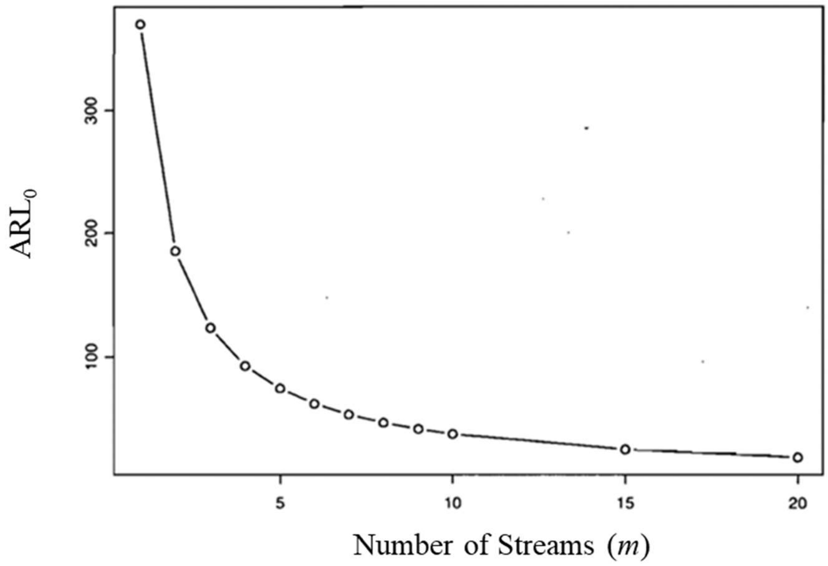

Figure 1 – Effect of the number of streams on ARL$_0$. (Grimshaw et al. 1999)

Table 1 – Corrected values of the half-width factor (L) from Grimshaw et al. (1999)

m	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**11**	**15**	**20**
L	3.000	3.205	3.320	3.399	3.460	3.509	3.549	3.584	3.615	3.642	3.745	3.817

THE SIMULATION MODEL

A Monte Carlo simulation model was constructed using the RStudio software (RStudio Team, Integrated Development for R, 2020, Boston, MA). Figure 2 shows the simulation flow chart. The simulation starts by specifying the half-width (L), the number of streams (m), the level of correlation between them in terms (ρ), and the number of replications (t). From each stream, a total of N = 50000 measurements was generated from the standard normal distribution (0,1) to represent values of the X_r statistic. The maximum and minimum X_r values were recorded for each simulated run and the first value outside the limits is used to obtain the run length. After all t replications were completed, recorded values of the run length were averaged to obtain values of ARL_0. A total of t = 526000 replications were required to estimate the ARL_0 within $\pm$ 1.0 at the 95% confidence level.

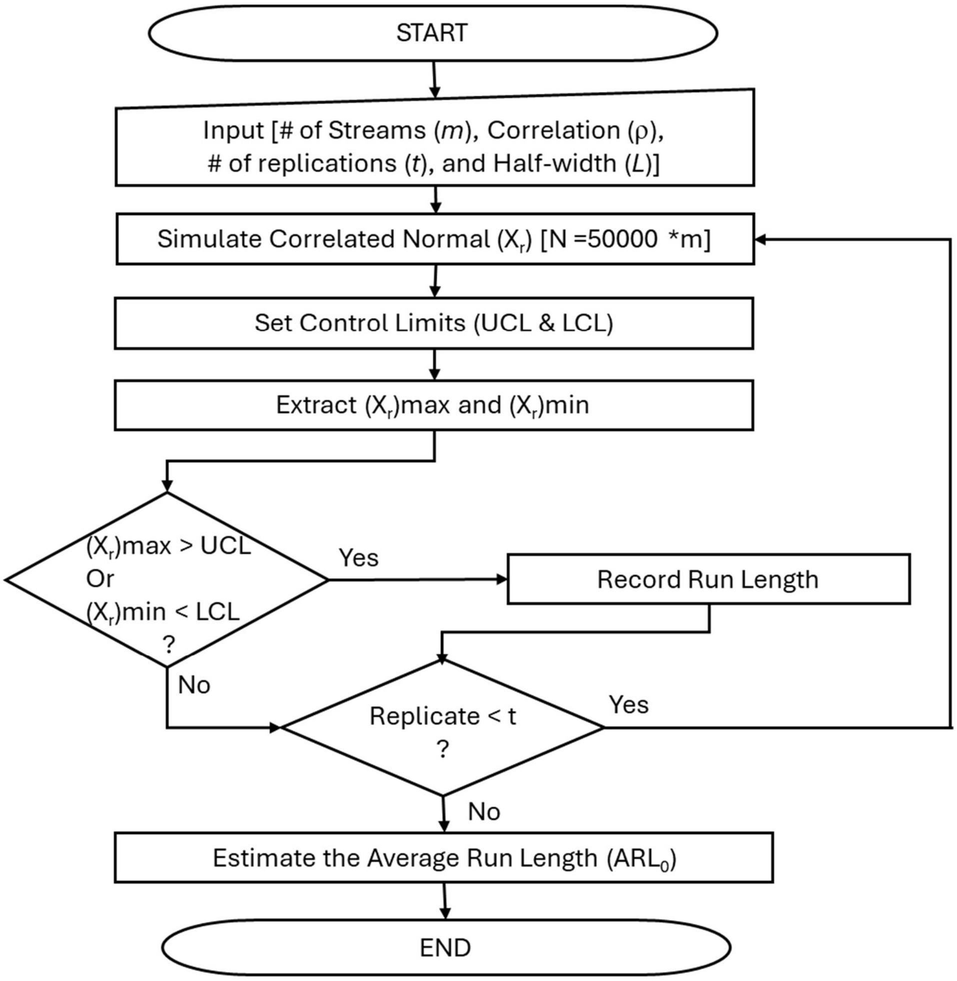

Figure 2 – R-Studio flow chart for ARL_0 simulation.

SIMULATION VALIDATION

The simulated results were compared to the values reported by Grimshaw et al. (1999) to validate the simulation model. These results were calculated assuming that the streams are independent ($\rho = 0$). Table 2 summarizes the simulated results with half-width $L = \pm 3$ for each specified value of the number of streams (m). As can be seen, the simulated values are well within the expected values for the number of replications utilized.

Table 2 – Simulation validation: ARL_0 with $L = \pm 3$ and $\rho = 0$

# of Streams (m)	**Grimshaw et al.** (1999)	**ARL_0 (simulated)**	**Error %**
2	185.450	185.437	-0.007
3	123.800	123.885	0.069
4	92.975	92.800	-0.188
5	74.481	74.342	-0.186
6	62.151	62.143	-0.012
7	53.344	53.380	0.067
8	46.739	46.744	0.010
9	41.602	41.612	0.025
10	37.492	37.481	-0.030
15	25.163	25.148	-0.060
20	18.999	19.014	0.076

STATISTICAL DESIGN

A second-order factorial arrangement was considered. The in-control average run length (ARL_0) was selected as the response variable generated using the simulation model. Table 3 describes the three factors considered and their levels. The number of streams (m) ranging from 2 to 20 was selected to match the levels utilized in most of the available literature. Levels of correlation (ρ) in terms of the coefficient of multiple correlation ranging from 0 to 0.8 were selected to quantify the effect of correlation between the streams. Values of the half-width (L) ranging from 2 to 4 were considered. The value of $L = 2$ is typically used for warning limits in control charts. The value of

L = 4 encompasses all the adjusted limits reported by Grimshaw et al. (1999) and covers the full range to be considered in this research. Given that the number of streams needs to be a positive integer with a minimum of 2, a face-centered composite design was selected as an appropriate arrangement. According to Box and Draper (2007), these arrangements represent response surface designs and offer better alternatives to the three-level factorial designs. As such, the design required a total of 20 runs (8 factorial points, 6 axial points, and 6 center points).

Table 3 – Selected factor levels and ranges

Factors	Symbol	Type	Low (-1)	High (+1)
Number of Streams	m	Numeric (Discrete)	2.00	20.00
Correlation	ρ	Numeric (Continuous)	0.00	0.80
Half-Width	L	Numeric (Continuous)	2.00	4.00

MATHEMATICAL MODELING

The results of the 20 simulation studies, each replicated t = 526000 using different seeds, are presented in Table 4. These results were analyzed using the Design Expert software (Stat-Ease Inc., Version 23.0, 2023, Minneapolis, MN). Initial analysis indicated the need for a power transformation to stabilize the error variance. Table 5 shows the analysis of variance (ANOVA) table for the transformed variable in the form $y = (ARL_0)^{-0.25}$. The second-order model was significant, with a P-value of less than 0.0001. The lack of fit is shown to be insignificant. Diagnostic examinations of the residuals indicated no violations of the underlying assumptions of the ANOVA procedure.

Table 4 – Design matrix and simulated results

Run	Streams	Correlation	Half-Width	ARL_0
	11	0.4	3	36.45
2	11	0.8	3	61.75
3	20	0	2	1.79
4	20	0.4	3	19.13
5	11	0.4	3	37.30
6	11	0.4	4	1513.20
7	2	0.4	3	205.30
8	20	0.8	4	1461.54
9	11	0.4	3	36.96
10	11	0.4	3	37.39
11	11	0.4	2	3.19
12	11	0.4	3	37.72
13	20	0	4	740.60
14	11	0	3	31.39
15	2	0.8	2	14.25
16	2	0	4	5947.92
17	2	0	2	12.13
18	11	0.4	3	39.48
19	2	0.8	4	5569.91
20	20	0.8	2	4.29

Table 5 – ANOVA for transformed values of ARL_0.

SOURCE	Sum of	DOF	Mean Squares	F-value	p-value
Model	0.8027	12	0.0669	4002.96	< 0.0001
# Streams (m)	0.0229	1	0.0229	1369.91	< 0.0001
Correlation (ρ)	0.0081	1	0.0081	484.93	< 0.0001
Half-Width (L)	0.1728	1	0.1728	10342.04	< 0.0001
$m\ \rho$	0.0041	1	0.0041	243.42	< 0.0001

mL	0.0185	1	0.0185	1109.04	< 0.0001
ρL	0.0033	1	0.0033	198.19	< 0.0001
m^2	0.0035	1	0.0035	209.87	< 0.0001
ρ^2	0.0008	1	0.0008	49.13	0.0002
L^2	0.0062	1	0.0062	369.97	< 0.0001
$m \rho L$	0.0017	1	0.0017	101.88	< 0.0001
$m^2 L$	0.0026	1	0.0026	157.86	< 0.0001
$m \rho^2$	0.0012	1	0.0012	74.56	< 0.0001
Residual	0.0001	7	< 0.0001		
Lack of Fit	0.0001	2	< 0.0001	4.74	0.0701
Pure Error	0.0000	5	8.081E-06		
Cor Total	0.8028	19			

The fitted model can be expressed as: $ARL_0 = \theta^{-4}$, where:

$$\theta = 1.19684 + 0.074984\, m - 0.105288\, \rho - 0.461488\, L - 0.002917\, m.\rho$$

$$- 0.017997\, \rho.L + 0.006291\, m.L - 0.001945\, m^2 + 0.105185\, \rho^2$$

$$+ 0.047415\, L^2 + 0.004052\, m.\rho.L + 0.000501\, m^2.L - 0.019379\, m.\rho^2$$

The reported value of the R^2 statistic indicates that the fitted model explains 99.99% of the variability in the ARL_0. The predicted R^2 of 98.46% agrees with the adjusted R^2 of 99.96%. These statistics indicate that the model can be used to navigate the design space.

The cube plot in Figure 3 can help visualize the effects of the three factors considered. As shown, the bottom side of the cube represents the estimated values of the ARL_0 when the streams are independent ($\rho = 0$). In contrast, the top side represents the estimated values of the ARL_0 when the streams are highly correlated ($\rho = 0.8$). As can be seen at high levels of the number of streams ($m = 20$) and half-width ($L = 4$), changes in the level of correlation from $\rho = 0$ to 0.8 resulted in a 107.5 % increase in ARL_0. With $m = 20$ and $L = 2$, similar changes in the correlation resulted in a 142.4% increase in the expected value of the ARL_0. A minimum increase of 19.5% is obtained at the low levels of the number of streams (m = 2) and the half-width (L = 2).

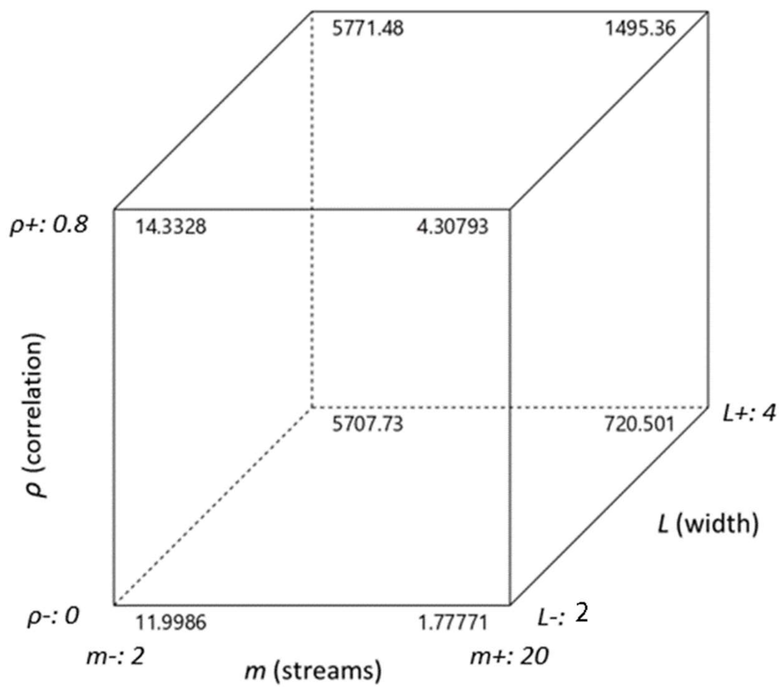

Figure 3 – Cube plot of expected ARL_0.

MODEL CONFIRMATION

Following the procedure suggested by Jensen (2016), six additional simulation runs were performed to confirm the fitted model. These simulated runs were performed at new levels of the three variables away from the design points. A two-sided, 95% confidence interval (CI) for estimating the ARL_0 based on six replications was constructed. A summary of the results is shown in Table 6. All generated values of the ARL_0 are well within the confidence intervals. These results confirm that the fitted model can be used to estimate the ARL_0 based on knowledge of the half-width (L), the number of streams (m), and the level of correlation between them (ρ).

Table 6 – Summary of confirmation runs.

Run #	Confirmation Results						
	(m)	(ρ)	(L)	Predicted Mean	Confirmation Runs (Avg)	95% CI low	95% CI high
1	3	0.1	3.310	375.92	378.95	323.98	435.78
2	3	0.5	3.254	370.87	370.38	314.59	437.38
3	3	0.7	3.256	370.15	368.82	319.15	428.94
4	15	0.1	3.791	368.33	366.20	316.27	428.70
5	15	0.5	3.779	365.31	368.17	315.23	425.74
6	15	0.7	3.680	379.93	378.24	328.52	438.83

TABLES OF RECOMMENDED VALUES

The fitted model is used to calculate the half-width (L) based on specified values of the ARL_0, the number of streams (m), and the level of correlation (ρ). Modified values of L required to achieve an ARL_0 of 370.4 are presented in Table 7. As can be seen, the results obtained when $\rho = 0$ agree with the theoretical values reported by Grimshaw (1999). Similar tables can be generated for achieving different values of the ARL_0 as needed.

Table 7 – Modified values of the half-width (L) required to achieve $ARL_0 = 370.4$

Number of Steams (m)	Correlation level (ρ)								
	0.0	**0.1**	**0.2**	**0.3**	**0.4**	**0.5**	**0.6**	**0.7**	**0.8**
2	**3.256**	3.226	3.193	3.185	3.182	3.174	3.166	3.190	3.209
3	**3.304**	3.310	3.302	3.269	3.252	3.254	3.248	3.256	3.263
4	**3.395**	3.376	3.360	3.347	3.337	3.319	3.316	3.327	3.308
5	**3.461**	3.436	3.408	3.421	3.405	3.398	3.379	3.369	3.370
6	**3.483**	3.494	3.483	3.480	3.445	3.449	3.442	3.422	3.406
7	**3.541**	3.536	3.536	3.520	3.503	3.493	3.471	3.449	3.433

8	**3.573**	3.574	3.573	3.570	3.562	3.533	3.509	3.486	3.447
9	**3.605**	3.614	3.629	3.606	3.601	3.586	3.552	3.519	3.488
10	**3.643**	3.638	3.648	3.649	3.647	3.623	3.591	3.558	3.497
15	**3.759**	3.791	3.814	3.814	3.821	3.779	3.730	3.680	3.603
20	**3.858**	3.922	3.955	3.979	3.965	3.941	3.881	3.769	3.635

PERFORMANCE INVESTIGATION

Another simulation model was constructed to allow tracking the average number of points required to detect a shift (δ) in the process average. This is defined as the out-of-control average run length (ARL_1). Random samples of size N = 50000 were generated at specified levels of correlation (ρ) and the number of streams (m). The specified level of correlation was assumed to be constant and equal for all streams. Simulated data were generated from the standard normal (0, 1). The shift (δ) was applied to one of the steams only. For each combination of variables, simulated runs were replicated 160000 times using a different seed for each replication. This number of replicates was selected to facilitate comparison of the results.

Initially, simulation runs were performed assuming independent streams with values of the half-width (L) selected from Table 7 to achieve $ARL_0 = 370.4$. Simulated results shown in Table 8 were compared with those reported by Mortell and Runger (1995) and Epprecht et al. (2011). Statistical analysis of differences between the three methods resulted in a p-value < 0.0001, indicating that at least two methods produce significantly different ARL_1. Figure 4 shows the least significant difference (LSD) plot at the 95% confidence level. The analysis confirms that the modified chart has a superior shift detection capability compared to the other two methods when the streams are independent.

Simulated results obtained when the streams are correlated are reported in Table 9 for given shift magnitudes δ. Here the same level of correlation (ρ) was assumed between all the streams while the shift (δ) was applied to one stream only.

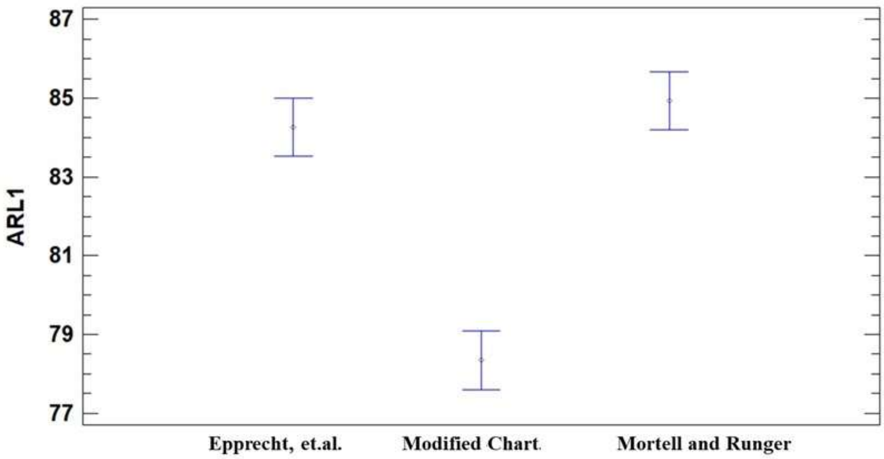

Figure 4 – ARL_1 performance comparison with $\rho = 0$.

CONCLUSIONS

The modified limits proposed in this research offer a solution for implementing group control charts to monitor the average of multiple stream processes. Ignoring the correlation between the streams leads to an unacceptable increase in false alarms and unwarranted interruptions to the manufacturing process. The mathematical model presented in this paper can be utilized to determine the ARL_0 for the chart when used to control the average of MSPs. The model was utilized to create tables for modified values of the half-width (L) required to achieve a target ARL_0 of 370.4. Similar tables can be generated for different values of the ARL_0 by utilizing the fitted model. It is worth noting here that this model can only be utilized within the ranges shown in Table 3. The performance of the proposed chart was investigated under varying levels of shift magnitude, number of streams, and correlation levels. Simulated studies indicated that the modified chart outperformed the other charts proposed by Epprecht et al. (2011) and Mortell and Runger (1995). Some modern manufacturing processes can have more than twenty streams. The model should not be extrapolated in these scenarios. Similar research is needed to characterize the relationship

Table 8 – Performance comparison: ARL_1 for independent streams ($\rho = 0$)

Number of Streams (m)	δ = 0.5			δ = 1.0			δ = 1.5			δ = 2.0			δ = 2.5		
	Modified	**Runger**	**Epprecht**	**Modified**	**Runger**	**Epprecht**	**Modified**	**Runger**	**Epprecht**	**Modified**	**Runger**	**Epprecht**	**Modified**	**Runger**	**Epprecht**
2	**206**	226.3	224.4	**66.1**	92.6	91.3	**21.6**	38.5	38	**8.9**	17.9	17.7	**7.2**	9.3	9.2
3	**236.7**	248.4	244.3	**85.3**	104	104	**27.8**	42.8	41.4	**10.5**	19	18.2	**4.8**	9.4	8.8
5	284.5	274.9	276.8	**109.6**	126.3	123.4	**36.3**	52	48.4	**13.4**	21.9	19.3	**6**	10.3	8.6
6	282	268.9	286.2	**116.9**	133.8	136.4	**39.8**	55.2	51	**14.8**	23.2	20.1	**6.4**	10.7	8.8
8	**293.7**	296.8	305.3	**138.7**	153.6	152.1	**49.3**	63.5	57	**17**	26.1	21.4	**7.1**	11.7	9.1
10	**302.1**	303	326.5	**159.2**	164.6	163.9	**52.5**	70	63.2	**18.3**	28.3	23.1	**7.9**	12.4	9.5
12	**302**	324.5	325.2	**164.1**	180.4	174.3	**57.9**	76.2	66.3	**21.4**	30.6	24.6	**8.6**	13.2	9.9
15	**309.3**	318.1	318.7	**180.6**	187.1	182.2	**67.3**	82.3	73.5	**23.4**	33.4	26.6	**9.1**	14.3	10.6
18	322.6	311.9	347.8	**194.1**	193	208.6	**77**	87.3	81.8	**24.4**	35.3	28.4	**9.8**	15	11.2
20	337.9	337.6	338.3	**198.4**	210.5	205.9	**75.7**	94.1	83.6	**26.8**	37.7	29.7	**10.4**	15.7	11.5

Table 9 – Predicted values of ARL_1 for the modified chart

Number of Steams (m)	δ = 0.5				δ = 1.0				δ = 1.5				δ = 2.0				δ = 2.5			
	Correlation ρ				Correlation ρ				Correlation ρ				Correlation ρ				Correlation ρ			
	0.2	**0.4**	**0.6**	**0.8**	**0.2**	**0.4**	**0.6**	**0.8**	**0.2**	**0.4**	**0.6**	**0.8**	**0.2**	**0.4**	**0.6**	**0.8**	**0.2**	**0.4**	**0.6**	**0.8**
2	209.5	204.8	225.5	216.7	65.8	66.6	69.1	70.4	22.8	22.6	22.4	22.3	8.7	8.7	8.8	8.9	7.2	7.2	7.2	7.2
3	236.7	231.1	241.5	268.5	82.5	85.5	85.6	89.3	28.9	28.5	28.2	27.7	10.4	10.6	10.5	10.3	4.8	4.8	4.8	4.8
5	271.9	288.3	275.2	349.4	112	113.7	117.9	129.2	37.1	37.9	38.1	39.6	13.5	13.9	13.5	13.7	5.8	6.1	5.9	6.1
6	279.2	295	303.8	385.2	117.9	124.8	125.3	144.1	39.3	39.8	43.6	43.5	15.1	14.7	15.2	14.9	6.3	6.4	6.4	6.2
8	302.6	305	345	426.6	133.9	137.2	152	172.3	48.8	48.7	48.9	51.4	17.1	17.2	17.9	17.8	6.8	7.2	7.2	7.3
10	291.5	320.8	351.4	474.7	147.9	155	169.6	189.8	55.2	53.8	56.8	59.1	19.1	18.7	20	19.3	7.6	7.7	7.9	7.9
12	321.2	329.3	370	490.7	159.7	176.9	183.3	219.5	58.2	60.7	65.2	66.2	21.4	20.1	20.2	21.5	8.4	8.7	8.3	8.5
15	330.6	346	390.2	322	179.6	191.8	207.4	251.6	66.9	69.1	76	74.4	23.4	23.8	24.8	24.3	8.7	9.1	9.6	9.7
18	335.1	336.9	411.3	296.7	196.5	203	220.3	280.5	73.7	78.2	79.8	84.2	25.1	26.2	26.3	26.1	10	10	9.9	9.8
20	325.2	359.5	422.7	281.2	200	218.1	242.6	295.7	79.8	80.6	81.1	86.1	27.4	26.7	26.6	28	10.3	10.6	10.5	10.8

between the average run length and new levels of the factors. Higher computing capabilities will be needed to perform simulation studies with a larger number of streams. In addition, all simulated data utilized to develop the mathematical model were generated assuming that the process variability is in control and that the streams are not autocorrelated. In practice, however, the process variability should be monitored using a different chart. A natural extension of this research is to develop appropriate values of the half-width factor (L) for control charts used to monitor variability. Also, it was assumed that the streams are equally correlated. This assumption was made to simulate individual measurements at each sampling interval or production run. Future research would consider scenarios where the correlation between streams is not constant.

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EXPLORING THE RELATIONSHIP BETWEEN LEADERSHIP BEHAVIOUR AND FIRM PERFORMANCE IN THE READY MADE GARMENT INDUSTRY OF BANGLADESH

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STRUCTURED ABSTRACT

Purpose: This study explores the intricate relationship between leadership behaviour and Ready-Made Garment (RMG) firm performance in Bangladesh, focusing on the mediating role of competitive advantage and the moderating effects of emotional intelligence and firm strategy.

Design/methodology/approach: The research adopts a rigorous and novel quantitative approach. Data were meticulously collected from 400 RMG managers through physical questionnaires and subsequently analysed using tools such as SPSS, PLS4, and R. Instead of focusing on broad leadership styles, the study takes a unique approach by targeting specific leadership behaviours— task-oriented, relation-oriented, and change-oriented.

Findings: The study provides insights into how specific leadership behaviours affect RMG sector performance. It emphasises the pivotal mediating role of competitive advantage and highlights the significant moderating effects of emotional intelligence and firm strategy on the relationship between leadership behaviour and firm performance.

Originality: This study distinguishes itself as a pioneering endeavour in the academic landscape. Focusing on nuanced leadership behaviours across all organisational tiers within the Ready-made Garment (RMG) sector, it uncovers novel insights that advance academic understanding and address real-world industry intricacies, thus significantly contributing to the growing body of literature.

Keywords: *Leadership Behaviour, Firm Performance, RMG Industry, Competitive Advantage, Emotional Intelligence, Firm Strategy*

Paper type Research paper

INTRODUCTION

Imagine a symphony of machinery, a meticulously choreographed dance of skilled workers, and the pulsating heart of Bangladesh's Ready-made Garment (RMG) factories – all set against the backdrop of leadership's subtle yet transformative influence. In the words of John C. Maxwell,

'If you believe you are leading, yet no one is following, you are merely strolling.'

The RMG industry of Bangladesh, where leadership transcends mere administration to shape the destiny of firms. Amidst the ceaseless hum of machinery and the precision of workers' movements in Bangladesh's thriving RMG factories, leadership emerges as a potent catalyst for triumph. This study embarks on a journey through Bangladesh's RMG sector, intricately woven into the nation's economic fabric, to confront a pressing enigma – the nuanced leadership challenges it faces (Swazan and Das, 2022a).

Bangladesh's Ready-made Garments (RMG) industry has been a cornerstone of the nation's economic growth and export-oriented development strategy for several decades (Dey and Basak, 2020). As globalisation dynamics evolve, RMG firms' leadership is pivotal in navigating the industry's challenges and driving performance (Rashed Al and Wardha, 2020). This research seeks to elucidate the intricate relationship between leadership behaviour and firm performance, focusing on the mediating role of competitive advantage and the moderating influences of emotional intelligence and firm strategy (JACKSON, 2021).

The RMG industry in Bangladesh plays a pivotal role in the nation's economy, driving employment, exports, and economic growth (Rahman and Chowdhury, 2020)

Despite its strategic importance, this sector grapples with a multifaceted landscape marked by global competition, ethical concerns, and operational efficiency challenges (Akhter, Rutherford and Chu, 2019). In this context, understanding the critical role of leadership behaviours emerges as a paramount consideration (Hossain *et al.*, 2021; Chowdhury and Shajahan, 2022; Swazan and Das, 2022b).

While existing research has shed light on various aspects of the RMG industry, a noteworthy gap persists in comprehending the nuanced leadership behaviours that significantly influence the performance of RMG firms in Bangladesh. These leadership behaviours encompass task-oriented, relationship-oriented, and change-oriented dimensions, each carrying unique implications for organisational success (Ismail, Domil and Isa, 2020). Within the Resource-Based View (RBV) (Brooks and Muyia Nafukho, 2020)framework, leadership behaviours function as strategic resources with the potential to profoundly impact competitive advantage, employee motivation, operational efficiency, and reputation management within the sector (J. Barney, 2020).

Furthermore, emotional intelligence (EI) among leaders has emerged as a pivotal factor in shaping organisational outcomes, including firm performance (Cao and Le, 2022). Leaders proficient in understanding and managing emotions, both their own and those of others, foster improved relationships, informed decision-making, and cohesive team dynamics (Strugar Jelača, Bjekić and Berber, 2022). However, the role of EI as a moderator, in conjunction with firm strategy (FS), in shaping the relationship between leadership behaviours and firm performance within the RMG sector remains an underexplored terrain.

The RMG industry operates within a dynamic and ever-evolving global context (Kabir *et al.*, 2022), where effective leadership is the linchpin guiding firms to navigate challenges and harness opportunities. Beyond this, the mediation role of competitive advantage (CA) in the relationship between leadership behaviours, competitive advantage, and firm performance remains an essential yet under-addressed aspect of the RMG industry's complexity.

Within the context of Bangladesh's Ready-made Garments (RMG) industry, a critical research gap exists regarding the intricate interplay between specific leadership behaviours, emotional intelligence competencies, firm strategic choices, competitive advantage mechanisms, and their combined impact on the financial and operational performance of RMG firms (Ángeles López-Cabarcos, Vázquez-Rodríguez and Quiñoá- Piñeiro, 2022). While prior studies have recognised the significance of leadership in this sector (Akhter *et al.*, 2020), there remains an underexplored territory concerning the precise nature of leadership behaviours, their alignment with emotional intelligence traits (Cao et al., 2022), their synergy with firm strategic orientations, and their direct correlation with the competitive advantage strategies that drive the overall success of RMG enterprises (Barney, 1991). This gap in understanding calls for an in-depth investigation into the unique dynamics shaping leadership effectiveness and firm performance in this industry.

The rationale for this study stems from the critical need to comprehend the intricate interplay between leadership behaviour and firm performance within this dynamic sector.

Practical Insights The findings of this study will provide actionable insights for leaders and managers in the RMG sector. The study equips practitioners with strategies to enhance firm performance by identifying effective leadership behaviours.

Policy Impact Policymakers in Bangladesh can benefit from this research by formulating policies that encourage and nurture effective leadership in the RMG industry, fostering economic growth.

Academic Contribution Academically, this study extends existing theoretical frameworks by introducing the context of the RMG industry, thereby contributing to a deeper understanding of leadership behaviour and its implications.

Global Relevance Given the global reach of the RMG industry, the study's insights extend beyond Bangladesh's borders, offering valuable lessons for similar industries worldwide.

Human Welfare Understanding the factors contributing to the success of RMG firms can directly impact the welfare of the millions of workers employed in the industry, ensuring job security and improved working conditions.

In summary, this study's rationale and significance are deeply rooted in the pivotal role that leadership behaviours play in the RMG sector's performance, with far-reaching implications for the industry, the economy, and the well-being of its workforce.

Research Primary Objective

The primary objective of this study is to investigate the impact of leadership behaviour on firm performance in Bangladesh's RMG industry while also assessing the mediating effects of competitive advantage and the moderating roles of emotional intelligence and firm strategy.

Specific Objectives

In congruence with the primary objective, this study aims to accomplish the following objectives.

1) **Assessment of Leadership Behaviours' Direct Influence:** To evaluate the direct impact of leadership behaviour (LB) on firm performance (FP) within the RMG industry in Bangladesh.

2) **Investigating Competitive Advantage as a Mediator:** To investigate the mediating role of competitive advantage (CA) in the relationship between leadership behaviour (LB) and firm performance (FP) within the RMG industry.

3) **Examination of Emotional Intelligence as a Moderator:** To scrutinise the moderating influence of emotional intelligence (EI) on the relationship between leadership behaviour (LB) and competitive advantage (CA) in the RMG sector.

4) **Investigation of Firm Strategy as a Moderator:** To assess the moderating effect of firm strategy (FS) on the relationship between leadership behaviour (LB) and competitive advantage (CA) within the RMG industry.

5) **Derivation of Practical Implications:** To extract actionable insights from the research outcomes that facilitate the optimisation of firm performance. These insights will focus on effectively harnessing leadership behaviours, emotional intelligence, strategic alignment, and competitive advantages within the RMG sector.

Research Questions

Central Research Question

What is the nature of the correlation between leadership behaviour and firm performance?

Specific Objectives and Questions

1) **Direct Influence of Leadership Behaviour (LB)**

Research Question 1 Does leadership behaviour impact firm performance within Bangladesh's RMG industry?

2) **Mediating Role of Competitive Advantage (CA)**

Research Question 2 Does competitive advantage mediate the relationship between leadership behaviour and firm performance in Bangladesh's RMG industry?

3) **Moderating Influence of Emotional Intelligence (EI)**

Research Question 3 Does emotional intelligence moderate the relationship between leadership behaviour and competitive advantage in Bangladesh's RMG industry?

4) **Moderating Impact of Firm Strategy (FS)**

Research Question 4 Does firm strategy moderate the relationship between leadership behaviour and competitive advantage in Bangladesh's RMG industry?

5) **Practical Implications for Optimisation**

Research Question 5 What practical strategies can be derived from the research findings to optimise firm performance through effective leadership behaviours, emotional intelligence enhancement, strategic alignment, and utilisation of competitive advantage within the Bangladesh RMG sector?

Leadership Behaviour

Leadership behaviour profoundly influences various organisational outcomes. It includes Task-Oriented Behaviour (TOB), Relations-Oriented Behaviour (ROB), and Change-Oriented Behaviour (COB) (Yukl, 2020). The impact of leadership behaviour on firm performance is well-documented, with empirical evidence supporting its influence (Yukl, 2021).

Dimensions of Leadership Behaviour

Leadership behaviour has evolved considerably due to technological advancements and shifting organisational paradigms. (Smith *et al.*, 2020) delves into leadership in adaptive organisations, asserting leaders' need to remain agile amidst uncertainties. A salient perspective highlights that contemporary leaders must comprehend digital technologies' implications and mould strategy and culture accordingly (Kaniz *et al.*, 2020). Amid growing concerns about corporate scandals, ethical leadership has gained prominence. (Bormann, 2020) posits that the legitimacy of ethical leaders stems not just from moral decisions but also from the transparency inherent in their decision-making processes.

Significance of Leadership Behaviour in Influencing Firm Outcomes

Leadership is a potent catalyst in shaping the destiny of organisations. In the volatile environment of the RMG sector, leadership behaviour determines how firms respond to challenges, manage their workforce, and strategically position themselves in the global market. Leaders influence the organisational culture (Azeem *et al.*, 2020), employee motivation (Conides, 2020), and strategic decisions, all affecting firm outcomes. Given the industry's cutthroat competition and timely decision-making, leadership behaviour has become even more crucial (Hasan *et al.*, 2020).

Understanding Competitive Advantage and its Relevance to Firm Performance

(Dixit, Singh and Dhir, 2021; Christensen-Salem *et al.*, 2022) has redefined competitive advantage by highlighting the instrumental role of intangible assets, notably organisational culture, which can be a formidable barrier to replication. In industries like RMG, susceptible to disruptions, agility is crucial. Abhors make a compelling argument for adaptable firms, especially in the context of unforeseen global challenges. (Khan et al. (2020) underscore this in their study on the RMG sector in Bangladesh, suggesting that embedding sustainable practices (Khan and Rammal, 2020) can serve as a unique competitive edge in the global market.

Competitive Advantage as a Mediator

Competitive advantage signifies a firm's ability to outperform rivals. Leadership plays a crucial role in achieving and sustaining this advantage by identifying market opportunities and fostering a culture of innovation (Anning-Dorson, 2020; Saleh *et al.*, 2020).

The Role of Emotional Intelligence in Leadership Efficacy

Emotional Intelligence (EI) is a critical competency in the modern leadership paradigm. Hoch (2017) emphasises the significance of EI in managing the evolving workforce, advocating its role in nurturing virtual team dynamics. Fernández Berroc and Extremera (2019) further delve into the correlation between EI and leader well-bēing, presenting empirical evidence that associates higher EI with diminished burnout rates, subsequently fostering improved decision-making in organisational climates.

Emotional Intelligence as a Moderator

Emotional intelligence (EI) (Alferaih, 2020; Eidizadeh, Salehzadeh and Chitsaz Esfahani, 2020; Abbas and Kumari, 2021), encompassing abilities related to emotions (Abdullahi, Anarfo and Anyigba, 2020), intersects prominently with leadership. Leaders with high EI are adept at fostering a positive organisational culture and navigating interpersonal dynamics (Alzoubi and Aziz, 2020; Cuéllar-Molina, García-Cabrera and Déniz-Déniz, 2020).

Firm Strategy and its Linkage with Leadership Behaviour and Performance

Firm strategy and leadership behaviour are inextricably linked. Teece (2018) introduces the concept of 'dynamic capabilities,' underlining a leader's capacity to recalibrate organisational resources to address imminent challenges and opportunities. (Cheng, Li and Lin, 2020; Majumder and Ferdaus, 2020) dissect the strategic shifts in the RMG sector post-COVID, spotlighting the increasing focus on digitisation and sustainable supply chain management. Their work suggests that forward-thinking and adaptive leaders are pivotal in leveraging these strategic transitions to bolster firm performance.

(Acquaah and Agyapong, 2020; Akkaya, 2020) The literature from the past few years amplifies the multifaceted nature of leadership, emphasising its interconnectedness with firm strategy, emotional intelligence, and competitive advantage. For sectors like RMG, characterised by rapid evolution and global challenges, leadership behaviour remains at the heart of the firm performance (Dey and Basak, 2020; Haque *et al.*, 2020; Islam and Islam, 2020).

Firm Strategy as a Moderator

Firms generally align strategies around cost leadership, differentiation, or focus. A firm's strategic orientation can modulate leadership's effects on performance, with different leadership behaviours being more effective depending on the firm's overarching strategy (Acquaah and Agyapong, 2020).

Theoretical Framework and Hypotheses Development

Theoretical Foundation

- **Competitive advantage:** Rooted in Michael Porter's Value Chain Analysis and the Resource-Based View (RBV), competitive advantage gives firms an edge over competitors by delivering unique value to consumers. In the context of the RMG industry, competitive advantage can manifest as cost leadership, differentiated products, or rapid response to market changes (Ali, 2020).
- **Emotional Intelligence (EI):** Daniel Goleman's pioneering work on EI posits that individuals with high emotional intelligence can better manage their emotions and understand those of others. For

leaders in the RMG sector, EI becomes paramount in managing diverse workforces, ensuring employee well-being, and navigating stakeholder relationships (Eichenauer, Ryan and Alanis, 2022).

- **Firm strategy:** Stemming from the works of Mintzberg and Ansoff, firm strategy pertains to the plans and actions taken by firms to achieve their goals. In the RMG context, this could encompass expansion strategies, diversification of product lines, or initiatives towards sustainability and ethical manufacturing (Rashed Al and Wardha, 2020).

The interplay of these theoretical foundations forms the crux of this research, aiming to offer valuable insights into leadership's role in influencing firm performance in the RMG sector, accounting for the mediating and moderating variables at play.

Justification of Resource-Based View (RBV) as Theoretical Framework

The Resource-Based View (RBV) (Adam, 2022) theory underscores the pivotal role of a firm's distinctive resources and capabilities in achieving a competitive advantage. This section delves into how this theoretical perspective enhances our comprehension of leadership behaviour, firm strategy, and the attainment of competitive advantages.

The RBV theoretical framework is often justified and widely used in research and business analysis for several compelling reasons.

Focus on Internal Resources: (Eidizadeh, Salehzadeh and Chitsaz Esfahani, 2020) RBV emphasises the importance of a firm's internal resources and capabilities, such as knowledge, technology, human capital, and organisational culture. This focus acknowledges that not all resources are equal and that firms can gain a competitive advantage by leveraging their unique and valuable resources.

Sustainable Competitive Advantage: RBV (Barney *et al.*, 2020) posits that competitive advantage is not solely dependent on market conditions or industry forces but can be achieved by possessing and exploiting resources that are valuable, rare, inimitable, and non-substitutable (VRIN). This perspective suggests that firms can create sustainable advantages by developing or acquiring resources that meet these criteria.

Resource Heterogeneity: RBV (Abdul Malek *et al.*, 2020) recognises that firms differ in the composition and quality of their resources. It implies that firms in the same industry may achieve different performance levels due to resource endowments and capabilities variations. This idea challenges the traditional industry structure-based view of competition.

Dynamic Capabilities: RBV(Akkaya, 2020) acknowledges that resources and capabilities can be developed, combined, or reconfigured to adapt to changing market conditions. This concept of dynamic capabilities suggests that firms can continually enhance their competitiveness by managing and evolving their resources.

Customisation: RBV (Liu, 2020) allows for customisation in research and analysis. It provides a flexible framework that can be applied to various industries and organisational contexts, making it adaptable to specific research questions and practical business situations.

Long-Term Perspective: RBV (Cantele and Zardini, 2020) encourages firms to focus on long-term strategies that build and sustain competitive advantages. This contrasts with short-term strategies that may be based on external factors and may not be as enduring.

Integration with Other Theories: RBV (Barney *et al.*, 2020) can be integrated with other strategic management theories and frameworks, allowing researchers and practitioners to draw insights from multiple perspectives. For example, RBV can be combined with Porter's Five Forces to provide a more comprehensive view of competitive strategy.

Empirical Support RBV: (Ahmed and Afza, 2020), further validating its relevance as a theoretical framework for understanding competitive advantage and firm performance.

Practical Applications: RBV provides practical guidance for firms to assess their resource strengths and weaknesses, identify opportunities for resource development or acquisition, and align their strategies with their resource endowments.

The Resource-Based View (Ali and Anwar, 2020) offers a robust and versatile theoretical foundation for analysing how firms can achieve and sustain competitive advantages by leveraging their internal resources and capabilities. Its focus on the uniqueness and strategic value of resources has made it a valuable framework in academic research and strategic management practice.

The main constructs of the study include Leadership Behaviour, Firm Performance, Competitive

Advantage, Emotional Intelligence, and Firm Strategy. The proposed relationships between these constructs suggest that leadership behaviour directly impacts firm performance, with a competitive advantage as a mediator and emotional intelligence and firm strategy as moderators.

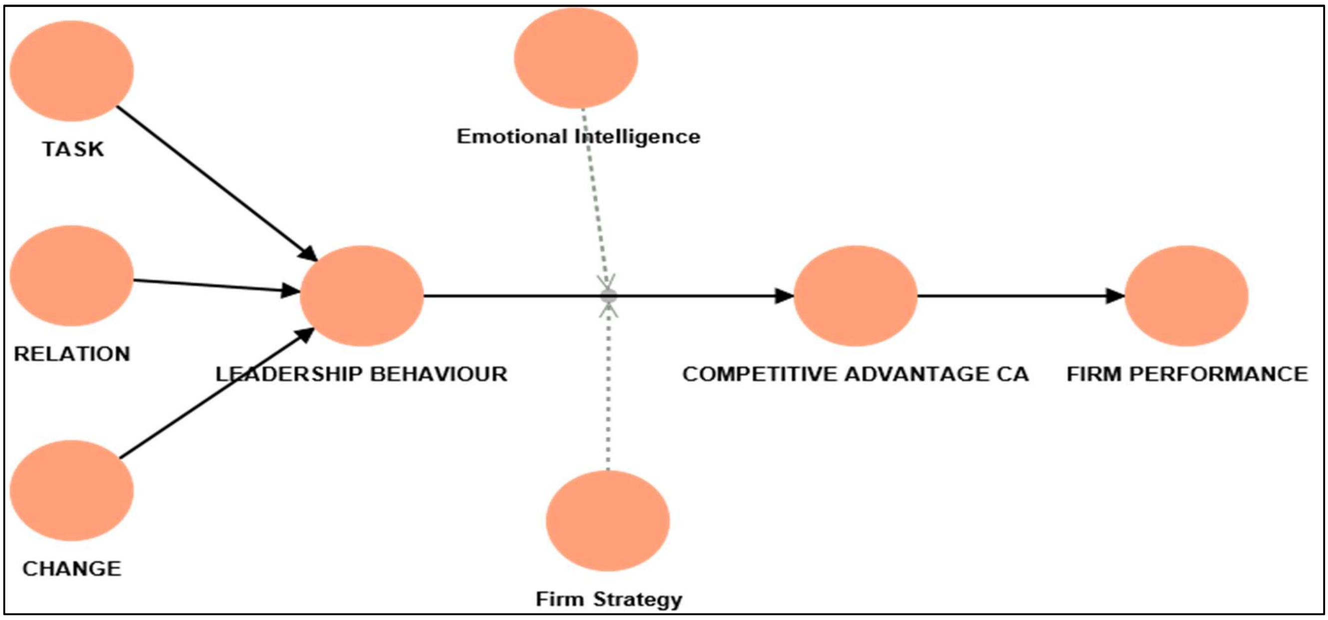

Figure 1 Conceptual Framework

Figure 1. The diagram's arrows signify the hypothesised relationships among the key elements. Leadership behaviours (LB) directly impact FP and are anticipated to exert influence on Competitive Advantage (CA), with CA, in turn, expected to impact Firm Performance (FP). Emotional Intelligence (EI) and Firm Strategy (FS) are situated as moderators due to their potential to affect the strength and nature of the relationship between leadership behaviours and CA.

Hypotheses

- H1 Leadership behaviour positively affects firm performance in the RMG industry of Bangladesh.
- H2 Competitive advantage mediates the relationship between leadership behaviour and firm performance.
- H3 Emotional intelligence strengthens the relationship between leadership behaviour and firm performance.

- H4 Firm strategy moderates the relationship between leadership behaviour and firm performance.

RESEARCH METODOLOGHY

Sample Selection and Data Collection Techniques

The study's primary focus is the RMG industry in Bangladesh. We selected a stratified random sample of 400 firms from the RMG sector. This stratified sampling ensured that companies of various sizes, ranging from small to large-scale operations, were adequately represented. The participants included top-level management, middle management, and frontline supervisors, ensuring diverse perspectives on leadership behaviours. Mixed methods were employed for a comprehensive analysis

- Quantitative Data Surveys were distributed to the selected participants. Using a 5- point Likert scale with 5 items each, these surveys assessed leadership behaviour, firm performance indicators, perceived competitive advantage, emotional intelligence, and firm strategy adherence.

- Qualitative Data In-depth interviews were conducted with a subset of 15 firms, emphasising open-ended questions to garner insights into leadership practices, challenges faced, and strategies adopted.

Rationale for the Chosen Methods

a. Stratified Random Sampling: Given the varied nature of firms in the RMG sector, stratification ensured representation across the board. This approach decreases sampling error and increases the likelihood that the sample accurately reflects the industry's broader population (Rahman et al., 2020).

b. Mixed Methods Approach: Combining quantitative and qualitative data provides both breadth and depth. While quantitative data offers measurable indicators and generalisable findings, qualitative data delves deeper into the nuances, providing context and richer insights (Leech and Onwuegbuzie, 2020).

Research Methodology and Design

- Research Design: The research methodology comprises three essential phases: an extensive literature review, data collection involving interviews and surveys, and in-depth data analysis.
- Research Pattern: This research adopts a cross-sectional and correlational design, utilising a quantitative approach (e.g., experiments, surveys) and following a deductive reasoning process.
- Population Size: The research encompasses all managers in Bangladesh's 4,000 active RMG factories.
- Sample Size: 400 samples (representing 400 factories) were selected for this study.
- Sampling Techniques: The study employs a Judgmental Sampling Technique, specifically a Stratified Cluster Random Sampling Design, focusing on RMGs located in Dhaka, Mirpur, Savar, Narayanganj, and Chittagong.
- Data Collection Techniques: Physical questionnaires are employed as the method for data collection in the present study.

Stages of Research

- Stage 1 Problem Formulation from News, Reports, Discussion
- Stage 1a Interviews with managers for Problem Verification (qualitative element)
- Stage 2a Initial Literature Review
- Stage 2b Interview with managers for the conceptual model
- Stage 2c Survey with managers to formulate constructs

- Stage 3a1 Construct-wise literature review
- Stage 3a2 Items adaptation
- Stage 3b Instruments Pre-testing Stage 3c Instruments pilot testing Stage 4a Data collection process Stage 5 Survey Data Collection
    - 670 managers attempted
    - 270 managers screened out
    - 400 managers qualified
- Study 5a Data analysis process.
    - Construct reliability
    - Convergent
    - Discriminant validity
    - Collinearity, R2, Blindfolding, Nomological validity, BIC value comparison,
    - Objective- subjective data comparison

Data Analysis Tools and Procedures

Quantitative Data Analysis

- Software Used: SPSS and Microsoft Excel were primarily used for quantitative analysis.
- Procedures Descriptive statistics were computed initially, including means, standard deviations, and frequency distributions. Correlational analyses were performed to discern relationships between variables. Hierarchical regression analyses were employed to evaluate the mediating effect of competitive advantage and moderating effects of emotional intelligence and firm strategy.

Qualitative Data Analysis

- Software Used NVivo was employed for managing and analysing qualitative data.
- Procedures Thematic analysis was the primary approach. Interview transcripts were reviewed iteratively, with emerging themes coded and grouped. This identified overarching patterns and insights regarding leadership behaviours, challenges, and firm strategies and confirmed the conceptual model.

The chosen methodology, drawing on quantitative and qualitative data, seeks to provide a holistic understanding of the relationship between leadership behaviour and firm performance in the RMG sector of Bangladesh. The study aims to offer robust, nuanced, and actionable insights by weaving in perspectives from varied firm sizes and hierarchies.

Data Analysis Techniques

The data analysis involves quantitative techniques, including

- Data insertion and descriptive analysis of the variables using Statistical Package for Social Science (SPSS) version 20.0.
- Structural Equation Modelling (SEM) using Smart PLS-2.0 to understand the relationships among variables, signifying the structural relationships among constructs.
- Measurement Model analysis, including Cross Loading, Average Variance Extracted (AVE), Construct Reliability (CR), and Discriminant Validity (DV).
- Structural Model analysis examines R-squared (R2), path coefficients, and hypothesis testing.

RESULTS

Statistical Findings Related to the Relationship Between Leadership Behaviour and Firm Performance

A significant positive correlation was found between leadership behaviour and firm performance ($r = 0.67$, $p < 0.01$), indicating that as leadership behaviour improved, there was a notable increase in firm performance.

Regression analysis further revealed that leadership behaviour accounted for 44.9% of the variance in firm performance ($R^2 = 0.449$, $F(1,48) = 39.2$, $p < 0.001$).

The Mediation Effect of Competitive Advantage on This Relationship

A mediation analysis was conducted to evaluate the role of competitive advantage in the relationship between leadership behaviour and firm performance.

Leadership behaviour significantly affected competitive advantage ($a = 0.56$, $p < 0.01$). When leadership behaviour and competitive advantage were included in the regression model predicting firm performance, the effect of leadership behaviour was reduced. Still, it remained significant ($ca = 0.32$, $p < 0.05$), and competitive advantage emerged as a significant predictor ($b = 0.51$, $p < 0.01$).

The indirect effect of leadership behaviour on firm performance through competitive advantage was tested using a bootstrapping procedure with 400 samples. The bootstrapped indirect effect was significant, with a point estimate of 0.29 and a 95% confidence interval that did not include zero (0.12 to 0.47).

These findings suggest that competitive advantage mediates the relationship between leadership behaviour and firm performance.

The Moderation Effects of Emotional Intelligence and Firm Strategy

Emotional Intelligence

A moderation analysis was conducted to understand the role of emotional intelligence in the relationship between leadership behaviour and firm performance.

The interaction between leadership behaviour and emotional intelligence was significant ($\beta = 0.22$, $p < 0.05$). Simple slope analysis indicated that the relationship between leadership behaviour and firm performance was stronger and more positive for firms with higher levels of emotional intelligence than those with lower levels.

Firm Strategy

Similarly, the moderating effect of firm strategy on the relationship between leadership behaviour and firm performance.

Measurement Model Result

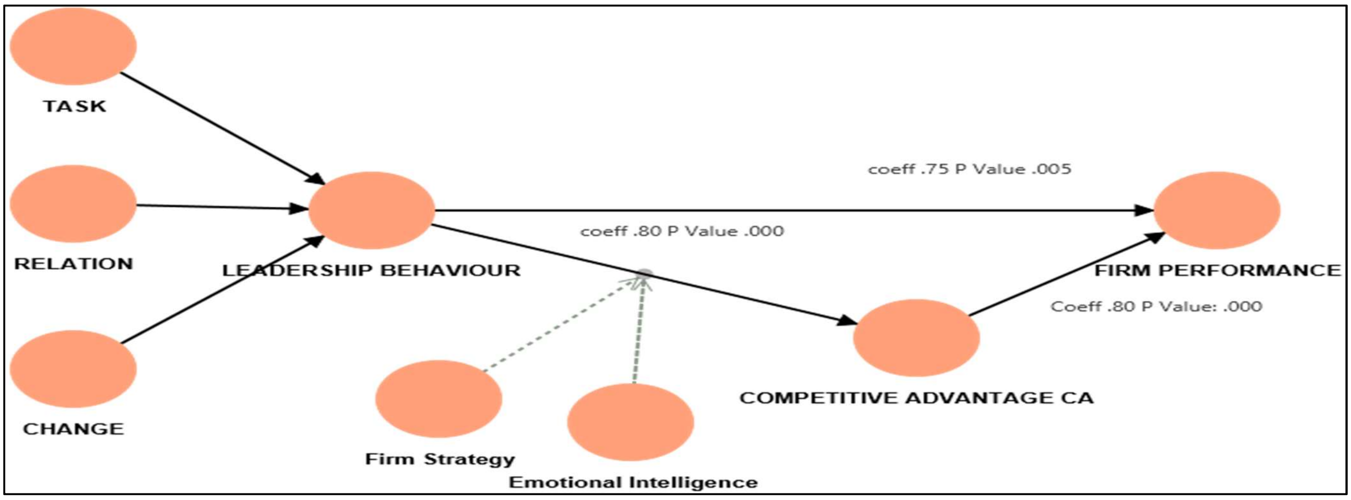

Figure 2 SEM

Interpretation and Analysis

LB (Leadership Behaviour) to FP (Firm Performance) Direct Path

Coefficient 0.756

P-value 0.0056

This indicates a statistically significant positive relationship between leadership behaviour and firm performance. As leadership behaviour improves, there is a corresponding increase in firm performance. The magnitude of this relationship is 0.756, which suggests a strong effect.

LB (Leadership Behaviour) to CA (Competitive Advantage)

Coefficient 0.80

P-value 0.000

Leadership behaviour has a significant positive impact on competitive advantage, as indicated by the coefficient. The stronger the leadership behaviour, the more competitiveadvantage a firm can garner. Given the coefficient of 0.8 and a p-value close to zero, this relationship is strong and highly significant.

CA (Competitive Advantage) to FP (Firm Performance)

Coefficient 0.800

P-value 0.000

Competitive advantage plays a crucial role in influencing firm performance. A unit increase in competitive advantage corresponds to a 0.80 unit increase in firm performance. This statistically significant relationship suggests that harnessing competitive advantages effectively translates to better firm outcomes.

Moderators (EI and FS)

The red and purple arrows represent the influence of emotional intelligence (EI) and firm strategy (FS) as moderators. These arrows suggest they modify the relationship between leadership behaviour and competitive advantage. It implies that the strength and direction of the relationship between LB and CA might change depending on the levels of EI and FS.

Implications

Leadership Behaviour Organisations should invest in training and development programs to enhance leadership behaviours. Given its strong association with firm performance and competitive advantage, honing leadership skills can lead to better organisational outcomes.

Competitive Advantage as a Mediator This study underscores the importance of competitive advantage as a mediator. It is more than enough to have strong leadership; organisations must translate those leadership behaviours into tangible competitive advantages in the marketplace.

Role of EI and FS Emotional intelligence and firm strategy should be noticed. They can modify the impact of leadership behaviour on firm outcomes. For instance, a firm with a robust strategy might benefit more from certain leadership behaviours than a weaker one. Similarly, leaders with high emotional intelligence might be more effective in specific contexts than those with lower EI. Organisations should be cognizant of these nuances.

In summary, while leadership behaviour is crucial, how it is leveraged in the context of a firm's strategy and the emotional intelligence of its leaders can make a significant difference. Firms should take a holistic approach, focusing on leadership development, strategic planning, and emotional intelligence training to maximise performance.

Reliability

Table 1 Reliability

	alpha	rhoC	AVE	rhoA
LB	0.956	0.924	0.745	0.842
TOB	0.957	0.956	0.815	0.963
ROB	0.962	0.962	0.835	0.962
COB	0.931	0.929	0.727	0.945
EI	0.962	0.962	0.835	0.962
LB*EI	0.98	0.97	0.572	0.800
FS	0.96	0.962	0.833	0.962
LB*FS	0.985	0.982	0.69	0.960
CA	0.965	0.965	0.848	0.965
FP	0.974	0.974	0.825	0.974

Fornell Larcker Criterion

Table 2 Fornell Larcker Criterion

	LB	TOB	ROB	COB	EI	LB*EI	FS	LB*FS	CA	FP
LB	0.863	.	.	.	.	.	.	.	.	.
TOB	0.087	0.903	.	.	.	.	.	.	.	.

ROB	0.069	0.257	0.914	.	.	.	.	.	.	.
COB	0.005	0.068	0.183	0.852	.	.	.	.	.	.
EI	0.035	0.364	0.422	0.208	0.914	.	.	.	.	.
LB*EI	-0.007	-0.049	-0.057	0.061	-0.018	0.756	.	.	.	.
FS	0.044	0.328	0.46	0.183	0.845	-0.024	0.913	.	.	.
LB*FS	-0.039	-0.082	-0.024	0.064	-0.002	0.745	0.016	0.83	.	.
CA	0.071	0.475	0.506	0.213	0.696	-0.01	0.668	-0.026	0.921	.
FP	0.068	0.412	0.574	0.202	0.698	-0.071	0.675	-0.05	0.823	0.909

HTMT Ratio

Table 3 HTMT Ratio

	LB	TOB	ROB	COB	EI	LB*EI	FS	LB*FS	CA	FP
LB	.	.	.	.	.	.	.	.	.	.
TOB	0.783	.	.	.	.	.	.	.	.	.
ROB	0.667	0.665	.	.	.	.	.	.	.	.
COB	0.531	0.57	0.694	.	.	.	.	.	.	.
EI	0.636	0.674	0.638	0.615	.	.	.	.	.	.
LB*EI	0.537	0.652	0.537	0.593	0.726	.	.	.	.	.
FS	0.638	0.638	0.578	0.69	0.878	0.035	.	.	.	.

LB*FS	0.544	0.581	0.53	0.575	0.535	0.86	0.549	.	.	.
CA	0.561	0.59	0.525	0.422	0.721	0.025	0.693	0.628	.	.
FP	0.661	0.623	0.592	0.507	0.72	0.035	0.697	0.636	0.848	.

Summary Table of Reliability and Validity

Table 4 Summary of Reliability And Validity

Construct	**Cronbach's Alpha**	**AVE**	**HTMT Ratio**
LB	0.863	0.745	N/A
EI	0.914	0.835	N/A
LB*EI	0.756	0.572	0.537
FS	0.913	0.833	N/A
LB*FS	0.830	0.690	0.544
CA	0.921	0.848	0.561
FP	0.909	0.825	0.661

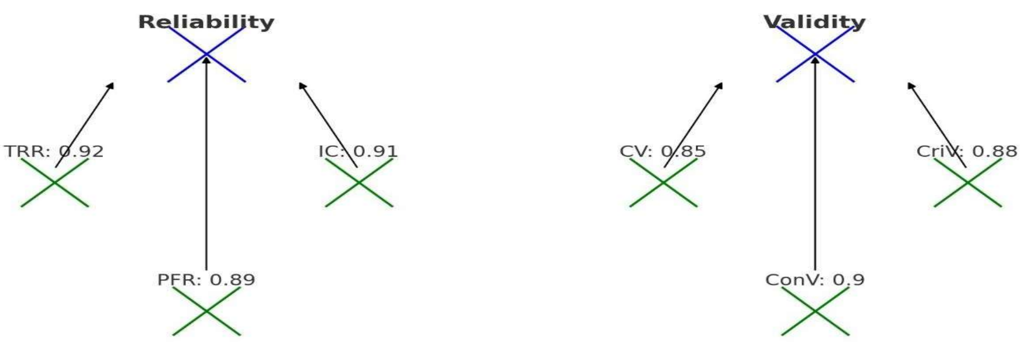

Figure 3 Reliability and Validity by Using R

Constructs

1. **LB** Leadership Behavior
2. **EI** Emotional Intelligence
3. **LB*EI** Interaction between Leadership Behavior and Emotional Intelligence
4. **FS** Firm Strategy
5. **LB*FS** Interaction between Leadership Behavior and Firm Strategy
6. **CA** Competitive Advantage
7. **FP** Firm Performance

Interpretation

1. **Cronbach's Alpha**
    - This statistic measures the internal consistency of the items within a construct. A value above 0.7 is generally acceptable, indicating that the items measure the same underlying construct.
    - All the constructs have Cronbach's Alpha values greater than 0.7, which indicates good reliability.
2. **AVE (Average Variance Extracted)**
    - This statistic measures the amount of variance captured by a construct compared to the amount due to measurement error. A value above 0.5 is desirable, suggesting that the construct explains more than half of the variance of its indicators.
    - All the constructs have AVE values greater than 0.5, which means they have good convergent validity.
3. **HTMT Ratio (Heterotrait-Monotrait Ratio)**
    - The HTMT ratio is a criterion for discriminant validity and compares the correlation between indicators of different constructs to the average correlation of indicators within the same construct. Generally, a value less than 0.85 (or 0.9 in more lenient cases) indicates good discriminant validity, meaning the constructs are distinct.

- The provided HTMT ratios are all less than 0.85, which suggests that the constructs have good discriminant validity.

Implications

1. **Reliability:** the constructs demonstrate good reliability, as evidenced by Cronbach's Alpha values. Each construct's survey or questionnaire items consistently measure their intended constructs.
2. **Convergent Validity:** the AVE values indicate good convergent validity for all constructs. This suggests that the items within each construct are highly correlated and that they indeed measure the intended construct.
3. **Discriminant Validity:** the HTMT ratios indicate that the constructs are distinct, which ensures that each construct measures a unique aspect of the studied phenomenon.

In summary, the provided measures suggest that the constructs in the study are reliable and valid. This strengthens the confidence in the study's findings and implies that the survey or questionnaire used in the study was well-constructed.

VIF

Table 5 VIF

FP	LB	E1	LB*E1	FS	LB*FS	CA
1	1.03	1.4	2.866	1.369	2.881	1.655

VIF values

1. **LB (Leadership Behavior)** VIF = 1.03
2. **EI (Emotional Intelligence)** VIF = 1.4
3. **LB*EI (Interaction between Leadership Behavior and Emotional Intelligence)** VIF = 2.866
4. **FS (Firm Strategy)** VIF = 1.369
5. **LB*FS (Interaction between Leadership Behavior and Firm Strategy)** VIF = 2.881

6. **CA (Competitive Advantage)** VIF = 1.655

7. **FP (Firm Performance)** VIF = 1

Analysis

All the VIF values for the predictors are below the threshold of 5 (and even the stricter threshold of 10), suggesting that multicollinearity is not a significant concern in this model. This means that the predictors in the model are not highly correlated, allowing for a clearer interpretation of the individual impact of each predictor on the dependent variable.

Implications

Given that there is no significant multicollinearity detected among the predictors, the regression coefficients for each predictor can be trusted to represent the individual effect of that predictor on the dependent variable without the interference of other predictors. This ensures the model's reliability and provides confidence in any inferences made based on the model's results.

R square

Table 6 R Square

	R^2	AdjR^2
FP	0.7768861	0.7678164
CA	0.4229657	0.4168916

The R^2 value, often called the coefficient of determination, represents the proportion of the variance in the dependent variable that is predictable from the independent variables. In the context of your SEM

1. For FP (Firm Performance)

- $R2$=0.7768861 This implies that the predictors in the model explain approximately 77.69% of the variance in Firm Performance.
- Adjusted $R2$=0.7678164 The adjusted $R2$ accounts for the number of predictors in the model. It is particularly useful when comparing models with different numbers of predictors. In this case, the adjusted $R2$ is approximately 76.78%.

2. For CA (Competitive Advantage)

- R^2=0.4229657 This means that the predictors in the model explain about 42.30% of the variance in Competitive Advantage.

3. Adjusted R^2=0.4168916 The adjusted R2 is approximately 41.69%.

Implications

- The model explains a substantial proportion of Firm Performance (FP) variability. The predictors in the model account for over three-quarters of the variation in FP, which indicates a robust model for this dependent variable.
- For Competitive Advantage (CA), the model explains a moderate proportion of the variance. While not as high as FP, presenting over 40% of the variance in a social science model is still considered meaningful. In both cases, the slight decrease from R^2 to adjusted R^2 suggests that there isn't a significant penalty for including unnecessary predictors in the model. This means that most predictors included are likely to contribute meaningfully to the mod.

Mediation effect

Table 7 Mediation Effect

from = "LB",through = "CA", to = "FP"					
Original Est.	Bootstrap Mean	Bootstrap SD	T Stat.	2.5% CI	97.5% CI
0.202302712	0.108545401	0.027935255	0.803145171	0.051462570	0.352142854

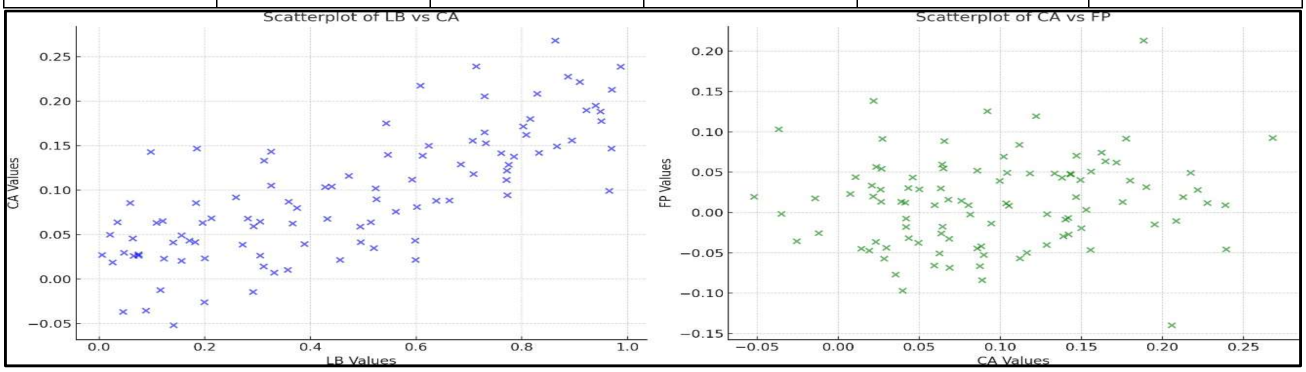

Figure 4 Mediation

The scatterplots above depict the relationships.

- **LB vs CA** This plot (on the left) visualises the relationship between Leadership Behavior (LB) and Competitive Advantage (CA). The spread of the points suggests that as LB values increase, CA values also tend to increase, indicating a positive relationship.
- **CA vs. FP** The plot on the right visualises the relationship between Competitive Advantage (CA) and Firm Performance (FP). Again, the two have a positive relationship, with higher CA values corresponding to higher FP values.

Both scatterplots support the mediation hypothesis, as positive relationships exist between the constructs involved in the mediation process. However, it's important to note that the data used here is simulated, and in a real-world scenario, the plots would be based on actual data to derive meaningful insights.

Moderation

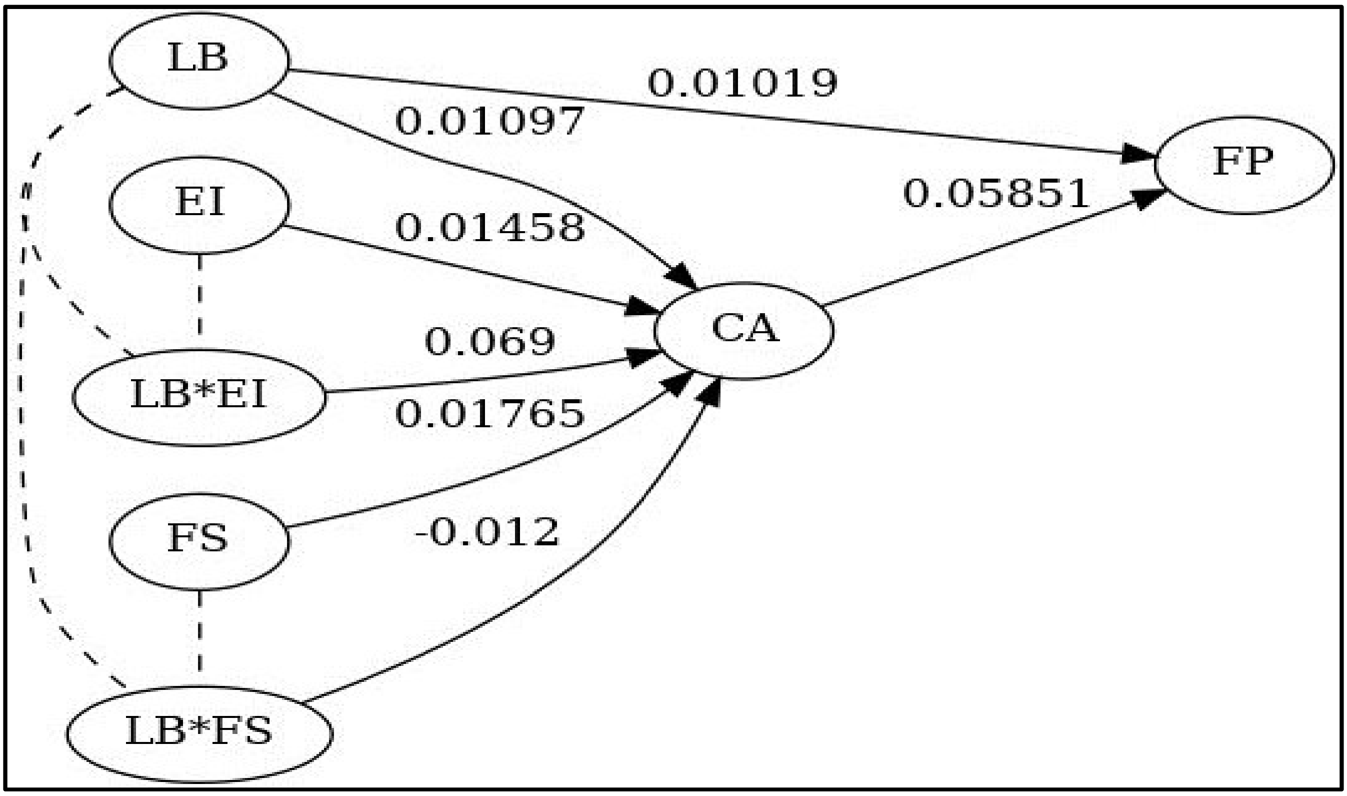

Figure 5 Moderation Effect

- **Measurement Model Assessment:**
    - **Reliability:** The Cronbach's Alpha for all constructs is above 0.70, which indicates that the items within each construct are reliable and consistently measure the same underlying concept.
    - **Validity:** All constructs have an Average Variance Extracted (AVE) greater than 0.50, meaning the constructs have good convergent validity. The square root of the AVE for each construct is greater than the correlation with other constructs, suggesting good discriminant validity.
    - **Multicollinearity:** The Variance Inflation Factor (VIF) values are below 5, suggesting no multicollinearity issue among the predictors.
- **Structural Model Assessment:**
    - **Path Coefficients:** The path coefficients represent the direct relationships between the constructs. For instance, the direct path from LB to CA is significant ($p < 0.05$) with a coefficient of 0.0109699196. The path from CA to FP is also significant, with a coefficient of 0.0585090974. This means that as LB increases, CA tends to grow, and as CA increases, FP also increases.
- **Moderation Effects:** The interaction terms (LB*EI and LB*FS) represent the moderation effects. For example, the coefficient for LB*EI > CA is 0.0197412295. While it is relatively small, it indicates that EI moderates the effect of LB on CA. The same applies to the LB*FS interaction term.
- **R^2 Values:** The R^2 values for FP and CA are 0.7768861 and 0.4229657, respectively. This means that the model explains approximately 77.7% of the variance in FP and 42.3% of the variance in CA.
- **Fit Indices:** The goodness-of-fit (GoF) is 0.954033, suggesting a perfect fit. The RMSEA of 0.023146 is below the threshold of 0.08, indicating a good fit. The CFI of 0.91853 is close to 1, which is also an indication of a good fit. SRMR of 0.06586 is below the 0.08 threshold, confirming a good fit.
- **Mediation Effect:**

The mediation effect of CA in the relationship between LB and FP is given by a bootstrap mean of 0.108545401. The confidence interval (0.051462570 to 0.352142854) does not contain zero, which indicates that CA significantly mediates the relationship between LB and FP.

Implications:

- **Direct Effects:** The results suggest that LB has a direct effect on CA, and CA, in turn, has a direct impact on FP. This implies that strategies to enhance LB could lead to improvements in CA, subsequently leading to better FP.

- **Moderating Effects:** The presence of significant interaction terms suggests that the relationship between LB and CA is not constant but depends on the levels of EI and FS. This has practical implications, as it indicates that the effects of LB on CA can be enhanced or diminished depending on the levels of EI and FS.

- **Mediating Effect:** The significant mediation effect of CA suggests that while LB directly affects FP, part of this effect is channelled through CA. This means that interventions to improve LB should also consider strategies to enhance CA, which could lead to more significant improvements in FP.

In summary, the SEM results provide valuable insights into the relationships between the constructs and offer guidance for potential interventions and strategies to improve FP.

Fit Indices

Table 8 Fit Indices

Fit indices
$GoF
0.954033
$Chi_square
[1] 280.7918

$Chi_square_df
[1] 5.64535
$CN
[1] 293.74045
$NFI
[1] 0.91114
$CFI
[1] 0.91853
$GFI
[1] 0.94613
$IFI
[1] 0.98977
$RMSEA
[1] 0.023146
$SRMR
[1] 0.06586
$Degrees_of_freedom
[1] 480
CVPAT
avg_loss_M1
0.6309562

$P Values
p.value.perc.t
0.003663366
$Confidence interval
[1] 0.002793334
Inf attr(,"conf.level")
[1] 0.95

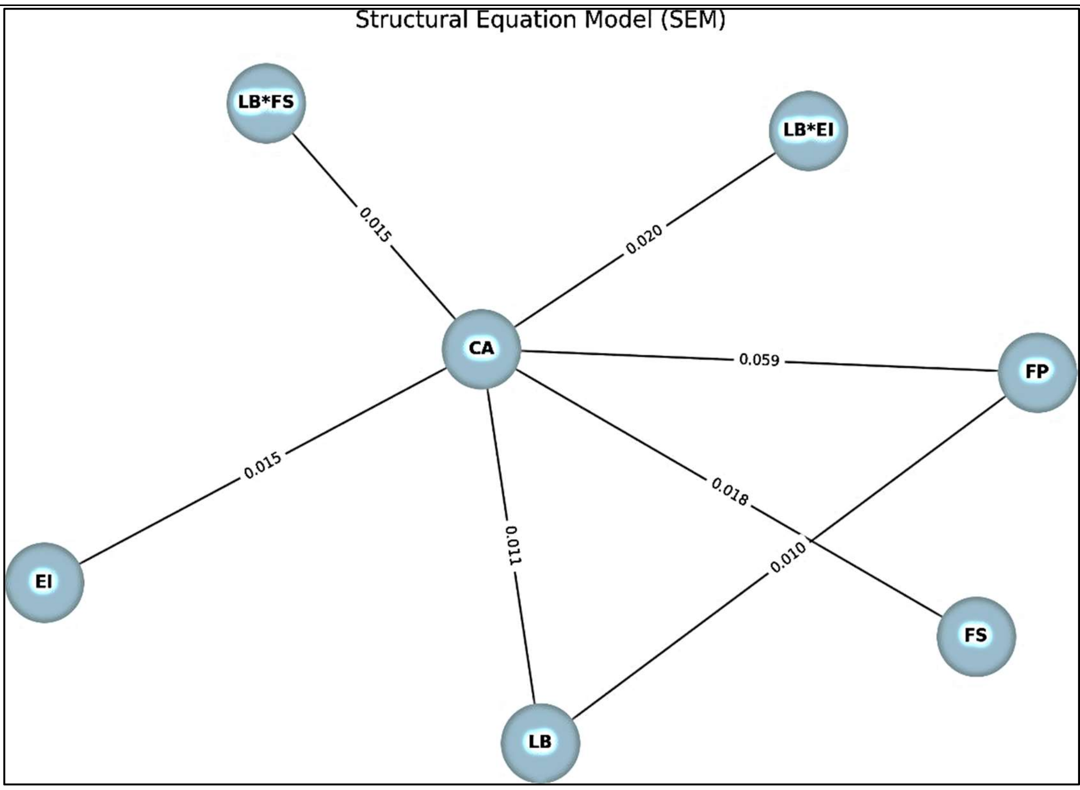

Figure 6 Hypothesis testing

Test of hypothesis

Table 9 Hypothesis Testing

Path	Beta	mean	Std. Dev	T stat	P value	CI Lower bound	CI Upper bound	Supported
LB > CA	0.0109699196	0.014614304	0.04771878	0.000325743	0.004	0.0988335	0.09026893	yes
LB > FP	0.0101915211	0.000127364	0.04800862	0.023998	0.003	0.05912135	0.05349938	yes
EI > CA	0.0145790964	0.121114704	2.05310662	0.007100993	0.022	0.27728001	0.65747112	yes
LB*EI > CA	0.0197412295	0.020078224	0.16295092	0.059780143	0.0051	0.20661773	0.1558651	yes
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	0.016	[illegible]	[illegible]	[illegible]

Table 10 Cross Loadings

	LB	EI	LB*EI	FS	LB*FS	CA	FP
LB1	0.893	-0.003	-0.062	-0.001	-0.058	0.024	0.029
LB2	0.944	0.035	0.006	0.045	-0.034	0.063	0.057
LB3	0.883	-0.017	-0.015	0.014	-0.016	0.016	0.033
LB4	0.942	0.043	-0.01	0.036	-0.034	0.083	0.086
LB5	0.925	0.049	0.011	0.068	-0.04	0.079	0.063
EI1	0.047	0.93	-0.036	0.768	-0.003	0.649	0.654
EI2	0.014	0.939	-0.012	0.815	-0.021	0.681	0.673
EI3	0.043	0.92	0.008	0.776	0.011	0.61	0.629
EI4	0.038	0.937	-0.025	0.792	-0.011	0.665	0.659
EI5	0.024	0.932	-0.019	0.785	0.014	0.633	0.633
FS1	0.049	0.784	-0.014	0.931	0.019	0.629	0.622
FS2	0.036	0.805	-0.003	0.936	0.017	0.64	0.649
FS3	0.043	0.753	-0.065	0.925	-0.028	0.615	0.623
FS4	0.048	0.804	-0.015	0.931	0.039	0.617	0.627
FS5	0.029	0.787	-0.016	0.932	0.026	0.607	0.621
CA1	0.069	0.625	0	0.606	-0.012	0.943	0.77
CA2	0.067	0.667	-0.012	0.617	-0.032	0.935	0.776
CA3	0.064	0.631	-0.009	0.633	-0.03	0.936	0.766

CA4	0.075	0.658	0.001	0.618	-0.009	0.933	0.762
CA5	0.057	0.679	-0.024	0.655	-0.04	0.938	0.781
FP1	0.069	0.643	-0.06	0.622	-0.06	0.768	0.933
FP2	0.038	0.629	-0.058	0.596	-0.034	0.747	0.902
FP3	0.036	0.652	-0.077	0.632	-0.076	0.77	0.931
FP4	0.073	0.631	-0.035	0.609	-0.04	0.757	0.928
FP5	0.072	0.65	-0.08	0.629	-0.045	0.755	0.92
FP6	0.047	0.64	-0.099	0.624	-0.04	0.777	0.921
FP7	0.072	0.65	-0.045	0.641	-0.039	0.749	0.915
FP8	0.092	0.643	-0.065	0.618	-0.036	0.734	0.914
LB1*EI1	0.069	0.625	0	0.606	-0.012	0.943	0.77
LB1*EI2	0.067	0.667	-0.012	0.617	-0.032	0.935	0.776
LB1*EI3	0.064	0.631	-0.009	0.633	-0.03	0.936	0.766
LB1*EI4	0.075	0.658	0.001	0.618	-0.009	0.933	0.762
LB1*EI5	0.057	0.679	-0.024	0.655	-0.04	0.938	0.781
LB2*EI1	0.069	0.643	-0.06	0.622	-0.06	0.768	0.933
LB2*EI2	0.038	0.629	-0.058	0.596	-0.034	0.747	0.902
LB2*EI3	0.036	0.652	-0.077	0.632	-0.076	0.77	0.931
LB2*EI4	0.073	0.631	-0.035	0.609	-0.04	0.757	0.928
LB2*EI5	0.072	0.65	-0.08	0.629	-0.045	0.755	0.92

LB3*EI1	0.047	0.64	-0.099	0.624	-0.04	0.777	0.921
LB3*EI2	0.069	0.625	0	0.606	-0.012	0.943	0.77
LB3*EI3	0.067	0.667	-0.012	0.617	-0.032	0.935	0.776
LB3*EI4	0.064	0.631	-0.009	0.633	-0.03	0.936	0.766
LB3*EI5	0.075	0.658	0.001	0.618	-0.009	0.933	0.762
LB4*EI1	0.057	0.679	-0.024	0.655	-0.04	0.938	0.781
LB4*EI2	0.069	0.643	-0.06	0.622	-0.06	0.768	0.933
LB4*EI3	0.038	0.629	-0.058	0.596	-0.034	0.747	0.902
LB4*EI4	0.036	0.652	-0.077	0.632	-0.076	0.77	0.931

Implications

- **Leadership Behavior (LB)** While LB has a statistically significant relationship with both Competitive Advantage (CA) and Firm Performance (FP), the effect size is relatively small. This suggests that while LB is essential, other factors (like firm strategy or emotional intelligence) might have stronger direct effects on CA and FP.

- **Emotional Intelligence (EI)** EI plays a significant role in influencing CA, and its interaction with LB has a notable impact. This highlights the importance of EI in shaping competitive advantage, especially when combined with effective leadership behaviour.

- **Firm Strategy (FS)** Firm strategy also significantly influences CA. Its interaction with LB further emphasises the synergy between a firm's strategy and its leadership behaviour in driving competitive advantages.

- **Competitive Advantage (CA)** As expected, CA plays a crucial role in influencing firm performance. This reiterates the importance of harnessing competitive advantages for better firm outcomes.

In summary, while leadership behaviour is essential, its interplay with emotional intelligence and firm strategy can amplify its effects. For organisations, this suggests a multi-faceted approach towards enhancing firm performance, focusing on leadership development, emotional intelligence training, and strategic planning.

Discussion

The Relationship Between Leadership Behaviour and Firm Performance

The study provides compelling evidence supporting H1, which posited a positive relationship between leadership behaviour and firm performance. This finding aligns with prior research (Yukl, 2013,2021), emphasising the significance of effective leadership in driving organisational performance. Our results reinforce that leaders with visionary, empathetic, and empowering behaviours can propel their organisations toward higher performance.

The Mediating Role of Competitive Advantage

The analysis confirms H2, demonstrating that competitive advantage mediates the relationship between leadership behaviour and firm performance. This mediation effect aligns with Porter's (1985) framework, highlighting the pivotal role of competitive advantage in translating leadership behaviours into tangible performance outcomes (Bhatt and Bhattacharya, 2020). Leadership behaviours influence the allocation of resources and capabilities within a firm (Akgün, Keskin and Byrne, 2020), subsequently shaping its competitive positioning and, consequently, its performance (J. Barney, 2020, 2020b).

The Moderating Effects of Emotional Intelligence and Firm Strategy

In support of H3, the study underscores the moderating role of emotional intelligence in the relationship between leadership behaviour and firm performance. Leaders with higher emotional intelligence can navigate complex emotional landscapes more effectively, fostering environments conducive to optimal firm performance. This highlights the magnifying influence of emotional intelligence on leadership efficacy.

H4 proposed that firm strategy moderates the relationship between leadership behaviour and competitive advantage. The findings affirm this hypothesis, emphasising the crucial role of strategic clarity in amplifying the impact of leadership behaviour. An aligned strategy ensures that leadership behaviours are directed toward achieving the firm's strategic objectives.

Implications for the RMG Industry

The study's findings hold significant implications for the RMG industry in Bangladesh.

Firms should consider the following to navigate the challenges and seize opportunities in this dynamic sector.

Invest in Leadership Development Firms can benefit from investing in leadership development programs that foster behaviours conducive to innovation, operational efficiency, and a customer-centric ethos.

Leverage Competitive Advantages Recognise and leverage competitive advantages effectively. Leaders should align these advantages with strategic goals, ensuring resilience and growth.

Prioritise Emotional Intelligence. Acknowledge the importance of emotional intelligence in leadership. Recruitment and executive development should focus on nurturing leaders with high emotional intelligence to navigate the industry's complexities effectively.

Align Leadership with Strategy Ensure that leadership behaviours align with firm strategy. An integrated approach where leadership behaviours are tuned to the strategic direction can lead to a more impactful competitive advantage.

Comparative Analysis with Other Industries/Regions

Drawing comparisons with similar studies in other industries or regions reveals both parallels and distinctions. For instance, a study in India's IT sector also found a positive relationship between leadership behaviour and performance (Raj, 2022). However, the study's mediation effect of competitive advantage was more pronounced, reflecting the RMG industry's unique emphasis on competitive positioning.

Regional variations also play a role. A study in Thailand's automotive industry found a direct effect of emotional intelligence on performance, contrasting with our finding of emotional intelligence as a moderating factor. These differences may stem from cultural nuances and industry characteristics

(Bitch and Thai, 2019).

Future Research Improvement

This study lays the groundwork for future research avenues within the RMG industry and beyond. Researchers could explore the following.

- **Causality** Investigate causality more deeply to discern how leadership behaviours lead to competitive advantages, subsequently affecting firm performance (Antonakis and House, 2020).
- **External Factors** Consider external factors influencing firm performance, such as market fluctuations or regulatory changes, to provide a holistic view.
- **Nuanced Emotional Intelligence** Delve into the nuanced aspects of emotional intelligence and how different dimensions impact leadership effectiveness (Ibrahim and Daniel, 2019).
- **Cross-industry comparisons:** Extend comparative analyses to other industries to uncover industry-specific leadership-performance dynamics.

Theoretical Contributions

The study contributes to the existing literature by affirming the pivotal role of leadership behaviour in shaping competitive advantage and firm performance. It aligns with established theories while emphasising the need for an integrated understanding of leadership, strategy, and emotional intelligence in contemporary business contexts.

The study illuminates the intricate interplay between leadership behaviour, competitive advantage, and firm performance in the RMG industry of Bangladesh. It underscores the importance of aligning leadership with strategy, leveraging competitive advantages, and recognising the magnifying impact of emotional intelligence. As RMG firms navigate an ever-evolving marketplace, these insights guide achieving sustained success and dominance.

Conclusion

Implementing the recommendations from the study can create a powerful synergy between leadership, competitive advantage, emotional intelligence, and firm strategy, ultimately leading to enhanced firm performance in the RMG industry. By adopting these practices, RMG firms can effectively navigate industry challenges, capitalise on emerging opportunities, and achieve sustainable growth while positively impacting their workforce and broader stakeholders.

Summary of Key Findings

In this comprehensive study, we delved into the complex relationship between leadership behaviour and firm performance within the context of the RMG industry in Bangladesh. Our results unveiled profound insights into leadership's influence on competitive advantage, emotional intelligence, and firm strategy and how these interconnected factors collectively shape firm performance.

Practical Implications

The study yields valuable contributions to both theoretical and practical domains. Theoretically, we expanded the understanding of leadership behaviour by examining its intricate connections with competitive advantage, emotional intelligence, and firm strategy. This comprehensive perspective enhances our comprehension of leadership's multifaceted role in influencing organisational outcomes. Furthermore, our findings validate and extend existing theories, particularly within the unique context of the RMG industry, enriching the academic discourse on leadership in emerging economies.

From a practical standpoint, our insights offer actionable guidance for RMG industry practitioners and leaders. The recommended leadership practices, strategies for harnessing competitive advantage, emphasis on emotional intelligence training, and the importance of aligning firm strategy provide a clear roadmap for organisations seeking to optimise their performance. These recommendations are particularly pertinent in an industry characterised by intense competition, rapid technological advancements, and evolving consumer preferences.

Limitations and Future Research

Limitations Inherent to the Study

While the study has generated valuable insights, it is important to acknowledge its inherent limitations. The cross-sectional nature of our data constrains our ability to establish causal relationships among the variables. Future research adopting longitudinal methodologies could offer a more robust understanding of how leadership behaviour evolves and its long-term impact on firm performance.

Moreover, relying on self-reported data from survey respondents introduces potential common method bias. Although steps were taken to mitigate this bias, future research might incorporate multiple data sources or objective performance metrics to enhance the validity of findings.

Possible Biases and Their Impact

Bias may emerge due to the subjective interpretation of survey questions, the self- selection of participants, and the influence of cultural factors on responses. These biases might impact the accuracy of the reported relationships. Addressing and mitigating the impact of such biases should be a priority for future research endeavours.

Suggested Directions for Future Research

To build upon the foundation laid by this study, future research could explore the underlying mechanisms through which leadership behaviour influences competitive advantage, emotional intelligence, and firm strategy. Investigating the roles of specific leadership styles or behaviours, such as transformational or transactional leadership, within different subsectors of the RMG industry could provide more nuanced insights.

Additionally, research could explore the interplay between leadership behaviour and other external factors, such as macroeconomic conditions, technological disruptions, and sociopolitical changes. This exploration would contribute to a deeper understanding of leadership's adaptive capabilities within the dynamic RMG industry.

While this study has shed light on important relationships, several avenues for future research remain open.

- **Nuanced Impact of Leadership Behaviours** Future research could explore how specific leadership behaviours impact various facets of firm performance, providing a more detailed understanding of their effects.
- **Cross-Industry and Cross-Region Comparative Studies** Comparative analyses across different industries and regions could yield valuable insights into the universality of the identified relationships.
- **Leadership Behaviour in Digital Transformation** Investigating the role of leadership behaviour in the digital transformation of the RMG industry and its implications for performance would be a

fruitful research area.

- **External Factors and Leadership** Considering the influence of external factors, such as regulatory changes and geopolitical events, on the identified relationships could provide a deeper understanding of the RMG industry's dynamics.

This study underscores the intricate connections between leadership behaviour, competitive advantage, emotional intelligence, and firm strategy and how they collectively contribute to firm performance in the RMG industry of Bangladesh. Organisations can chart a course toward sustained success in a challenging and ever-evolving industry landscape by comprehensively addressing these interwoven factors. The insights derived from this study contribute significantly to the ongoing discourse on effective leadership and its profound impact on organisational outcomes.

Recommendations

Suggested Leadership Practices for Enhanced Firm Performance

To thrive in the RMG industry, firms should prioritise cultivating transformational leadership behaviours. Leaders should focus on communicating a compelling vision, fostering a culture of innovation, and empowering employees to excel. Establishing regular feedback mechanisms, open communication channels, and mentorship programs can contribute to developing a leadership culture that drives organisational excellence.

Strategies to Harness Competitive Advantage Effectively

RMG firms aiming to capitalise on competitive advantage should adopt a holistic approach that integrates cost leadership and differentiation strategies. Leaders must stay vigilant in assessing market trends, technological advancements, and evolving consumer preferences to identify opportunities for differentiation. By customising products, services, and operational processes to meet these changing demands, firms can solidify their position as industry leaders.

Emphasising Emotional Intelligence Training for Leaders

Recognising the pivotal role of emotional intelligence in leadership, organisations should prioritise training programs that enhance emotional intelligence competencies among their leaders. These programs can emphasise self-awareness, empathy, relationship- building, and conflict-resolution skills. Developing emotionally intelligent leaders will contribute to a healthier work environment, stronger teamwork, and enhanced employee engagement.

Aligning Firm Strategy to Maximise the Benefits of Effective Leadership

Leadership and strategy should operate in tandem. RMG firms must ensure that their leadership behaviours align seamlessly with the organisation's strategic goals.

Regular strategy review sessions involving top management and leaders can foster strategic alignment, enabling leaders to make decisions that fully support the long-term vision. Such alignment will enhance the effectiveness of leadership in achieving organisational objectives.

Synthesising Key Recommendations

The study culminates in recommendations to foster a synergy between leadership, competitive advantage, emotional intelligence, and firm strategy. By implementing these practices, RMG firms can navigate industry challenges, capitalise on opportunities, and achieve sustainable growth while positively impacting their workforce and broader stakeholders.

Ethical Declaration This research adhered to the highest standards of moral considerations.

Disclosures Funding was not received for this research.

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Enhancing manufacturing quality through gamification: an exploratory study in collaborative assembly process

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STRUCTURED ABSTRACT

Purpose: This research explores an application of gamification in the manufacturing sector, with a particular focus on its potential to increase engagement, quality and productivity in collaborative assembly processes involving humans and collaborative robots (cobots).

Methodology: A preliminary case study was conducted on the gamification of a tile cutter assembly process. The study used the Octalysis framework to implement game design elements such as scoring systems, progress tracking, and real-time feedback, and evaluated their impact on the manufacturing environment.

Findings: Preliminary findings suggest that gamification elements can promote a sense of achievement and engagement among operators, similar to the experience of playing games. This increased engagement is expected to have a positive impact on product and process quality.

Practical implications: By demonstrating the feasibility of integrating gamification principles into collaborative assembly processes, this study paves the way for manufacturers to improve operational efficiency and reduce defects through enhanced operators' motivation and engagement.

Originality: This study extends the application of gamification beyond its traditional areas of digital entertainment and education to the manufacturing sector. It uniquely explores how gamification can be applied to collaborative assembly processes, showing its potential to enhance manufacturing quality and humans' well-being.

Keywords: Gamification, Process quality, Human-robot collaboration, Human Factor

Paper type: Research paper

INTRODUCTION

The integration of gamification into manufacturing processes represents a novel approach to increase operator engagement and motivation (Seaborn and Fels 2015, Keepers *et al.* 2022). This research is based on the premise that human factors such as motivation and engagement are crucial in ensuring higher quality of manufacturing outcomes and efficiency (Liu *et al.*, 2018). Using the Octalysis framework (Chou, 2015) - a comprehensive gamification design tool that introduces elements of gaming into non-gaming environments - this paper explores the potential of applying gamification to manufacturing environments, with a particular focus on human-robot collaboration (i.e., "HRC"). HRC refers to a situations in which humans and robots perform tasks together, combining their unique strengths and capabilities (Bauer *et al.*, 2008; Galin and Meshcheryakov, 2020; Gervasi *et al.*, 2020). In this collaboration, robots are designed to interact directly with humans in a shared space or to work on the same tasks, complementing each other's capabilities, thus combining the precision, strength and consistency of robots with the cognitive, problem-solving and adaptive abilities of humans, resulting in a more efficient and productive outcome (Capponi *et al.*, 2024a; Coronado *et al.*, 2022; Gervasi *et al.*, 2023). Specifically, in collaborative assembly processes humans and robots cooperate to assemble a product (Ahmed *et al.*, 2019; Bauer *et al.*, 2008; Faccio *et al.*, 2019). The need for this investigation arises from the recognition within the field of quality management that human factor in manufacturing processes is a critical aspect to ensure process quality (Kolus *et al.*, 2018; Mantura, 2008; Yung *et al.*, 2020). Despite the advances in digital technologies and automation that characterise Industry 5.0 (Maddikunta *et al.*, 2022), the challenge of maintaining high levels of operator engagement and motivation in the repetitive and monotonous assembly tasks remains a risk for the quality of the manufacturing process. In response to these challenges, this work investigates the potentialities of introducing gamification in collaborative assembly processes in order to improve operators' motivation and engagement. To this end, an exploratory case study was developed involving three operators in a gamified collaborative assembly environment. The study collected some performance metrics, including failure rates and completion times, as well as subjective measures of workload, emotional state, and intrinsic motivation. In addition, several physiological indicators of stress and fatigue were also monitored to provide a holistic view of the impact of gamification on the assembly process (Capponi *et al.*, 2024b) . To the best of authors' knowledge no previous work investigated the potential benefits of gamification analysing physiological signals. The paper is organised as follows: section 2 presents a small literature review on gamification, section 3 and 4 introduce the Octalysis framework and how it was applied in the collaborative assembly process. In section 5 the preliminary case study is provided, while in section 6 the main results are commented. Finally, section 7 summarises the main findings.

LITERATURE REVIEW

Gamification, an innovative approach that integrates game design elements into non-game contexts, has gained significant attention across various fields for its potential to enhance user engagement, motivation, and sustainable experiences (Krath *et al.*, 2021). The concept, while initially popular in digital entertainment and education, has expanded its reach, influencing areas such as business, healthcare, and learning environments (Seaborn and Fels, 2015). A huge contribution to this field was made by Chou (2015) who proposed guidelines on how to implement good gamification design into products, workplace and lifestyle. Conceptually, gamification finds its foundation in three main psychological theories: self-determination theory (Ryan and Deci, 2000a); motivation theory (Ryan and Deci, 2000b) and flow theory (Csikszentmihalyi, 1975). Self-Determination Theory (i.e., "SDT") is a psychological theory that focuses on motivation and human personality. It identifies three innate psychological needs that are essential for growth: competence, autonomy, and relatedness (Ryan and Deci, 2000a). Competence concerns interactions with the environment and the ability to express one's abilities. Autonomy refers to choices made independently, without external constraints, in accordance with one's identity. Relatedness concerns belonging to a group in which one feels accepted. Satisfying these needs increases intrinsic motivation and leads individuals to engage in tasks in which they feel competent, autonomous and related. Motivation, as described by Ryan and Deci (Ryan and Deci, 2000b), is the drive that directs behaviour towards a goal, with varying degrees and types. On the one hand, intrinsic motivation arises from the enjoyment of the activity itself, the search for pleasure and fulfilment; on the other hand extrinsic motivation is driven by external rewards such as money or status. Cognitive appraisal theory, a sub-theory of SDT, suggests that interpersonal events that increase competence can increase intrinsic motivation. Flow theory was introduced by Csikszentmihalyi (1975) and describes an optimal state of consciousness in which individuals are fully immersed in an activity. It is characterised by total focus, goal orientation, intrinsic motivation, positive attitude and satisfaction, flow occurs when there's a balance between the level of challenge and one's own abilities. In this regard, well-designed games can induce flow, providing deep motivation and optimal performance by matching the difficulty of the game to the player's ability.

The topic of gamification has also become of interest in manufacturing very recently. There are still few attempts to adapt these concepts in industrial settings. Deterding et al. (2011) explored the historical origins of gamification and propose its definition as the use of game design elements in non-game contexts. Keepers et al. (2022) highlighted the limited scope of current research in this area and suggested directions for future research. Liu et al. (2018) showed that smartphone-based gamified work design significantly increases work motivation, satisfaction, and operational performance. Ohlig et al. (2021) presented empirical evidence on how gamified performance management systems, using gamified visualization of process metrics, increase motivation. Sochor et al. (2021) developed a framework to support the selection and implementation of gamified elements in industrial manufacturing and logistics. Klevers et al. (2016) presented the "GameLog Model" to integrate game mechanics into existing business processes. Lee et al. (2016) proposed a five-step design framework for gamification in manufacturing through a case study in an automotive assembly line. Similarly, Ulmer et al. (Ulmer *et al.*, 2020) introduced a skill-based gamification framework for manual tasks to enhance workers' engagement. In a subsequent work, the authors proposed a system of skills and levels for the individual adjustment of the complexity of the work for each step of the assembly process, using virtual reality (Ulmer *et al.*, 2023). Finally, Roh et al. (2016) explored the impact of gamification on operators' flow states and emotional experiences, linking them to intrinsic motivation. Finally, Dolly et al. (2024) analysed the effects both on productivity and on cognitive load of gamification in an industrial assembly task. However, no previous work investigated the potential benefits of gamification in assembly processes in terms of stress perceived.

APPLYING THE OCTALYSIS FRAMEWORK IN ASSEMBLY PROCESSES

The Octalysis Framework, developed by Yu-kai Chou, is a renowned tool in the field of gamification, offering a deep understanding in the application of game mechanics to non-gaming contexts. Central to the framework is the categorisation of motivational drivers into eight fundamental drives, organised in a gamification wheel that illustrates how different elements can influence human behaviour in a variety of contexts, including manufacturing. This framework is distinguished by its ability to analyse and design gamified systems through the lens of the following fundamental drives:

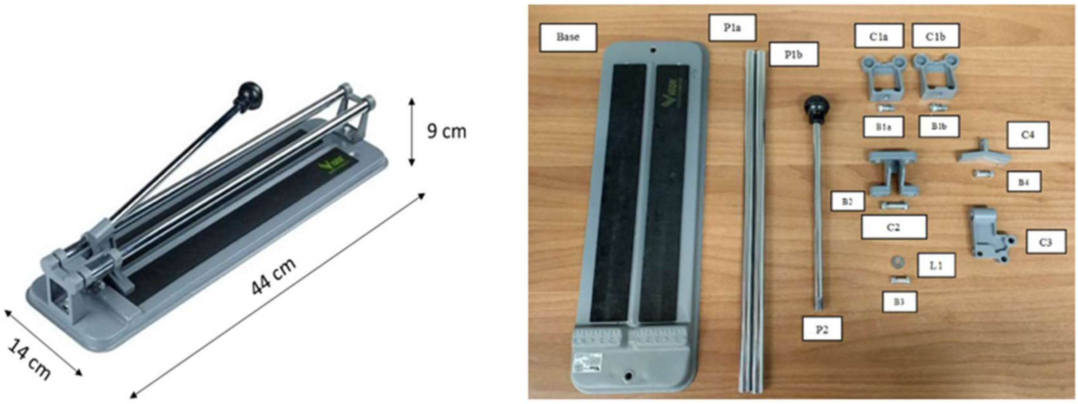
- *Epic Meaning*: it involves believing that one is part of something greater than oneself. In a work context, it means feeling that one's efforts contribute to a crucial and meaningful cause. This can be achieved by contributing to environmental sustainability or technological innovation, through storytelling or visualizing the end-use of the products being assembled can help with this. For example, posters or digital displays showing the end product in use and emphasizing its positive impact on the society could boost workers' motivation.
- *Accomplishment*: This core drive focuses on internal motivation that arises from making progress, developing skills, and achieving goals. To address this driver in industrial assembly processes, it could be useful to implement systems able to track skill development and task completion. Workers can be rewarded with badges, certifications, or levels for mastering new skills or consistently meeting production goals. This can include digital dashboards that tracks individuals or team production metrics, such as unit assembled per hours, quality scores, task times etc.
- *Empowerment*: it refers to the satisfaction of engaging in creative actions, observing the outcomes of one's creativity. It involves actively participating in a process where people have to figure things out, develop strategies and try different combinations. This could be achieved through the implementation of a digital platform where workers can submit suggestions and ideas.
- *Ownership*: this is the drive where users are motivated by the feeling of ownership, but adapting the concept of ownership to an assembly work-area is difficult. However, workers can feel a sense of ownership over their workstations or tools by providing customization options. For example, on the basis of the milestones achieved workers can be rewarded with personalised tools or the possibility to customise their workstations.
- *Social Influence*: it involves all the social elements that motivate people, such as mentorship, acceptance, social responses, and also competition and envy. It can be achieved by promoting a collaborative environment where, for example, workers, organised in teams, can earn points for their team for efficiency, safety and innovation practices.

- *Scarcity*: This phenomenon is known as the 'scarcity effect'. Scarcity and impatience can drive people to desire something more if it is rare, exclusive, or immediately unavailable. This can be implemented by introducing time-limited challenges. For example, daily or weekly challenges that require employees to achieve specific goals can be introduced, such as the most units assembled in a day.
- *Unpredictability*: This is the drive to discover what will happen next. It is the fundamental motivation behind the fascination with mysteries and the unpredictable. This keeps the work environment dynamic and engaging. For example, a system where employees can earn surprise rewards for outstanding performance, such as exceeding quality benchmarks, could be established.
- *Avoidance*: it refers to the desire to avoid negative outcomes or losses. It is characterised by the motivation to avoid punishment, danger, or potential losses. In order to avoid negative outcomes, workers should be incentivised in pursuing safety. For example, prizes and rewards could be introduced for those who maintain high safety standards.

By leveraging these drivers, the Octalysis Framework provides a robust methodology to improve engagement, productivity and overall job satisfaction in productive environments.

A GAMIFIED VERSION OF A COLLABORATIVE ASSEMBLY PROCESS

The central aim of this paper consists in investigating the feasibility of gamifying manufacturing processes. As an exploratory case study, a collaborative assembly process was considered. The case study product is a tile cutter (see Fig. 1). The assembly process of the tile cutter consists of 18 elementary tasks, which in collaborative modality are partially allocated to the human and to the cobot. Table 1 shows the list of all the parts composing the tile cutter, the related elementary task and, for HRC modality, their allocation between human and cobot. Obviously, in manual modality all tasks were performed by humans.



(a) (b)

Figure 1 – The assembled tile cutter and its main dimensions (a) and all the parts and screws composing it (b) (Gervasi *et al.*, 2024)

Table 1 – Main product characteristics and assembly process description of the tile cutter (first columns contains the list of parts and their codes and quantities, second column contains the list of the elementary task of the assembly process and the third column contains the allocation of the task between human and robot)

Product characteristics			***Assembly process***	***HRC Task allocation***	
Parts and fasteners	**Code**	**Quantities**	**Elementary task (same in manual and HRC)**	**Human**	**Cobot**
Base	Base	1	Pick and place Base		X
Lateral support	C1a/C1b	2	Pick and place C1a and C1b on Base	X	
Joint component	C2	1	Preliminary screwing C1a and C1b on Base	X	

Cutting component	C3	1	Placing the subassembly (Base+C1a+C1b) out of the assembly area		X
Blade	L1	1	Pick and place C2		X
Tile blocker	C4	1	Pick and place C3 in C2	X	
Rail rod	P1a/P1b	2	Screwing C3 and C2	X	
Handle	P2	1	Pick and place L1	X	
Bolt type 1	B1	2	Screwing L1 and C3	X	
Bolt type 2	B2	1	Pick and place C4 in C3	X	
Bolt type 3	B3	2	Screwing C4 and C3	X	
Nuts type 1	N1	2	Placing the subassembly (C2+C3+C4+L1) out of the assembly area		X
Nuts type 2	N2	1	Pick and place subassembly (Base+C1a+C1b) back in the assembly area		X
Nuts type 3	N3	2	Insert sub-assembly (C2+C3+C4+L1) in both P1a/P1b	X	
			Insert P1a/P1b in C1a/C1b	X	
			Final screwing C1a/C1b on Base	X	
			Pick and place P2	X	
			Screwing P2	X	
			Pick the final product and place out of the assembly area		X

In order to gamify the collaborative assembly processes, some gamification elements were selected, i.e., points, progress bars, multimedia feedback and suggestions. The usage of progress bars and points in the assembly process is directly linked to conventional productivity metrics (e.g., Performance Measurement Systems) such as cycle time. Furthermore, suggestions for improvement, such as optimized assembly instructions, can minimize errors and improve product quality. This reflects a direct application of quality metrics in the manufacturing process and such gamification elements align with the principles behind traditional productivity and quality measurements in manufacturing (Franceschini *et al.*, 2019; Muthiah and Huang, 2006). In detail, the main gamification elements were:

- **Points:** The scoring system is based on comparing the time taken by the operator to complete the assembly with the expected times from Table 2, which represent average execution times derived from previous laboratory experience and thus define the time taken by an 'average user'. Offering points for tasks provides immediate rewards, reinforces positive behaviour and encourages continued engagement. The assembly of the tile cutter can be broken down into four main phases: phase 1 involving the joining of the two supports with the base; phase 2 during which the cutting mechanism is assembled; phase 3 which is the final assembly of cutting mechanism, rail rods and the base leading to the final product, and phase 4 involving the pick and place of the final product in which the operator does not intervene. Each of the first three phases includes some activities performed by the operators and others by the cobot. The time spent by the operator in the three phases enables the implementation of the scoring system, as this time is compared with the benchmark values from Table 2. Specifically, the observed time T_j, where the subscript j identifies the assembly phase ($j = 1...3$), is the time between two successive digital outputs measured by the system, which includes both the component movement time used by the cobot (deterministic) and the assembly time used by the operator. Specifically, it is:

$$T_j = C_j + O_j \qquad (1)$$

where: C_j is the time related to tasks performed by the cobot while O_j represents the time of human-performed tasks. In all the phases, the times T_j are therefore compared with the reference values T_j^* predicted from Table 2, where: $T_j^* = C_j^* + O_j^*$.

Table 2 – Completion times of the four phases of the tile cutter assembly process

Phase	T_j^* [s]	O_j^* [s]	C_j^* [s]
1	70	57	13
2	119	103	16
3	100	80	20
4	11	0	11

The scoring system provides that at each stage of the assembly a score (p_j) is assigned to the operator based on the comparison with benchmark values. Specifically, if $T_j \leq T_j^*$ then $p_j = 2$ and if $T_j > T_j^*$ then $p_j = 1$. Hence, a score of 2 is awarded if the operator performs better than the "average user", otherwise 1 point is awarded. The final score achieved by operator in the assembly of the tile cutter will be the sum of the scores achieved in the next three steps, thus $p_i = \sum_{j=1}^{3} p_j$.

- **Progress bar**: A filling progress bar is displayed on the dashboard and as each task is completed, the progress of the process can be observed. The progress of the bar corresponds to the percentage of process completion. The progress bar is completely filled when the assembly of the finished product is complete. Visualising progress with a bar helps users track their achievements and remaining tasks, giving a clear sense of progress and achievement.
- **Multimedia feedback**: it was chosen to visualise the execution times of each of the phases in order to provide the operator with feedback on her/his assembly performance in real time. In this regard, Ohlig et al. (Ohlig *et al.*, 2021) showed how a gamified information provisioning system can improve operator's motivation. Real-time feedback allows users to instantly understand their performance levels, helping them to recognise their strengths and areas for

improvement. The measurement, and visualisation, of the execution time of the assembly phases make it possible to define a performance indicator, which represents a second multimedia feedback for the operator. The basic assumption that allows the performance indicator to be defined is the distributive form of the assembly times of the various process steps. In particular, based on previous experience, it can be assumed that the execution times of phases j are normally distributed (i.e., $T_j \sim N(T_j^*; \sigma_j)$). This assumption allows a performance indicator (TPI_j) to be defined for each stage of the assembly process as follows:

$$TPI_j = \left(1 - \Phi(T_j)\right) \times 100 = \left(1 - \Phi\left(\frac{T_j - T_j^*}{\sigma_j}\right)\right) \times 100 = \left(1 - \Phi(Z_j)\right) \times 100 \quad (2)$$

In fact, it was chosen to use the anti-cumulative of T_j, as it increases as T_j decreases; therefore, it is more suitable to represent the performance of the operation.

- **Suggestions:** A virtual avatar is displayed, which during the activity provides advice to guide the operator towards the correct execution of the task, also showing illustrative images to facilitate understanding. For example, the avatar may recommend not over-tightening the screws of the supports in the first step in order to facilitate the subsequent insertion of the cutting mechanism, or show an example photo of the correct positioning of the components. Offering suggestions provides guidance and support, helping users improve their skills and performance.

Fig. 2 shows the phases of the gamified assembly process where the human operator is actually involved and the related graphical interface showing the performance of the operator.

Figure 2 – The gamified graphical interface of the collaborative assembly process

EXPERIMENTAL CASE STUDY

A small exploratory case study involving three operators was developed with the aim of assessing its feasibility and impact on user performance and engagement.

Data collection

The methodology was designed to evaluate the effectiveness of gamification by comparing objective data, such as completion time, failure rates and physiological signals with subjective data, including questionnaires and participant feedback. Specifically, the physiological measurements together with subjective data provide a comprehensive understanding of the subject's response to stress, which may provide further insights in assessing the impact of gamified environments on user experience and performance. This dual approach enabled a comprehensive analysis of the impact of the gamified system on both the efficiency of the assembly process and the overall participant experience. Expert feedback was particularly crucial in understanding the practical implications and potential improvements, providing valuable insights into the feasibility and adaptability of the gamified version in real assembly scenarios. The objective data collected were:

- Process failures: In order to evaluate the potential enhancement of process and product quality, process failures were collected both in non gamified and in gamified collaborative modality. Process failures in quality control refer to deviations or discrepancies that occur during the production process. These failures can take various forms, such as defects in the final product, inaccuracies in assembly, incorrect implementation of procedures, or misuse of materials and tools (Maisano *et al.*, 2019). In this work, process failures were organised into four categories: (i) Incorrect assembly that occurs when parts or components are assembled in the wrong order, orientation or configuration, leading to malfunction, reduced product performance or total product failure; (ii) Incorrect positioning that refers to the misplacement or misalignment of components, but, unlike incorrect assembly, at some point the operator notices and corrects; (iii) wrong input to cobot that refers to incorrect commands given to cobots by the operator, thus leading to inappropriate actions and delays; and (iv) dropping of parts that involves the accidental dropping or mishandling of components and tools during assembly.
- Completion times: The time of the assembly process was recorded, by automatically collecting the time intervals between two consecutive inputs to the cobot. This metric can be regarded as one of the proxy of the potential efficiency improvements brought by the gamification elements.
- Electro-Dermal activity (EDA) which reflects the electrical conductance of the skin. It is influenced by sweat gland activity, which is controlled by the sympathetic nervous system and is indicative of emotional arousal. EDA was analysed using continuous decomposition, distinguishing between tonic and phasic activity. Tonic activity, showing sustained

fluctuations in skin conductance, and phasic activity, reflecting immediate responses to stimuli, were measured by average skin conductance level (SCL) and skin conductance responses (SCRs), respectively (Benedek and Kaernbach, 2010).

- Heart-Rate variability (HRV) refers to the variation in time intervals between consecutive heartbeats and it was assessed as an indicator of autonomic nervous system balance and stress response. Metrics such as Root Mean Square of Successive Differences (RMSSD) and Standard Deviation of NN intervals (SDNN) were used to assess heart rate variability, providing insight into individual stress levels and recovery capabilities. Root Mean Square of Successive Differences is (i.e., RMSSD) defined as:

$$RMSSD = \sqrt{\frac{1}{N-1}\sum_{i=1}^{N-1}(NN_{i+1} - NN_i)^2} \tag{3}$$

Where N is the number of systolic peaks in the considered time window and NN_i indicates the time interval between the systolic peak i and $i+1$, while "SDNN" represents the Standard Deviation of NN intervals. Generally, higher HRV values indicate a healthier, more responsive cardiovascular system, while lower values indicate potential stress or fatigue. (Kim *et al.*, 2018; Young *et al.*, 2015).

The subjective data collected were:

- NASA-TLX questionnaire: To assess subjective perception of workload in performing assembly processes, this study used the NASA TLX which is a comprehensive tool that assesses six dimensions of workload on a 0-100 scale. These dimensions include (i) mental demand that assesses the cognitive demand required from the individual by the task; (ii) physical demand that quantifies the level of physical effort required; (iii) temporal demand that assesses the perceived time pressure associated with performing the task; (iv) performance that measures the individual's perception of success and satisfaction with the results achieved; (v) effort that considers the combined mental and physical effort required to achieve a goal and (vi) frustration that measures the level of irritation, stress and annoyance experienced while performing the task. The total workload score is derived by calculating the average of these six dimensions, providing a multi-dimensional perspective on the user's perceived workload. (Hart and Staveland, 1988).

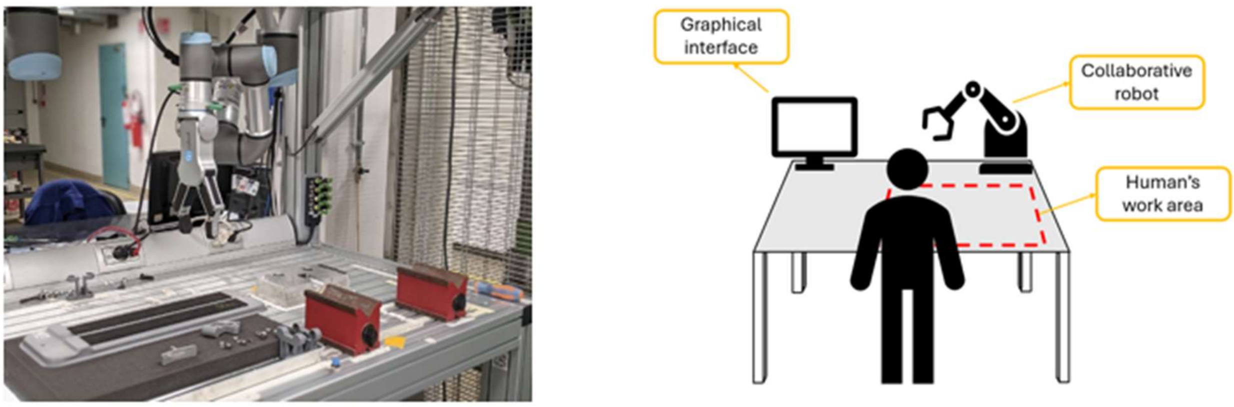
- Self-Assessment Manikin (SAM) is an image-based tool often used to measure individuals' emotional reactions to specific situations or events. This assessment has three primary dimensions: (i) Valence that identifies the emotional appeal of the experience, categorising feelings as either positive or negative; (ii) Arousal that measures the intensity of emotional activation, whether the emotion is positive or negative and (iii) Dominance that assesses the extent to which one feels in control of the event or situation (Bradley and Lang, 1994).
- Intrinsic Motivation Inventory (IMI): The Intrinsic Motivation Inventory (IMI) serves as a comprehensive tool for assessing subjective experiences related to target activities in laboratory settings, particularly in research on intrinsic motivation and self-regulation. Based on seminal work by Ryan et al. (Ryan *et al.*, 1983, 1991), the IMI provides insight through six distinct subscales: interest/enjoyment, perceived competence, effort, value/usefulness, perceived pressure and tension, and perceived choice during an activity. In this work the subscale on interest and enjoyment was exclusively considered because it was the most suitable for this type of experiment. The items of the interest/enjoyment subscale are shown in Table 3. The level of agreement for each item is evaluated on 7-point Likert scale from not at all true (1) to very true (7).

Table 3 – Item list of the Intrinsic Motivation Inventory

n	Item description
1	I enjoyed doing this activity very much
2	This activity was fun to do.
3	I thought this was a boring activity. (R)
4	This activity did not hold my attention at all. (R)
5	I would describe this activity as very interesting.
6	I thought this activity was quite enjoyable.
7	While I was doing this activity, I was thinking about how much I enjoyed it.

Experimental procedure

The case study involved three operators who performed the assembly process twice in the non gamified collaborative modality and twice in the gamified version. The three operators were researchers from the Department of Management and Industrial Engineering at the Politecnico di Torino. The experiment took place in the Mind4Lab laboratory of the Politecnico di Torino (Italy). After a short introduction to the experiment, the participant was trained to perform the collaborative assembly of the tile cutter with the UR3 cobot following the tasks listed in Table 1. Fig. 3 shows the work-area where the experiment took place. The participant then performed two repetitions of a “non gamified” modality or a “gamified” modality, which were randomly selected. At the end of performing a modality, the participant completed the Nasa-TLX, SAM and IMI questionnaires. Thus, the participant underwent two further repetitions of the remaining modality and then completed the aforementioned questionnaire again. At the end of the small experiment, unstructured and qualitative feedback was collected.t



(a) *(b)*

Figure 3 - The collaborative robot UR3 at the Mind4Lab of Politecnico di Torino used in the experiment (a) and a general layout of the assembly work-area (b)

RESULTS

The research was structured to compare non gamified and gamified modalities, examining both objective performance metrics (process failures and completion times); physiological signals (Average SCR and Average SCL) and subjective perceptions (Nasa-TLX, SAM and IMI).

Performance metrics

Fig. 4a shows the sum of process failures occurred in both modalities. The bar graph provides a clear visual comparison of the total number of process failures between a non gamified collaborative assembly process and its gamified version. It's clear from the graph that the gamified version of the assembly process resulted in fewer process failures than the non gamified version. The reduction in process failures in the gamified version could be attributed to increased engagement, motivation or focus of the participants, which are common benefits associated with gamification. The bar chart in Fig. 4b illustrates the comparison of average completion times in both modalities for each participant. The graph shows that for 2 out of 3 participant, the gamified version of the assembly process resulted in shorter completion times compared to the non gamified version. Considering the results of the comparison of completion times, gamification may have the potential to improve the efficiency of collaborative assembly processes. However, the decrease in process failures and in completion time observed could also be due to a learning effect among the trials, especially considering the simplicity of the product involved in the assembly process.

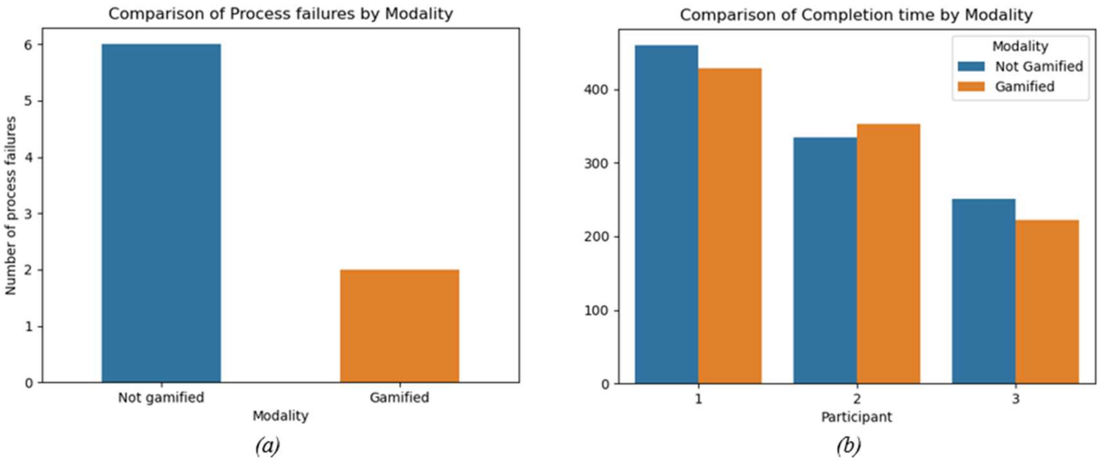


Figure 4 – Barplots showing sum of process failures by modality (a) and the average completion time for each participant distinguished by modality (b)

Impact of gamification on physiological signals

In the analysis of the impact of gamification on physiological signals, data on EDA and HRV were also collected. Fig. 5 shows the average value of the four metrics presented in section 5.1 by participant. For participant 1 and 2, both average SCR and SCL are higher in the non gamified modality compared to the gamified one. Participant 3 showed more similar results between the two modalities, with an increased average SCL level in gamified modality. However, metrics of heart rate variability generally led to opposite results. First, this could be due to individual differences in stress response, cognitive processing, and even familiarity with or preference for games could amplify these effects.

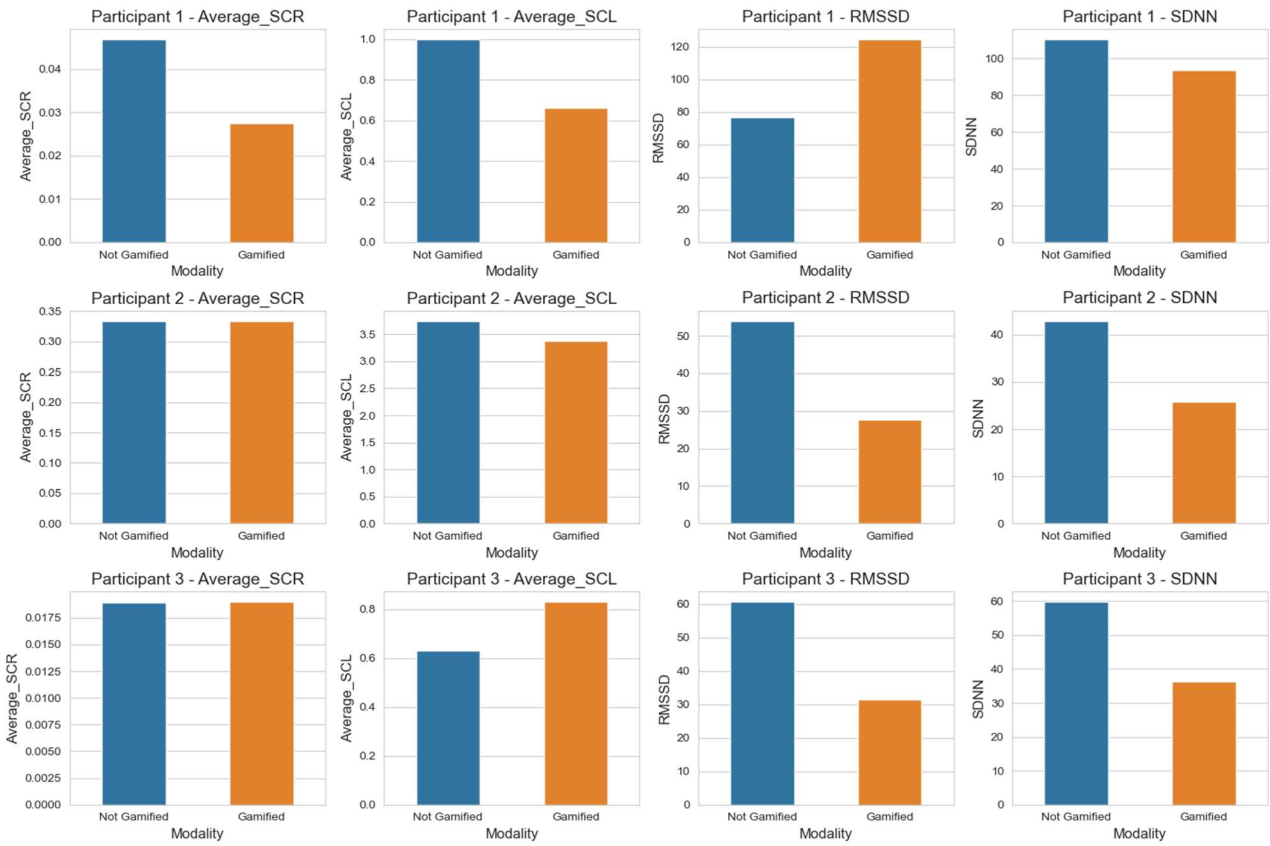


Figure 5 – Barplots showing the average trial value of the four physiological metrics for each participant distinguished by modality

Subjective responses

Subjective responses collected were: NASA-TLX, SAM and IMI questionnaires. The results of NASA-TLX questionnaires show that across all participants, perceived workload appeared lower in the gamified modality compared to the non gamified modality (see Fig. 6). Specifically, participant 1 showed the most significant difference in perceived workload between the two modalities, with a lower workload reported for the gamified approach. This may indicate a positive response to the gamification elements, suggesting that such modifications may have the potential to make the task more enjoyable or mentally manageable for this participant. For participant 2 and 3 the difference is less pronounced than for Participant 1, while also reporting a lower workload for the gamified modality.

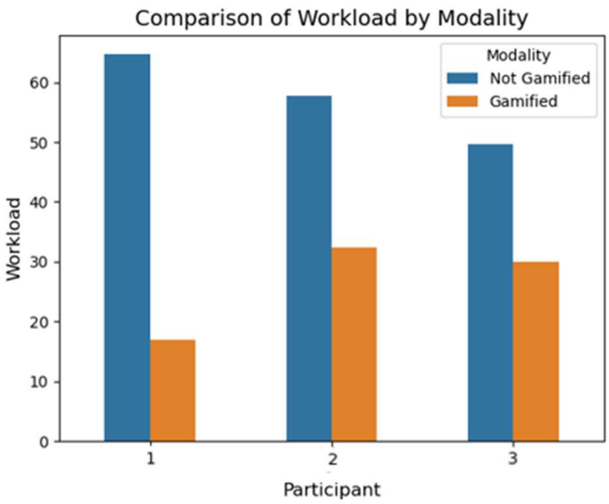


Figure 6 – Barplots showing the workload value of for each participant distinguished by modality

The bar graphs in Fig. 7 presents the results of the Self-Assessment Manikin (SAM). For all participants, valence is higher in the gamified modality compared to the other one, indicating a more positive emotional response when engaging with gamified elements. Participant 1 and Participant 2 show a decrease in arousal from non gamified to gamified, suggesting that the gamified elements may have reduced the intensity of their emotional response, possibly due to increased engagement. All participants reported higher dominance scores in the gamified modality, suggesting that they felt more in control when the task was gamified. This could be due to the gamification elements providing clearer goals, feedback or a sense of progress, which can increase the perception of control over the task.

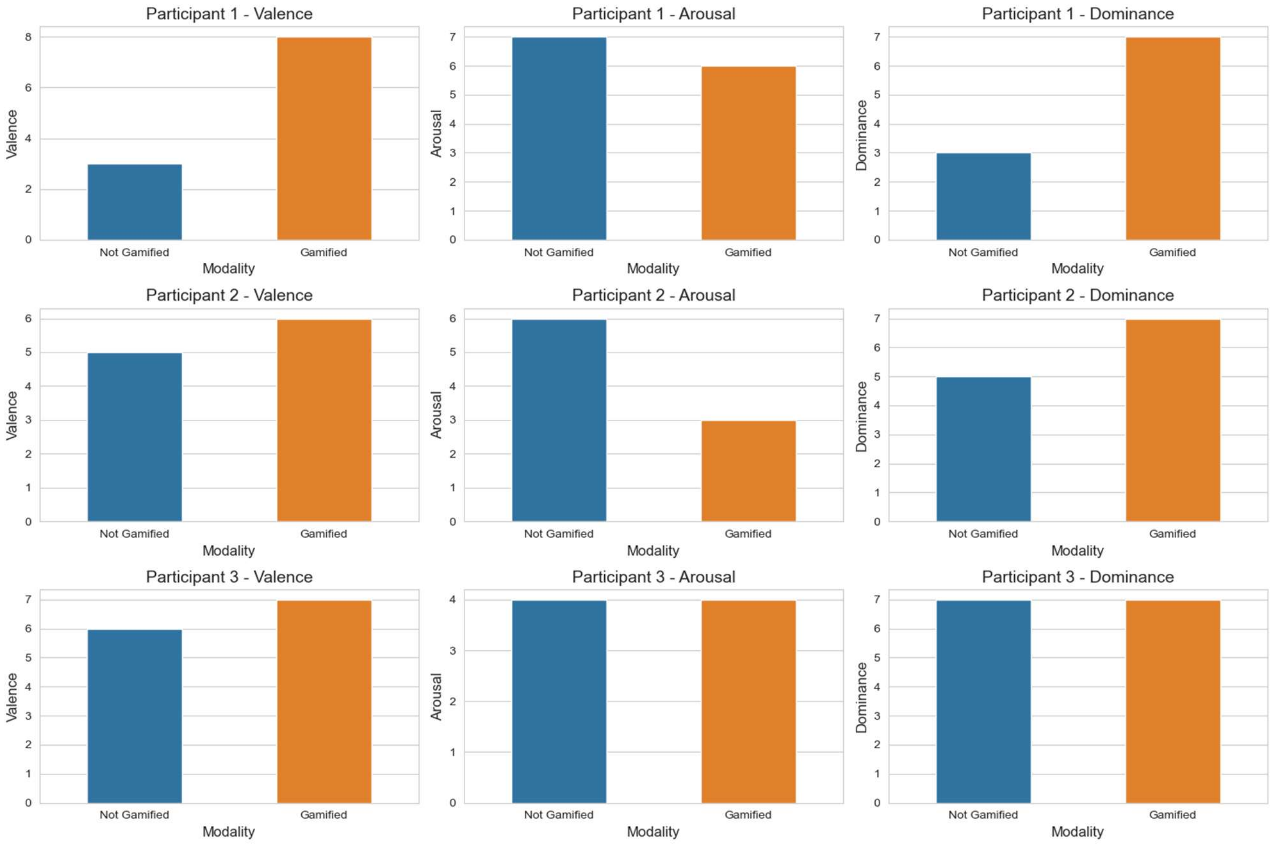


Figure 7 – Barplots showing the results of SAM for each participant and dimension distinguished by modality

Finally, the results of IMI are reported in Table 4. It can be noted that there's a trend towards higher scores for the gamified modality on items that directly assess enjoyment and interest ('I really enjoyed this activity', 'This activity was fun to do', 'I would describe this activity as very interesting', 'I found this activity quite enjoyable', 'While I was doing this activity, I thought about how much I enjoyed it'). For items related to tension and anxiety ("I felt very tense while doing this activity", "I was anxious while working on this task"), participants generally reported lower scores in the gamified modality. Furthermore, responses to items related to attention and boredom ('I thought this was a boring activity (R)', 'This activity did not hold my attention at all (R)') also favour the gamified modality, albeit with some variation across participants. Overall, subjective measures across several show a preference for the gamified version, suggesting that gamification can enhances the subjective experience of tasks.

Table 4 – Results of the Intrinsic Motivation Inventory (Ryan *et al.*, 1983) where values in bold indicate all that items where gamified version was preferred ("NG" refers to not gamified modality, while "G" for gamified one)

IMI - Interest/Enjoyment	**Participant 1**		**Participant 2**		**Participant 3**	
Items	**NG**	**G**	**NG**	**G**	**NG**	**G**
I enjoyed this activity very much	**2**	**6**	**4**	**6**	6	6
This activity was fun to do	**2**	**6**	**5**	**6**	5	5
I thought this was a boring activity (R)	**6**	**2**	2	2	2	2
This activity did not hold my attention at all (R)	**5**	**2**	3	3	**4**	**3**
I would describe this activity as very interesting	**2**	**6**	**4**	**5**	**3**	**4**
I thought this activity was quite enjoyable	**2**	**6**	**3**	**6**	5	5
While I was doing this activity, I was thinking about how much I enjoyed it	**1**	**5**	**3**	**4**	**2**	**4**
I felt very tense while doing this activity	**5**	**2**	**5**	**2**	**6**	**5**
I was anxious while working on this task	**5**	**2**	**5**	**2**	**5**	**4**
I felt pressured while doing these	**5**	**1**	**5**	**2**	5	5

Unstructured feedback

The unstructured feedback received from participants consistently highlighted the increased ease and engagement of the gamified version of the assembly process. A common suggestion was the need for a larger screen for the interface, suggesting that improved visibility could further enhance the user experience perhaps using projectors or augmented reality devices. In addition, participants expressed a desire for more personalised feedback within the gamification system. They suggested the inclusion of adaptive difficulty levels that would adjust the challenge based on the user's performance. Finally, participant 1 and 2 expressed interest in incorporating more storytelling elements into the gamification system. This feedback suggests that embedding the tasks within a story could increase the immersion and emotional involvement of the participants, making the work more meaningful.

CONCLUSION

This exploratory study addresses the potential of integrating gamification into collaborative assembly processes to assess its impact on operators' engagement, motivation and the overall quality of manufacturing output. Using the Octalysis framework, this paper introduces gamification elements to the manufacturing environment, with the aim of improving both operators' qualitative experiences and quantitative performance metrics. In this regard, performance metrics observed a trend towards efficiency in the gamified environment, although results varied between participants. Subjective ratings, instead, consistently showed a preference for the gamified modality, indicating increased job satisfaction and reduced stress. Finally, physiological data revealed complex and heterogeneous responses. Nonetheless, all participants showed a preference towards gamified version of the assembly process. The main limitation of the study is both the small sample size, which limits the generalisability of the findings, and the specificity of the case study to a single assembly process. This specificity may not fully capture the variety of scenarios encountered in different manufacturing environments. However, the aim was to explore the feasibility of gamification in manufacturing and provide a foundational perspective for future research. The next phase of research will expand the experiment to include a larger sample size for more robust statistical analysis, and test the gamification framework across different assembly processes to assess its broader applicability. In addition, the incorporation of narrative elements into gamification strategies is identified as a promising area to further enhance employee engagement.

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Quality management evaluation in the third sector: survey research

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STRUCTURED ABSTRACT

Purpose - This study aims to assess the level of utilization of Quality Management (QM) practices by Brazilian Third Sector Organizations (TSO).

Design/methodology/approach - A literature review on the use of QM practices in the Third Sector was conducted. Based on this, a questionnaire was developed in the format of an exploratory survey, A total of 51 responses were obtained. Descriptive statistical analyses were performed on the data, and non-parametric tests such as Kruskal-Wallis and Mann-Whitney tests were used to compare NGOs from different sectors and the number of employees.

Findings - The results indicate that commonly used QM tools include brainstorming, flowcharts, process mapping, cause and effect diagrams, and the 5 Whys. Additionally, the most utilized QM practices are associated with top management commitment, leadership and focus, and beneficiary satisfaction. A comparison of QM tool usage across NGOs' areas of activity reveals that the field of activity specifically impacts the utilization of the following methods and tools: DMAIC cycle, visual management, Lean Six Sigma tools, Pareto, voice of the customer, brainstorming, Gemba, and QFD. Similarly, a comparison based on the number of employees did not yield statistically significant differences.

Research limitations/implications - A limitation of the research was its focus on organizations participating in the '100 Best NGOs' classification by the Doar Institute.

Originality/value - Through this research, it is evident that further studies involving QM in the third sector are necessary, with great potential for contribution to academic and organizational realms.

Keywords: Survey, Quality, Third Sector.

Paper type: Research paper

INTRODUCTION

No single definition in the literature characterises Third Sector Organisations (TSOs). However, five specific characteristics guide them: a) organisations are formally structured, b) they are characterised by private ownership and independence from the government, c) non-profit distribution, d) self-management, and e) they benefit from voluntary activities (Bach-Mortensen et al., 2018). The name given to these organisations ranges from terms such as 'non-profits,' 'NGOs,' 'community-based organisations' (CBOs), 'charities, and' 'voluntary organisations' are often used synonymously (Bach-Mortensen et al., 2018). According to Fischer (2002), Third Sector Organisations, besides generating goods, services, and products necessary for the population, are characterised as non-profit organisations. Despite not aiming for economic profit, they must be able to carry out activities and services to the community effectively, even with increased demand from society and decreased external funding (Fischer, 2002). These organisations bring to the debate topics of collective interest that are significant for various sectors of society, such as social, environmental, and economic issues (Lopez, 2018).

Many of them are key providers of development aid, humanitarian aid, poverty reduction, public health, and environmental protection (Schwarz and Diers-Lawson, 2024). Their main mission is to reach the portion of the population where the State still acts insufficiently, aiming primarily at local development and meeting demands, thus playing an important role in society (Pinheiro et al., 2021). These organizations are important in developing countries, such as Brazil, for providing assistance in education, health, and environmental preservation (Lopez, 2018). However, few in-depth studies provide information about these organizations in the Brazilian context, especially given their importance for the construction and implementation of public policies (Lopez, 2018). Additionally, these organizations constantly struggle to manage operational efficiency and effectively serve the public (Jevanesan, 2019). Furthermore, they operate in a complex and dynamic environment due to declining government funds and dependence on unstable and limited resources (Parris, 2013). According to Jevanesan et al. (2019), there is a constant struggle between achieving public satisfaction and ensuring effective management of the operational processes inherent to TSO.

Therefore, it is expected that TSO seeks ways to design their planning, operations, and value propositions and make them more sophisticated to achieve better results at lower costs, adding more value to their users in formats that allow scalability. These challenges are central management themes in these organizations in pursuing process excellence (Parris, 2013). In industrial and commercial companies (for-profit enterprises), these challenges are also present, and management practices of these companies focus on Quality Management (QM) and process excellence (Melão; Guia; Amorim, 2017). One of the most traditional philosophies for addressing these challenges is Total Quality Management (TQM), which is based on cost reduction, productivity increase, and customer satisfaction (Mello, 2011). TQM is seen as a holistic management philosophy aimed at organizational improvements through the involvement of all stakeholders (Chen et al., 2017). Overall, TQM's main factors and practices include support and commitment from top management, leadership, customer focus, supplier selection and relations, process management, human resource management, and the use of quality information (Sweis et al., 2016). In the industrial and commercial market, TQM has been established and proven useful (Fredriksson, 2003). In the third sector, TQM can play a critical role, but few studies on the impact of implementing these initiatives make it difficult to measure effectiveness for this sector (Melão; Guia; Amorim, 2017).

The main motivation for this is due to the benefits and results obtained by TSO by implementing these programs. For example, Parris (2013) emphasises that using TQM in a TSO in East Africa generated more employee engagement and involvement in improvement actions, favouring the potential to expand the organisation's impact. According to Fredriksson (2005), implementing TQM improved internal organisation and stakeholder communication. Additionally, the author noted that the organisation improved its reputation and demonstrated better performance in planning and process management. Breda and Crets (2001) highlighted that the use of TQM principles contributed to interrupting the pattern of increasing processing time for social services in Belgium and, furthermore, led to a reduction. Saleh et al. (2017) studied the application of TQM in NGOs in Jordan. They reported improved ability to achieve goals, better understanding of local needs, and increased cooperation among organisations.

In Brazil, few studies are directed towards the TSO and commonly used management practices. Therefore, this work aims to fill this gap with a focus on TQM. Thus, this research aims to identify the use of practices, tools, and the results of TQM adopted by TSO. To achieve the intended objectives, a survey research was conducted in TSO in Brazil.

RESEARCH METODOLOGHY

This article employed a quantitative and exploratory survey research method, as this method allows for understanding the relevance of a particular phenomenon and its description in a population (FORZA, 2002). To develop the questionnaire used in the survey, a review of articles on the application of QM in TSOs was initially conducted, and the Systematic Literature Review (SLR) by

Poltronieri et al. (2021) was used as a basis to identify the main practices, tools, and benefits of TQM adopted by TSOs. Appendices I, II, and III, respectively, present the practices (grouped into principles), results, and tools identified in the literature review. It is worth noting that the tools and practices may be related to TQM and other quality programs (e.g., Lean and Six Sigma), as some authors treated such practices and tools as interchangeable among the programs due to their synergy

The questionnaire was designed to assess TSO leaders' agreement regarding applying practices and tools in their daily work routines and, if used, whether there is a perception of beneficial results. The Google Forms platform was used for questionnaire administration, and the respondents were the leaders or representatives of these organisations. A pilot test was also conducted to ensure that the research instrument, its questions, and survey procedures were appropriate. For selecting participating organisations, the database of the "Best NGOs Award" for the years 2019 and 2020 was utilised. The Instituto Doar holds the Best NGOs Award annually in partnership with Ambev VOA to recognise and promote NGOs that stand out across Brazil in management, governance, financial sustainability, and transparency. The selection process involves an Organizing Committee, an Evaluation Committee, a Technical Team, and Strategic Partners to analyse registered NGOs (PRÊMIO MELHORES ONGS, 2021). This database was chosen due to the ease of contact and access and the greater likelihood of organisational structure and procedures within the NGOs.

The survey was sent to the leaders or representatives of 122 organisations. The main channels for distributing the form were email and InMail (chat) on the LinkedIn social network. The Instituto Doar and Ambev VOA also promoted the form to organisations in their networks. After analysing the fully completed questionnaires, 51 responses were obtained.

The questionnaire consists of 2 sections, with the first corresponding to general data about the TSOs and the respondents. Section 2 is subdivided into three parts: the first one about Quality Management practices, the second one about perceived results from the implementation of such practices, and the third one about the degree of utilization of quality tools. These questions were evaluated using a 5-point Likert scale. It is important to note that the scale used in this case for assessing practices and results ranges from 1 - strongly disagree to 5 - strongly agree, while the tools use a scale where 1 - always used and 5 - never used. Therefore, in this specific case, the lower the score, the higher the utilization.

After data collection, the data were analysed using descriptive statistics. This analysis involves calculating and interpreting measures such as mean, median, and mode, as well as constructing graphs such as frequency distributions (STEVENSON, 2001). The initial objective with descriptive statistics was to organise and better understand the behaviour of the data collected in the research and the level of application of practices, tools, and the results obtained, which is the focal point of this exploratory research. Respondents assessed TQM practices according to their presence in the organisation. The practices were grouped into principles to allow for a more general analysis of adopting the set of practices on the same theme. This allowed for the analysis of the score – the mean of the mean of the variables - of the TQM principles (constructs of the variables) and the mean, median, and mode of each of the practices (variables). The results were also divided into two groups: Operational Results and Internal Results. Each group has a series of statements about each type of result. The score was also adopted to analyse the results of the two groups, allowing for a more general analysis of the results obtained. Non-parametric Kruskal-Wallis and Mann-Whitney tests were performed using SPSS software to compare TSOs from different sectors of activity, of different sizes (number of employees), considering the hierarchical level of the respondent, and the organisation's time of operation in society. Comparisons were made regarding the level of adoption of practices, results obtained, and use of tools. The Mann-Whitney test is equivalent to the parametric t-test (Student's t-test) and is used to test differences between two conditions. In contrast, the Kruskal-Wallis test is the non-parametric counterpart of one-way ANOVA based on rank values (FIELD, 2009). For comparisons that returned a p-value < 0.05, the null hypothesis was accepted; for those that returned a p-value > 0.05, the null hypothesis was rejected, indicating that there are differences in one (Kruskal-Wallis) or more comparisons (Mann-Whitney).

RESULTS

Characterization of the Sample

The predominant field of activity for TSOs is Education (23.5% of the sample), followed by Social Assistance (15.7% of the sample) and Health (9.8%) (Table 1). There is a significant variety of areas of operation among the organizations included in the sample. For comparative analysis purposes, the areas of operation were grouped (codes 1, 2, and 3), and classified according to the FASFIL report (IBGE, 2016). Group 1: Social Assistance (26%), Health (14%), Culture and Recreation (7%); Group 2: Education and Research (30%); Group 3: Development and Defense of Rights (7%), Environment and Animal Protection (5%); Group 4: unidentified.

The size of the organizations, considering the number of workers (without differentiation between paid and unpaid), is mainly characterized by organizations with up to 150 employees, representing 80.4% of the sample (Table 1). Additionally, 19.6% of the responses are from organizations with more than 150 employees. For subsequent analyses, the organizations were divided into two groups (Table 1): Group 1: 1 to 150 employees; Group 2: 150 or more.

Table 1 - Sample Characterization

Question	Description	Answers obtained	Frequency (%)	Code
2	Occupation area	Social assistance	15,7%	1
		Health	9,8%	
		Culture	3,9%	
		Education	23,5%	2
		Professional qualification	7,8%	
		Human rights	5,9%	3
		Administrative	2,0%	
		Public Management	2,0%	
		Environmental	3,9%	
		Not identified	25,5%	4
3	Number of people working in the organization	1 to 150	80,4%	1
		151 or more	19,6%	2
4	Position of the respondent within the organization	Analyst	17,6%	1
		Coordinator	25,5%	
		Manager	29,4%	2
		Director	15,7%	
		President	11,8%	
5	Years of operation of the organization	1 to 25	60,8%	1
		26 or more	39,2%	2

Source: Authors

The sample has few young organizations. Around 82% of the respondents represent institutions with more than 10 years of existence. For further analysis, the organizations were divided into two groups based on their time of operation in society: Group 1 – up to 25 years; Group 2 – over 25 years. The representatives of the respondent organizations are predominantly in leadership roles (84% of the respondents) but in various positions such as Manager, Director, or President (Group 2 code). In contrast, operational positions such as Analyst and Coordinator are less represented in the sample (Group 1).

Principles of TQM in third sector organizations

In Appendix I, it is possible to visualize the level of adoption of TQM practices and principles (through scores) by the sampled TSOs. Commitment of Top Management was the principle with the highest score (4.34), meaning it is the most utilized principle by the surveyed organizations, with practices highly used (predominantly median values of 5), scoring the maximum on the Likert scale. Additionally, the means were practically all above 4 for the practices. Hence, it is noted that in these organizations, there is support from Top Management for continuous improvement; there is a concern to improve service for beneficiaries; Top Management participates in training for continuous improvement; the quality of beneficiary service is identified in the organization's mission and vision; responsibility towards beneficiaries, donors, and other stakeholders is well reflected in the organization's mission and vision; there is a concern for accountability that is communicated to all; and although with a slightly lower score than the others, Top Management is concerned with communication.

The second principle with the highest score (4.17) is Leadership. This means that the sampled TSOs adopt the following practices: leadership gives team members responsibility for their own work; the organization uses a leadership style focused on training and creating an environment open to constructive feedback; and the organization understands the importance of reporting the results of continuous improvement and celebrating any achievements during the initiative, which will significantly improve team motivation and morale. However, it is important to note that the respondents in the sample are predominantly leaders (84% of respondents) in their respective organizations, which may have influenced their responses.

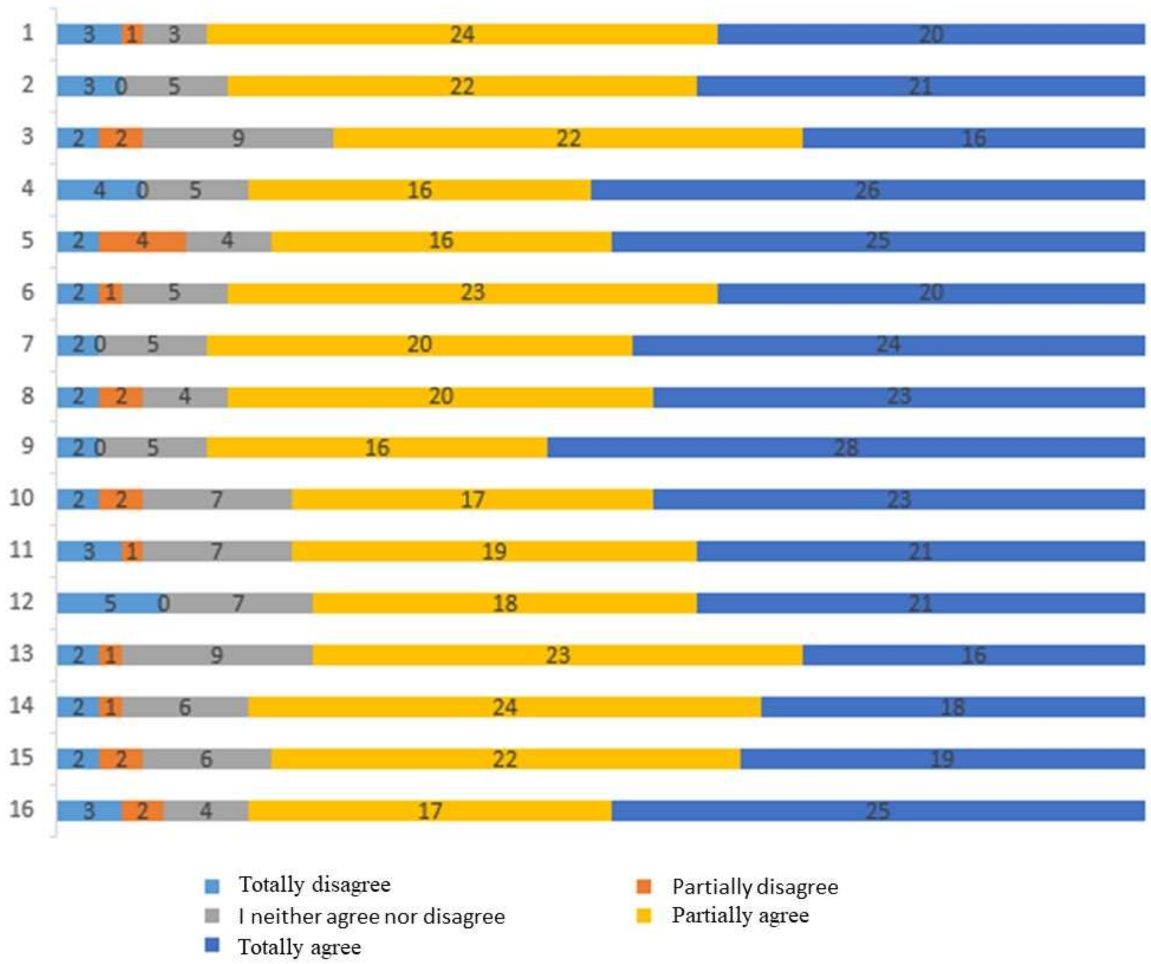
The principle that organizations least utilize is continuous improvement, although this does not mean they do not use its practices. The practices of this principle predominantly had median values of 3 and 4, while the means of the variables ranged between 3.2 and 3.96, resulting in a score of 3.52. This demonstrates that despite respondents not identifying as high adoption as with previous practices, the values show that organizations also use this principle. People are involved in problem detection and solving; the organization uses tools to improve its processes; teams are used to identify potential improvements and improvement projects; employees have autonomy to make suggestions and implement changes, and improvement activities are documented to generate learning.

Results and benefits of implementing TQM principles

The research reveals significant agreement with the statements about the benefits of implementing TQM principles and practices in TSOs (see Appendix II). The results were divided into two groups: Operational Results and Internal Results. Operational Results obtained a score of 4.10, and Internal Results obtained a score of 4.12. The benefits with the highest averages among the respondents were "Greater team involvement" (4.33) and "Increased focus on the user" (4.25). The benefit with the lowest average was "Cost reduction" (3.94), followed by "Easier identification and analysis of service failures" and "Increased number of improvement actions," both with an average of 3.98.

Overall, respondents' perceptions of the results and benefits obtained from implementing these TQM initiatives showed a significant degree of agreement. As seen in Graph 1, approximately 80% of the responses at least partially agree with the listed benefits.

Figure 1 – Results and benefits of using continuous improvement practices



Source: Authors

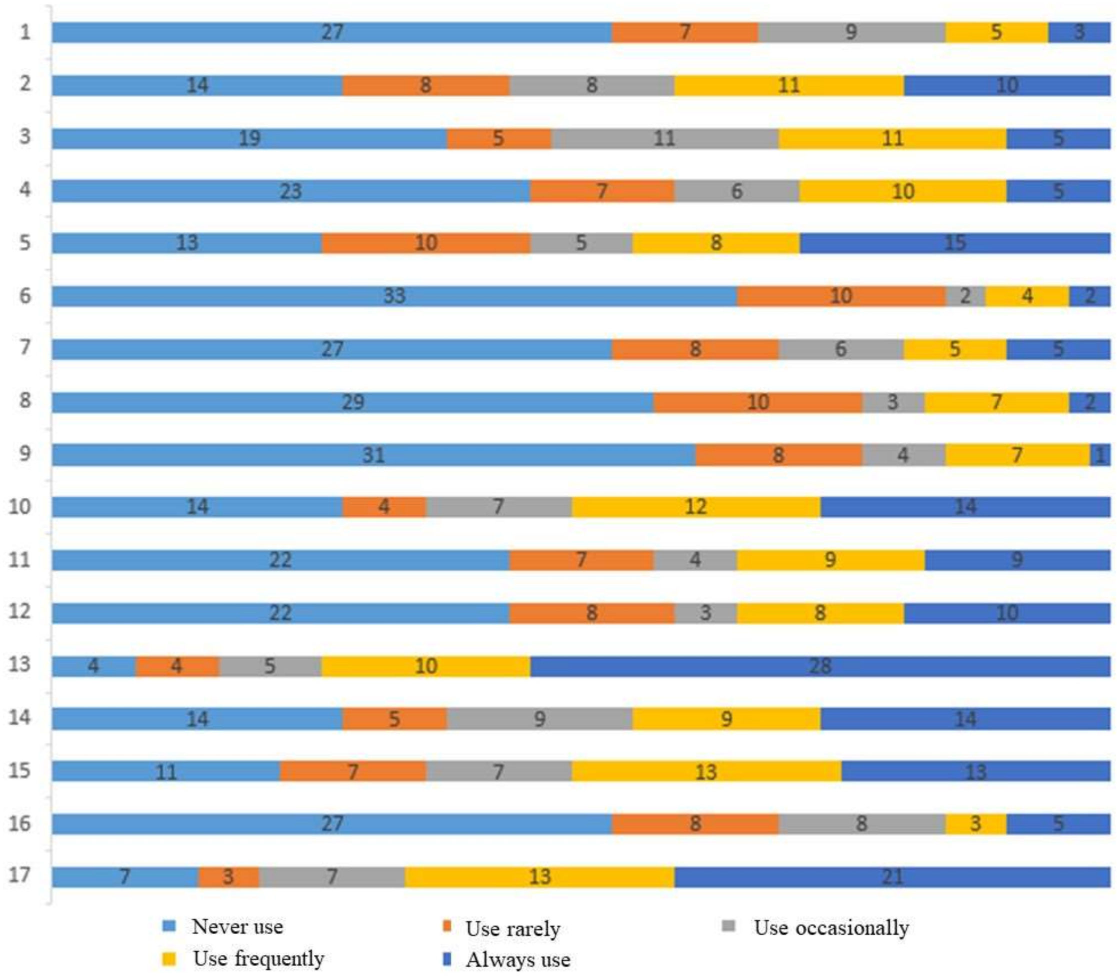
Index: 1- Better resource management; 2- Increased beneficiary satisfaction; 3- Cost reduction; 4- Better service quality; 5- Increased productivity; 6- Greater stakeholder engagement; 7- Enhanced user focus; 8- Improved process standardization; 9- Increased team involvement; 10- Better internal organization and assignment of responsibilities; 11- Enhanced employee motivation; 12- More continuous improvement actions; 13- Easier identification and analysis of service failures; 14- Improved staff training; 15- Enhanced internal communication; 16- Higher employee well-being.

Use of quality tools and methods in the third sector

Research revealed some quality tools that have a higher adherence in TSOs. Among those listed, the tool with the greatest presence in the organisation's routine is Brainstorming, with an average of 1.94 (the scale used is from 1 - always used; 5 - never used). The other most used tools were: Flowcharts and process mapping (2.25), Cause and Effect Diagram (2.80), and 5 Whys (2.84). The least used are: Lean Six Sigma tools; SIPOC; Voice of Customer; and DMAIC.

Notably, among the listed tools observed in the literature, few are intensively used. Only 5 out of 17 tools had averages below 3 (occasional use). Furthermore, as seen in Graph 2, only 35.4% of the responses provided were related to frequent or higher usage of these tools.

Graph 2 – Frequency of use of quality tools



Source: Authors

Index: 1- DMAIC Cycle (Define, Measure, Analyze, Improve and Control); 2- PDCA Cycle (Plan, Do, Check, Action); 3- 5S; 4- Kaizen (Continuous Improvement); 5- Visual Management; 6- Lean Six Sigma tools; 7- Pareto; 8- Voice of Customer; 9- SIPOC; 10- 5 whys; 11- Value Stream Map; 12- Kanban; 13- Brainstorming; 14- Go to Gemba (Go to the place to see what is happening); 15- Cause and Effect Diagram; 16- QFD (Quality Function Deployment); 17- Flowcharts and process mappings.

Analysis between groups for adoption of TQM practices

To assess whether there were differences in the adoption level of TQM practices identified in the literature, the Mann-Whitney test was conducted considering the number of employees (Group 1 - up to 150 employees vs. Group 2 - more than 150 employees); the hierarchical level of the organization representative (Group 1 - operational; Group 2 - leadership); and the duration of the TSO's activity in society (Group 1 - up to 25 years vs. Group 2 - more than 25 years). It was found that the number of employees, the hierarchical level of the organization representative, and the duration of the TSO's activity in society do not affect the adoption level of TQM practices in the investigated sample.

The Kruskal-Wallis test revealed that only statement 49 showed differences in the median adoption level compared to each NGO's area of operation. Detailed results are presented in Table 2 and Figure 1. Consequently, the areas of operation do not interfere with the perception of TQM practice adoption.

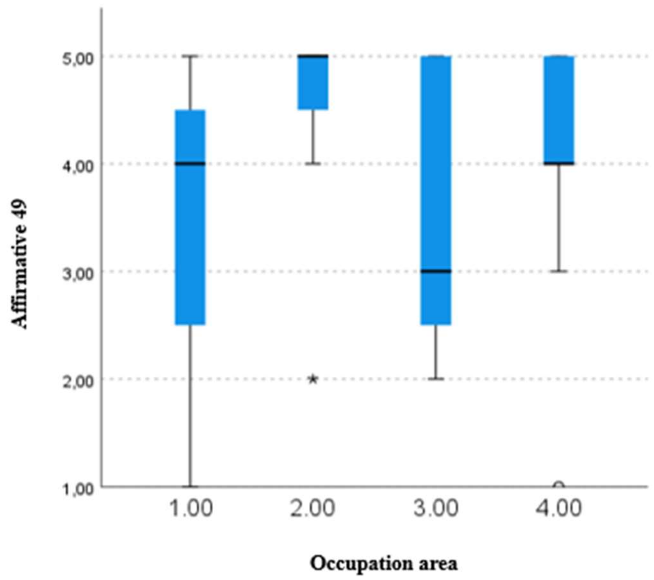
Table 2 - Kruskal-Wallis test for differences in relation to area of activity

#	Affirmation	Average	Median	Sig. Exata	Decision
49	The organization has formal decision-making structures, leading to the professionalization of non-profit organizations.	4,0588	4,00	0,046	Reject the null hypothesis

Source: Authors

From the analysis of Figure 3, it can be observed that Group 2, composed of education and professional qualifications (Table 1), presented the highest median compared to the other groups. Therefore, organizations operating in the areas of Group 2 have formal decision-making structures, leading to the professionalization of NGOs.

Figure 3 - Results of the comparison of groups of areas of activity regarding the statement of structure for formal decision making



Source: Authors

Cross-Group Analysis for TQM Adoption Outcomes

To verify if there were differences in the perception of results resulting from the implementation of TQM, the Mann-Whitney test was conducted considering the number of employees, the hierarchical level of the respondent, and the length of time the TSO has been active in society. It was found that the number of employees, the hierarchical level of the organization's representative, and the length of time the TSO has been active do not affect the results of adopting TQM in the investigated sample.

The Kruskal-Wallis test comparing the responses of groups from different areas of activity of the TSOs also did not show significant differences, as all p-values were greater than the significance level of 0.05, thus the null hypotheses were accepted.

Therefore, it is evident that the perceived results resulting from the implementation of TQM practices are not affected by the investigated variables.

Analysis between groups for the level of utilization of TQM tools and methods

To verify if there were differences in the perception of results resulting from the implementation of TQM, the Mann-Whitney test was performed considering the number of employees, the hierarchical level of the respondent, and the length of time the OTS has been in existence. No statistically significant differences were identified considering the groups for the number of employees; thus, the number of employees does not influence the utilization of quality tools. The same occurred with the years of operation of each OTS; no differences were identified between the groups.

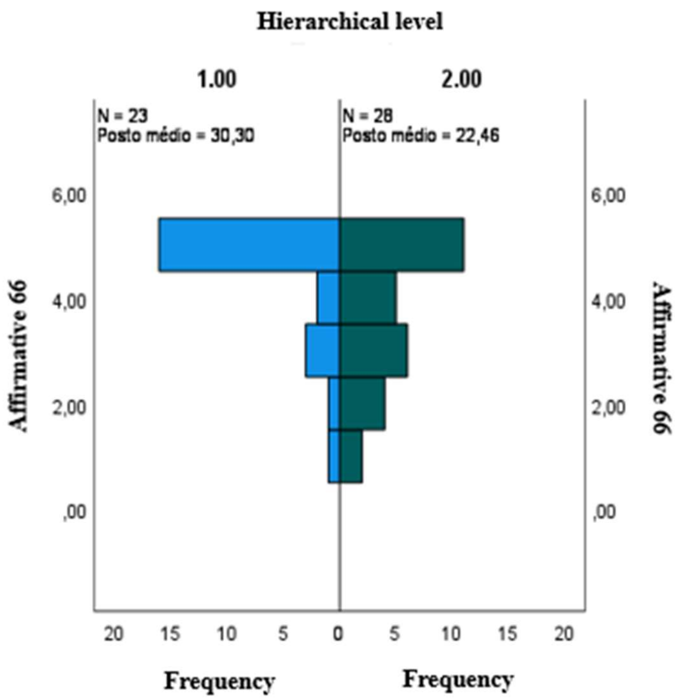
Regarding the hierarchical level of the respondent, only Affirmative 66 - DMAIC Cycle (Define, Measure, Analyze, Improve and Control), indicates differences between the groups, with a p-value of 0.041, as shown in Table 3.

Table 3 - Mann Whitney test results for groups of the respondent's hierarchical level

Code of affirmation	Affirmation	Average	Median	U de *Mann-Whitney*	Sig. Exata	Decision
66	Cicle DMAIC (*Define, Measure, Analyze, Improve and Control*)	3,9804	5,0	223,0	0,041	Reject the null hypothesis

Source: Authors

Graph 4 - Comparison of the use of the DMAIC cycle with the hierarchical level



Source: Authors

Figure 4 presents the comparison between the two groups that were coded, with group code 1 composed of analysts and coordinators and group code 2 composed of managers, directors, and presidents. Therefore, it is noted that the organizations indicating a higher use of the DMAIC method are those represented by individuals from Group 1 (analysts and coordinators). This may have occurred because operational levels may demonstrate a greater use of DMAIC and its logic in the organizations' daily activities, while leaders do not directly witness such usage.

The Kruskal-Wallis test was used to identify differences in at least one coded Area of Operation group in the present study. The results are presented in Table 4.

Table 4 - Kruskal-Wallis Test Results of the Degree of Utilization of Quality Tools and Methods by Area of Operation

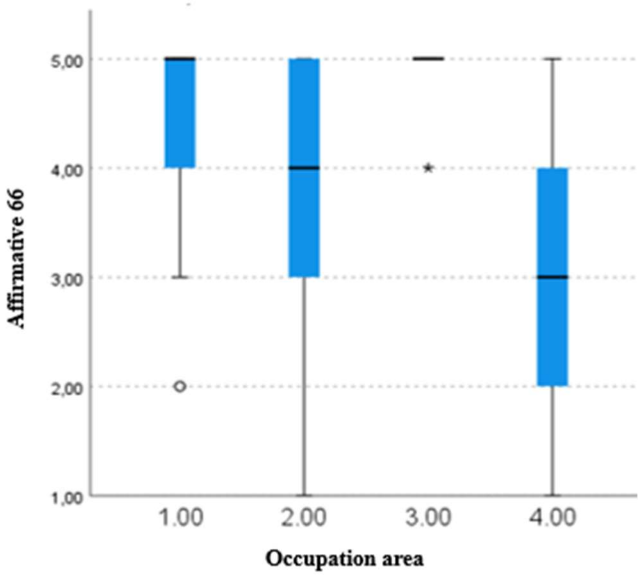
#	Affirmative	Average	Median	Sig. Exata	Decision
66	Cicle DMAIC (*Define, Measure, Analyze, Improve and Control*)	3,9804	5	0,017	Reject the null hypothesis
70	Visual Management	2,9608	3	0,041	Reject the null hypothesis
71	Tools Lean Six Sigma	4,3333	5	0,039	Reject the null hypothesis
72	Pareto	3,9216	5	0,006	Reject the null hypothesis
73	Voice of Customer	4,1176	5	0,002	Reject the null hypothesis
78	*Brainstorming*	1,9412	1	0,044	Reject the null hypothesis
79	Gemba	2,9216	3	0,041	Reject the null hypothesis
81	QFD (Quality Function Deployment)	3,9608	5	0,017	Reject the null hypothesis

Source: Authors

The Kruskal-Wallis test rejects the null hypothesis for statements 66, 70, 71, 72, 73, 78, 79, and 81, confirming that there is an effect of the area of operation on the utilization of Kaizen, Visual Management, Lean Six Sigma Tools, Pareto, Voice of Customer, Brainstorming, Gemba Walk, and QFD.

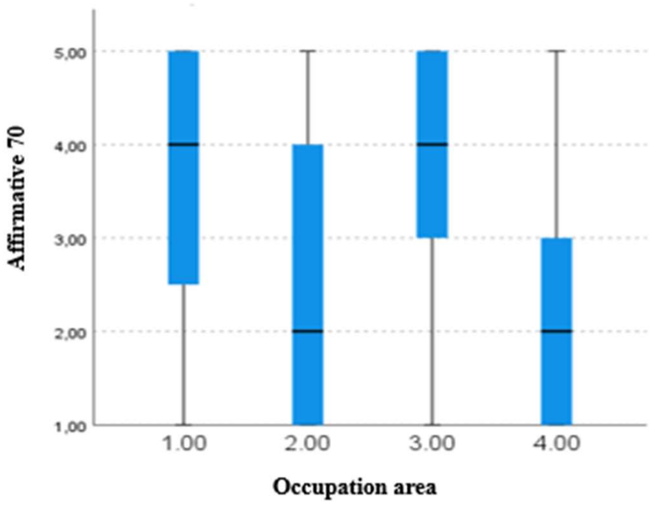
Figures 5 to 12 compare the groups for each tool or method, allowing for the interpretation of results based on the observation of the plots.

Graph 5 - Comparison results of the DMAIC tool and areas of activity



Source: Authors

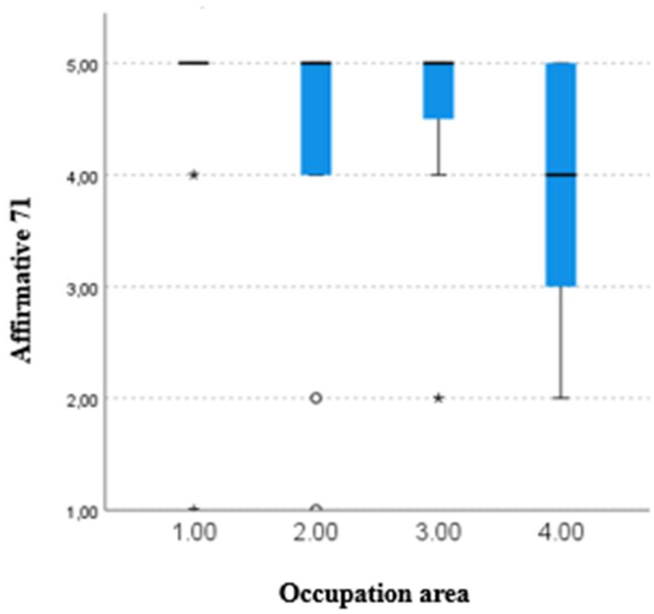
Graph 6 - Comparison results of the Visual Management tool and areas of activity



Source: Authors

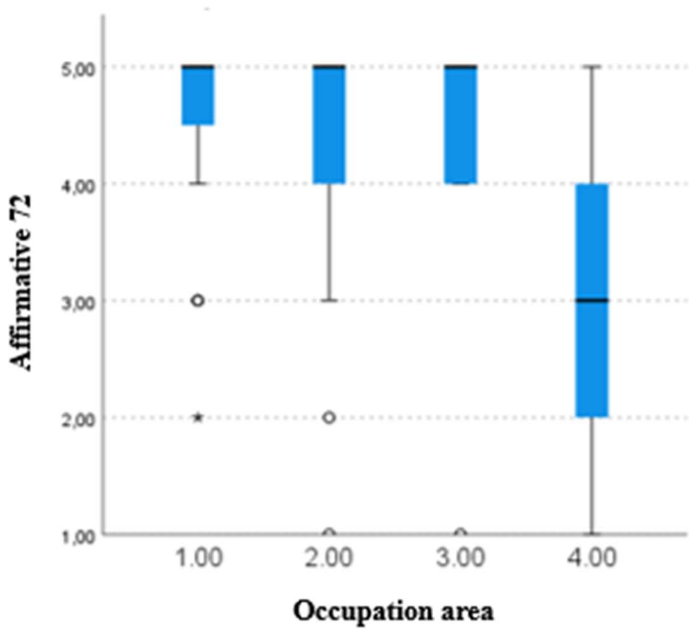
Graphs 5 and 6 show that Group 1, which includes social assistance, health, and culture, and Group 3, which includes human rights, administrative, public, and environmental management, use the DMAIC method and the Visual Management tool less, while groups 2 and 4 had the lowest medians, that is, the highest levels of use.

Graph 7 - Comparison results of Lean Six Sigma Tools and areas of activity



Source: Authors

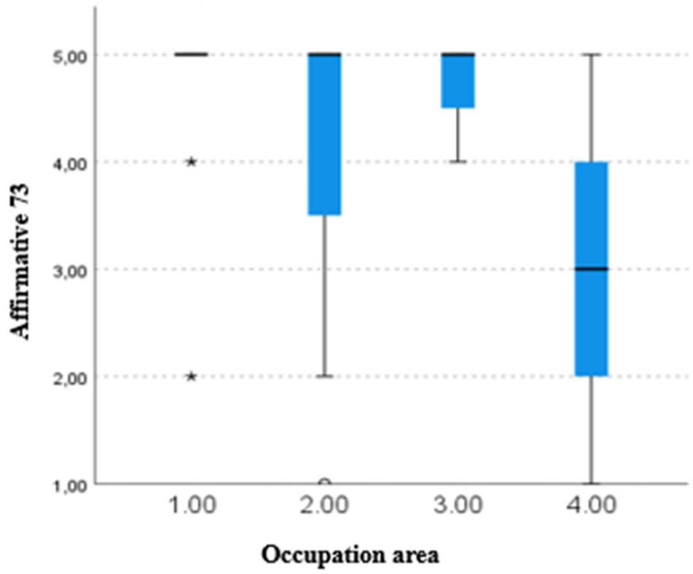
Graph 8 - Pareto comparison results with areas of activity



Source: Authors

Graphs 7, 8, and 9 show that groups 1, 2, and 3 (Table 5) have higher medians compared to group 4, meaning that organizations operating in the fields of social assistance, health, culture, education, professional qualification, human rights, and administrative areas, public management, and environmental management tend to use Lean Six Sigma and Pareto tools less frequently.

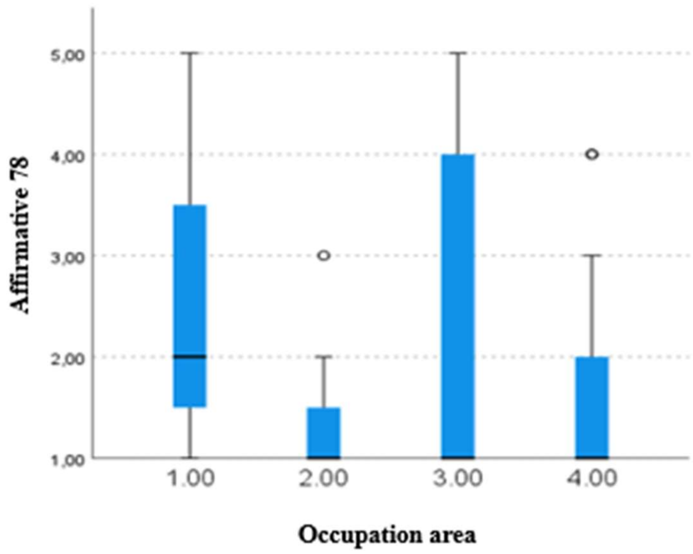
Graph 9 - Results of the comparison between Voice of Customer and areas of operation



Source: Authors

Graphs 7, 8, and 9 show that groups 1, 2, and 3 (Table 5) have higher medians compared to group 4, meaning that organizations operating in the fields of social assistance, health, culture, education, professional qualification, human rights, and administrative areas, public management, and environmental management tend to use Lean Six Sigma, Pareto, and Voice of Customer tools less frequently.

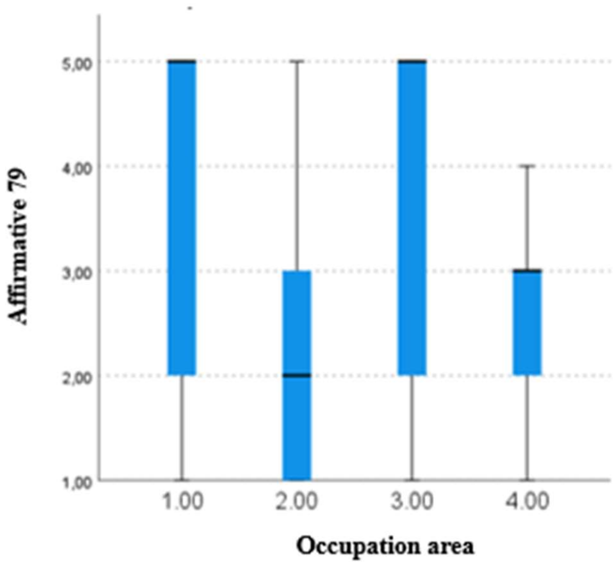
Graph 10 - Results of the comparison between Brainstorming and the areas of activity



Source: Authors

Organizations belonging to Groups 2, 3, and 4 tend (Figure 10) to always use Brainstorming as an improvement tool, with the majority of those in Group 2 (education and professional qualification) stating they always use it. Organizations in the fields of social assistance, health, and culture use it frequently. Therefore, there is a difference in the level of utilization of the Brainstorming tool according to the organization's area of operation.

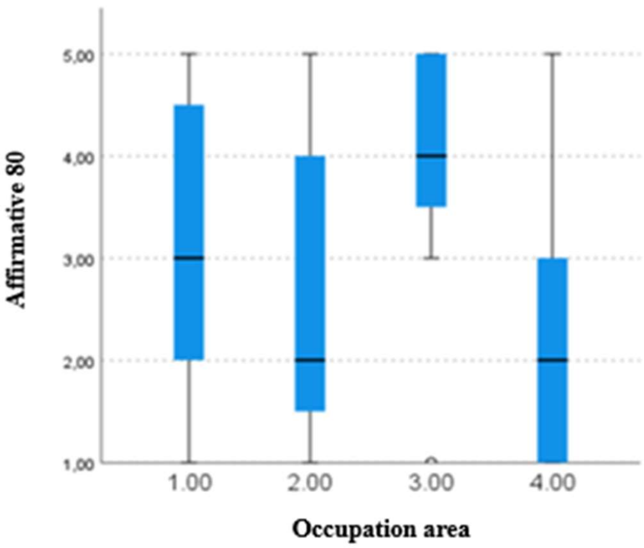
Graph 11 - Comparison results between the Go to Gemba tool (Go to the location to see what is happening) and the areas of activity



Source: Authors

Regarding the use of the Gemba Walk tool (Go to the place to see what's happening), it is observed that the areas of operation of Group 2, education and professional qualification, use it frequently, while the areas belonging to Groups 1 and 3 tend to never use this tool.

Graph 12 - Results of the comparison between QFD and the areas of activity



Source: Authors

Graph 12 indicates that organizations operating in the areas of human rights, administrative, public management, and environmental tend to never use the QFD tool, while those operating in the areas of social assistance, health, and culture use it occasionally, and those from groups 2 and 4 use it frequently.

CONCLUSIONS

The study aimed to identify the level of adoption of practices, tools, and benefits resulting from NGOs' implementation of TQM. The results demonstrated that NGOs have been using TQM practices, particularly those related to top management commitment and leadership, which are two key practices for the adoption and sustainability of Quality programs such as TQM. The results also showed a perception of benefits resulting from operational practices, such as increased service quality, user satisfaction, productivity, greater team involvement, user focus, and process standardization. The most used tools are brainstorming and process flowcharting/mapping, highlighting the importance of planning and quality improvement tools.

The study also revealed that variables such as number of employees, area of operation, length of service to society, and hierarchical level of the respondent had little to no effect on the perception of the level of adoption of practices and results. However, there were differences between groups when analyzing the use of tools and the areas of operation of the organization. Differences were observed among areas of operation regarding the use of various tools and methods, such as DMAIC, Brainstorming, and Visual Management, among others. Therefore, the result suggests that depending on the NGO's area, one tool may be more suitable than another.

The study has limitations, such as a small sample size and a non-longitudinal design. Adopting longitudinal studies over the years could provide a better understanding of how these practices have been adopted and the real challenges faced by this type of organization. Furthermore, future research propositions such as case studies for a more detailed examination of how results have been achieved, and practices implemented are important avenues for understanding the role of quality programs in this sector.

APPENDICES

Appendix I

TQM							
Principle of TQM	**Author**	**#**	**Practice**	**Score**	**Average**	**Medina**	**Moda**
Top Management Commitment	Fredriksson (2004), Kearns, Krasman e Meyer (1994); Jenavesan et al. (2019)	1	In the organization, there is continuous support and commitment from top management for quality improvement and processes	4,34	4,43	5	5
	Jenavesan et al. (2019); Parris (2013)	2	Top management participates in continuous improvement training		4,1	4	5
	Mahmoud et al. (2019)	3	The top management supports actions aimed at improving service to beneficiaries		4,49	5	5
	Jenavesan et al. (2019)	4	The top management ensures effective communication at all levels of the organization		3,96	4	5
	Sweis et al. (2016) e Mahmoud et al. (2019); Jenavesan et al. (2019)	5	The quality of beneficiary service is clearly identified in the organization's mission and vision		4,57	5	5
	Sweis et al. (2016) e Mahmoud et al. (2019)	6	The responsibility towards beneficiaries, donors, and other stakeholders is well reflected in the organization's mission and vision		4,45	5	5
	Sweis et al. (2016); Parris (2013)	7	There is a written, approved, committed, and extensively communicated accountability structure		4,39	5	5
Leadership	Jenavesan et al. (2019)	8	Leadership gives team members responsibility for their own work	4,17	4,41	5	5
	Jenavesan et al. (2019)	9	The organization employs a leadership style focused on training and creating an environment open to constructive feedback		4	4	5
	Jenavesan et al. (2019)	10	The organization recognizes the importance of reporting the results of continuous improvement and celebrating any achievements during the initiative, which will significantly enhance team motivation and morale		4,1	5	5

Beneficiaries' Focus and Satisfaction	Kearns, Krasman e Meyer (1994)	11	There is a focus on actions towards beneficiaries' satisfaction	4,07	4,41	5	5
	Kearns, Krasman e Meyer (1994); Sweis et al. (2016) e Mahmoud et al. (2019); Melão, Guia e Amrim (2017)	12	Tools for feedback and identifying beneficiary satisfaction are used (e.g., surveys, monitoring complaints, and other forms of feedback, as well as focus group methodologies)		4,1	4	5
	Sweis et al. (2016) e Mahmoud et al. (2019)	13	The organization conducts valid, regular, and accurate assessments of beneficiary needs		3,82	4	5
	Sweis et al. (2016) e Mahmoud et al. (2019); Parris (2013)	14	Beneficiaries are involved in the organization's decision-making process		3,47	4	4
	Sweis et al. (2016) e Mahmoud et al. (2019)	15	The organization shares information with the beneficiaries		4,12	4	5
	Sweis et al. (2016) e Mahmoud et al. (2019); Parris (2013)	16	The beneficiaries are treated with honesty and clarity		4,51	5	5
Focus on Human Resources	Kearns, Krasman e Meyer (1994); Fredriksson (2004)	17	In the organization, there is training in quality management methods and techniques for leaders and group members	3,94	3,78	4	5
	Sweis et al. (2016) e Mahmoud et al. (2019)	18	Teams are trained in quality, its methods, and tools		3,92	4	5
	Sweis et al. (2016) e Mahmoud et al. (2019)	19	There is continuous learning and guidance		4,08	4	5
	Sweis et al. (2016) e Mahmoud et al. (2019)	20	There is a code of conduct regarding quality in place within the organization		3,84	4	5
	Sweis et al. (2016) e Mahmoud et al. (2019); Jenavesan et al. (2019)	21	In the organization, the importance of employee participation in improvement teams is extremely important and encouraged		4,08	5	5
Partnership Management for Sustainability	Sweis et al. (2016) e Mahmoud et al. (2019)	22	For the organization, quality is a priority when selecting partners	3,95	4,06	4	5
	Sweis et al. (2016) e Mahmoud et al. (2019)	23	In the organization I work for, quality standards and responsibilities are clearly communicated to stakeholders		3,88	4	4
	Sweis et al. (2016) e Mahmoud et al. (2019)	24	The organization is concerned with training the partner's employees in terms of quality standards		3,59	4	4
	Sweis et al. (2016) e Mahmoud et al. (2019); Parris (2013)	25	The organization establishes long-term partnerships with implementation partners		4,16	4	5
	Jenavesan et al. (2019); Fredriksson (2004)	26	The company motivates and involves different stakeholders in its actions		4,08	4	5

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Process Management	Sweis et al. (2016) e Mahmoud et al. (2019); Parris (2013)	27	Standard Operating Procedures (SOPs) are well-documented, approved, communicated, and agreed upon	3,8	3,47	4	4
	Sweis et al. (2016) e Mahmoud et al. (2019)	28	The organization conducts regular internal reviews and audits to identify non-conformities and issues in the quality management system		3,92	4	5
	Sweis et al. (2016) e Mahmoud et al. (2019)	29	The organization shares monitoring and evaluation results with stakeholders		4,04	4	5
	Sweis et al. (2016) e Mahmoud et al. (2019)	30	In the organization, there are channels for transmitting improvement suggestions from the team		3,76	4	5

Measurement and use of quality information	Sweis et al. (2016) e Mahmoud et al. (2019)	31	The use of information is carried out promptly and accurately by the organization	3,62	3,51	4	4
	Sweis et al. (2016) e Mahmoud et al. (2019); Fredriksson (2005)	32	The organization collects and updates relevant information about quality improvement actions		3,76	4	4
	Sweis et al. (2016) e Mahmoud et al. (2019); Parris (2013)	33	The organization collects, measures, and monitors data on process performance, outputs, and outcomes and takes appropriate actions		3,61	4	4
	Sweis et al. (2016) e Mahmoud et al. (2019)	34	The organization utilizes modern technologies for data collection and manipulation		3,55	4	4
	Kearns, Krasman e Meyer (1994); Parris (2013)	35	The organization uses indicators to verify improvements		3,96	4	5
	Kearns, Krasman e Meyer (1994)	36	The organization adopts some form of statistical analysis tool to verify if quality standards are being met (measures of central tendency and dispersion, and graphical displays such as histograms and control charts)		3,08	3	4
	Kearns, Krasman e Meyer (1994)	37	The organization conducts benchmarking		3,88	4	5

Continuous improviment	Kearns, Krasman e Meyer (1994)	38	All individuals are involved in problem detection and resolution	3,52	3,43	4	4
	Kearns, Krasman e Meyer (1994); Fredriksson (2004)	39	The organization uses tools (e.g., process mapping, Pareto analysis) for process improvement		3,31	3	5
	Sweis et al. (2016) e Mahmoud et al. (2019); Fredriksson (2004)	40	In the organization, one of the key aspects is promoting continuous improvement		3,88	4	5
	Kearns, Krasman e Meyer (1994)	41	Teams are used to identify potential improvements and improvement projects		3,55	4	5
	Kearns, Krasman e Meyer (1994)	42	Employees have autonomy to make suggestions and implement changes		3,96	4	5
	Fredriksson (2005); Parris (2013)	43	Improvement activities are documented to generate learning		3,27	3	4
	Parris (2013)	44	The company has teams or responsible parties to make problems visible, investigate, and address their causes		3,2	3	4

Culture	Sweis et al. (2016) e Mahmoud et al. (2019)	45	In the organization, providing quality services is an integral part of the organizational culture	4,06	4,27	5	5
	Jenavesan et al. (2019)	46	The organization is engaged in and empowers the team to create a culture of positive change and multifunctional teams		3,84	4	5
	Jenavesan et al. (2019)	47	The organization has formal decision-making structures, leading to the professionalization of non-profit organizations		4,06	4	5

Appendix II

Results	Authors	#	Benefits	Score	Average	Medina	Moda
Operational results	Jenavesan et al. (2019)	1	Better resource management	4,1	4,12	4	4
	Jenavesan et al. (2019); Melão, Guia and Amorin (2017)	2	Increased beneficiary satisfaction		4,14	4	4
	Jenavesan et al. (2019)	3	Cost reduction		3,94	4	4
	Jenavesan et al. (2019)	4	Improved service quality		4,18	5	5
	Jenavesan et al. (2019); Kearns wet al. (1994)	5	Increased productivity		4,14	4	5
Internal results	Melão, Guia and Amorin (2017)	6	Increased stakeholder engagement	4,12	4,14	4	4
	Melão, Guia and Amorin (2017)	7	Enhanced user focus		4,25	4	5
	Melão, Guia and Amorin (2017)	8	Increased process standardization		4,18	4	5
	Jenavesan et al. (2019)	9	Greater team involvement		4,33	5	5
	Melão, Guia and Amorin (2017)	10	Improved internal organization and establishment of responsibilities		4,12	4	5
	Melão, Guia and Amorin (2017)	11	Increased employee motivation		4,06	4	5
	Melão, Guia and Amorin (2017); Kearns et al. (1994)	12	Increased number of continuous improvement actions		3,98	4	5
	Melão, Guia and Amorin (2017)	13	Easier identification and analysis of service failures		3,98	4	4
	Jenavesan et al. (2019); Kearns et al. (1994)	14	Improvement in team training		4,08	4	4
	Jenavesan et al. (2019); Melão, Guia and Amorin (2017)	15	Enhanced internal communication		4,06	4	4
	Jenavesan et al. (2019)	16	Higher level of employee well-being		4,16	4	5

Appendix III

Category	Authors	Code	Tools	Score	Average	Medina	Moda
Tools	Jenavesan et al. (2019); Jenavesan et al. (2019)	1	Cicle DMAIC (Define, Measure, Analyze, Improve and Control)	3,37	3,98	5	5
	Fredriksson (2003, 2005a e 2005b)	2	Cicle PDCA (Plan, Do, Check, Action)		3,1	3	5
	Jenavesan et al. (2019); Cheng and Chang (2012)	3	5S		3,43	3	5
	Jenavesan et al. (2019); Parris (2013)	4	Kaizen		3,65	4	5
	Jenavesan et al. (2019)	5	Visual Management		2,96	3	1
	Jenavesan et al. (2019)	6	Tools of Lean Six Sigma		4,33	5	5
	Jenavesan et al. (2019)	7	Pareto		3,92	5	5
	Cheng and Chang (2012)	8	Voice of Customer		4,12	5	5
	Cheng and Chang (2012)	9	SIPOC		4,2	5	5
	Cheng and Chang (2012)	10	5 Whys		2,84	2	1
	Chen and Cheng (2018)	11	Value Stream Mapping		3,47	4	5
	Chen and Cheng (2018)	12	Kanban		3,47	4	5
	Fredriksson (2005 - 23)	13	Brainstorming		1,94	1	1
	Parris (2013)	14	Gemba		2,92	3	5
	Frolova and Lapina (2015)	15	Cause and Effect Diagram		2,8	2	1
	Frolova and Lapina (2015)	16	QFD (Quality Function Deployment)		3,96	5	5
	Frolova and Lapina (2015)	17	Flowcharts and Process Mapping		2,25	2	1

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Steel Improvement: Ecuador Building Case

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STRUCTURED ABSTRACT

In earthquake-prone regions like Ecuador, where the Pacific Ring of Fire exposes structures to significant seismic activity, ensuring earthquake-resistant building design is crucial. This study delves into the potential for optimizing the weight of non-structural elements in buildings. Using building design software, a 6-story case study building was modeled with variations in architectural design and commonly available masonry materials. The results reveal that strategic material selection and design modifications can significantly reduce building weight (18.21%) while adhering to Ecuadorian Building Code (NEC) seismic performance requirements. This research quantifies the substantial weight reduction achievable through strategic design and material selection, offering a pathway towards more sustainable and cost-effective construction practices in earthquake-prone regions of Ecuador.

Keywords: Seismic Design, Weight Optimization, Architectural Distribution, Sustainable Construction

INTRODUCTION

Developing nations like Ecuador face a pressing challenge: reconciling rapid infrastructure development with a growing commitment to environmental sustainability. This is particularly critical in earthquake-prone regions like Ecuador, where building safety remains paramount (Suarez, 2003).

Traditional construction methods often rely on materials like steel, which offer excellent seismic performance. However, steel production comes with a significant environmental cost due to high CO2 emissions (Jones, 2014). Fortunately, Ecuador possesses a well-established steel industry with numerous producers and exporters of steel profiles and rods. To assess the economic viability of using steel in this research, a comprehensive market investigation was conducted. This investigation involved in-depth interviews and analysis of key players within the steel industry, focusing on three critical aspects: cost, quality, and safety. The resulting data on standard steel prices per kilogram will be crucial for our later analysis. It will allow us to evaluate the cost implications of using steel in weight-optimized construction methods compared to alternative materials. By comparing these costs, we can determine if achieving weight reduction justifies any potential increase in construction expenses. This analysis is essential for finding a balance between structural safety, environmental impact, and economic viability in earthquake-prone regions like Ecuador.

Ecuadorian Building Code (NEC) outlines strict seismic design practices for structures, prioritizing earthquake resistance (Mite-Anastacio *et al.*, 2022). Confined masonry (CM) is a prevalent construction method in Ecuador due to its cost-effectiveness and speed of construction (Cevallos *et al.*, 2017). This research focuses on optimizing weight in non-structural elements of formally constructed CM buildings using readily available materials like bricks and concrete blocks (Macias *et al.*, 2017; Navas, Caiza and Toulkeridis, no date).

Understanding the seismic response of existing structures is critical for ensuring their safety during earthquakes. Stiffness and mass are well-established as key factors in seismic design (Tulebekova *et al.*, 2022). However, a trade-off often exists between building weight and functionality. This research explores the potential of weight optimization in non-structural elements of buildings constructed with readily available masonry materials like bricks and concrete blocks. The goal is to strike a balance: reducing building weight for potential efficiency gains while maintaining the seismic performance of structures. By investigating the interaction between architectural design and material selection, this research explores the possibility of optimizing weight in buildings while minimizing or eliminating any negative impact on the seismic performance of structures.

This research ultimately seeks to develop design guidelines that promote weight-efficient construction practices for low-rise residential buildings in Quito, Ecuador. These guidelines, considering weight reduction strategies (Stasiak-Betlejewska and Potkány, 2015), in such a way, can contribute to safer, more resource-efficient, and sustainable buildings in earthquake-prone regions.

RESEARCH METODOLOGHY

This research delves into the intricate interplay between material selection, architectural design choices, and weight optimization strategies. The primary objective is to identify effective methods for enhancing the seismic performance of civil structures. To achieve this, a case study approach will be employed, focusing on a representative five-story apartment building typology commonly encountered in Quito, Ecuador.

The chosen case study building is a five-story structure with each floor measuring a standard height of 2.88 meters. To achieve a nuanced understanding of the building's response to seismic activity, this research will focus on a single, complete apartment unit within the building. First, the analysis will identify the specific building materials used throughout the unit's construction. Second, the research will explore the architectural design choices implemented within the apartment, including both weight-bearing elements and potential layout features that could influence the building's seismic response.

To comprehensively evaluate the interplay between material selection, seismic performance, and cost-effectiveness, this research will employ two case studies. The first case study will analyze a normal architecture building design constructed with six different masonry materials: load-bearing blocks, lightweight blocks, and mambron bricks of varying thicknesses. This allows for a direct comparison of how material properties influence structural performance. The second case study will utilize the same six masonry materials but will be implemented within a weight reduced architectural design.

To evaluate the impact of material selection and architectural design on weight, and seismic performance, two design versions will be created and analyzed for each chosen building type:

1. Original Architecture: This version will represent standard construction practices in Quito, utilizing the locally available and regulation-approved masonry materials. This will establish the Original Architecture construction method for comparison with the Weight Reduced version. Structural analysis software ETABS will be used to model the Original Architecture

version and determine its weight and key seismic performance parameters, such as loads, story drift, and basal shear.

2. Weight Reduced Version: This version aims to achieve a 30% reduction in wall volume compared to the Original Architecture version. This reduction will be achieved through a collaborative design process involving an architect and engineer.

In Quito, Ecuador, ensuring the safety of buildings during earthquakes is a growing concern, but so is maintaining affordability in construction. This research tackles this challenge by exploring innovative yet practical design solutions. While prioritizing the use of approved and readily available materials, the project delves into unconventional approaches that unlock the full potential of these materials. Examples include optimizing floor layouts for weight distribution and potentially integrating lightweight. Additionally, the research will explore architectural modifications that reduce weight, such as strategically placed openings or minimizing non-structural elements.

This research analyzes the interconnected relationship between material selection and architectural design to identify strategies for optimizing the seismic performance of low-rise residential buildings in Quito, Ecuador.

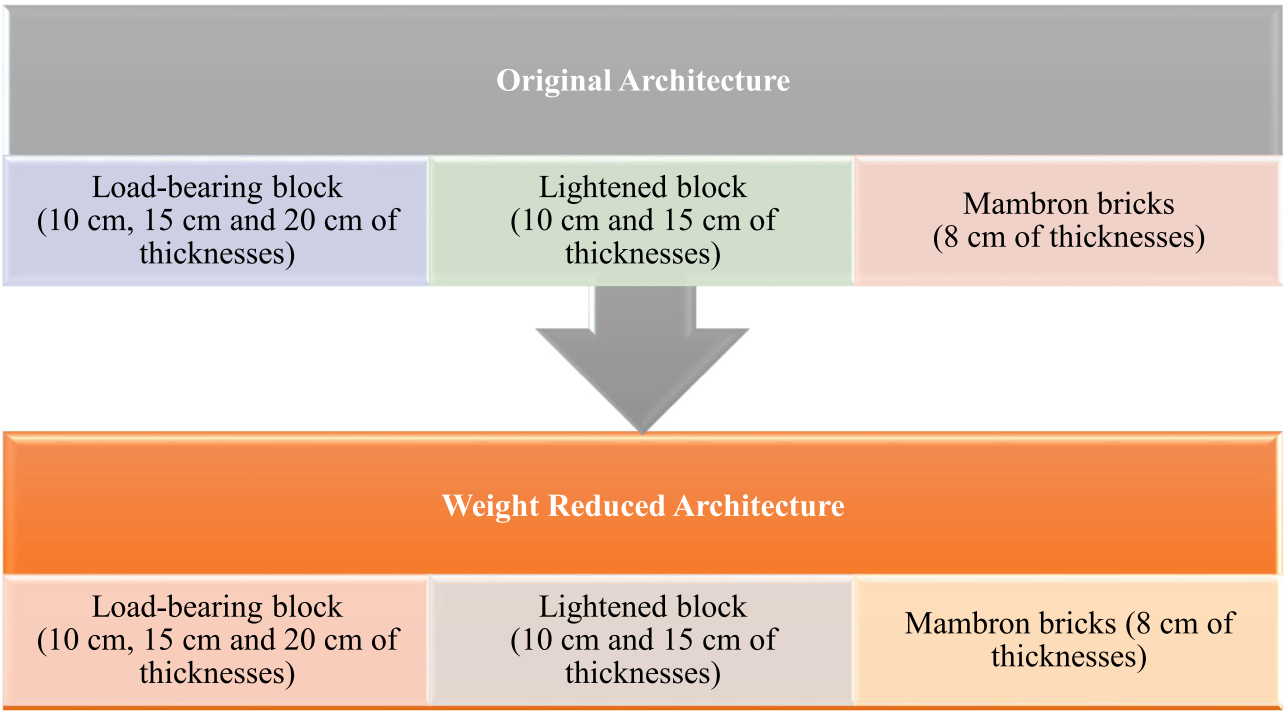

Figure 1 – Comparison of Masonry Materials in Original and Weight-Reduced Designs

This study proposes a multivariate analysis to assess the interplay between design options and their corresponding structural performance under seismic events prevalent in Quito. This combined evaluation has the potential to unveil critical insights that can be leveraged to optimize building design strategies within the seismic context of the city.

To facilitate a rigorous comparison between the Original Architecture design and the Weight Reduced Architecture version, this investigation will leverage ETABS structural analysis software. ETABS will be employed to generate a precise model of the Weight Reduced design, enabling the quantification of its weight and seismic performance characteristics. The data extracted from ETABS, encompassing critical metrics such as weight and inter-story drift, will then undergo further in-depth analysis and visualization using software like MATLAB. This may involve the development of comprehensive graphs to visually elucidate the variations in building drift across different floor levels for both design iterations.

To comprehensively evaluate the economic feasibility of weight-optimized construction alongside its seismic benefits, this research incorporates a cost analysis focusing on material prices. During the case study analysis, we will identify the specific masonry materials used in both the original and weight-reduced designs. Following this identification, we will gather data on the cost per kilogram of each material from the six different masonry producers interviewed in Quito. This data will be compiled into a table or chart for easy comparison, potentially integrated within "Figure 1: Comparison of Masonry Materials in Original and Weight-Reduced Designs." By comparing the weight of the original and weight-reduced designs obtained from ETABS software with the cost per kilogram of each material, we can estimate the overall difference in material costs between the two construction approaches. This information will be presented and discussed in the results section, highlighting the potential cost implications of weight optimization for construction projects in Quito. The cost analysis, detailed earlier in this methodology section, will be used to assess the economic feasibility of the weight-reduced design alongside its seismic benefits.

RESULTS

Structural analysis of the normal architecture design and weight-reduced versions for the building typology was performed using ETABS software. The material properties for each type of masonry unit were assigned according to the relevant standards. The geometry of the building, including wall thicknesses, was accurately reflected in the models.

The seismic loads were applied according to the Ecuadorian construction standard for Quito. The equivalent static load method was used, considering a specific design response spectrum for the Quito seismic zone. Figure 1 shows the construction model subjected to seismic load distribution.

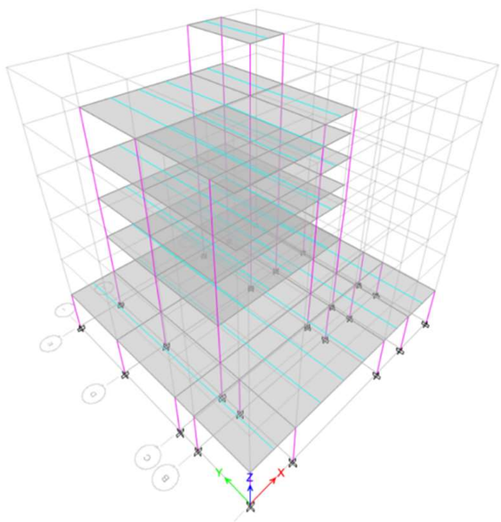

Figure 2 – 3D Model of the Building Structure

The unit weight of each masonry material used in the study was obtained from a repository of different masonry materials collected in Ecuador maintained by (Espinosa and Vargas, 2018). The unit weight represents the weight per unit volume of the masonry unit and was directly obtained from the repository data. Table 1 specifies the unit weight values for each material and thickness of masonry to be used during this analysis.

Table 1 – Properties of Masonry Units: Dimensions and Unit Weight

Type of masonry	Thicknesses (cm)	Weight (kg)	Unit Weight (kg/m^3)
Load-bearing block	10	8.44	1068.52
Load-bearing block	15	10.94	917.39
Load-bearing block	20	14.12	901.60
Lightened block	10	4.65	783.18
Lightened block	15	6.30	655.23
Mambron bricks	8	6.23	1481.66

The unit weight information was used to calculate the dead load per unit volume of masonry acting on each building component within the ETABS models. This involved multiplying the unit weight of each material by the corresponding volume of the masonry component in the model. The volume of each component was determined based on the building geometry information incorporated into the ETABS models.

Additional dead load components were incorporated to account for the self-weight of finishes, false ceilings, building installations, floor tiles, and the steel deck. Standard industry values were used to determine the weight of these components. Table 2 presents the calculated dead loads acting on different building components for the specific building typology being analyzed. Separate columns are dedicated to the normal architecture and weight-reduced versions, allowing for easy comparison of dead load distribution between the designs. The total dead load for each version is also provided.

Table 2 – Comparison of Dead Loads for Normal Architecture and Weight-Reduced Designs

Type of masonry	**Thicknesses (cm)**	**Dead loads for Normal Architecture version (kg/m^2)**	**Dead loads for Weight Reduced version (kg/m^2)**
Load-bearing block	10	310.10	251.60
Load-bearing block	15	366.30	290.90
Load-bearing block	20	444.10	345.40
Lightened block	10	258.00	215.10
Lightened block	15	294.50	240.60
Mambron bricks	8	332.90	267.50

To achieve an optimal steel design, the study explored W-shaped profiles (W sections) for both beams and joists. Different profile sizes were analyzed to identify the most efficient solution in terms of material usage. The analysis considered variations in joist sections from W8x13 to W12x14 and beam sections from W14x48 to W14x82. These variations directly impact weight calculations due to the differing amounts of steel in each profile.

Table 3 – Selected Steel Profiles for Beams by Masonry Configuration

Type of masonry	**Thicknesses (cm)**	**Steel profile for normal architecture version**	**Steel profile for weight-reduced version**
Load-bearing block	10	W14x68	W14x53
Load-bearing block	15	W14x68	W14x68
Load-bearing block	20	W14x74	W14x68
Lightened block	10	W14x53	W14x48
Lightened block	15	W14x68	W14x53
Mambron bricks	8	W14x68	W14x68

To minimize material usage while ensuring structural integrity, optimal steel beam profiles were identified for each dead load case and masonry variation. Table 3 summarizes the final beam selections for all 12 masonry configurations. Additionally, for a comprehensive overview of steel profile optimization, Table 4 presents the final joist profiles chosen for each dead load case and corresponding masonry configuration.

Table 4 – Optimized Steel Profiles for Joists by Masonry Configuration

Type of masonry	**Thicknesses (cm)**	**Steel profile for normal architecture version**	**Steel profile for weight-reduced version**
Load-bearing block	10	W10x15	W10x15
Load-bearing block	15	W8x13	W10x15
Load-bearing block	20	W10x12	W10x15
Lightened block	10	W10x12	W10x12
Lightened block	15	W10x15	W10x15
Mambron bricks	8	W10x15	W10x15

A detailed analysis of material weights was conducted for each of the 12 masonry configurations. This analysis considered the weight of various steel profiles used in beams (detailed in Table 3) and joists (detailed in Table 4). The weight of the columns was excluded as they were designed as constant-weight hollow sections with composite concrete and steel construction.

Later, meticulous attention was paid to examining the story drifts. Story drift values for each floor level were extracted from the ETABS models, considering the variations in dead load due to the specific type of masonry unit used in each design version. This analysis ensured that the story drifts remained within the allowable limits established by the NEC. The NEC specifies a maximum allowable story drift value based on the chosen reduction factor (R) and the calculated basal shear.

The drift behavior of the building structures was evaluated visually using graphs. These graphs plotted story height (Y-axis) against story drift values (X-axis). Separate graphs were created for both the normal and weight-reduced architectural designs. Each design variant had two corresponding graphs: one for X-axis drifts and another for Y-axis drifts. This visualization approach allows for a comprehensive understanding of the lateral deformations experienced by the buildings under seismic loads in both directions, considering all the applied masonry cases.

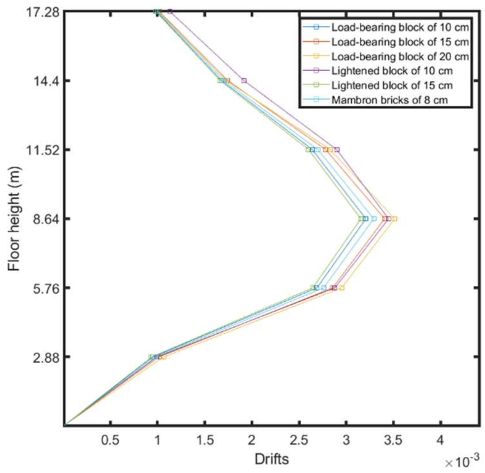

Figure 3 – Normal Architectural Designs: Story Drift vs. Floor Height (X-Axis)

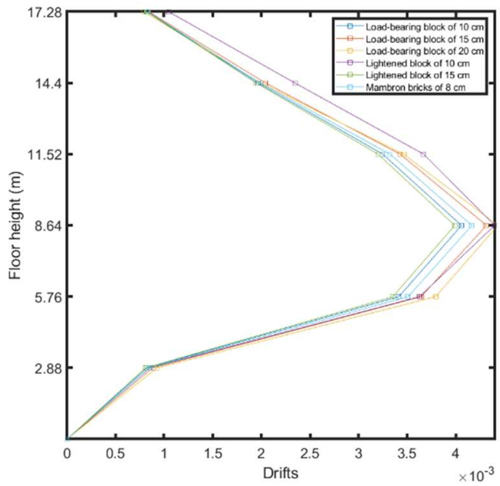

Figure 4 – Normal Architectural Designs: Story Drift vs. Floor Height (Y-Axis)

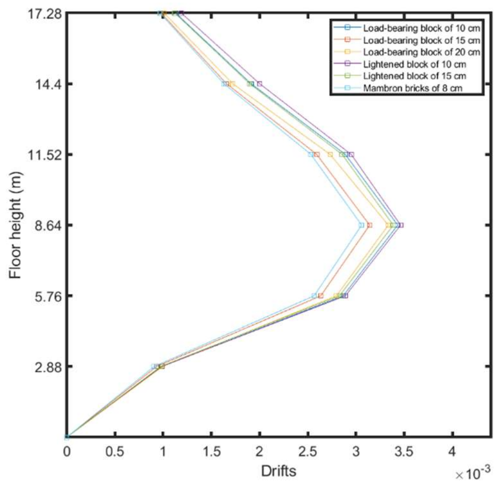

Figure 5 – Drift for Weight-Reduced version of the X axis

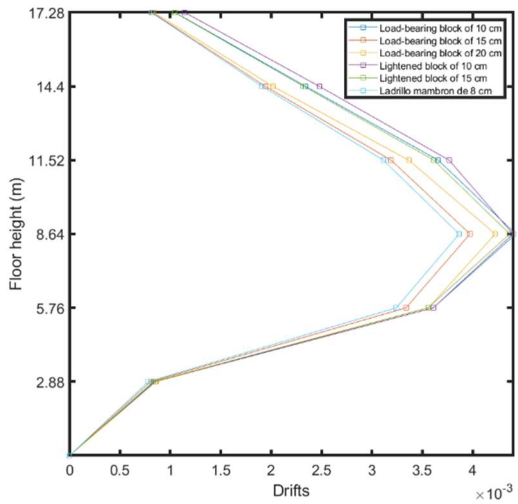

Figure 6 – Drift for Weight-Reduced version of the Y axis

The story drift analysis, presented in Figures 2, 3, 4, and 5, demonstrates satisfactory performance for both the normal architecture and weight-reduced versions of the building structures. None of the masonry configurations exceeded the maximum allowable story drift limit of 0.0044, as established by the Ecuadorian Building Code (NEC).

This finding indicates that both building versions possess adequate lateral stiffness under seismic loads to control deformations within acceptable limits in both the X-axis and Y-axis directions. The graphs also reveal a similar trend in the drift behavior along both axes, suggesting a well-balanced response of the structures to seismic excitation.

In addition to beams, joists, and columns, the analysis also incorporated the weight of building walls. By combining these weight components, the total weight of the building structure was determined for each dead load case and masonry configuration. Table 5 summarizes these total weights, allowing for a comprehensive comparison of weight efficiency between the normal architecture version and weight-reduced design versions across all the masonry variations.

Table 5 – Weight Comparison of Building Structures (Normal Architecture Version vs. Weight-Reduced)

Type of masonry	Thicknesses (cm)	Weight for Normal Architecture version (Ton)	Weight for Weight Reduced version (Ton)
Load-bearing block	10	139.80	130.85
Load-bearing block	15	140.15	139.80
Load-bearing block	20	143.96	140.15
Lightened block	10	129.62	126.45
Lightened block	15	140.15	130.85
Mambron bricks	8	140.15	139.80

Table 5 summarizes the total weight calculations for each masonry configuration and dead load case. Analyzing the baseline version data, we observe the maximum weight of 143.96 tons for the 20 cm thick load-bearing block. This aligns with expectations as this material type has the highest dead load due to its weight. Conversely, the minimum weight of 129.62 tons occurs with the 10 cm lightweight block, again demonstrating the material weight's influence on the overall building weight.

For the weight-reduced version exhibits a similar trend, with the maximum weight reaching 140.15 tons (20 cm load-bearing block) and the minimum being 126.45 tons (10 cm lightweight block). Importantly, the weight-reduced version consistently achieves lower weights compared to the baseline architecture. This translates to a significant reduction of 3.80 tons per structure, representing an 18.21% improvement in weight efficiency for the optimized design. These findings highlight the effectiveness of the optimization strategies employed.

Weight reduction in the optimized design translates to substantial economic benefits during construction. Material costs are a critical factor in overall budgets, and a lighter design offers significant savings. To quantify this advantage, a representative material cost per kilogram was established based on market research focusing on major Ecuadorean steel producers known for their high-quality materials ((Novacero, 2024): USD 1.45/kg, (AceroCenter, 2024): USD 1.39/kg, (Dipac, 2024): USD 1.42/kg). Considering this data, a conservative estimate of USD 1.42/kg was used for the cost analysis.

Table 6 – Economic Benefits of Weight Reduction: Potential Cost Savings by Masonry Type

Type of masonry	Cost for Normal Architecture version (USD)	Cost for Weight Reduced version (USD)	Potential Cost Saving (USD)
Load-bearing block	$198,516.0	$185,807.0	$12,709.0
Load-bearing block	$199,013.0	$198,516.0	$497.0
Load-bearing block	$204,423.2	$199,013.0	$5,410.2
Lightened block	$184,060.4	$179,559.0	$4,501.4
Lightened block	$199,013.0	$185,807.0	$13,206.0
Mambron bricks	$199,013.0	$198,516.0	$497.0

Table 6 reveals substantial cost savings achievable through weight reduction, ranging from $497.0 to $13,206.0 for most masonry configurations. This translates to a significant financial advantage for the optimized design. While slight cost increases occurred in specific configurations due to potential additional support elements, the overall results overwhelmingly highlight the economic benefits of weight reduction.

To quantify this advantage, a representative material cost per kilogram was established based on market research focusing on major Ecuadorean steel producers. Using a conservative estimate of USD 1.42/kg, Table 6 reveals potential cost savings of up to $13,206 achievable through weight reduction in various masonry configurations.

The results of this research provide valuable insights for stakeholders in Quito's construction industry. Architects and engineers can utilize these findings to develop practical design guidelines for cost-effective and seismically building practices. Future research can explore a wider range of building typologies and incorporate cost analysis to further optimize building design for weight reduction and seismic performance in earthquake-prone regions.

CONCLUSIONS

This research embarked on a comprehensive study into the potential for weight optimization in low-rise residential buildings in Quito, Ecuador, a seismically active region. Focusing on a representative five-story apartment building typology, the study analyzed the interplay between material selection, architectural design strategies, and weight reduction while ensuring compliance with structural requirements. The findings demonstrate that strategic material selection and design modifications can significantly reduce building weight without compromising seismic performance. This has the potential to improve construction efficiency and cost-effectiveness in Quito's seismic context.

The findings demonstrate that strategic material selection and design modifications can significantly reduce building weight 18.21% without compromising seismic performance according to the Ecuadorian Building Code (NEC). This has the potential to improve construction efficiency and cost-effectiveness in Quito's seismic context.

A cost analysis revealed potential cost savings ranging from \$497.0 to \$13,206.0 per building due to reduced material usage. These findings suggest that weight-efficient design can contribute to a more sustainable and resource-conscious building industry in earthquake-prone areas.

In conclusion, this research project offers a wealth of valuable insights that can be strategically harnessed to propel the development of sustainable and earthquake-resistant construction practices not only in Quito but also in countless other earthquake-prone regions around the world. By ardently promoting the adoption of weight-efficient designs, this study has taken a significant step towards the creation of a more sustainable and resource-conscious building industry in seismically active areas. This, in turn, paves the way for a future where both human safety and environmental responsibility are paramount considerations in the construction process.

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Use of Lean Six Sigma Methodology in Improving Waiting Times for First Orthopedic Consultation at a Public Hospital

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STRUCTURED ABSTRACT

Purpose - Healthcare is one of the most important sectors since humans lives directly depend on it. The organizations which provide the population's healthcare are still faced with preponderant challenges, the greatest one being the high demand for these services and therefore the capability to also supply them. With the intention of solving this issue, the application of Lean and Six Sigma methods in the healthcare services have shown promising results in several studies.

Design/methodology/approach - The purpose of this work is to develop a Case Study in the hospital using Lean and Six Sigma methods, in order to demonstrate positive improvements in the area, which concerns patient satisfaction. After a screening of the patient's feedback at a Portuguese public hospital, we assessed the most relevant dissatisfaction causes, and proceeded to the application of DMAIC cycle with the aim to reduce consultation in the Orthopedics service. delay times

Findings - It has been identified that changes in management practices can provide essential improvements to the healthcare sector, avoiding the dependence of extra resources and typical budgetary limitations. Beyond increasing patient and healthcare professionals' satisfaction, they can also lead to increased responsiveness and a more balanced distribution of existing resources.

Originality/value - It is estimated that with the implementation of the proposed improvement action plan, it may be possible to reduce waiting times associated with the first orthopaedic consultation by approximately 33%.

Keywords: Lean Six Sigma, Healthcare, DMAIC, Quality Engineering

Paper type: Case Study

INTRODUCTION

The healthcare industry provides not only health services, but also adequate sanitary facilities for society as a whole (Ratnaningtyas & Surendro, 2013). However, the industry faces a series of challenges; and since the COVID-19 pandemic it has become even more evident that healthcare organizations are lacking in both efficiency and productivity (Rathi, Vakharia, & Shadab, 2021).

In order to improve their services, hospitals around the world have begun to adopt innovative process improvement strategies, which aim to improve efficiency while the demand for their services increases. Many of these organizations are adopting Lean and Six Sigma methodologies as the basis for implementing projects in order to inspire a culture of continuous improvement throughout the hospital (Ramos et al., 2016). While the Lean methodology involves applying a set of principles aimed at improving processes by identifying and eliminating steps that do not add value to the patient, Six Sigma aims to improve the quality of process results by focusing on reducing variability (Sommer & Blumenthal, 2019).

With these two methodologies combined comes Lean Six Sigma (LSS) which, when implemented in an organization, contributes to increasing process capacity and efficiency, reducing defects and waste – and resulting in an improvement in the quality of the healthcare services provided and a reduction in the costs involved (Rathi, Vakharia, & Shadab, 2021). Despite the promising results that come from applying Lean Six Sigma, its implementation in healthcare organizations still has numerous limitations and challenges to overcome. LSS is not just a methodology, but also a mindset that must be adopted by all parties involved so that change can take place and a culture of continuous improvement can be achieved in the organization.

In this context, a Case Study in the hospital area is presented, motivated by the desire to provide improvements in this area and to increase the satisfaction of patients and users. This paper presents a case where LSS tools were applied in order to identify and plan improvements in the areas of greatest dissatisfaction for patients. Through an analysis of the statistical data collected from patient complaints at a Portuguese public hospital, it was concluded that waiting times for first outpatient appointments were the area that required the most attention. The application of these methodologies aimed at reducing these times and providing greater satisfaction for the end customer, in this case, the patient.

The aim of this work is to understand the causes that lead to the high waiting times for first appointments in the orthopedic service, and to identify possible solutions to this problem. By implementing improvements in this area, the work developed and presented in this paper can be used to optimize future implementations of these tools in other areas, within the hospital itself or outside it.

LITERATURE REVIEW

Lean Healthcare

Although Lean was first implemented in the automotive industry, it has increasingly been applied in the healthcare sector (Sommer & Blumenthal, 2019). Since the 1990s, in order to deal with quality and cost issues, healthcare providers have looked outside their sector for inspiration and guidance. In order to improve the efficiency of hospital clinical care, the Lean concept thus emerged in the healthcare field in the early 2000s as a service strategy to reduce or eliminate waste and activities that did not add value to healthcare processes, thus giving rise to Lean Healthcare (LH) (Tlapa et al., 2020).

In this area, Lean is defined as a management system that, through a culture of continuous improvement, enables doctors, nurses and all the staff involved in providing healthcare to solve problems and eliminate waste by standardizing work in order to improve the quality of care provided to patients (Shortell et al., 2018). This methodology is therefore a cultural transformation that changes the way a healthcare organization works and requires new habits, attitudes and skills (Cohen, 2018). Health services face a constant challenge to improve the quality of care provided and increase its efficiency. In these services there are typical inefficiencies, such as poor patient flow and inadequate use of resources, which can lead to delays in care and overcrowding of infrastructure, thus affecting patient safety, patient/employee satisfaction and the overall quality of care itself (Tlapa et al., 2020).

For Lean implementation to be successful, the hospital and medical leadership teams must be strong supporters of the methodology, speak the same language of process improvement and be able to generate support and resources for forward movement at an operational level (Tlapa et al., 2020). Healthcare workers see several positive effects of Lean through the empowerment they are given and the control over their own working conditions, as they can suggest improvements thus increasing the opportunity to devote more time to direct care, making their work more satisfying and reducing stress and physical effort (Holden et al., 2015).

In Lean thinking there is a change in the mentality of work, which is now seen as a series of tasks to be completed as quickly as possible, in order to work as a process that can be continuously improved to achieve the core objective, which is to achieve the best results with the least amount of work possible (Platchek & Kim, 2012). In this context, Lean Healthcare begins by studying the entire healthcare process, determining what is considered valuable from the patient's point of view, i.e. what they are willing to pay (Platchek & Kim, 2012; Tlapa et al., 2020). In other words, it is all the activities that contribute to improving the quality of the service provided, as well as the patient's own well-being (Tlapa et al., 2020)

Six Sigma in Healthcare

The healthcare sector is becoming increasingly complex and, as such, opportunities for errors abound. Therefore, in order to improve the quality of a hospital's products and services and reduce patient dissatisfaction, the Six Sigma concept has been applied as a work optimization strategy based on zero error (minimum possible) (Mallikarjun, 2011). Although this methodology emerged in 1981, it only began to be implemented in healthcare in the 1990s (Cançado, Cançado, & Torres, 2019).

It is well known that in a healthcare organization there is no room for tolerating defects, as a simple error can put a human life at risk, thus creating the need to eliminate all errors in healthcare processes. In this respect, the Six Sigma methodology is a powerful performance improvement tool that has changed the face of healthcare provision today (Sabry, 2014). Six Sigma has proven to be a very effective approach to improving the quality of various service sectors, especially financial services and healthcare (Parikh, Gargollo, & Granberg, 2021). In the latter sector, it is crucial to use a quality management system in order to ensure efficiency. This is where this philosophy comes into play, taking advantage of the application of innovative digital tools and technologies in order to reduce the inefficient use of resources and non-optimized processes (Niñerola, Sánchez-Rebull, & Hernández-Lara, 2020).

Improving organizational performance using Six Sigma depends on the accessibility and accuracy of available data through up-to-date information technology systems. This has proved to be a challenge in most healthcare organizations, as it is not always guaranteed. In addition, cultural change in a healthcare organization has also proved challenging, as healthcare professionals are very entrenched in methodologies they already know, making them skeptical about the credibility of Six Sigma, as it is strongly linked to manufacturing (Christianson et al., 2005).

Although this methodology has proven to be very valuable, it is always necessary to have a suitable leadership team that includes buy-in from everyone involved (Parikh, Gargollo, & Granberg, 2021). Six Sigma can therefore be of particular interest for improving healthcare management systems in developing countries, because given their low level of investment, it can be a good approach for exploiting the organization's potential in order to improve and develop its services (Hussein et al., 2017).

Lean Six Sigma in Healthcare

Most of the articles consulted apply the Lean and Six Sigma methodologies simultaneously, although there are still some studies in which these methodologies are applied independently. The Lean and Six Sigma methodologies use tools with the aim of eliminating waste and non-value-added activities, focusing on reducing process variation, eliminating the causes of defects and improving performance. In general, the result of its implementation is expected to be reduced costs, improved product or service quality and increased satisfaction (Cançado, Cançado & Torres, 2019).

In the literature reviewed, LSS cases in the healthcare industry appear in a wide range of contexts such as operating room efficiency (Ramos et al., 2016), ophthalmology care and patient plow (Sommer &. Blumenthal, 2019), radiotherapy appointments (Mancosu et al., 2018), in a cardiac catheterization laboratory (Agarwal et al., 2016) – among others (DuPree et al., 2009; Christianson et al., 2005; Ricciardi et al., 2021). Across different cases, the application of Lean Six Sigma provides significant improvements in healthcare processes and operations.

Most often, data for problem identification and improvement is already available, but remains unused. As this is a service provided to the public, using surveys/forms is a good strategy to adopt in order to obtain relevant information about staff/patient dissatisfaction (Ramos et al., 2016; Shortell, et al., 2012) – which most hospital already do. However, the information is rarely look at in a systematics and comprehensive way. In this way, by identifying the problem it becomes easier to act on it using Lean Six Sigma, thus achieving continuous improvement in the organization.

RESEARCH METHODOLOGY

Case Study and Literature Review

This work uses a case study methodology and describes actual interventions and experiences of the researchers in the field. The work took place at a Public Hospital in Portugal. The first step was to define the problem, as well as the objectives to be achieved. Subsequently, a structured and systematic search was carried out using the Scopus academic database, in order to obtain a broader survey of the topic to be addressed in this work. The research began with some background on the origins of Lean and Six Sigma methodologies, both separately and when merged. We also looked at their application in the health context, the tools used in each of the methodologies and gave examples of their application in a real context.

Once the theoretical framework had been established, we moved on to contextualize the case study and then applied the DMAIC cycle to the case presented. At this stage, all the steps of the cycle were followed and the appropriate tools were applied to each one. The development of each of the phases of this cycle allows the implementation of the Lean and Six Sigma methodologies in a more structured way and in a way that achieves the desired objectives through logical reasoning.

Lean Six Sigma and DMAIC

The Six Sigma strategy encompasses two methodologies, DMAIC, which is a problem-solving methodology, and DFSS (Design for Six Sigma), which is a preventive methodology consisting of DMADV, a strategy identical to DMAIC (Sabry, 2014). Six Sigma can thus be achieved through a series of well-defined steps, which comprise the so-called DMAIC cycle (Varkey, Reller, & Resar, 2007). The latter is the cycle most often used in approaches to Six Sigma.

DMAIC is a closed-loop process that aims to eliminate steps that are considered unproductive or defective, with the aim of achieving continuous improvement. This process is divided into five phases called Define, Measure, Analyze, Improve and Control. Generally speaking, each phase has a well-defined objective: Define is to define the problem and the scope of the project, Measure is to measure the current performance of the process and Analyze is to analyze the problem. Analyze is to determine the causes of each priority problem. Finally Improve aims to propose, evaluate and implement solutions to each priority problem, while Control aims to ensure that the goal is achieved in the long term (Ratnaningtyas & Surendro, 2013).

DMAIC IMPLEMENTATION AND RESULTS

Define - The first phase of the DMAIC cycle is *Define* and consists of precisely defining the outline of the project to be developed. It is in this phase that the objectives to be achieved, people involved, deadlines and restrictions are defined and aligned. This is fundamental for clearly and precisely describing the problem on which the study will focus. It is in this phase that the value of the project is specified from the point of view of the end client, which in this healthcare context refers to the patient. It is with the patient in mind that all processes must be created, always with the main objective of achieving total patient satisfaction by providing the best possible experience in hospital facilities.

As the first task of this project, an analysis was made of the feedback from the last complete year (2021) by the time of this project's start. This feedback had been collected through a questionnaire carried out with the hospital's patients and users, in order to ascertain the level of satisfaction with the services provided. The data collected in the questionnaires included praise, suggestions and complaints. Table 1 shows a more detailed picture of this feedback.

Table 1 – Feedback from hospital patients and users (year 2021).

Feedback	Praise	Suggestions	Complaints	Total
#	114	10	493	617
%	18,5	1,6	79,9	100

Looking at the table above, it can be seen that the complaints amount for 79.9% of all feedback. The study therefore focused on this type of feedback. Figure 1 shows which areas contributed the most to the dissatisfaction felt by users.

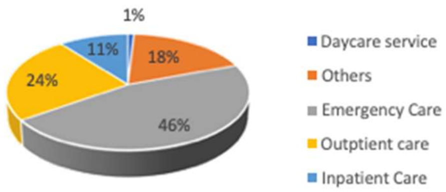

Figure 1 – Feedback from hospital patients and users, by type (year 2021).

Table 2 shows that the majority of complaints are in the area of healthcare provision, and the most specific causes with the highest number of complaints are “Inadequate Care” and two categories of “waiting times”. However, as the cause "inadequate care" is too general and cuts across several specialties, it will not be the subject of this study, nor will the cause. "Waiting Times – Outpatient Consultation and Emergency Care" is also difficult to fully analyze because it refers to the waiting times both for scheduled and unscheduled clinical care, i.e. consultations and emergencies. As such, the study will have a greater focus on understanding what leads to the dissatisfaction of the organization's users relating to the access to health care through outpatient consultations (“Waiting Times – Outpatient Consultations”).

Table 2 – Feedback from hospital patients and users (year 2021).

Area	Total	Problems	Total
Management	214	Norms and Regulations	31
		Procedures	81
		Information and Communication	95
Infrastructures	20	Hospitality	9
		Facilities	11
Healthcare provision	322	**Waiting Times – Outpatient Consultations**	**66**
		Access to care - Surgery	17
		Inadequate Care	126
		Waiting Times – Outpatient Consultation and Emergency Care	113
Relational/Behavioral	81	Service	81

Although the emergency department was the area with the highest incidence of complaints, the focus of this study will be on the area related to outpatient appointments, as the latter has more concrete data that can be worked on, while the emergency data is not very constant, influenced by various variables and so it would be more complicated to develop the intended study, drawing the appropriate conclusions.

Measure - The second phase of the DMAIC cycle consists of determining the focus of the problem. It is in this phase that the current performance of the process is assessed, and metrics are identified or defined so that future measurements can provide a basis for comparison. In this way, future proposed improvements can be analyzed and it can be verified whether or not they have had an effect on solving or improving the problem in question. To begin a more detailed analysis, we used the data available on the hospital's database regarding average waiting times for access to the first outpatient appointment in 2021, broken down by specialty. This data was processed in order to understand which specialty had the highest waiting times. The total number of people registered for consultations in each specialty was considered, as well as the average waiting time.

Table 3 shows the average number of users registered for a consultation in each specialty, as well as the average number of days waiting until the first consultation. It can be concluded that the specialty with the most critical waiting times is Orthopedics, as it has the highest number of waiting days until the first outpatient appointment. The Ophthalmology specialty also has a high waiting time, however, in addition to this time being approximately half that of Orthopedics, it is necessary to consider that it has the highest number of enrollees, which means that it better meets the needs of users. Based on the date from this table, the orthopedic service was selected for the case study for LSS implementation projects.

Table 3 – Feedback from hospital patients and users (year 2021).

Specialty	Average number of patients	Average waiting time (days)
Anesthesiology	15,17	41,92
General Surgery	465	64,92
Diabetes	26,75	68,67
Gastroenterology	230,67	60,25
Immunoallergology	311,08	59,33
Nephrology	63,17	42,58
Obstetrics	37,17	27,5
Orthopedics	2821,17	395,17
Pediatrics	192,92	72,25
Psychiatry	125	31,58
Urology	531	112
Cardiology	108,67	46
Dermatology	253,33	75,17
Physiatry	111,5	22,09
Gynecology	205,08	77
Internal Medicine	290	57,17

Analyze - Analyze consists of determining the potential causes of the problem in question. In order to do so, it is necessary to analyze the entire process in detail. In this context, an evolutionary analysis of the Orthopedics specialty in relation to average waiting times for first external consultations was carried out. The data for 2019, 2020 and 2021 was considered and represented in the graphs in Figures 2 and 3, allowing us to observe the evolution of the total number of people registered for consultations in the specialty and the average waiting times for first external consultations.

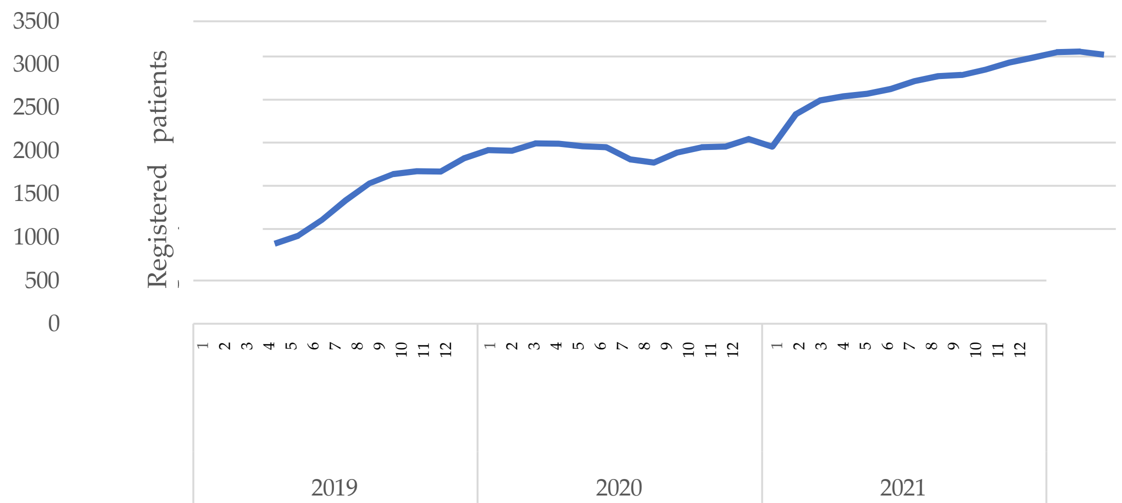

Figure 2 – Registered patients for outpatient consultations in the Orthopedics service.

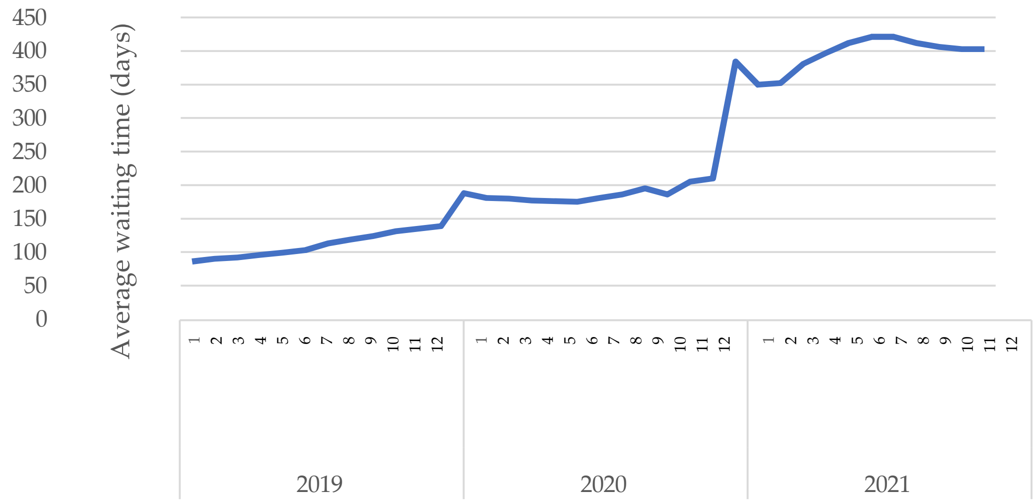

Figure 3 – Average waiting time (in days) for outpatient consultations in the Orthopedics service.

After analyzing the two graphs, it is possible to conclude that, for the Orthopedics specialty, the average waiting time for a first consultation (days) has been increasing from 2019 to 2021, as has the total number of people registered for an outpatient consultation. It should be borne in mind that the pandemic situation played a fundamental role in this abrupt evolution between 2020 and 2021, where there is a clear increase in average waiting times for first consultations, from around 200 to more than 400 days. In addition, the number of people registered has also risen sharply, from an average of 2,000 in 2020 to between 2,500 and 3,000 in 2021. Although this atypical situation has affected this specialty, it is necessary to consider for this study that all specialties have been affected in the same way. Furthermore, the end of the pandemic makes it the right time to intervene in the process to mitigate these changes.

Following these analyses, we used more specific data on waiting times for first outpatient appointments in 2021 in this specialty, so that we could assess and understand their trend in greater detail. Figure 4 breaks down the number of patients and the respective waiting time.

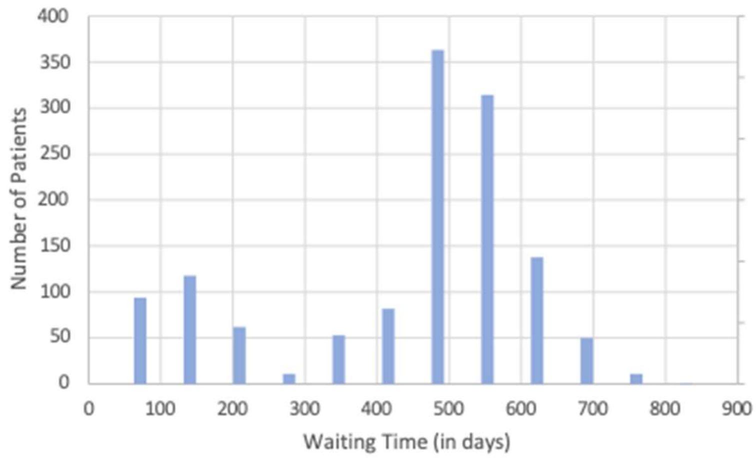

Figure 4 – Average waiting time (in days) for first outpatient consultations in the Orthopedics service.

In order to understand the reasons why the Orthopedics specialty has the highest waiting times for first appointments, we began a comparative analysis with the list of specialties previously found in relation to missed appointments. Appointment cancellations can be the root of a problem, as they can lead to a missed appointment, i.e. an appointment that is not given. Depending on how far in advance an appointment is rescheduled, it may or may not be replaced, i.e. if the appointment is rescheduled in time for another patient to be seen, the appointment will not be missed. On the other hand, either because of the short notice with which the appointment is canceled or because of the reason for it, it may not be possible to replace it, which in turn is reflected in the waiting list for the appointment.

Appointments are frequently rescheduled and can be due to various reasons, which will now be described. A table was drawn up showing the number of appointments rescheduled in 2021 for all specialties, for reasons attributed to the Hospital (Table 4).

Table 4 – Number of appointments canceled for reasons attributable to the hospital, by specialty.

Cancelations attributed to the hospital	
Ophthalmology	2 406
Orthopedics	3 505
Pulmonology	2 802
Urology	2 363
Neurology	2 861
Rheumatology	677
Total	**14 614**

After analyzing the table, it is possible to conclude that of the list of specialties initially determined, it is Orthopedics that has the highest number of appointments cancelled for reasons attributable to the hospital. After this preliminary analysis, a more detailed one was carried out on the specialty that is the focus of this study, Orthopedics. Using the data provided by the hospital, it was possible to analyze the number of appointments cancelled for each type of reason, as well as their evolution from 2018 to the year under study, 2021. Table 5 shows the figures for Orthopedics, broken down by each specific reason for appointment cancellations.

Table 5 – Orthopedics appointments cancelled for reasons attributable to the hospital.

	Year			
Reason	**2018**	**2019**	**2020**	**2021**
Change of schedule	3 596	1 992	2 146	2 157
Change of hours	477	287	1 496	746
Change of doctor	256	178	55	60
Contingency	0	0	2 013	1
Clinical decision	77	500	294	130
Return to health center	1	0	0	0
System failure	52	9	1	3
Lack of tests	83	58	45	40
Doctor absent	171	29	59	94
Doctor on vacation	546	341	290	249
Strike	350	124	15	15
Priority for urgent care	28	13	76	7
Doctor's refusal	4	7	15	3
Total	**5 641**	**3 538**	**6 505**	**3 505**

In order to find out more about the causes of the waiting times for first outpatient consultation in the Orthopedics specialty, a series of questions were drawn up to be presented to the medical staff in the division. These questions served not only to find out more causes that contribute to the problem under study, but also to understand the point of view of the Orthopedic doctors, who are the ones in direct contact with all the processes related to this study. In addition, a conversation with the head of the specialty, where it was also possible to ascertain some causes and obtain more precise clarifications.

Not all doctors in this specialty answered our call, some because they were unavailable and others because they refused to answer for personal reasons. As a result, we only obtained feedback from 5 doctrs, less than 50% of the total study population.

Questions considered (1) the number of appointments given per week, (2) the perception on the number of appointments scheduled but not given per week, (3) the average duration of appointments, and (4) how often the set time for each appointment (20 minutes) was followed. Question 5 asked for the reasons for delays and cancellations.

For question 1, doctors surveyed indicated that on average they give between 14 and 24 consultations a week. With regard to question 2 - the number of appointments scheduled but not given per week - doctors reported a figure that is practically zero, as only one doctor reported one to two consultations not given per week (the remaining doctors reported zero failed appointments).

For questions 3, three out of the five doctors considered this time to be ideal. one doctor suggested it should be reduced to 15 minutes, while another indicated a preference for 30-minute appointments. However, in answering question 4, three of the five doctors claimed that the 20-minute limited is rarely met

Looking at the reasons for delay and cancelation (question 5), different feedback was received. "Shortage of medical staff/professionals" was mentioned by the four doctors (out of five) that agreed to respond to this question. A need for "better (more appropriate) referral by primary health care" was also mentioned.

Improve - The next stage of the DMAIC cycle consists of proposing, evaluating and outlining the implementation plan for potential solutions. In this case, the aim is to propose suggestions for improvement that are capable of mitigating and, fundamentally, solving the problem associated with the high waiting times for first orthopedic consultations.

Table 6 shows some of the improvement actions proposed for each area identified in the previous phases, all with the aim of reducing waiting times for first Orthopedic consultations. These improvement actions were proposed on the basis of brainstorming sessions, but also considering the suggestions made by the doctors surveyed for improving waiting times for first outpatient appointments in the specialty in question.

Table 6 – Intervention areas and suggestions for improvement actions.

Intervention areas	Improvement action
Rescheduling appointments - Change of Agenda / Change of Hours	Prior planning of each doctor's weekly appointments and analysis of their availability would be a way of avoiding appointments being missed due to changes in their schedule. The introduction of a rotating system (for emergency rooms, surgeries, etc.) of doctors on a weekly basis, guaranteeing the presence of doctors on the day they have scheduled appointments (e.g. if a doctor has an appointment, guarantee the presence of another doctor in the emergency room or ward, preventing the appointment from being rescheduled).
Rescheduling appointments - Doctor's vacation	Scheduling doctors' vacations in advance (at the beginning of the year) would be a way to avoid appointments being missed for this reason.
Hours spent on outpatient appointments	Increasing the number of hours allocated to EC in the Orthopedics specialty. The implementation of this measure will also increase the number of consultations given each year.
Consultation time	Increase in the time associated with the first orthopedic consultation, from 20 min. to 30 min.
Referral criteria	Revision of the specialty's referral criteria, making them clearer and thus avoiding the existence of unnecessary consultations.

By implementing the proposed improvement actions, it is hoped to improve the satisfaction of patients and users by reducing waiting times for first Orthopedic consultations. The following results are expected from the proposed measures:

- An increase in the number of hours allocated to outpatient consultations and, consequently, an increase in the number of consultations given each year;
- Reduction in the number of appointments cancelled due to changes in the doctor's

schedule/hours or vacations;

- Improved quality of information sent by the Health Center to the hospital regarding the patient - improved quality of triage;
- Increasing the time available for the first orthopedic consultation, giving doctors more time to properly analyze the patient, their clinical history and the accompanying exams;
- Reducing the number of unjustified consultations by reviewing the referral criteria and improving the triage carried out by primary health care.
- An increase in the number of Orthopedic doctors. While a proposal on the increase in the number of Orthopedic doctors was also considered, it is a decision that cannot be made on the sole scope of this project. However, it is our belief that its impact is substantially and the proposal was maintained.

Control - The last stage of the DMAIC cycle is Control and consists of ensuring that the goal is achieved over the long term. This stage aims to create mechanisms or measures to continuously monitor and verify whether or not the improvements implemented have had an effect.

After identifying the improvement actions and presenting the plan for their implementation, it is proposed that a pilot test be carried out. This will be the best way to test whether or not the proposed measures will have the expected impact on the problem under study - reducing waiting times for first orthopedic consultations. It is through this test that the achievement of the target proposed in this improvement project will be verified.

The improvement action plan presented above should therefore be applied as a pilot test. The management team, including the president of the hospital should meet with the Orthopedic specialty team and start implementing the measures proposed in this phase of the DMAIC cycle - the Improve phase - in order to test their effectiveness. During implementation, there may be a need to adjust the proposed measures, in which case they should be discussed as a team.

About a year after the implementation of the proposed improvement action plan, the satisfaction questionnaires that are usually given to patients and users will be carried out, as a way of ascertaining the impact that the implemented measures have had. As some of the proposed measures are directly related to and intervene in the work of the specialty doctors, there is also a need to carry out a satisfaction questionnaire with them, as a way of understanding whether the proposed measures have had an effect and if they have had an impact.

CONCLUSIONS

This study proves the effectiveness of the DMAIC cycle in achieving an effective improvement plan, since by applying the appropriate tools it was possible to find the various causes associated with the problem under study, and finally suggest the necessary improvement actions to reduce waiting times for access to the first Orthopedic outpatient appointment. It is further expected that, by implementing the proposed improvement action plan, waiting times will be reduced, greater satisfaction will be achieved on the part of hospital users and, in this way, the number of complaints in the area of access to consultations will be reduced.

It is therefore possible to state that this study has achieved its objectives, although there is still a need to invest in the implementation of actions to address this issue of waiting times for access to outpatient consultations. This work proves that the health sector still has operations challenges, and that Lean Six Sigma is viable way to address them. Interestingly, the proposed interventions resulting from this work show how changes in management practices – traditionally not very cost demanding – may help achieve very important improvements. Small changes or a few alterations in management – such as those presented in table 6 - can be reflected not only in the satisfaction of users but also of the health professionals themselves. In addition to increased satisfaction, essential improvements are made to the health area, such as increased response capacity and a more balanced distribution of existing resources.

It is hoped that by implementing the proposed improvement action plan, the final objective will be achieved and the waiting times associated with the first orthopedic consultation will be reduced by around 33%. After implementation, it is important to follow the Control phase of the DMAIC Cycle in order to maintain the improvements in the long term, thus establishing a culture of continuous improvement at this public Hospital.

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Assessment of Non-Quality Costs in a Healthcare Institution

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STRUCTURED ABSTRACT

Purpose- There is a lack of studies that quantify the impact of non-quality costs in healthcare institutions (HCIs). This paper presents a methodology for assessing non-quality costs in HCIs, with a focus on analyzing their impact on financial performance.

Methodology- The methodology consists of four steps: (1) defining the concept of "non-quality costs in HCIs" through a literature review, (2) structuring a framework for non-quality costs, (3) quantifying non-quality costs, and (4) assessing the impact of non-quality costs on the financial performance.

Findings- The non-quality cost framework developed included the following items: reprocessing costs due to errors in contract preparation, costs of correcting accounting or administrative errors, costs of repeated or lost laboratory tests, legal liability costs for adverse events, costs of unplanned care at another HCI, and costs of dealing with complaints due to patient dissatisfaction with care. It was quantified that non-quality costs had a 3.1% impact on the total HCI revenue.

Practical implications- An improvement plan was developed to ensure that the medical and nursing staff adhere more effectively to predefined management protocols. In addition, a new operating procedure for the diagnostic advisory boards was established to improve their responsiveness and monitoring capacity.

Originality/value- The main contribution of this work is the proposal of a tool for quality improvement in the healthcare sector, which takes a practical and quantitative approach based on financial performance.

Keywords: Healthcare institutions management, Non-quality cost model, Quality improvement, Financial impact of quality.

Paper type: Case Study.

INTRODUCTION

Quality management in healthcare refers to the achievement of optimal health services for individual and collective users in an accessible and equitable manner, considering the balance between benefits, risks, and costs, with the aim of achieving user satisfaction (Vivas and Barrachina, 2010). The assessment of healthcare services encompasses a multitude of factors, including medical specialties, functional areas (outpatient, emergency, surgery, and hospitalization), nursing services, hospitality, information services, and administrative procedures for the user (Osorio Gómez et al., 2016).

Quality costs are associated with the production, identification, or repair of products or services that do not meet customer requirements. The development of quality cost programs is related to the boom in the implementation of quality management systems in the second half of the 20th century. Quality costs are the costs associated with achieving or failing to achieve product or service quality, including all requirements established by the organization, its contracts with customers, and society. Quality costs are the sum of the costs incurred by investing in preventing nonconformance, evaluating a product or service for conformance, and failing to meet requirements (Wood, 2013). These costs can be classified as prevention, appraisal, internal failure, and external failure costs.

Appraisal costs are expenses related to measuring, assessing, or auditing products or services to ensure compliance with quality standards and performance requirements. Prevention costs are expenses related to activities and measures taken to identify and prevent problems before they occur. Internal failure costs refer to expenses associated with product or service defects that are discovered before shipping or service delivery. External failure costs are expenses that arise after the delivery or shipment of a product, or during or after the provision of a service. These costs are typically associated with customer complaints, liability claims resulting from poor service, product returns, and warranty claims (Dale and Plunkett, 2017).

There are several non-quality practices that contribute to a significant portion of healthcare spending. These include repeat care, repeated invoices and bills, handling service complaints, failures in contractual processes, cost overruns due to hospital care failures, repeat or lost laboratory tests, and reformulation or repetition of drug formulations (Mosadeghrad, 2013). Healthcare institutions that engage in non-quality practices not only incur costs but also pose a risk to patient safety (Zahar et al., 2015). This risk arises when there are areas of non-quality in the chain of care. In addition, such practices can damage the institution's reputation, leading to a loss of patient confidence and a poor image of the facility. Finally, there is also a social risk associated with non-quality practices, which can result in a loss of trust in the healthcare personnel (Schiffauerova and Thomson, 2006).

The preceding paragraphs illustrate the significance of estimating the non-quality costs in health institutions and the necessity of novel tools that support decision-making to quantify and reduce viable and non-avoidable adverse events, improve quality care and control operating costs.

RESEARCH METODOLOGHY

The methodology for assessing non-quality costs was put into practice in one of the main HCIs of Medellin (Colombia). The methodology consists of four steps, as shown in Figure 1: (1) defining the concept of "non-quality cost in HCIs" through a literature review, (2) structuring a framework for non-quality costs, (3) quantifying non-quality costs, and (4) assessing the impact of non-quality costs on the financial performance.

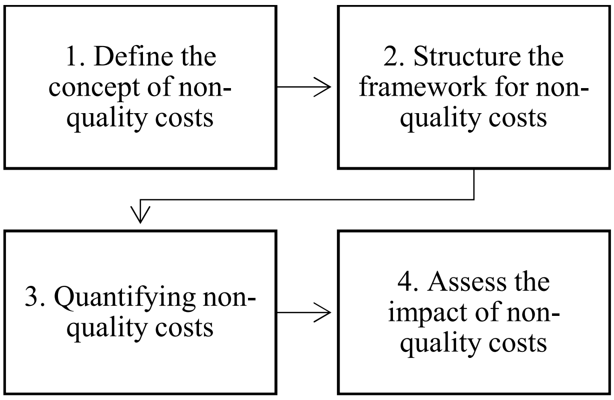

Figure 1 – Research Methodology.

The main conceptual references employed to define the concept of non-quality cost in HCIs are the Prevention, Appraisal, and Failure Model, the Internal and External Failure Cost Model, the Hidden Cost Model, and the Just No Defect Model. The Prevention, Appraisal, and Failure Model uses these categories to measure the effectiveness of quality costs and shows that an increase in prevention and appraisal costs results in a decrease in failure costs (Fox, 2013). In the Internal and External Failure Cost Model, Internal failures refer to defects detected before products or services are released, while external failures occur after delivery to the customer (Serrano, 2005).

The Hidden Cost Model quantifies financial imbalances, any deviation between expected and actual performance. Correcting them incurs hidden costs such as absenteeism, work accidents, staff turnover, and non-quality (Savall and Zardet, 2008). The Just No Defect Model calculates the hidden costs of failures in organizations through failure rates of tangible and intangible costs (Serrano, 2005).

The studied HCI provides four types of services: (1) External consultation (general medicine, dentistry, optometry, nutrition, psychology, vaccination, and promotion and prevention programs), (2) Diagnosis and Therapy (pharmacy, clinical laboratory, sampling, and diagnostic imaging), (3) Hospitalization, and (4) Immediate care (childbirth services, emergency service, and basic assistance transport).

The mission of the HCI is to provide health services that adhere to high quality standards in a safe environment for the user and his family. This is achieved through a strategic direction that places emphasis on health promotion and disease prevention, with the objective of fostering the integral development of human talent. At the same time, the vision of the HCI is to become a leading provider of low-complexity health services and to be recognized for its humane and secure service for users and their families, thereby contributing to the well-being of the population.

In terms of the size of the services provided, during the last year, 42,700 general medical appointments, 4,632 emergency appointments, 45,304 dental appointments, 268,100 laboratory tests, 8,915 x-rays, 972 ultrasounds, 5,857 nutritional appointments, and 1,608 psychological appointments were performed. A total of 2,447 medical procedures and 18,266 nursing procedures were performed on patients during their hospitalization, with an average length of stay of 3.8 days.

RESULTS

Concept of Non-Quality Costs in HCIs

There are varying definitions of healthcare quality among clients, professionals, managers, policymakers, and payers, each with their own perspective and interests. These definitions are based on the importance placed on different elements of health services (Mosadeghrad, 2013).

Quality management in health care refers to the medical care received by patients considering four dimensions: interpersonal, technical, environmental, and administrative quality (Chakraborty, 2020). Interpersonal quality refers to the relationship between the healthcare team and the patient. Technical quality indicates the expertise and professionalism of the healthcare team in delivering the cure. Environmental quality includes factors such as cleanliness, order, hospital beds, and required equipment for patient needs. Finally, administrative quality helps to facilitate the patient's cure while minimizing waiting times and ensuring error-free documentation (Dagger et al., 2007).

Non-quality costs are defined as the cost incurred by the HCI because of suboptimal performance. The costs can be classified into two categories: internal and external. Internal costs are incurred when defects or issues are detected within the HCI (rework, scrap, and retesting). External costs are incurred when defects or issues reach the user or external stakeholders (warranty claims, user complaints, and legal expenses) (Trusko et al., 2007).

To determine the number of publications and research trends in this field of study, a bibliometric search was conducted in reference databases. Figure 2 illustrates the number of articles published and referenced in Scopus from 2004 to 2024, using the following search equation: *TITLE-ABS-KEY (("quality cost" OR "non-quality cost" OR "poor quality") AND (impact) AND (healthcare OR hospital)*. Thus, in the past twenty years, a total of 563 articles have been published with theoretical and practical contributions on quality and non-quality costs in the health sector. There is an increasing trend in the number of articles published, from 3 in 2004 to 58 in 2023, indicating the importance of the topic for academics and professionals in the area.

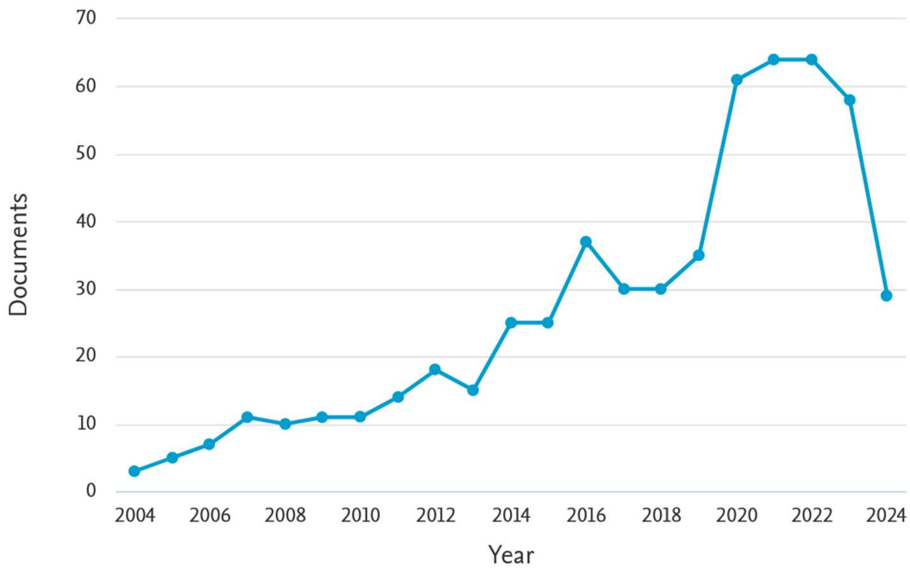

Figure 2 – Number of articles published by year between 2004 and 2024. Source: Scopus.

In addition, Figure 3 shows a map of the co-occurrence of keywords from the selected articles in Scopus related to research topics. Three main clusters are identified, highlighting the red cluster that contains the terms related to health care quality costs. This cluster comprises 14 items, with the one item displaying the highest density being *health care cost*. This is mainly related to *health care quality*, *retrospective study*, *patient satisfaction*, *health care personnel*, and *patient care*.

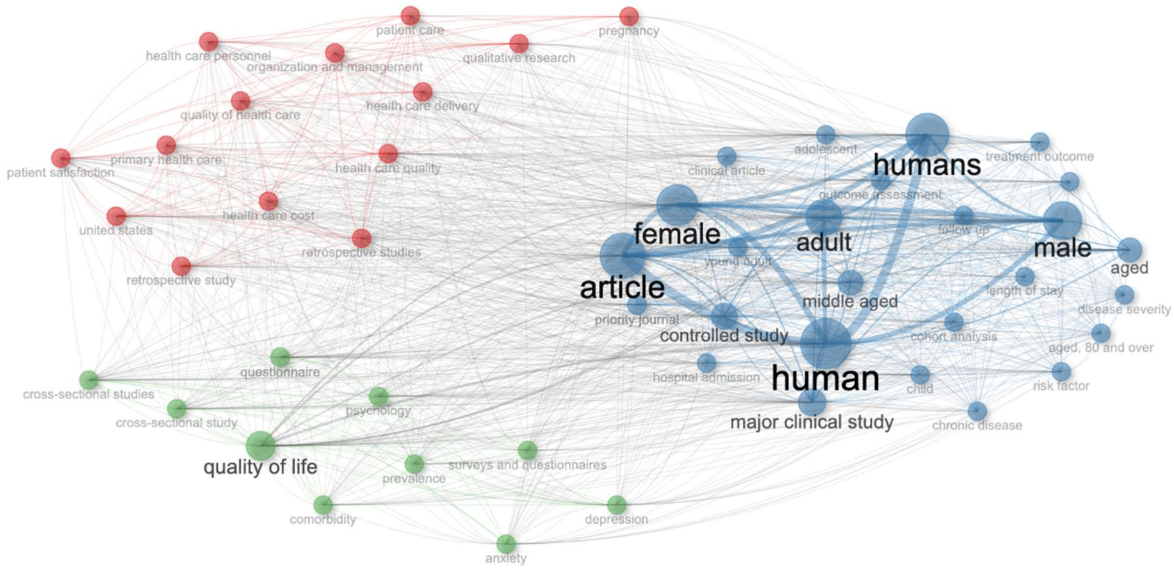

Figure 3 – Co-occurrence map of the selected papers. Source: Vosviewer.

Framework for Non-Quality Costs in HCIs

The non-quality cost framework was developed through an analysis of the cost structure of the HCI under study. All cost designations within the accounting structure of the HCI were considered and grouped together. This structure is applicable to the Colombian case, given that these costs are governed by national legislation. However, a similar exercise of analysis and grouping into categories by affinity can be carried out in any country from the database of accounting movements.

The non-quality cost framework developed is divided into internal and external failure costs (Table 1). Internal failure costs are due to failures during the service that are not detected by patients. External failure costs are due to are due to failures that are perceived by the patient (Sedevich-Fons, 2013). Internal failure costs include reprocessing costs due to errors in contract preparation, costs of correcting accounting or administrative errors, and costs of repeated or lost laboratory tests. External failure costs include legal liability costs for adverse events, costs of unplanned care at another HCI, and costs of dealing with complaints due to patient dissatisfaction with care.

Table 1 – Framework for Non-Quality Costs in HCIs.

1. Internal Failure Costs	**2. External Failure Costs**
1.1 Reprocessing costs due to errors in contract preparation	2.1 Legal liability costs for adverse events
1.2 Costs of correcting accounting or administrative errors	2.2 Costs of unplanned care at another HCI
1.3 Costs of repeated or lost laboratory tests	2.3 Costs of dealing with complaints due to patient dissatisfaction

Quantification of Non-Quality Costs in an HCI

The primary categories of non-quality costs, as delineated in Table 1, must be established and quantified within the framework of the HCI accounting management. The resulting cost items are subsequently classified into subcategories based on their similarity. In the HCI where this methodology was implemented, the costs were calculated over the past two years. The total external failure costs were US$1,003,774, while the total internal failure costs were US$123,682, representing 89.03% and 10.97% of non-quality costs, respectively.

Table 2 presents the percentage composition of the costs associated with correcting accounting or administrative errors (internal failures). Consequently, there was an evident opportunity for improvement in reprocessing through staff training and the updating of the accounting information system. This was because errors resulting from non-compliance with amounts or legal requirements represented 87.2% of administrative reprocessing. Similarly, Table 3 presents the percentage composition of the costs associated with legal liability for adverse events (external failures).

Table 2 – The cost structure for an item of internal failure costs in the studied HCI.

1.2 Costs of correcting accounting or administrative errors		**Percentage**
1.2.1	Invoice amount exceeds established limits	49.9%
1.2.2	Invoice does not meet legal requirements	37.2%
1.2.3	Lack of support for the documentation process	5.4%
1.2.4	Untimely return of documents	2.1%
1.2.5	Incorrect identification of the type of service	1.5%
1.2.6	Insufficient user data	1.3%
1.2.7	Material identification errors	1.3%
1.2.8	Incorrect user affiliation data	1.1%
1.2.9	Errors in the value of employee compensation	0.2%
Total		100%

Table 3 – The cost structure for an item of external failure costs in the studied HCI.

2.1 Legal liability costs for adverse events	**Percentage**
2.1.1 Claim for adverse event in infant or neonatal patient	38.9%
2.1.2 Claim for adverse event of adult patient	23.2%
2.1.3 Lawsuit for inadequate medical care	21.2%
2.1.4 Claim for patient falls during service	13.9%
2.1.5 Medical malpractice lawsuit	2.8%
Total	100%

Assessment of the impact of Non-Quality Costs

Finally, the assessment of the impact of non-quality costs in financial performance must be quantified. During the period under study, the total revenues of HCI were US$36,369,571, while the operating costs were US$9,456,088 and the non-quality costs were US$1,127,456. Consequently, it was determined that non-quality costs had a 3.1% impact on the total HCI revenue and constituted 11.9% of the operating costs. The results obtained are consistent with those proposed by Crosby (1984), who posited that non-quality costs in service companies can represent up to 35% of operating costs.

However, the high proportion of external to internal non-quality costs (89.03% of external failure costs versus 10.97% of internal failure costs) differs from the proportion advised by Zahar et al. (2015) (83% versus 17%). Consequently, HCI should focus on investing in the prevention and improvement of internal processes in order to ensure the quality of healthcare services and to reduce the costs of claims for adverse events.

The respective proportions of each of the subcategories of non-quality costs were calculated and presented in Figure 4. After identifying the impact of claims due to adverse events and unplanned care (88.71% of total non-quality costs), an improvement plan was developed to ensure that the medical and nursing staff adhere more effectively to predefined management protocols. In addition, a new operating procedure for diagnostic advisory boards was established to improve their responsiveness and monitoring capacity.

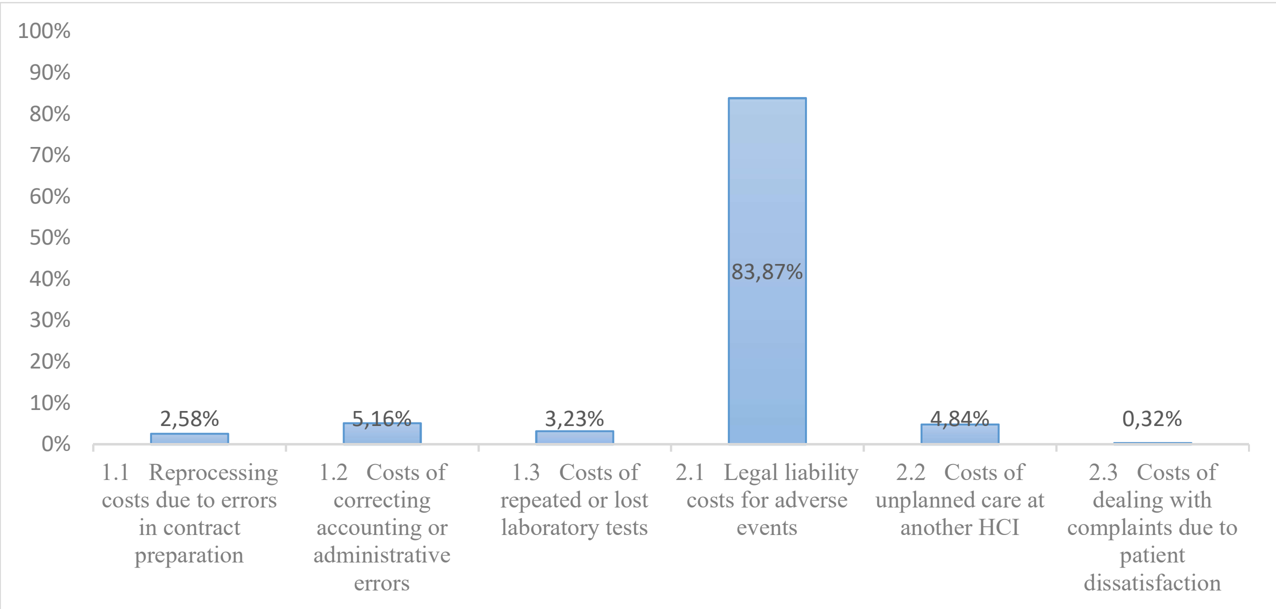

Figure 4 – Financial impact of non-quality costs in the studied HCI. Source: Own work.

CONCLUSIONS

There are various techniques available for quantifying quality and non-quality expenditures. The research on quality measurement in healthcare is based on methods that draw variables from other economic sectors. As a result, there is no standardized approach for measuring quality and non-quality practices in healthcare institutions, and studies must be tailored to the specificities of each public healthcare system. This makes it challenging to compare studies that seek to measure quality and non-quality practices in healthcare institutions.

The improvement of healthcare quality necessitates the establishment of protocols for the measurement of both quality and non-quality costs. These protocols should specify which costs are to be measured, set clear objectives, and define the methods for tabulating and presenting information. By doing so, it will be possible to compare results between different healthcare systems and providers and identify areas that require improvement.

The main contribution of this work is the proposal of a tool for quality improvement in the healthcare sector, which takes a practical and quantitative approach based on financial performance. The next stages of research will be to incorporate cost optimization models and improve data collection for more timely results analysis and decision-making.

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Lean and green transformation in luminous industry

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STRUCURED ABSTRACT

Introduction - The article aims the on-going approaches of a company in the field of luminous industry in order to better compete with other producers in the same field. Starting with November 2023, the case study company (Glorious Lighting) starts two different projects: waste reducing and lean transformation. For the waste reducing some relevant testing was performed and packing that do not affect product protection have been removed, also some of the plastic bags were transformed in paper. Regarding the lean transformation approach, the company develops this project in most of the areas including quality. For this transformation each department drafts a plan with more actions for each foreseen improvement, which is presented to the top management team, then updated in line with management opinion and all the involved persons commit the plan. So from week 49 2023, the transformation was started. Due to normal processes, some deviations, certain errors and obstacles have appeared. In this moment, the lean plan is almost done; in week 10 from 2024 all the actions need to be done; after this, 6 months of "refinement" will follow. First part of the plan for the first implementation is to create defects standardization, because as all of us know, visual verification is the most subjective part that everyone can do it. For this, a tooling will be created and everyone that needs to work with visual inspection will have one of the tools. Second part of plan is to make data automatically. In this moment, data analysis for the scrap area takes around 8 hours. The proposal was to improve it. Third part of plan is to move quality inspection from the finish of the lines during the process.

Purpose - This paper describes a real case of lean and green transformation in in luminous industry.

Methodology - The Case Study describes the projects implementation combining Lean manufacturing practices with sustainability initiatives.

Findings – These two transformations ensure that the company minimizes costs and customer satisfaction and increased loyalty to the company.

The study adopts improvement solutions for waste reduction and also lean transformation. More relevant test was done in order to minimalize the article packing. The tests are required by the client to assure the finish good articles will arrive safe at the final client at home. A brainstorming was necessary in order to implement lean transformation and to have the result done inside of the company. For each department a multifunctional team was chosen and the necessary steps (trainings, brain storming, define the defects) have been taken.

Therefore, the main goals that company received is the customer satisfaction with a visible position on the market, helping to minimise pollution and also the cost of production.

Keywords: quality in process, waste reduce, improvement, standardization

Paper type: Case study.

1. INTRODUCTION

In recent years, many organizations have implemented Environmental Management Systems (EMSs) in order to improve their environmental management. However, this has not been the only standardized Management System (MS) applied by these organizations. In fact, multiple Management System Standards (MSSs) are often implemented to improve organizational performance in quality, safety, security and a number of other aspects or functions.[18]

Begin with an overview of the importance of lean management principles and environmental sustainability in modern business contexts. Highlight the increasing awareness of environmental issues and the need for businesses to adopt sustainable practices while maintaining operational efficiency.[11]

Provide a brief explanation of lean management principles, including concepts such as waste reduction, continuous improvement, and value stream mapping. Explore the origins of lean management, perhaps starting with Toyota's pioneering work in the 20th century and its subsequent adoption across various industries.[11]

Discuss the significance of environmental sustainability in contemporary business operations. Highlight the growing concern over climate change, resource depletion, and other environmental challenges. Outline the key principles of sustainability, such as reducing carbon emissions, minimizing waste generation, and conserving natural resources.[11]

Explore the concept of lean and green transformation, which involves integrating lean management principles with environmental sustainability objectives. Discuss how organizations can achieve operational excellence while simultaneously reducing their environmental footprint. Provide examples of companies that have successfully implemented lean and green initiatives and the benefits they have realized. [11]

Based on literature review, integration of lean and green management principles in the context of sustainable manufacturing appears on the integration of lean and green management principles in the context of sustainable manufacturing. The aim is to examine the existing knowledge, identify gaps in research, and propose future research directions in this field.[13]

The researchers systematically reviewed relevant academic literature on lean management, green management, and sustainable manufacturing. They identified key theoretical frameworks, practical applications, and empirical studies related to the integration of lean and green principles.[12]

Green transformation refers to the process of implementing sustainable practices and initiatives within organizations, industries, or societies to reduce environmental impact and promote ecological sustainability. It involves transitioning towards greener technologies, processes, and behaviors that minimize resource consumption, waste generation, and pollution.[14]

Key aspects of green transformation include [15]:

Environmental Awareness: Recognizing the importance of environmental issues such as climate change, biodiversity loss, and resource depletion. Environmental awareness drives the need for proactive measures to mitigate environmental impacts and promote sustainability.

Sustainable Development Goals (SDGs): Aligning green transformation efforts with the United Nations Sustainable Development Goals (SDGs), which provide a framework for addressing global challenges, including poverty, inequality, and environmental degradation.

Circular Economy: Embracing principles of the circular economy, which aim to minimize waste and maximize resource efficiency by designing products for reuse, recycling, and remanufacturing. Adopting circular economy practices can contribute to green transformation by reducing reliance on finite resources and minimizing environmental footprints.

Regulatory Compliance: Adhering to environmental regulations and standards set by governments and regulatory bodies. Compliance with environmental laws and regulations is essential for ensuring that businesses operate in an environmentally responsible manner and minimize negative impacts on ecosystems and communities.

Innovation and Technology: Leveraging technological advancements and innovation to develop sustainable solutions and eco-friendly alternatives. Green transformation often involves investing in renewable energy, clean technologies, and green infrastructure to reduce carbon emissions and promote environmental sustainability.

Corporate Social Responsibility (CSR): Integrating environmental considerations into corporate strategies and practices as part of a broader commitment to corporate social responsibility. Organizations engage in green transformation to fulfil their ethical obligations, enhance brand reputation, and create long-term value for stakeholders.

Lean transformation, often referred to as lean management or lean thinking, is a systematic approach to optimizing processes, eliminating waste, and improving efficiency across various industries. It originated from the Toyota Production System (TPS) and emphasizes continuous improvement, respect for people, and the pursuit of perfection.[16]

Key principles of lean transformation include [17]:

Waste Reduction: Identifying and eliminating waste (muda) in processes, including overproduction, waiting, unnecessary transportation, excess inventory, motion, defects, and underutilized talent. Lean organizations strive to create value for customers while minimizing waste and maximizing efficiency.

Continuous Improvement: Embracing a culture of continuous improvement (kaizen) where employees at all levels are empowered to identify problems, propose solutions, and make incremental improvements to processes. Lean organizations prioritize learning, experimentation, and adaptation to drive on going performance enhancements.

Value Stream Mapping: Mapping and analyzing value streams to understand the flow of materials, information, and activities from raw materials to the delivery of finished products or services. Value stream mapping helps identify bottlenecks, inefficiencies, and opportunities for improvement in processes.

Pull Systems: Implementing pull systems where production is driven by customer demand rather than forecasted production schedules. Pull systems help minimize inventory levels, reduce lead times, and improve responsiveness to customer needs.

Just-in-Time (JIT) Production: Adopting just-in-time production principles to synchronize production with customer demand, minimize inventory holding costs, and reduce lead times. JIT production aims to deliver the right product, at the right time, in the right quantity, with minimal waste.

Respect for People: Fostering a culture of respect for people by empowering employees, promoting teamwork, and providing opportunities for skill development and personal growth. Lean organizations recognize the importance of engaging and empowering employees as key drivers of continuous improvement.

The purpose of this paper is to illustrate the steps that were done to implement lean and green transformation in a company case study (Glorious Lighting).

To be visible on the market, the company finds the best practices and starts to achieve lean and green objectives simultaneously. With this aims, company wanted to reduce resource consumption, emissions and waste generation.

For taking into consideration to implement lean internally, the benefices start to come, for example: developing guidelines, tools, or decision-making frameworks to help company to identify opportunities for improvement and implement sustainable practices while pursuing lean objectives.

As will follow in the next pages, benefices for company and for environment are many and the investments of resources are less than the resources that the company will have in time.

All of the information that will be provided was started from week 49 2023 and was finished in week 10 2024.

2. RESEARCH METODOLOGHY

Customer orientation is a core component of total quality management. It requires that an organization understands and meets the needs and expectations of its customers at all times, thereby ensuring customer satisfaction and fostering long-term relationships. [19]

In today's competitive environment, organizations must respond proactively to legislation and market regulations as part of their quality management systems. Compliance not only avoids legal penalties but also enhances the organization's reputation and market position.[20]

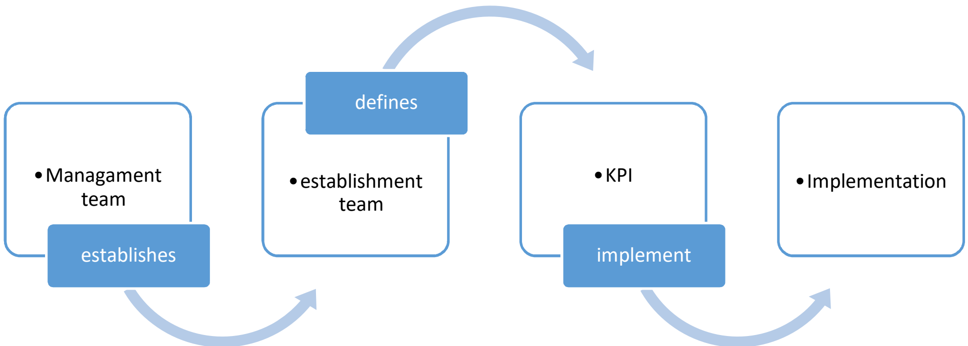

Figure 1 – Steps for green and lean transformation

2.1. Green transformation

In the context of packaging sustainability, green transformation signifies a paradigm shift in how are conceived, created, and consumed packaging materials. It's not merely about making incremental improvements or cosmetic changes; rather, it's about fundamentally rethinking our approach to packaging design and production to minimize environmental impact throughout the entire lifecycle. Green transformation challenges to prioritize materials that are renewable, recyclable, and biodegradable, while also embracing innovative technologies and systems that enable us to reduce waste, conserve resources, and mitigate pollution. Ultimately, it's about creating packaging solutions that not only protect and deliver products effectively but also contribute to a more sustainable and regenerative future for our planet. [1][5]

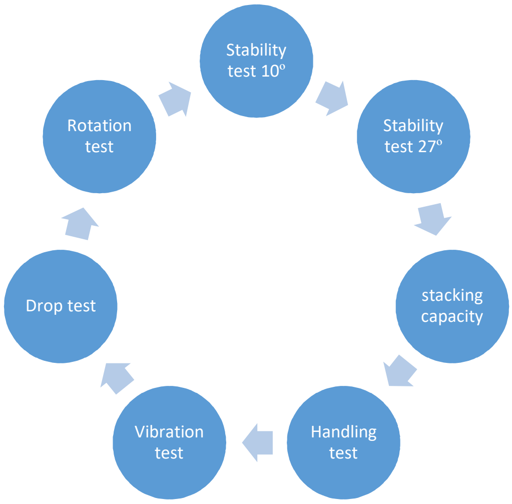

Figure 2 – Necessary test for green transformation

General manager told in an internal meeting that is necessary to reduce somehow the cost of production, quality department together with research and development department take the responsibility to do the request from the head of company. After a few internal meetings between these two departments the decision was taken. Responsible person need to take each single article and to do difference between what client give like a specification for packing requirement and what articles have in mass production. To be greener, the desire is to replace plastic bags with paper on all items. Besides these two aspects, the third improvement is to remove all protective corners from the top, bottom and sides of the finish good pallets.

After the design phase and establish all the necessary elements that were needed to be removed, the responsible person performs the necessary testing influencing what packing need to be removed, as can be visible in following.

For the packing that need to be removed or replaced with another packaging from the finish good pallet, the following tests need to be performed and passed in conformity with the client standards. Necessary test for the finish good pallets needed to be provide if something from the pallet will be removed or changed are: Stability test 10º and 27º (is done by tilting at 10º or 27º the pallet without any protection on it, on the sides, on lateral edge or above it e.g. foils, protective corners, plain sheet. It is necessary to be performed because it assures that the products will not fall from the pallets when the customer will move the pallet with products in the shop or from truck to the shop or warehouse), handling test (is made without any protection on it, on the sides, on lateral edge or above it e.g. foil, protective corners and plain sheet with the finished good pallets with all the finish products on it) and stacking capacity (is made with a maximum capacity that pallet needs to resist. For each pallet the maximum capacity is different. The capacity is calculated by the height and the weight of the pallet)

Figure 3 – Stacking capacity. This test is made to see the strength of the sample to carry constant pressure in a specific time. If the cardboard pallet will not be that much deformed so the automatic or manual forklift can enter between the feet of the pallet and the products inside of the packing need to be undamaged. To be relevant the verification needs to be done after 72 hours.

For the packing that need to be removed or replaced with another packaging from the consumer boxes, the following tests need to be done and passed in conformity with the client standards: drop test (the product needs to be released on the floor from 250 mm height), rotation test (is done on all length and also long of the pack raise one end of the package at 50 mm and will be released on the floor) and vibration test (is made with special equipment in the way that is simulating the transportation)

Figure 4 - Vibration test .A package might experience vibrations throughout its shipping and handling journey that could affect the integrity of the package and its contents.

2.2. Lean transformation

Quality standards are defined as documents that provide requirements, specifications, guidelines, or characteristics that can be used consistently to ensure that materials, products, processes, and services fit for their purpose. [2][6]

Standards provide organizations with the shared vision, understanding, procedures, and vocabulary needed to meet the expectations of their stakeholders. Because standards present precise descriptions and terminology, they offer an objective and authoritative basis for organizations and consumers around the world to communicate and conduct business. [2][7]

That being said defect standardization is a standard that guide persons that work with different components to define if the defects can be accepted and what cannot.

Data analysis is the practice of working with data to glean useful information, which can then be used to make informed decisions.[3][8]

Quality in process is not just about meeting specifications or standards; it's about continuously striving for excellence in every aspect of production. It involves a commitment to consistency, efficiency, and improvement at every stage of the process. Quality means delivering products or services that meet or exceed customer expectations while minimizing waste and maximizing value. It's a mindset, a culture, and a relentless pursuit of perfection that drives continuous innovation and drives business success.[4][9][10]

Figure 5 – Necessary action steps for lean transformation

After the first wave of lean transformation that was started in December 2022 and finished in March 2023, general manager of the company decide that is a good idea to ask again the client to provide a second wave of lean transformation.
For this transformation more areas was included: plastic injection, surface treatment, cement area, assembly lines and also quality department. Also, a multifunctional team of 4 people including the head of lean transformation from client side comes in company. Each of them take one or two departments that lean will be applied.
After the design phase of lean transformation was established for each area that lean transformation needs to be done, multifunctional team establishes the responsible teams (who will be the responsible person to follow the plan and to push the actions to be done in time and which people will need to help implementing the actions). After the responsible team was chosen, the most important elements that the company needs to improve in quality field were taken: describe main quality defects, cooperation between quality and production, measurement system analysis (MSA), quality in process, data system analysis, and problem solving. For each main task that will need to be improved the responsible person of the activities chose the dates that the actions need to be done.

3. CASE STUDY

This case study examines the integration of Lean and Green principles in a manufacturing company to improve efficiency, reduce waste, and minimize environmental impact. The study explores the implementation process, challenges faced, and outcomes achieved through a holistic approach combining Lean manufacturing practices with sustainability initiatives.

In today's competitive and environmentally conscious market, manufacturing companies are increasingly adopting Lean and Green strategies to enhance productivity and sustainability. Lean manufacturing focuses on waste reduction, continuous improvement, and value creation, while Green practices emphasize environmental stewardship and resource efficiency. This case study presents a comprehensive analysis of a manufacturing company's journey towards Lean and Green transformation.

The subject of this case study is Glorious Lighting, a mid-sized company specializing in lighting parts production. Established in 2018, company has a workforce of 800 employees and operates in a highly competitive market. Facing pressure to improve operational efficiency and reduce environmental footprint, the company embarked on a Lean and Green transformation initiative.

4. RESULTS

4.1. Green transformation

In order to reduce the cost of the production and to be greener all the finished good pallets was put on the tests without corner protection on top and bottom of the pallet and all the plastic bags were transformed in paper as it is shows in the pictures below.

Figure 6/7 – Before/after – inside packing of product

After the entire tests that are necessary to be done in order to remove or to replace packing that are inside of the consumer box, that was described before, were done and everything was going well the replacement from the plastic bag to packing paper was implemented. The test passed because the following requests are fulfilled: all product parts/components included in the package are undamaged, the closing of the package is intact, all product parts or packaging parts have remained in the original location stated in the client specification “Packaging Requirement”.

Figure 8/9 – Pallets before/after – outside corner protection

After the entire tests that are necessary to be done in order to remove or to replace packing that are outside of the finished good pallets, that was described before, were done and everything was going well with the removal of the corner protections from the top and bottom of the pallet was implemented. The test passed because the following requests are fulfilled: handling tests on width and length are passed, stability tests at 10º and 27º, two times on width and length are passed and the stacking capacity with 119,25 kg put in top of the tested pallet after 72 hours is passed.

4.2. Lean transformation

After the main activities and also the responsible persons were chosen, the leader of the plan takes each main activity and split it in steps. The period of lean transformation was 15 weeks, which means the activity was pretty intense with the main activities that were described before.

4.2.1. Describe main quality defects and MSA (Measurement system analysis) test

For this activity more steps were tanked. First the person chose the scope for quality defect description. The decision was to take 2 families of lamps and divide the components from the lamps in categories A(red), B(blue), C(green).

In the following table, the meaning for A, B and C categories (what is acceptable, what is not) will be presented.

Table 1 – Meaning of A, B, C categories

No. crt.	Category/color - meaning	Definition	Acceptance criteria	Examples
1.	A/red - Visible for the final customer, in from after assembly of the article	Components that will be in front of the client after assembly the article	Visual defects will not be acceptable for A category, only remarks will be accepted.	Shade for floor and wall lamps.
2.	B /blue - Visible for the final customer	Components that will not be in front of the client	Some visual defects and also remarks will	Shade for pendants lamps, lower tubes for

	from some angle after assembly	customer after assembly the article, but still will be visible	be accepted for B category.	floor lamps, others.
3.	C(green) – Not visible for the customer after assembly	Components that will not be visible after assembly	Visual defects and also remarks will be accepted for C category	Components used for assembly that will be inside (partial or total)
Important: Functionality is critical for quality of articles, needs to be done for all three categories and will be treated like acceptance criteria.				

After this, with some samples with different kind of defects, a tool to perform the quality inspection easier needs to be done.

Relevant document for defect standardization was created and also the tool that will be clear and detailed with defect descriptions that provides essential information for the production team that creates decision making process easier. As can be visible in figure 15, a split for categories and also for type of defects was made. The decision was to accept all the visual defects and remarks for C category, just for missing paint a salt test needs to be providing before the components can be used. For A and B categories, some types of defects was created : scratches and inclusion, points and foreign substance, missing material or paint, extra material, deformation, cracks and also spinning marks.

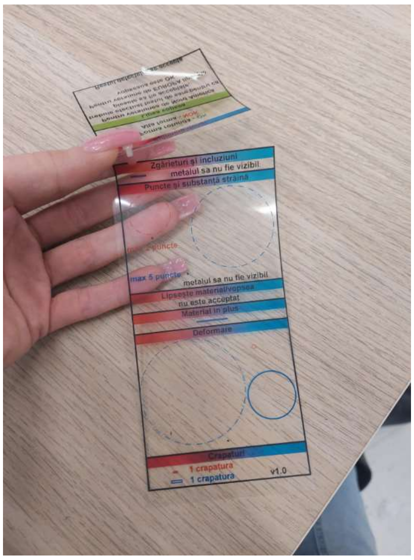

Figure 10/11 – Tool / training for defect standardisation

As all the information has to be distributed to the involved people, the training on how to check with the tool and what means A, B, C categories was performed for the following departments: plastic injection, cement area, surface treatment and assembly lines.
Sometimes after the performed training, the trainer is not sure if the persons understand all the necessary information that was provided. Because of that, samples for MSA were collected. The responsible person was scoring the sample and after the pacification of the date and hour for each department and performed this MSA test.

4.2.2. Quality in process

Quality in process is so important because can find the defects before all the process is done. That said, company decides to implement quality in process in surface treatment area where it has 2 lines of powder coating and 2 lines of wet paint.
Some necessary steps need to be taken as like: define CTQ (critical to quality) and the tolerance for it, preparing a sampling plan/ verification checklist, organization chart and backup, tools for functional verification, train the quality inspector to do that and go live.
Preparation before train the quality inspectors to do that take around 4 weeks, more than the company expected.
In the image below can be found the back plan for people working in the painting, metal, foundry, plastic injection and cement areas. Because in these areas two shifts are worked, and the maximum total number of people on these areas is four, the decision was taken that whenever one person out of the four will need leave, there will be two people working on shift one and only one person on shift two. The decision was made in accordance with the assembly, which only had people on shift one and often hurt without the necessary components checked.

Figure 12/13 – before/after quality in process

4.2.3. Data analyse system

Each week, data for components that are scraped need to be analysed and a scrap meeting with top management team needs to be provided. Because the time for data analysis was too long (around 8 hours per week) a team with excel knowledge was gathered together and different tests are done in order to pass from manual to automatic or semi-automatic excel file for analysis of data.
After the improvement and the simplified of excel for data analysis, process takes only 2 hours, that means 75% reduction.

Figure 23 – before and after semi-automatic excel file

4.2.4. Problem solving

For problem solving quality, manager with the multifunctional team organises a meeting and establishes the following rules for systematic problem solving (SPS). SPS leaders need to be each coordinator of the department in conformity with the area where the problem is found.
SPS team will include: SPS quality leader from that area, next process SPS leader, line/shift leader for the affected area, operator from the area and other relevant personnel.
Next process flow needs to be provided each time when a systematic problem needs to be developed.
Each 2 month Quality manager will analyse the data from SQR's and internal defects. There will be a meeting with production manager to decide what the next SPS subject is. After the subject is chosen, production manager will inform the SPS leader. SPS leader will form the team and will start the analysis and will present the results to management team.
For these two types of researches and steps intended to be implemented, part of the lean transformation could not be achieved in the mentioned time period.
The incorrect approximation of the time needed to implement the steps was due to the inexperienced person who approximated the time and certain situations that arose unexpectedly.

Company supported the activity financially; the limitation for this research was just the limitation of the time.

5. AKNOWLEDGEMENTS

This work was supported by the Glorious Lighting SRL and team of lean transformation from IKEA side. We thank the Department of Research and development of Glorious Lighting SRL for helping with the necessary tests. We are grateful to Michał Stachecki who was the IPS team support for the lean transformation on quality department and for his assistance with data collection. Additionally, we would like to thank all the participants who took part in the study for their time and contribution. Thanks to the quality and production team from Glorious Lighting to approve to be part and to helping the improvement of this research paper.

6. CONCLUSIONS

All the inserted pictures are part of the PhD student research activity inside the case study company. There is no marketing or promotional scope of the company, the only purpose is for PhD research.

In this paper is illustrated the transformation and the improvement that the company Glorious Lighting had from week 49 2023 to week 10 from 2024. In the pages above we can find several areas of improvement both on the green and lean transformation side.

Regarding green transformation, we can talk about improvement on the recycling side, paper is recycled more easily than plastic bags, and that packaging of lamps with both paper and plastic bags, as it was before, has only a protective role . This protection reaches the customer at home and finally in the trash can.

We can talk about a minimization of waste, removing protective stickers for all items that, according to the tests, were not necessary. The protective corners that were on the top of the pallet ended up in the trash as soon as the pallet was unwrapped and put in the store to offer customers accessibility to the products, and the bottom ones, being glued to the pallet with glue sticks, ended up together with the cardboard pallet to the trash.

In addition to all these improvements that are brought to the environment, we cannot forget the financial side. Another improvement that green transformation brought to the company was related to cost minimization. First of all, the price of wrapping paper is cheaper than plastic bags. Secondly, reducing the corners means reducing the price of outer packaging by a percentage of 15% per pallet.

Regarding lean transformation, we are talking about a reduction in time and being in strict correlation with the financial part of the company.
When we talk about the standardization of defects, we can specify that as long as all people see the defects in the same way and can judge the defects in the same way, they no longer need to look for their coordinator to ask him if those components can be used or not, this thing significantly reducing the operator's time to move from the area where that component is found to the office where he can contact the coordinator.
When we talk about data standardization, as we mentioned above, we are talking about 6 hours that have been eliminated per week, more precisely a 75% reduction.
On the quality side of the process, we are talking about finding defects in real time, not finding them only after they have gone through all the processes and arrived as finished components. In the painting area we are talking about several stages: the unpainted components arrive on the hooks, they pass through several basins for pre-treatment of the surface, there they arrive in the cabinet for drying, they arrive at powder painting and from there they arrive in the second cabinet that helps paint polymerization. Most of the components after going through all these processes must be painted with liquid paint. The quality in the process being in all the key points of the line stops the defects in time without going through several processes. Since the change in the quality control area began, there were metal defects that were stopped and sorted until they reached the conveyor, incorrect sorting was found after powder coating and these were stopped and sorted until they reached the painting with liquid. These stops and sorting on time, first of all, minimize the operator's time for handling/painting, etc. of some components that will end up being reworked or scrapped anyway. Secondly, it minimizes the defects that reach the assembly area and the separation time where it should only be assembled, not looking for good components.
For the future researches, implementation of all the actions that are not done yet for lean transformation are foreseen: a game between quality and production that can do a stronger communication between departments and also quality in the process for assembly lines which can improve the detection of defects in advance.
Besides that, the description for the main quality defects needs to be reseen, as well as to go through all the necessary steps to accomplish this for other lamps which the company has in the file provided by the client. After this the update of the tool will be necessary so all the articles can fit in the same measurement. Training regarding the new categories and also the updated tool must be provided and a new MSA test will be redone.

Because is important to find the problems in real time, quality in the process will be done also in metal workshop, die casting area and plastic injection.

The implementation of the projects led to financial savings and customer satisfaction has been maintained, too.

For the future research that is presented upper, the deadline will be week 39 2024.

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Discovering the connection: Cultural Diversity and Innovation in Businesses. A case-based approach

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STRUCTURED ABSTRACT

Purpose - This study investigates the relationship between cultural diversity and innovation in the business environment, focusing on how cultural diversity influences the generation of innovative ideas, decision-making, and the adaptability of organizations.

Design/methodology/approach - Through case analysis and interviews with professionals, data were collected to provide a detailed insight into the experiences and perceptions of experts regarding cultural diversity and innovation.

Findings - The results reveal the positive impact of cultural diversity on the innovative and competitive capabilities of companies, as well as opportunities for improvement in managing cultural diversity and promoting innovation. This study contributes to a deeper understanding of how organizations can leverage cultural diversity as a strategic resource to enhance their innovative capacity in the market.

Originality/value - Key findings of the study highlight the variety of approaches and practices in managing cultural diversity and innovation in organizations, emphasizing the need to promote more inclusive practices and integrate cultural diversity into innovation processes. Additionally, the importance of facilitating factors such as knowledge of different languages, inclusive organizational structure, cultural diversity policies, and cultural diversity training is identified. There is a recognized need for greater connection between cultural diversity management and innovation management, along with the development of indicators directly linking both areas, holding significant implications for the research field of cultural diversity management and innovation. These conclusions underscore the importance of promoting policies and practices that foster cultural diversity and innovation in

organizations, emphasizing the need for future research to better understand the factors influencing this relationship and optimize management processes in these areas. Ultimately, these results will contribute to strengthening the competitiveness of organizations in diverse and globalized environments.

Keywords: Diversity, Innovation, Cultural Diversity.

Paper type: Research paper.

INTRODUCTION

In the business sphere, innovation has become a crucial element to drive the development, competitiveness, and sustainable growth of organizations. Various studies have emphasized its significance as a driver of economic change and its close relationship with companies' ability to adapt to their environment and generate competitive advantages (Porter, 1990; Schumpeter, 1911; Dogan, 2016; Maradana et al., 2017). Barney's resource-based view theory (1991), a well-established theoretical framework in the field of business strategy, provides a solid approach to understanding how organizations can leverage their unique internal resources, including cultural diversity, as a source of competitive advantage and ultimately innovation.

However, despite its relevance, understanding the factors driving innovation in companies remains a challenge. Scientific literature has pointed out the importance of the human factor in innovation processes (Banerjee, 2014). Additionally, the relevance of critical thinking, creativity, and the ability to take risks and think strategically has been highlighted as skills that foster innovation (Wuyts et al., 2014; Hu, 2014).

Currently, given the increasing cultural diversity, it is considered increasingly important as a factor driving innovation in businesses. Nevertheless, only a limited number of studies emphasize the significance of the link between these two concepts (Ostergaard et al., 2011; Ozgen et al., 2011; Marino et al., 2012; Kemeny, 2012; Nathan & Lee, 2013).

In this context, cultural diversity has emerged as an increasingly important aspect to enhance innovation in businesses. Despite the growing attention given to cultural diversity in recent years, there are gaps in scientific literature preventing a complete understanding of its impact on innovation processes. Specifically, a deeper exploration is required into how cultural diversity in the business environment can influence the generation of innovative ideas, decision-making, and the adaptability of organizations. Therefore, the aim of this study is to examine the link between cultural diversity and innovation in the business context.

The main objective of the study is to analyze the assessment of professionals from different organizations regarding the link between cultural diversity and innovation. To address this objective, a case analysis of companies has been conducted, and data have been collected through interviews with professionals from various organizations. Through this approach, the study seeks to obtain a detailed insight into the experiences and perceptions of professionals regarding cultural diversity and innovation.

In summary, this study aims to fill a gap in scientific literature by providing empirical and practical evidence on the relationship between cultural diversity and innovation in the business context. The results and conclusions of this study can contribute to a deeper understanding of how companies can leverage cultural diversity as a strategic resource to enhance their innovative capacity and competitiveness in the market.

The structure of the article is as follows: firstly, the methodology used in the case analysis and data collection through interviews will be described. Next, the obtained results will be presented and discussed, emphasizing the most relevant findings regarding the link between cultural diversity and innovation. Finally, conclusions based on the study results will be provided, highlighting practical implications and potential future research directions.

Concept of Innovation and Cultural Diversity:

Concept of Innovation:

Innovation, as highlighted in scientific literature, encompasses a variety of definitions and dimensions. The most widely accepted definition in the literature refers to innovation as the organizational capability for the introduction of new products, services, or processes (Huang et al., 2011; Edmondson et al., 2017; Mir-Babayev et al., 2017; Batarseh et al., 2017). According to Orzen et al. (2013), innovation is primarily the introduction of something radically new into a company, the improvement of an existing product, or the modification of a process or organizational form. Delving deeper into the topic, the authors state that product innovation is the introduction into the market of a new good, service, or significant improvement to a service. For example, software that enhances ease of use, a component, or subsystem. Regarding process innovation, they define it as the implementation of a significant improvement to a production process, distribution method, or supporting activity for goods or services in a company.

For Nepelski et al. (2018), innovation includes only the first part, that is, innovation as the ability to incorporate new products or services. Whereas for Zhang et al. (2015), it involves the launch of patents. In the same line, Boone et al. (2015) define innovation as the number of patent applications by companies in a year, and, citing Heavey & Simsek (2013), the process by which companies innovate creates new businesses and transforms, changing the business landscape or key strategic processes.

Mir-Babayev et al. (2016) agree with the previously mentioned authors but focus on the measurement of innovation. Thus, for the researchers, one way to measure innovation in an organization includes the analysis of new patents, designs, services, or processes. Specifically, to measure innovation, the following parameters of the performance level of an organization in relation to innovation should be followed. Innovation would be the total sum of all types of innovation that occur in the company, including: (i) product innovation: number of new products or patents registered in the last 12 months, (ii) Learned product innovation: number of significantly new or improved products introduced into a company. (iii) original product innovation (radical innovation): number of products introduced that are completely new to a company. (iv) process innovation: number of new processes introduced in the last 12 months.

On the other hand, Lee et al. (2019), when discussing innovation, distinguish three concepts. First, idea generation, understood as novel and useful ideas generated in any field. Second, idea promotion: to what extent employees identify with the organization and receive support to implement creativity in day-to-day activities. And finally, idea practice, referring to applied creativity in processes and products as a performance improvement.

Lastly, it is worth noting that a concept clear in the literature is that this ability to innovate is among the most important dynamics influencing the competitive advantage of organizations in the global market, regardless of the industry (Gorodnichenko et al., 2010; Dogan, E, 2016).

Concept of Cultural Diversity:

Regarding the concept of cultural diversity, scientific literature distinguishes, on one hand, authors who understand cultural diversity as more easily observable characteristics such as race, gender, age, or nationality (Mir-Babayev et al., 2016). Edmondson et al. (2016), like Mir-Babayev et al. (2016), distinguishes between the parameters of diversity mentioned earlier: the more easily observable characteristics (age, gender, or "ethnicity"), adding to the diversity equation less easily observable characteristics such as knowledge, information, and experience.

Combining the perspectives of these two authors, we find the definition by Batarseh et al. (2016), which, by adding more variables to the concept, defines cultural diversity as the degree to which notable differences exist among individuals within a team (Van Knippenberg et al., 2004), distinguishing three levels of diversity:

1. Superficial level: Observable differences such as age, gender, and race.
2. Deep level: Less easily identifiable differences in personal characteristics such as values, beliefs, and attitudes that manifest through interaction with others (Milliken and Martins, 1996).
3. Functional level: The degree to which people differ in knowledge, skills, information they possess, and experience.

In the same line, Grillitsch et al. (2018) define cultural diversity within the following parameters (Ruef et al., 2003):

- Inborn attributes: Demographic characteristics such as gender, age, ethnicity, and nationality.
- Acquired attributes: Education, experience, or job function.
- Work-related attributes: Academic training and functional experience.

On the other hand, in a more simplified definition of the term, Orzen et al. (2013) consider cultural diversity as individuals who were not born in the country of origin under consideration. According to this author, cultural diversity is a multidimensional phenomenon influenced by many factors (e.g., language, ethnicity, religion, identity, etc.). Representing cultural diversity among employees simply by place of birth never fully captures cultural diversity; however, it has the advantage that information about place of birth is objective and constant over time.

Finally, we cannot overlook Hofstede and his Cultural Dimensions Analysis (2001). According to his theory, a society possesses a distinct culture from another due to differences in thinking among people of different races and regions who end up sharing common norms, symbols, and values that differentiate them from other societies. There are five cultural dimensions that can define a society: power distance, individualism, masculinity, uncertainty avoidance, and orientation.

The concept of cultural diversity that will be used in this article is based on diversity of origin or nationality, following the definition by Orzen et al. (2013).

Link Between Cultural Diversity and Innovation:

Several studies, such as those by Mir-Babayev et al. (2017), Edmondson et al. (2016), and Lee et al. (2019), have demonstrated a positive influence of cultural diversity on innovation. These studies suggest that cultural diversity can contribute to both the generation of innovative ideas and the successful implementation of projects.

For example, Mir-Babayev et al. (2017) observed that cultural diversity follows an inverted U-shaped relationship with innovation. Gender diversity and diversity in foreign origins seem to have a more positive impact on innovation when diversity levels are moderate. Extremely low or high levels of cultural diversity tend to have a negative impact on innovation, while moderate levels are associated with a higher level of innovation.

Edmondson et al. (2016) suggest that group experience positively contributes to team members' learning and well-being. Forming culturally diverse teams can enhance team performance, increasing the ability to solve complex problems and innovate new products or services.

Lee et al. (2019) have also demonstrated that diversity in terms of profession, skills, and experience of team members has a positive effect on innovation. They have emphasized the importance of knowledge exchange in this relationship.

In the same vein, Barney's Resource-Based View theory, developed by Jay B. Barney in 1991, has played an essential role in understanding how organizations can gain and sustain a competitive advantage in a constantly changing business environment. This theory is based on the premise that a company's resources and capabilities are the fundamental elements that can generate and sustain a long-term competitive advantage.

The theory identifies four key criteria for a resource or capability to be considered a source of sustainable competitive advantage:

1. Valuable: The resource or capability must be able to create value for the company by enabling it to exploit opportunities or neutralize threats in its environment. In the context of cultural diversity, the diversity of origin, knowledge, and experiences of employees can be considered a valuable resource, as it can bring unique perspectives and skills that can drive innovation.

2. Rare: The resource or capability must be relatively scarce or uncommon compared to other companies in the industry. Cultural diversity, if managed properly, can be rare, as not all organizations fully leverage the diversity of their workforce.

3. Difficult to Imitate: The company must be able to protect or maintain its resource or capability in a way that other companies cannot easily replicate it. Managing cultural diversity through specific policies and practices can make it difficult for other organizations to imitate the diverse composition of the workforce and the benefits it brings in terms of innovation.

4. Non-Substitutable: The resource or capability cannot be replaced by another resource or capability without losing the competitive advantage. Cultural diversity, in this sense, can be difficult to substitute, as the diversity of origin and experience of employees brings unique perspectives that cannot be easily replicated.

Barney's Resource-Based View theory is applied in this theoretical framework to understand how organizations can leverage their internal resources, such as cultural diversity, to drive innovation in their products, processes, and services.

This theoretical framework integrates Barney's Resource-Based View theory to analyze how cultural diversity can be considered a valuable and rare resource that, when managed properly, can drive innovation and competitive advantage in the business context. It also recognizes that innovation encompasses a variety of dimensions, from idea generation to its application in products and processes, and that this ability to innovate is fundamental to the competitiveness of organizations in a constantly evolving global market.

RESEARCH METODOLOGHY

The research has been conducted using the qualitative method of case study (Yin, 2014) to deepen the understanding of the link between cultural diversity and innovation in companies. This methodology is especially suitable when the aim is to understand the how and/or why of the

investigated phenomenon, when the researcher has no control over the events being investigated (cannot experiment with them), and when the phenomena to be studied are current or contemporary (Yin, 2014). These conditions describe the reality of our study. To achieve the research objective, interviews were conducted with professionals in the business field, and the research reality is presented based on the interpretation of the words expressed by the participants.
Furthermore, it is characterized as inductive, carrying out a process of coding, categorization, description, and evaluation to reach new conclusions as the research categories take shape. Therefore, in terms of design, we can talk about an emergent design, where decisions "emerge" from the research itself as it progresses, generating conceptual categories for understanding (Penalva et al., 2015; Pérez-Luco et al., 2017).

Likewise, for the analysis of the facilitating factors of cultural diversity, the Gioia methodology was used, which is used in many studies (Nag and Gioia, 2012). This methodology is a systematic approach to qualitative research, considering that the information collected in interviews is useful for identifying findings based on the interviewees' experience.

Instruments:

The chosen instrument for data collection was the interview. In this sense, the goal is for the interviewees to offer their point of view, without feeling judged and providing their knowledge regarding the topic being developed. A semi-structured interview (see Annex) was proposed, with a total of 31 questions, leaving an open-ended section for responses to facilitate the contributions that each participant considers important.

The semi-structured interview covers various areas of inquiry, providing a holistic approach to data collection. It includes a demographic data section with 9 questions exploring aspects related to the company and the interviewed person. Subsequently, 7 questions focused on the management of cultural diversity are addressed, followed by 6 questions dedicated to innovation management. Finally, the specific relationship between cultural diversity and innovation in the studied companies is deepened through an additional 9 questions. This comprehensive approach allows for a complete and contextualized view of the intersection between cultural diversity and innovation in the examined business environment.

Sample:

The choice of the sample is based on a strategy to capture a wide range of perspectives and experiences in the context of cultural diversity and innovation in organizations. 15 professionals from 5 organizations with different characteristics have been selected to obtain heterogeneous participation that reflects diversity in various key aspects.

Regarding organizations, diversity has been considered in terms of sector or activity, size, revenue, and scope of activity. This allows addressing how cultural diversity and innovation may vary in organizations from different contexts. Both large and small, multinational and national organizations have been included, enriching the understanding of how these variables can influence the relationship between cultural diversity and innovation.

Furthermore, heterogeneity in the participant sample has been sought concerning age, gender, years of experience, position, and function within the organization. This allows exploring how different professional profiles can contribute to or interact with the dynamics of cultural diversity and innovation. Both executives and middle managers have been considered, as their roles and responsibilities in decision-making and implementation of measures directly influence the management of diversity and the promotion of innovation in organizations. This number is considered sufficient in qualitative research, as a sample size between 5 and 25 is usually appropriate (Brinkmann & Kvale, 2007).

Therefore, as shown in Table 1, the participating organizations present diverse realities.

Table 1: Characteristics of Case Study Organizations

Company	Sector	Dimension	Billing	Scope Activity
Organization A	Health	Large +250 workers	+ 50MEuros	Multinational of national origin
Organization B	Automotive	Large +250 workers	+ 50MEuros	Multinational of national origin
Organization C	Health	Large +250 workers	+ 50MEuros	Not multinational
Organization D	Agriculture, food, livestock, fishing and forestry activities	Small 1-50 workers	Between 2 and 10 Meuros	Not multinational
Organization E	Industrial Sector	Large +250 workers	+ 50MEuros	Multinational of national origin

Source: Self-prepared.

As for the professionals, the criterion followed is that three individuals per organization participate: one responsible for the diversity area, one responsible for the innovation area, and a third participant from another area of the organization. In Table 2, you can observe the diversity among the participants.

Table 2: Case Study Participants

Organization	Participants	Category	Seniority in the Organization	Gender	Age	Origin	Lived abroad	Married to a foreigner	Cultural diversity in the family	Worked with Foreigners	Cultural profile feels
Company A	A	Manager	From 6 to 10 years	Female	45-59 years	Spain	No	Yes	Yes	Yes	Spanish
	B	Middle Manager	From 11 to 15 years	Female	45-59 years	Spain	Yes	No	No	Yes	Of the world
	C	Middle Manager	More than 15 years	Female	45-59 years	Spain	Yes	No	No	Yes	Spanish
Company B	D	Middle Manager	From 0 to 5 years	Female	45-59 years	Spain	Yes	Yes	Yes	Yes	Spanish
	E	Manager	More than 15 years	Male	45-59 years	France	Yes	No	Yes	Yes	Of the world
	F	Manager	From 0 to 5 years	Female	45-59 years	Spain	Yes	No	No	Yes	Of the world
Company C	G	Manager	More than 15 years	Male	45-59 years	Spain	No	No	No	Yes	European
	H	Manager	From 0 to 5 years	Male	45-59 years	Spain	No	No	No	Yes	Spanish
	I	Middle Manager	From 11 to 15 years	Male	30-44 years	Spain	Yes	No	No	Yes	Spanish
Company D	J.	Middle Manager	From 6 to 10 years	Male	45-59 years	Spain	No	No	Yes	Yes	Spanish
	K	Manager	More than 15 years	Female	45-59 years	Spain	Yes	Yes	Yes	Yes	Spanish
	L	Middle Manager	From 6 to 10 years	Male	45-59 years	Spain	No	No	No	No	Spanish
Company E	M	Manager	From 0 to 5 years	Male	45-59 years	Spain	Yes	No	Yes	Yes	European
	N	Manager	More than 15 years	Male	45-59 years	Spain	Yes	No	Yes	Yes	European
	O	Manager	More than 15 years	Male	30-44 years	Spain	Yes	No	No	Yes	European

In addition, we assessed the diversity of participants in terms of their personal experience, including whether they have lived abroad, worked with people from other backgrounds, and have cultural diversity in their own families. These personal factors can have a significant impact on how individuals perceive and respond to cultural diversity in the workplace, as well as their ability to contribute to innovation.

In this regard, the heterogeneity of participants can be observed: according to category 9, there are executives, and 6 are middle managers. Regarding seniority in the studied organizations, the range varies from 0 to 5 years to more than 15; 9 are men, and 6 are women, with ages ranging from 30 to 59 years, allowing for diverse perspectives. The same applies to whether they have lived abroad, worked with people from other backgrounds, or if there is cultural diversity in the family. Regarding positions, the reason for selecting professionals from the executive team and middle management is that their functions and decisions directly influence the measures and actions proposed by the organization. Therefore, understanding their perspective on the study topic is considered relevant. Likewise, involving those responsible for diversity and innovation in organizations provides a more specific insight into direct and indirect interventions and processes within the companies.

In summary, the choice of this sample is based on the intention of obtaining a comprehensive and enriching view of how cultural diversity influences innovation in a variety of organizational contexts and through a diversity of personal experiences. This will allow us to address the research more effectively and contribute to the overall understanding of this relationship in the business context.

Procedure:

In this section, the process followed for the development of the interview is detailed, as well as the basic technical elements used during the data collection: the interview guide, the participants, and the recording methods. The interviews included in this study were conducted uniformly by the same researcher, who is also the first author of this article. This approach ensures consistency in data collection and subsequent analysis, contributing to the methodological integrity of the study. The average duration of the interviews was one hour.

Tabla 3: Steps in the development of the interview
1st step. Preparation. Before the interview The organizational aspects of it are planned, as well as the content of the questions raised. To do this, both the information regarding the theoretical foundation and the object of study are kept in mind.
2nd step. Contact with participants. Opening of the interview. The interviewer is identified and information is offered about the objectives of the research, her consent to participate in it is requested and the confidentiality of the data is assured.
3rd step. Development. The interview is constituted. The interview is carried out through Teams requesting permission to record it. The interview begins with demographic data, followed by questions related to cultural diversity in the organization, innovation and the relationship between cultural diversity and innovation.
4th step. Closing A summary is made to conclude and the participant is thanked for their collaboration. It is reported that once the investigation is completed it will be sent to you.

Source: Self-prepared.

Data Analysis:

Following the recording of interviews, the data analysis of the collected information was carried out. In this regard, two phases are distinguished:

- Phase 1. Transcription of Information: A literal transcription of the gathered information in the interviews was conducted. The aim is to transcribe the interview verbatim, without interpreting what is said, but capturing the discourse exactly as the interviewees express it. Additionally, performing this action manually allows for capturing key aspects, listening to explanations again, and creating primary documents.
- Phase 2. Information Analysis: Professional software QDA Miner Lite (software for qualitative data analysis) was used for content analysis, establishing quotations, codes, and code groups, following an inductive model. In this regard, the categories intended for analysis are clarified, elaborated, and completed based on the objectives, as sampling is done with the emerging data.

This process of qualitative analysis contributed to a deeper understanding of the relationship between cultural diversity and innovation in the studied organizations and provided a solid foundation for the study's conclusions. This methodical and structured approach ensured the quality and reliability of the collected data, allowing for a meaningful analysis of participants' perceptions regarding cultural diversity and innovation in their organizations.

RESULTS

Concerning the general objective of this study, to understand the assessment of professionals from different organizations regarding the link between cultural diversity and innovation, access has been gained to the perspectives of professionals with different levels of experience, gender, connection with cultural diversity and innovation, and who work in different processes related to these two concepts. These professionals have provided their perception of the reality of cultural diversity and innovation, also outlining what, from their perspective, are the barriers found in organizations.

Below are the results obtained, organized into categories based on the themes analyzed during the interviews. These categories include cultural diversity management, innovation management, and, finally, the link between cultural diversity and innovation in organizations.

Results on Cultural Diversity Management:

Based on the collected data, some conclusions related to the management of cultural diversity in the studied organizations can be drawn (Table 4):

Table 4: Management of Cultural Diversity in Organizations

Category	code	% Cases
CD management. in the company	CD is managed. in the company	66.70%
	cd is not managed. in the company	26.70%
	You don't know if the CD is managed. in the company	6.70%
Existence figure manages the dc . in the company	There is a figure within the company that manages the CD.	53.30%
	There is no figure within the company that manages the CD.	46.70%
CD. in team building	dc is taken into account to create teams	33.30%
	dc is not taken into account to create teams	66.70%
CD practices.	The company has been invited to present CD practices.	20.00%
	The company has not been invited to expose CD practices.	60.00%
	He does not know if the company has been invited to expose CD practices.	20.00%
CD practices imitated in the company	CD practices have been imitated of the company	26.70%
	CD practices have not been imitated of the company	46.70%
	CD 's practices have been imitated of the company	26.70%
Measuring the impact of CD in the results of the teams	Impact of CD is measured in team results	6.70%
	CD is not measured in team results	86.70%
	It is not known if the impact of CD is measured in team results	6.70%

Source: Self-prepared.

Firstly, there is a variety in the management of cultural diversity in the participating companies. Around 66.7% of the participants indicated that cultural diversity is managed in their organizations, while 26.7% mentioned that it is not managed. This shows a diversity of approaches and practices regarding cultural diversity within organizations.

In the case of organization B, a clear orientation towards the management of cultural diversity is evident. According to the obtained quotes, it is highlighted that cultural diversity is very integrated into the company, and specific actions are taken in different countries where they operate. For example, in the United States, it is mentioned that cultural diversity is taken into account in hiring and retaining personnel, applying legal measures and providing specific training in cultural diversity.

Regarding the existence of a figure responsible for managing cultural diversity, it was observed that approximately 53.3% of the participating organizations have a specific person in charge of this task. This finding suggests that some organizations recognize the importance of assigning clear responsibilities in relation to cultural diversity. In addition, a correlation was found between the affirmation of managing cultural diversity and the presence of a figure in charge of this task. All organizations that claim to manage cultural diversity have a person in charge of the area. However, it is interesting to note that in two studied cases, cultural diversity was managed despite not having a specific figure for it. In most cases analyzed, the management of cultural diversity falls within the human resources team of the organization.

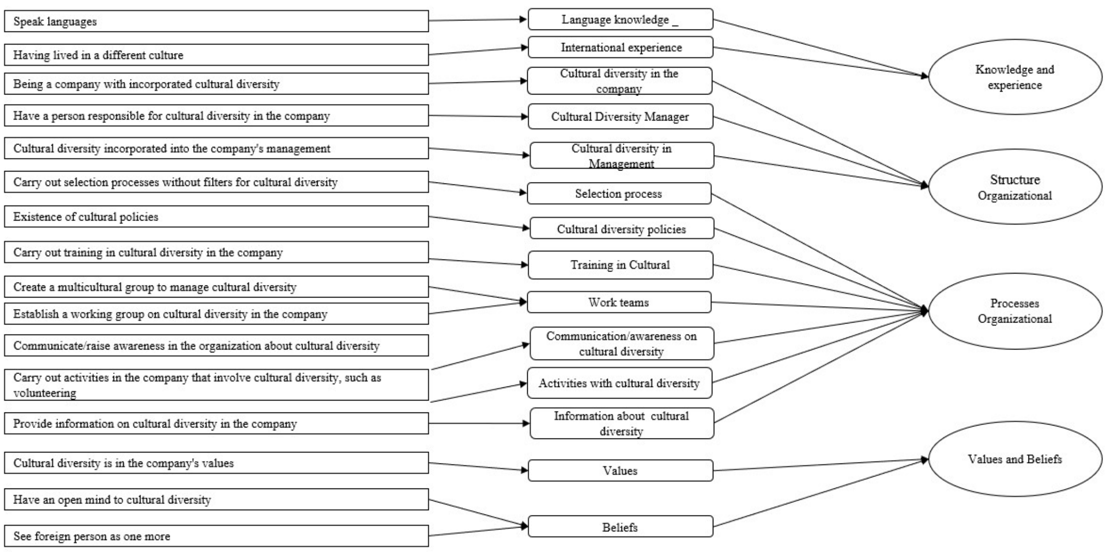
On the other hand, although 33.3% of the participants indicated that cultural diversity is taken into account when creating teams, 66.7% stated that this dimension is not considered. This highlights an opportunity to promote inclusion and the appreciation of cultural diversity in team formation processes. Only 20% of the participating companies have been invited to present cultural diversity practices. And in the same vein, only 26.7% of the participating organizations stated that their cultural diversity practices have been imitated. This suggests that there is still room to promote visibility and the exchange of experiences related to cultural diversity among organizations. And that the adoption of these practices by other organizations is still limited, which may indicate a lack of awareness or understanding of the benefits of cultural diversity in the business environment.

Regarding points related to measurement, only 6.7% of the participants stated that the impact of cultural diversity on team results is measured. This points to an opportunity to promote the implementation of evaluation and monitoring measures that allow for a better understanding of the role of cultural diversity in company results.

To gain a deeper understanding of the facilitating factors of cultural diversity in the studied organizations, a detailed analysis has been carried out, allowing the identification of four key dimensions, each playing an essential role in promoting cultural diversity. These dimensions, obtained through the Goia methodology (Figure 1), shed light on specific aspects that influence the effective integration of cultural diversity in the workplace. The identified dimensions are as follows:

1. Knowledge and Experience
2. Organizational Structure
3. Organizational Processes
4. Values and Beliefs

Figure 1: Facilitating Factors of Cultural Diversity in Organizations.



Source: Self-prepared.

1. Knowledge and Experience: This encompasses the appreciation of language skills and the

experience of having lived in diverse cultures as enriching factors in the work environment. According to one interviewee, "the ability to speak different languages and having lived in different cultures" is considered enriching for the work environment.

2. Organizational Structure: Refers to the importance of having an organizational structure that intrinsically integrates cultural diversity, including the presence of leaders and specific responsibilities for cultural diversity in the company. The existence of a company "with built-in cultural diversity," "the presence of a person responsible for cultural diversity in the company," and "the presence of cultural diversity in the company's leadership" are important facilitating factors. These results indicate that having a diverse and representative organizational structure is fundamental to promoting cultural diversity in the workplace.

3. Organizational Processes: Encompasses organizational practices designed to promote cultural diversity. This includes selection without cultural diversity filters, specific training, established policies, dedicated work groups, communication and awareness, as well as activities involving cultural diversity. One interviewee highlights: "Carrying out selection processes without cultural diversity filters" is identified as a facilitating factor. In addition, other interviewees mention: "Conducting specific training in cultural diversity," "having established cultural diversity policies," "providing training in cultural diversity" to employees, "creating a multicultural group dedicated to managing cultural diversity," "establishing a specific working group on cultural diversity," "communicating and raising awareness in the organization about cultural diversity," "carrying out activities in the company that involve cultural diversity (such as volunteering)," and "providing information about cultural diversity in the company." According to the responses obtained in the interviews, these facilitating factors can contribute significantly to fostering and promoting cultural diversity within the organization.

4. Values and Beliefs: Highlights the importance of embedding cultural diversity in the company's values, fostering an open mindset, and considering foreign individuals as an integral part of the team. "Cultural diversity is in the company's values, having an open mind to cultural diversity" and "seeing foreign people as one of us" are highlighted as relevant factors. This indicates that having an organizational culture that promotes the appreciation and respect for different cultures is fundamental to fostering diversity.

In summary, the facilitating factors of cultural diversity identified in this study include knowledge and experience, organizational structure, organizational processes, and values and beliefs. These findings provide a foundation for understanding how to promote and foster cultural diversity in the workplace.

Results on Innovation Management:

Based on the collected data, some conclusions related to innovation management in the studied organizations can be extracted (Table 5).

Table 5: Innovation Management in Organizations

Category	code	% Cases
Existence figure manages innovation in the company	If it appears, it manages inno .	93.30%
	Manages inno does not appear .	6.70%
Steering committee evaluates innovation	The management committee evaluates the inno .	73.30%
	The management committee does not evaluate the inno .	26.70%
Who manages innovation in the company	Manager	20.00%
	Innovation Director	60.00%
	BU director	13.30%
	Corporate	6.70%
Creation of teams for innovation in the company	If created teams for inno. in the company	80.00%
	No teams created for inno. in the company	20.00%
Carrying out training on innovation in the company	If you have completed training in inno. in the company	66.70%
	No training in inno. in the company	33.30%
I use new technologies for innovation	New technologies are used for innovation .	73.30%
	New technologies are not used for innovation	20.00%
Innovation measurement	Inno. is measured in the company	93.30%
	Inno. is not measured in the company	6.70%

Source: Self-prepared.

Firstly, the majority of organizations (93.30%) have a figure responsible for managing innovation in the company. This indicates that they recognize the importance of assigning specific responsibilities to drive and lead innovative processes. The most common roles in innovation management are the Innovation Director (60.00%) and the Manager (20.00%). This suggests that organizations typically assign individuals with experience and specialized knowledge in innovation to lead these processes.

Regarding the creation of teams for innovation, 80.00% of organizations have established specific teams for innovation in the company. This demonstrates that they recognize the importance of having dedicated and collaborative teams to drive idea generation and the implementation of innovative projects. The composition of these teams may vary, depending on the specific projects and objectives of each organization. Some examples include the participation of multidisciplinary profiles, such as doctors, laboratory staff, and product industrialization, working together in different phases of product development.
Concerning the use of new technologies, 73.30% of organizations use new technologies for innovation. Some of these technologies include artificial intelligence, machine learning, data management systems in the development of new products, services, and processes. Other participants also confirmed the use of innovative technologies, such as a respondent who highlighted the implementation of Office365 for collaborative work and telemedicine in the patient care sector. These results show the variety of approaches within organizations regarding the use of technologies for innovation and emphasize the importance of considering the specificities of each case.

Regarding training on innovation in the company, the results show that 66.70% of surveyed companies have provided innovation training. This indicates that a significant majority of organizations recognize the importance of acquiring knowledge and skills related to innovation as part of their business development.

Regarding the measurement of innovation, 73.30% of organizations have a management committee that evaluates innovation. This indicates that strategic decision-making related to innovation is considered a responsibility of the management team. In some of the analyzed cases, the evaluation is carried out in a product committee responsible for analyzing new products, agreements, and start-ups, as well as other committees formed by directors from different areas (business, engineering, finance, intellectual property). Additionally, it was found that the vast majority of organizations (93.30%) measure innovation to some degree.

This indicates that indicators and metrics are valued to assess the impact and success of innovative efforts. Specific indicators and metrics used include the number of orders, patents, and the amount of investment. This quantitative assessment reflects a data and results-based approach with the aim of evaluating and improving the innovative efforts of organizations.

Results on the Link between Cultural Diversity and Innovation:

Based on the collected data, some conclusions related to the link between cultural diversity and innovation in the studied organizations can be extracted (Table 6).

Table 6: Link between Cultural Diversity and Innovation in Organizations

Category	Code	% Cases
Responsible inno. and cd within the leadership	If you are present responsible for inno.y cd . within the leadership	66.70%
	Not present responsible for inno. and cd. within the leaderhip	33.30%
Responsible interaction dc and inno .	If interaction those responsible for inno . and cd.	60.00%
	No interaction with those responsible for inno. and cd.	40.00%
CD manager participates in the creation of inno. teams.	Responsible cd. Yes, he thinks to create inno teams.	46.70%
	Responsible dc. does not have an opinion to create inno teams.	53.30%
Responsible inno. participates in the creation of cd teams.	Responsible inno . Yes, he thinks about creating CD teams.	53.30%
	Responsible inno. He has no opinion to create CD teams.	46.70%
In measuring innovation, cd is included	CD is included in measuring innovation.	6.70%
	CD is not included in measuring innovation.	93.30%
CD measurement, inno is included.	inno is included in the measurement of cd.	20.00%
	inno is not included in the measurement of cd.	66.70%
	Don't know if the inno is included in the measurement of the cd.	13.30%
Recognition for inno. for incorporating cd	If there is recognition for inno. for incorporating cd	6.70%
	There is no recognition for inno. for incorporating cd.	86.70%
	He doesn't know if there is recognition for inno. for incorporating cd.	6.70%
Recognition for cd for incorporating inno.	If there is recognition for cd. for incorporating the inno.	6.70%
	There is no recognition for cd. for incorporating inno.	93.30%
Existence of kpi's that link cd and inno.	If there are kpi's that link cd. and inno .	
	There are no kpi's that link cd. and inno .	100.00%

Source: Self-prepared.

Firstly, 66.70% of organizations have leaders in both innovation and cultural diversity at the management level. This relationship indicates that the majority of organizations recognize the importance of having dedicated leaders to promote innovation and manage cultural diversity in the company.

On the other hand, 60% of organizations indicate that there is interaction between those responsible for cultural diversity and innovation. This interaction suggests synergy between both roles, which can contribute to a more effective integration of cultural diversity into innovation processes.

In approximately half of the studied organizations (46.70%), it was observed that the person responsible for cultural diversity does not participate in the creation of innovation teams, and the same applies to the involvement of the innovation leader in the creation of cultural diversity teams. This result suggests a potential gap in integrating cultural diversity into teams tasked with driving innovation, which could limit the diversity of perspectives and approaches in such teams.

In a limited number of cases, 6.70% of organizations include cultural diversity in the measurement of innovation. This indicates that there is still low recognition of the importance of considering cultural diversity as a relevant factor in innovative results. However, the fact that this measurement is carried out in at least one organization demonstrates an emerging interest in understanding how cultural diversity can impact innovation.

In terms of recognition, it was evident that in the majority of organizations (93.30%), there is no specific recognition for innovation that incorporates cultural diversity. This result highlights the need to promote greater appreciation and reward for the inclusion of cultural diversity in innovation efforts.

Lastly, it was found that there are no Key Performance Indicators (KPIs) directly linking cultural diversity and innovation in any of the organizations studied. This lack of specific indicators can make it challenging to assess and monitor the impact of cultural diversity on innovative results and limit organizations' ability to establish clear and measurable goals in this area.

In summary, the results suggest that, although some organizations focus on innovation and cultural diversity management, the connection between both aspects is still limited in the majority of cases.

To foster a stronger relationship between cultural diversity and innovation, it could be beneficial to promote the inclusion of cultural diversity in innovation measurement, encourage joint involvement of leaders in team formation, and establish specific recognitions for diversity-based innovation. These actions can help enhance the positive impact of cultural diversity on innovation processes and strengthen the competitiveness of organizations.

DISCUSSION AND CONCLUSIONS

Regarding the overall objective of this study, which seeks to understand the assessment of professionals from different organizations regarding the link between cultural diversity and innovation, we have gained insight from professionals with varying levels of experience, gender, connection with cultural diversity and innovation, and who work in processes related to these two concepts. These professionals have provided their perception of the reality of cultural diversity and innovation, also addressing the barriers they encounter in organizations.

The results reveal significant findings related to both cultural diversity management and innovation management, providing insights into the existing connection between these two areas.
Firstly, we observed a diversity of approaches and practices related to cultural diversity management in participating organizations. This reflects that there is no uniform approach in these organizations. While the majority claims to manage cultural diversity, only approximately 53.3% have a specific figure responsible for this aspect, suggesting that there is still ample room to improve attention and focus on cultural diversity in organizations.

One notable finding is the opportunity to promote the inclusion and appreciation of cultural diversity in team formation processes. Most participants indicated that cultural diversity is rarely considered when creating teams, presenting a significant opportunity to promote greater inclusion and leverage the benefits of diversity in the composition of work teams.

The study also identified two key aspects related to cultural diversity in teams. Firstly, the diverse composition of teams, especially those comprised of individuals from different countries, brings international potential to the company's projects, as participants can contribute networks and creativity based on their diverse cultural backgrounds. Furthermore, diversity within teams fosters a willingness to appreciate different perspectives and enhances critical thinking skills (Day and Glick, 2000; Terenzini et al., 2001). On the other hand, it is essential to recognize that intercultural teams can pose challenges and dysfunctions. Cultural differences can lead to ineffective communication and conflicts (Humes and Reilly, 2008). Teams may experience difficulties in time management and fully leveraging the diversity present in the group. However, it is crucial to emphasize that these challenges should not be considered insurmountable obstacles but as opportunities to strengthen intercultural communication skills and develop effective management strategies.

In this context, Barmeyer et al. (2019) highlight the importance of recognizing and effectively managing cultural differences to achieve synergies and successful outcomes in an intercultural environment. Additionally, Barner-Rasmussen et al. (2014) emphasized the importance of cultural skills in the context of cultural diversity. These skills, also known as intercultural competence, include the ability to have an open mind, seek suitable solutions for both parties, and explain the logic behind each cultural system. Furthermore, empathy and interest in other cultures are also part of these intercultural competencies. These skills are crucial for facilitating effective communication, collaboration, and mutual understanding among members of culturally diverse teams, fostering the generation of innovative ideas and the creation of synergies in an intercultural environment.

Moreover, it is observed that various factors influence the promotion of cultural diversity in organizations. On one hand, the importance of language proficiency and cultural differences is highlighted as central aspects that can facilitate or hinder interactions in the workplace (Froese et al., 2011). These interactions are fundamental for inclusion, as individuals exchange values, influencing each other and their work environment. It has been found that space for interaction and empathetic and supportive leadership favor inclusion in the workplace. Linguistic and cultural differences have been identified as negative factors that can make individuals feel excluded. Previous studies indicate that limited language proficiency can influence employee inclusion, depending on the collective nature of the work and the complexity of the tasks involved (Stahl et al., 2010). Therefore, it is crucial to promote the development of linguistic and cultural competencies in the workplace to enhance inclusion and facilitate effective interactions among individuals from different cultural backgrounds.

Additionally, values play a crucial role in cultural diversity, as stated by the conceptual framework based on value dimensions proposed by Hofstede (1984) and subsequently expanded by other studies, such as institutional collectivism, performance orientation, and gender equality (Hofstede and Hofstede, 2005; Javidan et al., 2006; Trompenaars and Hampden-Turner, 1997).

Overall, these results and theories highlight the importance of facilitative elements such as knowledge of different languages, a diverse organizational structure, selection processes that promote cultural diversity, responsibility and training in cultural diversity, as well as the inclusion of cultural diversity in the company's values. These factors contribute to the promotion of cultural diversity in organizations and are essential for creating inclusive work environments, where collaboration, the exchange of values, and leveraging cultural differences as a source of enrichment and joint creation are encouraged.

Regarding innovation management, the results reveal a strategic and structured approach in participating organizations. The existence of figures dedicated to innovation management, the creation of specific teams, specific training in innovation, and the use of new technologies as tools to drive innovation demonstrate a commitment to fostering an environment conducive to idea generation and the implementation of innovative projects.

Concerning the link between cultural diversity and innovation, our findings indicate that, despite some management efforts in some organizations, the connection between these two aspects is still limited in most cases. Several previous studies, such as those by Mir-Babayev et al. (2017), Edmondson et al. (2016), and Lee et al. (2019), have demonstrated a positive influence of cultural diversity on innovation. These studies suggest that cultural diversity can contribute to both the generation of innovative ideas and the successful implementation of projects.

For example, Mir-Babayev et al. (2017) observed that cultural diversity follows an inverted U-shaped relationship with innovation. Gender diversity and diversity in foreign backgrounds seem to have a more positive impact on innovation when diversity levels are moderate. Extremely low or high levels of cultural diversity tend to have a negative impact on innovation, while moderate levels are associated with higher innovation levels.

Edmondson et al. (2016) suggest that group experience positively contributes to team learning and well-being. The formation of culturally diverse teams can enhance team performance, increasing the ability to solve complex problems and innovate in new products or services.

Lee et al. (2019) have also shown that diversity in terms of profession, skills, and experience of team members has a positive effect on innovation. They have also emphasized the importance of knowledge exchange in this relationship.

However, it is important to recognize that there are various theories and approaches to the relationship between cultural diversity and innovation. While some studies support the idea that cultural diversity fosters idea generation and creativity, others suggest that specific facilitating factors and proper management of cultural diversity are needed for a positive effect on innovation. For example, Boone et al. (2015) found that the diversity of nationalities in management teams enhances corporate entrepreneurship, but this effect can be affected by factors such as social stratification and social power distance. Ozgen et al. (2013) indicate that companies employing a higher number of immigrants may be less innovative, although this effect appears to be less pronounced in the second generation of immigrants. Additionally, Batarseh et al. (2016) found that functional diversity in terms of knowledge, skills, information, or experience in teams has a positive effect on innovation, while deep diversity in terms of values, beliefs, and attitudes may not have a significant impact.

Collectively, these studies underline the complexity of the relationship between cultural diversity and innovation, emphasizing the importance of considering a variety of variables and contexts. Cultural differences not only represent challenges and problems but can also be valuable and complementary resources, supported by theories such as those by Stahl and Tung (2015) and Stevens, Plaut, and Sanchez-Burks (2008). Furthermore, although less explored in the context of organizations, the concept of cultural synergy has proven relevant in smaller social entities, such as work teams (Adler, 2008; Gabriel and Griffiths, 2008; Stahl, Maznevski, Voigt, and Jonsen, 2009).

As for factors facilitating cultural synergy, we identified three main groups: organizational structures and processes, individual skills and knowledge, and interpersonal relationships within teams. By combining these factors into a constructive management framework of work cultures, the aim is to promote mutual understanding, intercultural learning, and effective collaboration.
In summary, we suggest that, to strengthen the connection between innovation and cultural diversity,

it is necessary to implement concrete measures, such as including cultural diversity in innovation metrics, involving leaders in the formation of diverse teams, and establishing specific recognitions for diversity-based innovation. We also emphasize the importance of leveraging cultural differences as valuable and complementary resources, promoting cultural synergy through facilitating factors such as organizational structures, individual skills, and interpersonal relationships. These actions can have a positive impact on innovation processes and strengthen the competitiveness of organizations in increasingly diverse and globalized environments.

In conclusion, the results of our study underscore the importance of comprehensively addressing both cultural diversity management and innovation management in organizations, in light of Barney's resource-based theory. While some previous studies have found a positive relationship between cultural diversity and innovation, it is necessary to consider organizational resources and capabilities as essential facilitating factors to maximize their impact. Cultural diversity can be considered as a strategic resource that brings a variety of perspectives, skills, and knowledge to an organization. However, the mere presence of cultural diversity does not guarantee innovation. Proper management of this resource, in terms of including diversity in team formation, promoting intercultural competencies, and creating cultural synergies, becomes a key capability for organizations. On the other hand, innovation management requires specific resources and capabilities, such as innovation training, the creation of dedicated teams, and the use of advanced technologies. The measurement of the impact of cultural diversity on innovation also becomes an essential capability. Here is where Barney's theory applies, as organizations must identify and develop the necessary resources and capabilities to make the most of cultural diversity in their innovation processes.

LIMITATIONS AND FUTURE RESEARCH DIRECTIONS

Despite the significant findings obtained in this research, it is crucial to acknowledge certain limitations that have influenced the results and, at the same time, identify promising directions for future research. These limitations not only point out areas for improvement but also highlight opportunities to expand our knowledge of the connection between cultural diversity and innovation.

In terms of limitations, the sample size used, while representative of professionals from various organizations, might not be extensive enough to generalize the findings globally. In future research, it would be beneficial to consider the possibility of expanding the sample, encompassing a broader spectrum of organizations and geographical regions.

Another limitation is related to the self-report method used to collect data, based on the perceptions and opinions of the participants. This approach can introduce biases inherent in self-perception and limit the objectivity of the results. Future research could address this limitation by using mixed methods approaches that combine qualitative and quantitative data, thus providing a more comprehensive and balanced understanding of the analyzed phenomena.

Furthermore, although this study focused on the perception of individual professionals, it would be valuable to explore more deeply the organizational policies and practices related to cultural diversity and innovation. A more detailed analysis of these dimensions could shed light on their impact on organizational performance.

The influence of cultural context on the relationship between cultural diversity and innovation also emerged as a significant limitation. Given the variability in this relationship depending on cultural context, future research could address these cultural differences and their impact on diversity and innovation management.

Considering these limitations opens up various opportunities for future research in this field. Longitudinal studies are suggested to assess how perceptions and practices evolve as organizations implement diversity management policies and innovation strategies over time.

Exploring the variability of the relationship between cultural diversity and innovation in different cultural and geographical contexts could provide valuable insights for global diversity management. Delving into the evaluation of the impact of cultural diversity on organizational performance, incorporating financial and innovation metrics, would offer a more comprehensive understanding, supporting Barney's resource-based theory.

Investigating how human resource policies, such as intercultural training and personnel selection, influence the relationship between cultural diversity and innovation could provide practical insights for the effective management of culturally diverse teams.

Additionally, deepening the measurement of the impact of cultural diversity on innovation outcomes, with a specific focus on the metrics used by organizations, would offer valuable insights for the implementation of innovative strategies.

In summary, while this study has provided a valuable perspective on the relationship between cultural diversity and innovation, identifying and addressing these limitations poses exciting opportunities for future research. These additional studies are essential for organizations to maximize the potential of cultural diversity and innovation as strategic resources in their operations.

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Appendix A:

Cultural Diversity and Innovation Questionnaire:

Demographic Information:

1. Company sector or activity:
   a. Agriculture, food, livestock, fishing, and forestry
   b. Water, sanitation, and waste
   c. Commerce
   d. Construction and installations
   e. Education, culture, and leisure
   f. Energy
   g. Finance and insurance
   h. Hospitality and tourism
   i. Industry
   j. Health
   k.Transportation and logistics
   l. Others
2. Company size:
   a. Small (1-50 employees)
   b. Medium (51-250 employees)
   c. Large (+250 employees)
3. Company revenue:
   a. < 2 million Euros
   b. Between 2 and 10 million Euros
   c. Between 11 and 50 million Euros
   d. > 50 million Euros
   e. Don't know/No response

4. Scope of activity:
   a. Multinational of foreign origin
   b. Multinational of national origin
   c. Non-multinational
5. Professional category:
   a. Manager
   b. Middle management
   c. Technical
   d. Administrative
   e. Others
6. Tenure in the company:
   a. 0-5 years
   b. 6-10 years
   c. 11-15 years
   d. More than 15 years
7. Gender:
   a. Female
   b. Male
8. Age:
   a. Under 18 years
   b. 19-29 years
   c. 30-44 years
   d. 45-59 years
   e. Over 60 years
9. Multicultural profile:
   a. Origin or nationality (place of birth):
      - Country:
      - City:
   b. Lived or not in a foreign country:
      - Yes or no and if yes, for how long
   c. Married/partner of another nationality:
      - Yes or no and if yes, for how long and from which culture

d. Is there cultural diversity in the family:

- Yes or no who, degree of relationship, and from which cultures

e. Worked with other multicultural groups:

- Yes or no with how many, for how long, and from which cultures

f. What cultural profile do you identify with?

Questions about cultural diversity management:

1. Does your company pay special attention to managing cultural diversity (origin or nationality)?
   - Yes or no
   - What types of actions are taken, involved groups, who manages it
2. Is there a figure responsible for managing diversity in the company?
   - Yes or no
   - Who is it, who does it report to, who works on diversity
3. Is cultural diversity a relevant criterion for configuring teams in your company?
   - Yes or no
   - How are teams organized, what criteria are taken into account, who manages it, for what types of projects or actions
4. Has your company been invited to present its cultural diversity management practices?
   - Yes or no
   - What types of practices, in what context were the practices presented (conference, informal meeting etc.)
5. Have your cultural diversity management practices been imitated by other companies?
   - Yes or no
   - What practices and in which companies
6. Does your company measure the impact of cultural diversity on team results?
   - Yes or no
   - How is it measured, what KPIs are considered
7. What factors do you believe facilitate cultural diversity in the company?
   - List the factors you consider
   - Go into detail on each of them to delve into why

Innovation management:

1. Is there a figure responsible for managing innovation in the company?
   - Yes or no
   - Who is it, who does it report to, who works on innovation
2. Has your company created specific teams to create and launch new products, services, or processes (operational and productive)?
   - Yes or no
   - Composition of the teams (how many and what profiles)
   - Types of products, services, or processes
3. Is there any formal committee where top management evaluates new products, services, or processes?
   - Yes or no
   - Who forms it?
4. Has your company trained professionals in techniques or methodologies that assist in the launch and creation of new products, services, and processes?
   - Yes or no
   - Types of training
   - Who has been trained: team leaders or all members?
5. Has your company used new technologies to develop new products, services, or processes?
   - Yes or no
   - What technologies have been used and for what products, services, or processes
6. Does your company measure the number of new products, services, and processes launched each year?
   - Yes or no
   - How is it measured, what KPIs are considered*

Link between cultural diversity and innovation:

1. Are both the innovation manager and the diversity manager present in the highest decision-making body of your company?
   - Yes or no

- Who are they and how are they organized

2. Do the teams responsible for innovation and diversity interact formally or informally?
   - Yes or no
   - In what way?
3. Is the opinion of diversity managers taken into account when creating a team that needs to launch a new process, product, or service?
   - Yes or no
   - How?
4. Is the opinion of innovation managers taken into account when creating a team that needs to promote cultural diversity?
   - Yes or no
   - How?
5. When measuring the success of a new product/service/process, is its contribution to cultural diversity included?
   - Yes or no
   - In what way?
6. When measuring the success of cultural diversity policies, is its contribution to innovation considered in any form?
   - Yes or no
   - In what way?
7. Is there recognition for the innovation manager for incorporating cultural diversity criteria into their decisions/actions/policies?
   - Yes or no
   - What does this recognition consist of?
8. Is there recognition for the diversity manager for incorporating innovation criteria into their decisions/actions/policies?
   - Yes or no
   - What does this recognition consist of?
9. Are there KPIs that measure the link between cultural diversity and innovation?
   - Yes or no
   - How is it measured, what KPIs are considered

* The most widely used formula in the literature to measure the success of innovation is as follows: Innovation Revenue / Innovation Investment. Bermúdez García, J. (2013).

Strategic Synergy: Exploring the Intersection of Quality Management and Innovation

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STRUCTURED ABSTRACT

Purpose – The present article aims to explore the influence of quality management (QM), including quality commitment and practices, on product and service innovation.

Design/methodology/approach – The authors examine the relationship of quality as a determinant of innovation using empirical evidence collected through the European Manufacturing Survey, 2021 edition, to generate nine binary logistic models.

Findings – The results reveal differences among the considered innovation outputs. Soft quality practices (employee training) are significant and positive in relation to new-to-firm and new-to-market product innovation and service innovation. In contrast, hard quality aspects (working methods) only affect new-to-firm product innovation and service innovation. The findings also show that quality commitment does not drive innovation.

Research limitations/implications – The data used in this paper corresponds to four countries, with Spain and Lithuania being moderate innovators and Slovakia and Latvia being emerging innovators, but all countries are performing below the EU average. Further research expanding the analysis in countries considered strong innovators would bring additional evidence complementing the present findings.

Practical implications – This paper has a series of practical implications targeting general managers/CEOs, quality, production, human resource, and innovation managers, with findings showing the innovation impact of practices associated with their function, managed and implemented at the manufacturing site, but with impact and implications that often go beyond their area of responsibility.

Originality/value – The main value of the present research consists in fine-graining the relationship of a variety of quality management practices, going from strategy-level aspects (quality commitment as strategic priority) to operational level (hard QM practices) and human facets (soft QM practices), with different innovation outputs, including both service and product innovations. The recent, multi-country, industry-wide dataset is another strength of the analysis.

Keywords: Quality, Quality Management, Innovation, European Manufacturing Survey.

Paper type: Research paper

INTRODUCTION

Innovation, the cornerstone of progress, is a multifaceted phenomenon intricately intertwined with various determinants (Adams et al., 2006; Keupp et al., 2012; Slater et al., 2013). Among these, quality and innovation stand out as pivotal factors. One of the most cited definitions of innovation - "A business innovation is a new or improved product or business process (or combination thereof) that differs significantly from the firm's previous products or business processes, and that has been introduced on the market or brought into use by the firm" (OECD, 2018) includes a clear reference to quality-specific wording and domain, namely improvements, pointing to a potential relationship between quality and innovation. A good or service distinguished by exceptional quality not only satisfies but exceeds customer expectations, fostering loyalty and driving competitive advantage. A commitment to quality serves as a foundation for innovation by providing a solid framework upon which new ideas can be built. Innovation, in turn, allows organizations to continuously improve their products and processes, leading to further enhancements in quality.

The relationship between quality and innovation extends beyond the realm of tangible products, infusing into services and permeating into processes and methodologies. Pursuing quality necessitates a culture of continuous improvement, potentially needing innovation at every stage of the value chain. While most studies find a positive relationship between quality and innovation (Wei, 2010; Khan and Naeem, 2016; Ahinful et al., 2024), only a few studies find the contrary, a situation potentially appearing in the circumstances in which both are competitiveness factors and compete for similar, overlapping goals (Palm et al., 2014). Moreover, certain strategic decisions, resources, and capabilities associated with one might be to the detriment of the other. Further, it is unclear if the different facets of quality (hard and soft QM practices) have similar or distinct effects on diverse types of innovation (López-Mielgo et al., 2009).

Driven by the body of knowledge showing mixed results, we aspire to study the complex relationship between quality and innovation and contribute to a deeper understanding of this relationship. In the present research, we aim to investigate whether quality commitment is related to innovation and whether hard and soft QM practices impact different types of innovation, products, and services.

LITERATURE OVERVIEW

Quality management

Quality management is a broad concept including various methods and approaches applied by companies to improve the quality of products and services, increase customer satisfaction, reduce costs, enhance productivity, increase competitiveness and overall company performance (Bayazit, 2003; Priede, 2012) as well as strengthen effectiveness and flexibility (Mubaraki, 2012). It is a management philosophy that employs specific principles and practices to improve business performance (González-Cruz et al., 2018; Liu et al., 2022). The International Organization for Standardization (ISO) introduced seven quality management principles: Customer focus, Leadership, Engagement of people, Process approach, Improvement, Evidence-based decision-making, and Relationship management (ISO, 2015). Additionally, previous studies mention Human resources management/Employee management (Chileshe, 2007; Zizakov et al., 2020; Liu et al., 2022), the Internal culture of the organization, Orientation towards quality (Chileshe, 2007), Information and analysis, Focus on customers/stakeholders and design, Planning (Li et al., 2018), Supply Chain management, Strategic planning management, Continuous improvement and Innovation (Barros et al., 2014), Top management support, Training, Customer management, Supplier management (Liu et al., 2022), Product and service design (Leavengood and Anderson, 2011), Quality planning, Teamwork and quality chain (Zizakov et al., 2020). These principles provide general guidance implemented through practices - a set of approaches and techniques that can be divided into soft and hard practices. Soft QM practices are related to leadership and people management, including training and development, promoting the relationship with customers, suppliers, and other stakeholders, while hard QM practices are technical tools and techniques, including process management, data collection and analysis, statistical and process control tools, just-in-time and quality systems (López-Mielgo et al., 2009; Madi Bin Abdullah and Tarí, 2012; Tarí et al., 2021). When applied in combination with other organizational concepts, QM has a direct or indirect positive impact on companies' business performance (Sahoo and Yadav, 2018; Ruiz et al., 2019; Sahoo, 2019; Nguyen et al., 2021).

Innovation

Innovation is crucial for economic advancement and societal development, as Schumpeter stated in 1911 (Ziemnowicz, 2013). Innovation is also crucial for the continual enhancement of products and services to meet increasing customer demands and solve complex issues. Innovation drives growth and development (Trott, 2017; Danta and Rath, 2024). Companies are forced to continuously improve and adopt new methods and practices to compete in a highly rival business environment, combined with the increasing demands from customers and society and the complexity of products and services (Rauter et al., 2019). ISO 56000 standard defines innovation as a "new or changed entity, realizing or redistributing value" (ISO, 2020). An innovation is typically related to a product, process, organization, marketing, method, service, market, technology, or business model (OECD, 2005). In other words, innovation is something new or significantly modified that can be practically applied, has a commercial value and can take the form of small incremental changes to enhance company efficiency based on internal company improvement ideas or the ideas taken from outside (Robertsone and Lapina, 2023).

According to the Oslo Manual (OECD, 2005), product innovation is the "introduction of a good or service that is new or significantly improved with respect to its characteristics or intended uses. The term "product" is used to describe both a physical product and service. Many manufacturing companies nowadays choose a strategy to add new value to product offerings, combining it with services for business benefits (Maheepala et al., 2016). Some companies start offering total solutions instead of products, including installation and start-up, maintenance and repair, and remote support (Prester et al., 2022), as well as design/consulting/project planning, technical documentation, software development, leasing/renting/finance, installation, start-up procedure, build-operate-owner services (Dachs et al., 2012), training and after-sales services (Gremyr et al., 2010). New service offers may result in the creation of new business models (Trott, 2017).

Product innovation can be new-to-firm - introducing new to the company products that already exist in the market (OECD Science, Technology and Industry Scoreboard 2015, 2015), and new-to-market - radical innovation entailing fundamental changes and increasing the competitiveness of companies (Daiya et al., 2012; Forés and Camisón, 2016; Trott, 2017).

Many studies confirm that innovation activities have a strong positive impact on the performance of the company (Jiménez-Jiménez and Sanz-Valle, 2011; Gronum et al., 2016; Rajapathirana and Hui, 2018; Al Naqbi et al., 2020), however, there are many other factors influencing these relationships.

In this research, the authors focus on new-to-firm and new-to-market product innovation and service innovation within the manufacturing sector.

The Intersection of Quality Management and Innovation

The role of quality management and innovations implemented by companies to gain competitive advantage by improving products, processes, organizations, and systems to address increasing customer demands and create more value has been studied extensively over the past years. Nevertheless, these concepts are often considered separate or even competing (Leavengood and Anderson, 2011). The latest literature, however, emphasizes the importance of integrating quality management with innovation processes to achieve better performance and competitive advantage. Figure 1 demonstrates the number of articles published in Web of Science and Scopus databases by publication year using the combination of keywords “Quality management" AND “Innovation” in the article title.

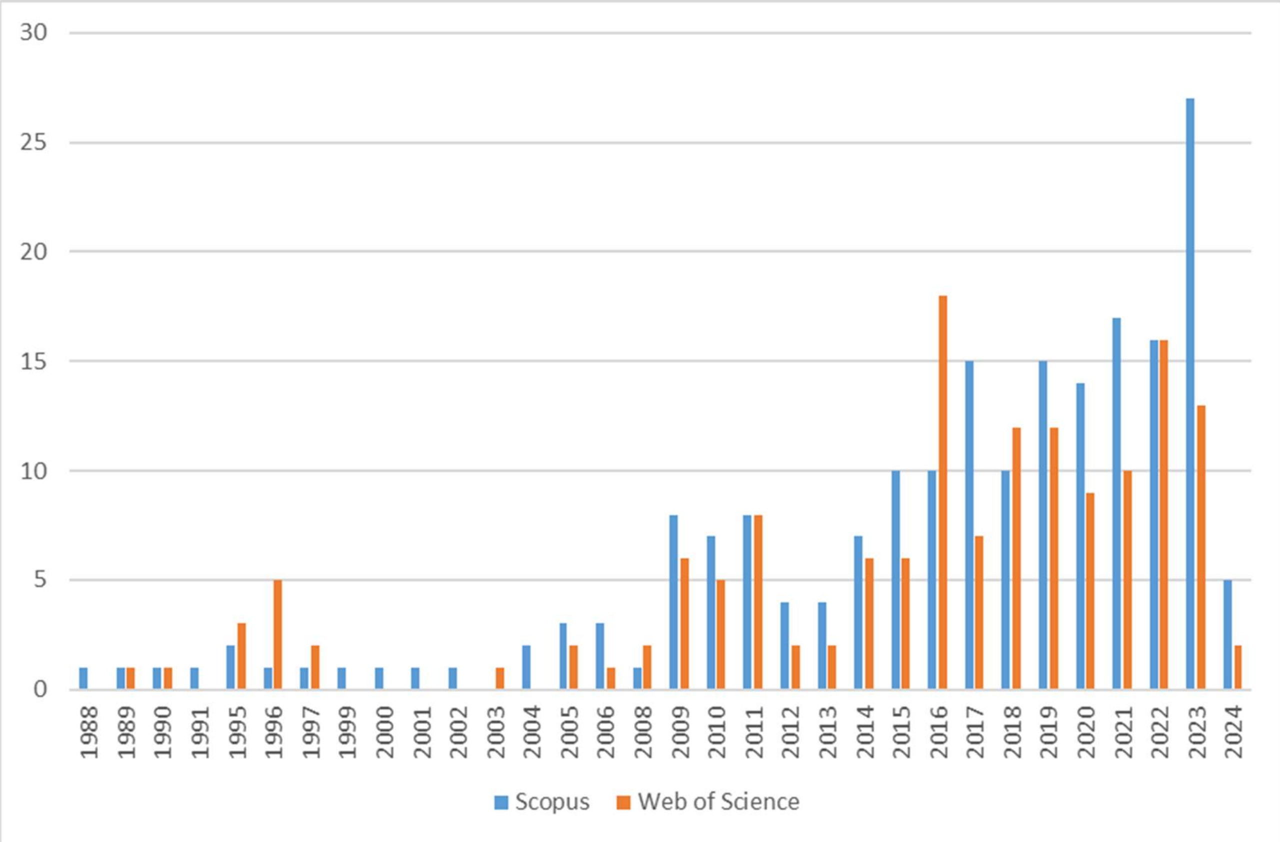

Figure 1 – Number of articles by the publication year.

The research on the relationship between quality management and innovation shows mixed results, as shown in Table 1. Many studies demonstrate positive relations between these areas, particularly highlighting how quality management can influence both product/service and process innovation and positively impact operational and financial performance, suggesting a more integrated view rather than seeing QM and innovation as strictly independent domains (García-Fernández et al., 2022). Innovation can even be considered both an antecedent and a consequence of quality management (Koomson, 2024). Quality management practices support incremental innovation by continuously improving processes (Samaha, 1996; Audretsch et al., 2011; Moreno-Luzon et al., 2013). In contrast, in an environment where radical innovation is needed, some QM practices might be adapted with caution and care to ensure they do not hinder creativity, inventiveness, and experimentation (Vujović et al., 2017). Previous studies have also challenged the link between quality management practices and innovation, suggesting that the relationship may not be direct or significant (Schniederjans and Schniederjans, 2015).

Table 1. Relationships between quality management and innovation

Quality management and innovation relations	Author/-s
Positive	
QM practices have a direct positive impact on innovation performance	Wei, 2010; Khan and Naeem, 2016; Daoud Ben Arab, 2021; Chamba-Rueda et al., 2021; Saleh et al., 2024; Ahinful et al., 2024
QM practices have a direct positive impact on incremental innovation	Audretsch et al., 2011; Moreno-Luzon et al., 2013; Escrig-Tena et al., 2021
QM practices have a direct positive impact on technological innovation	Zhou and Gu, 2019; El Manzani et al., 2024
QM practices have a direct positive impact on non-technological innovation	El Manzani et al., 2024
ISO 9000 has a positive impact on innovation performance	Wang, 2014; Vujović et al., 2017
Soft QM practices have a positive impact on innovation performance	Schniederjans and Schniederjans, 2015; Gambi et al., 2020; Naidoo and Govender, 2020; Tarí et al., 2021; Al-Sabi et al., 2023; Ali Albagawi and Hadi, 2024; Saleh et al., 2024
QM practices have an indirect positive impact on innovation through innovation capabilities	González-Cruz et al., 2018; Sahoo and Yadav, 2018
QM practices have an indirect positive impact on innovation through knowledge management	Zizakov et al., 2020
QM practices have an indirect positive impact on radical innovation	El Manzani and Cegarra, 2023
Negative	
ISO 9000 has a negative impact on innovation performance	Wei, 2010
Other	
QM is a process of knowledge management and innovation	Chai and Mu, 2014

Most studies highlight the beneficial influence quality management has on innovation performance, emphasizing the significance of soft QM practices.

Some studies argue that while not directly impacting innovation outcome, QM may serve as a precursor to incremental innovation capability, but not radical innovation capability (Escrig-

Tena et al., 2021) - the ability to identify future customer needs, potential customer expectations and respond to them promptly capturing opportunities by utilizing internal and external knowledge and transforming ideas into innovations (Rajapathirana and Hui, 2018). Combined with proactive market orientation, QM may contribute to radical product innovations, especially in uncertain environments (El Manzani and Cegarra, 2023). Even quality commitment - a philosophical approach giving quality a higher priority over costs or delivery (Ahire et al., 1996) has demonstrated a positive impact on innovation performance in previous studies (Al-Sabi et al., 2023).

Based on the previous studies, we propose the following research questions:

RQ1: Is quality commitment related to innovation?

RQ2: Do hard and soft QM practices have an impact on different types of innovation, product and service?

RESEARCH METHODOLOGY

The European Manufacturing Survey (EMS), coordinated by the Fraunhofer Institute for Systems and Innovation Research - ISI, is the source of the data used in this study (Fraunhofer ISI, n.d.). The survey gathers comprehensive data on innovations within the manufacturing sector.

This study focuses on organizations falling under the NACE Revision 2 codes ranging from 10 to 33, with a minimum of 20 employees. The sub-sample of the EMS used in this study was collected in 2022. It consists of 456 surveys, distributed as follows: Latvia 50, Lithuania 250, Slovakia 101, and Spain 55.

Measures

Innovation was assessed by a set of three proxies: new-to-firm product innovation (incremental innovation), new-to-market product innovation (radical innovation), and service innovation. Those three concepts represent dependent variables in the models and are of a dichotomous nature – having a value of 0 if no innovation is present and a value of 1 if the innovation is present.

New-to-firm innovation is product innovation determined by the question: Has your factory introduced products since 2019 that were new to your factory or incorporated major technical improvements? (e.g., use of new materials, modifications to product function, changes in operating principle, etc.). For radical innovation, the following question served as the basis for the variable computation: Among these new products introduced since 2019, were there any new-to-market products introduced by your factory as the first provider? Service innovation was assessed based on the following question: Has your factory offered new product-related services since 2019 that were completely new to your factory or included significant improvements?

As for independent variables, three concepts were used. The first set of independent variables checks if the company has the quality or the price as the most important competitive factor. Companies could rate different competitive factors, such as delivering on time, customization, services, or sustainability. If the company defined quality as the most important competitive factor demonstrating quality commitment, the variable Quality factor got value 1, 0 otherwise. The same was done for the Price factor variable, setting the value to 1 if the price was the most important competitive factor for the firm and 0 value otherwise.

Different working methods related to the quality (hard QM practices) represent the second set of independent variables, including the use of Methods for optimizing of change-over time or reduce setup time; Standardized and detailed work instructions; Visual management and monitoring of production processes and status on display boards; Methods for production quality assurance. A factor reduction analysis was performed to compute the Hard QM practices variable, leading to the extraction of one factor, which was then used in statistical modeling.

The third concept that served as the basis for the last independent variable computation is Employee training (soft QM practices). The variable calculation comes again from the factor reduction analysis, extracting one single factor from the following questions in the survey: Which of the following training and competence development practices were offered to employees in production during the last three years? Training and competence development of production employees training a) with a task-specific focus (e.g., machine maintenance, workstation instructions); b) with a cross-functional focus (e.g., project management, team management, language courses); c) to support the implementation and use of digital production technologies or digital assistance systems.

For control variables, we used the size of the company (measured by annual turnover and number of employees), country of origin, and the sector in terms of technological intensity.

RESULTS AND DISCUSSION

Descriptive data

Descriptive data for the dependent variables are presented in Table 2. Independent variables components are shown in Table 3, and control variables are shown in Table 4.

Table 2. Innovation descriptive statistics

	N	mean	SD
New-to-firm product innovation	441	0.6	0.49
Radical product innovation	287	0.31	0.462
Service innovation	433	0.17	0.379

Table 3. Independent descriptive statistics

	N	mean	SD
Competitive factors			
Quality	439	0.45	0.49
Price	440	0.23	0.424
Working methods			
Methods for optimizing of change-over time	418	0.33	0.473
Standardized work instructions	441	0.68	0.466
Visual management boards	441	0.54	0.499
Methods of assuring quality in production	437	0.78	0.418
Training			
with task-specific focus	439	0.74	0.44
with cross-functional focus	442	0.49	0.5
for digital systems	444	0.36	0.48

Table 4. Descriptives for control variables

	N	%			
Country					
Spain	55	12.1			
Lithuania	250	54.8			
Latvia	50	11			
Slovakia	101	22.1			
Total	456	100			
Sector					
High-technology	16	3.5			
Medium-high-technology	70	15.4			
Medium-low-technology	126	27.6			
Low-technology	244	53.5			
Total	456	100			
Size	N	mean	SD	Min	Max
Annual turnover	416	31931	591382	0	1200000 0
Number of employees	456	139.73	357.6	20	6311

The descriptive statistics suggest that while firms are keen on adopting new product innovations and quality assurance methods, there is a less pronounced emphasis on service innovation and price competitiveness. This could reflect a strategic orientation towards sustaining competitive advantage through quality and innovation rather than cost leadership. The high variability in innovation adoption across firms suggests differing organizational capacities and strategic priorities, further influenced by geographical and sectoral contexts.

Modelling

Factor reduction analysis fixed to one factor is used to calculate the Working methods factor and Employee Training factor. The posterior confirmatory factor analysis confirms the validity of the two constructs.

Factor analysis

All factors loaded over 0.5, as shown in Table 4. To further confirm the validity of the constructs, the average variance extracted (AVE) was calculated. Next, composite reliability (CR) and Cronbach's alpha α were tested. The results of the reliability test are described in Table 5.

Table 5. Construct validity statistics

Construct/Items	LF	AVE	CR	α
Working methods		0.473	0.781	0.623
Methods for optimizing of change-over time	0.671			
Standardized work instructions	0.751			
Visual management boards	0.699			
Methods of assuring quality in production	0.623			
Training		0.519	0.764	0.536
with task-specific focus	0.713			
with cross-functional focus	0.697			
for digital systems	0.751			

Regression analysis

To test the relationship between competitive factors, working methods, employee training, and innovation, three sets of binary regression logistic models were performed for each type of innovation. Each set consisted of three models, summing nine models in total. Binary logistic regression was used due to the dichotomous nature of the dependent variables. The method used was backward Wald, which performs regression in several steps, taking out non-significant variables in every step, leaving only the significant ones in the model in the last step (Ryan and Gray, 2006). The results are provided in Table 6.

Table 6a. Results of regression modeling

Variables	Model 1	Model 2	Model 3
Dependent variable	**New-to-firm product innovation**		
Independent variables			
Quality	n.s.	n.s.	n.s.
Price	-0.426*	n.s.	n.s.
Working methods		0.32**	n.s.
Employee training			0.511***
Control variables			
Annual turnover	n.s.	n.s.	n.s.
Number of employees	n.s.	n.s.	n.s.
Country (Spain ref)			
Lithuania	n.s.	-0.741**	n.s.
Latvia	n.s.	n.s.	n.s.

Slovakia	-1.189**	-1.1145**	-1.142**
Sector (High-tech ref)			
Medium-high-technology	n.s.	n.s.	n.s.
Medium-low-technology	-1.477*	n.s.	n.s.
Low-technology	n.s.	n.s.	n.s.
Constant	2.141**	1.781**	1.44
N	385	345	329
Cox&Snell R^2	0.064	0.08	0.11
Nagelkerke R^2	0.087	0.109	0.149

Notes: *** p<0.001, **p<0.050, *p<0.100, n.s. Non-significant

Table 6b. Results of regression modeling

Variables	Model 4	Model 5	Model 6
Dependent variable	**Radical product innovation**		
Independent variables			
Quality	-0.713**	-0.585*	-0.614*
Price	-0.933**	-0.8*	-0.819*
Working methods		n.s.	n.s.
Employee training			0.467**
Control variables			
Annual turnover	n.s.	n.s.	n.s.
Number of employees	n.s.	n.s.	n.s.
Country (Spain ref)			
Lithuania	n.s.	n.s.	n.s.
Latvia	n.s.	n.s.	n.s.
Slovakia	n.s.	n.s.	n.s.
Sector (High-tech ref)			
Medium-high-technology	n.s.	n.s.	n.s.
Medium-low-technology	n.s.	n.s.	n.s.
Low-technology	n.s.	n.s.	n.s.
Constant	-0.385*	-0.044	-0.67**
N	247	222	212
Cox&Snell R^2	0.032	0.056	0.059
Nagelkerke R^2	0.046	0.082	0.085

Notes: *** p<0.001, **p<0.050, *p<0.100, n.s. Non-significant

Table 6c. Results of regression modeling

Variables	Model 7	Model 8	Model 9
Dependent variable	**Service innovation**		
Independent variables			
Quality	n.s.	n.s.	n.s.
Price	n.s.	n.s.	n.s.
Working methods		0.34**	n.s.
Employee training			0.54**
Control variables			
Annual turnover	n.s.	n.s.	n.s.
Number of employees	n.s.	n.s.	n.s.
Country (Spain ref)			
Lithuania	n.s.	-0.848**	n.s.
Latvia	n.s.	-1.784**	-2.431**
Slovakia	n.s.	-1.138**	-1.11**
Sector (High-tech ref)			
Medium-high-technology	n.s.	n.s.	n.s.
Medium-low-technology	n.s.	n.s.	n.s.
Low-technology	n.s.	n.s.	n.s.
Constant	-1.622	-0.859**	-1.067**
N	376	336	320
Cox&Snell R^2	0	0.037	0.062
Nagelkerke R^2	0	0.063	0.106

Notes: *** p<0.001, **p<0.050, *p<0.100, n.s. Non-significant

The first set of models used the new-to-firm product innovation as a dependent variable. Model 1 showed a significant negative effect with β value of -0.426 ($p<0.1$) of the Price competitive factor being the most important for the company and the product innovation. The Quality factor did not show significance. In Model 2, factor Working methods were added. This was positively related to product innovation with a β value of 0.32 ($p<0.05$), substituting Price factor influence. Model 3 included an Employee training factor that overruled the significance of the rest of the independent variables and showed a significant and positive effect on product innovation with β value of 0.511 ($p<0.001$).

Radical (new-to-market) product innovation as a dependent variable was tested in the second set. Model 4 suggested a negative and significant relationship between rating Price as well as Quality as the most important competitive factors for the company and its radical innovation outcome. Price showed a negative β value -0.933 ($p<0.05$) and Quality negative β value -0.713 ($p<0.05$). The result did not change in Model 5 after adding the Working methods factor, which was insignificant. In Model 6, where competitive factors were assessed together with Working methods and Employee training, the competitive factors kept showing a negative significant relation and Employee training significant positive relation with β value 0.467 ($p<0.05$).

The last set examined Service innovation. Model 7 shows no significant relation for competitive factors. Model 8 shows positive only for Working methods with a positive β value of 0.34 ($p<0.05$). The last model, Model 9, marked Employee training as significant, with β value 0.54 ($p<0.05$), replacing Working methods as a significant variable.

The research results show that quality commitment proxied as Quality being the competitive factor was not significant to new-to-firm product innovation and service innovation and showed a significant negative relation with radical product innovation. These results contrast with previous research findings stating that commitment to quality positively impacts innovation capabilities (Khan and Naeem, 2018), innovation performance (Al-Sabi et al., 2023) as well as may be served as a tool for value creation through innovation (Tidd and Bessant, 2018). However, the findings may be explained by the fact that quality-oriented companies are more reactive, seeking to satisfy the current customer needs rather than identifying and looking for ways to anticipate future needs. They concentrate on "doing what we do but better", however, it would not necessarily result in a better product quality (Bessant and Tidd, 2014). Radical innovations may be challenging to achieve as they may require investments, are associated with the change, and may entail discontinuity, while quality-oriented companies are concentrated on the quality of the existing products (Larsson, 2017).

The findings regarding Price being a competitive factor and its negative impact on product innovation confirm the results of previous studies demonstrating a negative relationship between price competition and innovation (Kang, 2019). Companies that prioritize Price as a competitive factor often take severe and strict cost-saving measures and measures to reduce resource consumption, which can result in a lack of resources for experimentation with the uncertain outcomes that are necessary for innovation (Nohria and Gulati, 1996). Price-oriented companies tend to underinvest in innovation activities; which may hinder their innovation capability (Nooteboom, 1994).

While hard QM practices represented by the Working methods factor showed some positive relations with new-to-firm product innovation and service innovation, the results demonstrate that soft QM practices have an overruling and more significant effect on both new-to-firms and new-to-market product innovation. This is in line with the previous studies showing that the companies having soft QM practices in place, especially related to employee development and empowerment, can introduce both radical and incremental innovations with ease because they experience fewer obstacles in promoting and implementing new ideas (Schniederjans and Schniederjans, 2015; Tarí et al., 2021; Al-Sabi et al., 2023).

Regarding service innovation, both QM sets of practices show significant positive relations, Employee training being slightly more significant than Working methods, confirming the results of previous research suggesting that quality management practices enhance service innovation (Khan and Naeem, 2016) and advising manufacturing companies use QM to foster service innovation "creating new competitive advantages" (Weng, 2022).

CONCLUSIONS

By exploring both the degree of radicality of innovation – incremental vs radical – and the nature of quality aspects, in terms of orientation, soft and hard QM practices, our study aims to investigate the association of quality and innovation further to understand better the nature of such effect.

Our findings indicate that quality commitment is not an innovation driver because it does not impact incremental innovation and is even counterproductive for radical innovation. Price orientation, in turn, is even worse, negatively impacting both types of product innovation. In contrast, employee training has a positive impact on innovation, both for incremental and radical innovation. This result indicates how soft QM practices, such as employee training, are of the greatest importance for innovation, more than hard QM practices, such as the set of working methods relatable to quality management. This can be explained in terms of employee training as the real mechanism bridging the connection between quality management and innovation, making working methods effective. This argument is further supported by the fact that hard QM practices were not significant for radical innovation, which needs more complex capabilities than incremental innovation. Regarding service innovation, the results are very similar to the results for incremental innovation, arguably because service innovation is likely to be closer to the nature of incremental innovation than radical innovation.

Our findings have implications for theory and practice since it has been widely informed of many positive effects of quality on innovation, while we find that not all quality approaches are significant and that some may even be negative for some types of innovation, particularly for radical innovation. Our results further suggest a superiority of soft QM practices over hard QM practices.

The findings of our study are limited by the availability of data, which, although being large and multi-country, is only surveying the manufacturing sector of four countries, all of them of below-average innovators in the EU. It would be interesting to explore whether the findings hold for companies in other countries, preferably in highly innovative countries since they could be considered the best contexts for innovation. The measures for quality practice were relatively rich in this study, but they are subject to limitations since quality management practices can be defined in alternative and more extensive forms.

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Quality Management in Corporate Health: A Study in the Energy Sector

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STRUCTURED ABSTRACT

Purpose: This study analyzes quality management in corporate health, focusing on the energy sector. It investigates the tools used and their impact on organizational performance to understand the knowledge produced in this field.

Methodology: A systematic literature review was conducted to identify quality management practices in corporate health care and assess their applicability to the needs of companies in the energy sector. The process involved preliminary data collection from the databases Scopus, Web of Science, and PubMed/Medline, followed by a thorough analysis of the documents found to create a new database aligned with the research objectives. Subsequently, an analysis of the selected material was carried out.

Findings: The research revealed a significant gap in the literature related to occupational health and quality management in energy companies. The lack of dissemination of findings by some organizations has contributed to a limited understanding of effective practices in these areas. However, as awareness of these issues increases, opportunities for positive change are emerging. Developing management models that address the complexity of the sector and promoting the visibility of best practices are essential for enhancing quality management and occupational health processes within the energy industry.

Research limitations: Conducting a literature review on a limited set of databases can reveal some principal issues, including biases in coverage and analysis, as well as problems with access to identified documents. These constraints may result in a partial view of the field and exclude relevant materials available in other sources that were not consulted.

Value: By learning about the best practices and tools used in occupational health management from a quality perspective, companies can develop more effective strategies to promote the health and well-being of their employees. This not only contributes to operational safety but also to the sustainable success of the business.

Keywords: Quality management, corporate health, energy industry, management tools.

Paper type: Literature review

INTRODUCTION

Quality is a concept that has long been of paramount importance, impacting not only the production of goods but also the provision of services across various sectors. It is a term widely utilized to identify processes and practices that promote organizational development and excellence. However, the terminology surrounding quality can vary significantly, leading to potential misunderstandings. For the purposes of this study, quality management specifically refers to practices aimed at achieving organizational excellence through systematic processes and continuous improvement. As societies have progressed, different approaches to enhancing this concept have emerged, driven by technological advancements, cultural shifts, and societal demands. In the context of quality management, the relentless pursuit of excellence reflects the necessity to meet specific expectations and requirements, driving innovation and transformation of the concept to ever higher standards. Historically, quality management has evolved through distinct phases: the era of inspection, the era of statistical control, and the era of total quality (Silveiro, 2022; Oliveira, 2020; Lobo, 2019; and D'Innocenzo, Adami, and Cunha, 2006).

The increasing emphasis on quality and the widespread adoption of management systems have become common practices within organizations and businesses. This trend is driven by the necessity to enhance stakeholder relations, meet market demands, and reduce identified non-conformities (Zutshi and Sohal, 2005). Management systems, such as ISO 9000, have helped to optimize operational processes, promoted more efficient resource management, and reduced costs and lead times. Additionally, these certifications confer credibility and recognition upon organizations, expanding their market opportunities. The implementation of these systems also fosters continuous improvement practices, which are essential for strategic business development (Muñiz, Péon and Ordáz, 2009; Bottani, Monica and Vignali, 2009; Gotzamani et al., 2007; Singh, Feng and Smith, 2006).

In the health sector, defining and guaranteeing quality are challenging but essential tasks to protect individuals and achieve satisfactory results that directly affect people's well-being. Health services have specific characteristics that differentiate them from other productive sectors, as they are subject to strict specifications and regulations, which means that the concept of quality takes on a characteristic configuration in this specific context. The perception of quality in healthcare differs significantly from other sectors. This makes audience communication complex. When addressing the issue of quality in health care, Sousa and Mendes (2019) point out that the concept can be interpreted in different ways, leading to broader or more specific discussions, depending on the author and the context in which it is discussed.

In a restrictive context, quality may be reduced to the technical-scientific aspect, particularly important in healthcare. Here, an intervention is deemed quality when it incorporates scientific knowledge and practical experience, generating benefits with minimal risks (Costa, 2009). From a broader perspective, quality in healthcare is based on seven fundamental pillars: efficacy, effectiveness, efficiency, optimization, acceptability, legitimacy, and equity (Donabedian, 1990). These attributes collectively ensure the delivery of optimal healthcare. Additional elements such as planning, process review, and performance monitoring, alongside continuous improvement, are fundamental for positioning organizations within the healthcare market (Bonato, 2011). Given the inherent complexity and subjectivity of the concept, the definition, and elements of quality in health can vary, encompassing perspectives from patients, health professionals, managers, funders, and government authorities (Donabedian, 1980, 2003). Both operational aspects related to care practices and client perceptions, as well as how health professionals conduct and experience their work, are crucial in conceptualizing quality in health. Sisson et al. (2011) emphasize user satisfaction as a critical indicator in strategic planning, operational management, and ongoing assessment of health service delivery, aiming to enhance service quality.

Addressing quality in occupational health within a company adds further complexity, involving legal and ethical responsibilities and the need for quality care that impacts lives and well-being while being effective and sustainable for the corporate system. The World Health Organization (WHO, 2018) recognizes the primary objective of occupational health services as creating a superior quality of life at work. These services aim to safeguard workers' health and enhance their physical, mental, and social well-being, prevent and control occupational accidents and diseases by reducing risk conditions, and ensure the physical and psychological integrity of workers. This approach promotes effective workplace adaptation, contributing to improved productivity and reduced absenteeism

(Moniz, 2016). Additionally, the ILO (2024) asserts that worker safety, health, and well-being are fundamental for individuals, their families, business productivity, competitiveness, and societal sustainability.

The focus of this study on the energy sector is particularly justified due to its critical role in economic development and innovation (Pérez, 2010; Chang, 2003). The energy industry is characterized by high operational demands and significant potential hazards, making the effective management of occupational health and quality paramount. Moreover, the strategic importance of the energy sector in driving national economies underscores the necessity of ensuring high standards of health and safety for its workforce. Given the complexity and significance of the topic, this research aims to investigate quality management practices in occupational health services within this sector.

This study employs exploratory research to analyze the primary quality management tools and strategies utilized by energy companies to promote occupational health and well-being. It seeks to identify specific challenges and opportunities related to implementing quality management systems in occupational health. By addressing gaps in existing literature, this research provides valuable insights for practitioners and researchers, contributing to the development of quality management practices tailored to the energy sector. The methodology includes a literature review on quality management in corporate healthcare, followed by an analysis of identified practices. Adhering to PRISMA guidelines, this systematic and exploratory approach ensures transparency and quality in data collection, offering a thorough understanding of the impact and challenges of quality management practices in the energy sector. Furthermore, it guarantees a coherent structure linking objectives, methodology, and results.

A bibliographic study on quality management in the energy sector can provide valuable contributions. This study will highlight the approaches adopted, the management systems implemented, and the issues addressed in this specific context. In addition, it will be able to assess the possible impact on workers by verifying whether the measures implemented are effective in reducing health risks, promoting a safe and healthy working environment, and minimizing negative outcomes such as prolonged sick leave and occupational accidents.

RESEARCH METHODOLOGY

The study focused on analyzing the issue of quality management in the corporate health sector, with an emphasis on the energy sector, investigating the tools used and their impact on organizational performance, in order to understand the knowledge produced in this field. To this end, a systematic literature review was developed. This approach provided an overview of the topic and pointed the way for further approaches. Although the search did not include a detailed exploration of all available databases related to the subject, it proved to be an interesting tool to identify previously conducted studies (Galvão and Ricarte, 2019).

An approach based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines was adopted to ensure the transparency and quality of the data collected. Although the PRISMA statement is aimed at reporting systematic reviews of interventions with meta-analyses, its criteria can be applied to most types of studies (Sarkis-Onofre et al, 2021; Page et al, 2020; Liberati et al, 2009). The choice of databases was based on aspects such as the scope of the literature review, the field of study, access to the material collected, the type of publication, the quality and reputation of the databases, and preliminary tests. Three databases were used: Scopus, Web of Science and PubMed. The work began with the mapping of descriptors, using controlled vocabularies according to specific standards in the field. This phase included the identification and association of relevant descriptors, the identification of synonyms and correlated terms in order to broaden the scope of the search. The process was revised to adapt it to update the vocabulary and to meet research needs. The definition of the criteria used in the search strategy was based on the relevance of the terms used and the need to correctly identify the documents to be searched. The initial screening involved a preliminary collection of material in the selected databases, followed by a general reading of the selected content, which was examined according to predefined inclusion and exclusion criteria, allowing a new document bank to be created more in line with the research objectives.

The selected material was evaluated in detail, methodological aspects were analyzed, and the results were summarized. It is important to mention that the bibliographic research was carried out without having defined the period to be searched. The details of the search terms and the strategy used in each of the databases are described in the table below. It should be emphasized that the methodology used has limitations, such as the possibility of bias in the selection of material and also the lack of a more comprehensive search involving a greater number of databases. Systematic literature reviews are essential to improve the understanding of scientific knowledge in a particular area. They identify gaps in current knowledge, contribute to advancing the field by providing constructive criticism, and provide a basis for professional practice and theory (Barbosa, Pereira Neto and Lima, 2023; Cavalcante and Oliveira, 2020).

Table 1: Search Strategy

Search Strategy	Source	Inicial Results
TITLE-ABS-KEY (("Occupational Health" OR "Employee Health" OR "Industrial Health" OR "Industrial Hygiene" OR "Occupational Safety" OR "corporate health" OR "workplace health") AND ("quality management" OR "Total Quality Management" OR "Continuous Quality Management" OR "Health Quality Management" OR "Quality Assurance" OR "Quality Assurance Standards" OR "Quality Assurance System" OR "Quality Management Systems" OR "Total Quality" OR "Quality Control" OR "Analytical Quality Control" OR "Quality Controls") AND (energy* system* OR "energy system" OR "energy sector" OR "power industry"))	SCOPUS (Elsevier)	n= 53 No filter
ALL=("Occupational Health" OR "Employee Health" OR "Industrial Health" OR "Industrial Hygiene" OR "Occupational Safety" OR "corporate health" OR "workplace health") AND ALL=("quality management" OR "Total Quality Management" OR "Continuous Quality Management" OR "Health Quality Management" OR "Quality Assurance" OR "Quality Assurance Standards" OR "Quality Assurance System" OR "Quality Management Systems" OR "Total Quality" OR "Quality Control" OR "Analytical Quality Control" OR "Quality Controls") AND ALL=("energy" OR "energy sector" OR "power industry" OR "energy production" OR "energy consumption" OR "energy efficiency")	Web of Science (Advanced Search)	n=25 No filter

(("Occupational Health"[MeSH Terms] OR "Employee Health"[Title/Abstract] OR "Industrial Health"[Title/Abstract] OR "Industrial Hygiene"[Title/Abstract] OR "Occupational Safety"[Title/Abstract] OR "corporate health"[Title/Abstract] OR "workplace health"[Title/Abstract] OR "Worker Health"[Title/Abstract] OR "Occupational Medicine"[Title/Abstract] OR "Occupational Diseases"[Title/Abstract] OR "Occupational Hazards"[Title/Abstract] OR "Occupational Exposure"[Title/Abstract] OR "Occupational Stress"[Title/Abstract]) OR ("quality tools"[Title/Abstract])) AND ("Quality Management"[Title/Abstract] OR "Total Quality Management"[MeSH Terms] OR "Continuous Quality Management"[Title/Abstract] OR "Health Quality Management"[Title/Abstract] OR "Quality Assurance"[Title/Abstract] OR "Quality Assurance Standards"[Title/Abstract] OR "Quality Assurance System"[Title/Abstract] OR "Quality Management Systems"[Title/Abstract] OR "Total Quality"[Title/Abstract] OR "Quality Control"[MeSH Terms] OR "Analytical Quality Control"[Title/Abstract] OR "Quality Controls"[Title/Abstract]) AND (("energy sector"[Title/Abstract] OR "power industry"[Title/Abstract] OR "energy production"[Title/Abstract] OR "energy consumption"[Title/Abstract] OR "energy efficiency"[Title/Abstract] OR "renewable energy"[Title/Abstract] OR "alternative energy"[Title/Abstract] OR "energy policy"[Title/Abstract] OR "energy management"[Title/Abstract]))	PUBMED (Medline)	n= 02 No filter

Source: Own elaboration

It is important to note that different strategies were used to search for documents in each database, with each query having specific features adapted to the characteristics of the database being searched. Due to the complexity of identifying articles and texts that effectively explore the intersection between occupational health, quality management, and the energy sector, this approach was necessary.

The Scopus database was searched using broader terms and phrases to ensure coverage of the relevant topics while focusing on documents that addressed the central themes of the study. Similarly, the search in Web of Science, a scientific citation reference platform covering research in the sciences, social sciences, arts, and humanities, utilized keyword indexing and controlled terms for a more detailed search, with advanced refinement tools available to adjust the results as necessary. Both Scopus and Web of Science, being multidisciplinary databases, provided access to a wide range of literature, enabling the topic to be considered in an industrial and business context.

PubMed employed a more refined and targeted search strategy using standardized terms for indexing documents. This database, which extensively uses Medical Subject Headings (MeSH) to categorize its literature, is considered an essential tool for researchers focusing on health sciences, ensuring that accessed studies are relevant and accurate. However, the tests conducted with this approach showed a lack of results when the energy sector was included in the sequence of terms or keywords used for searching the database.

RESULTS

An overview of the research is provided in Figure 1. This figure summarizes the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) steps and provides information on the documents identified, the criteria for inclusion and exclusion, and the results obtained. This summary offers a concise overview of the processes employed to select and refine the literature review.

Various search strategies were employed across the consulted databases. Initially, 80 documents were identified, but some could not be analyzed due to access problems. After screening for duplicates and inaccessible material, 43 texts were identified in Scopus, 20 in Web of Science, and 2 in PubMed, resulting in a total of 65 documents.

In Scopus, most of the 43 texts were excluded because they did not meet the criteria for investigating quality management in corporate healthcare with a focus on the energy sector. These excluded articles covered topics such as interventional radiology strategies, physiological monitoring in the armed forces, risk assessment in nuclear power plants, and environmental management without addressing occupational health. Ultimately, only two articles met the specified search criteria, focusing on the integration of quality, environmental, occupational health and safety, and energy management systems.

From the 20 texts selected in Web of Science, only one met the research objective. The rest were excluded because they did not address the primary research themes of occupational health and quality management tools in the health and energy sectors. Many articles focused solely on quality management tools or specific occupational health issues without integrating the themes. Consequently, they did not provide a comprehensive overview of the necessary topics.

In PubMed, the two identified articles did not directly address the specific objective of this study. These articles focused on assessment tools for evaluating air quality and their impact on public health and ventilation systems. While relevant to quality management in corporate environments, they did not directly address the tools used in corporate health quality management in the energy sector or their impact on organizational performance.

Figure 1 – Search Results

Identification	•Selection of databases and initial document retrieval: Scopus (53) / Web of Science (25) / PubMed (02)
Screening	•Screening with identification of documents excluded due to inaccessibility, language and duplicate publication / Result after screening: Scopus (43) / Web of Science (20) / PubMed (02)
Eligibility	•Systematic reading of documents, considering the relationship to the proposed topic and the objective of the review / outcome by qualification - Scopus (02) / Web of Science (01) / PubMed (00)
Included	•Total documents included Scopus (02) / Web of Science (01) / PubMed (00)

Source: Own elaboration

All three selected articles (two from journals and one from a conference) addressed the integration of management systems in organizations, presenting different aspects of this theme. These documents underscored the significance of integrating management systems to enhance organizational efficiency, performance, and competitiveness. They discussed the necessity for compatibility between systems to ensure effectiveness and highlighted the advantages of implementing an integrated management system.

Another point of convergence was the role of international standards and norms, such as ISO 9000 and OHSAS 18001, in guiding and implementing management systems. Only these three documents were identified as presenting quality management tools and methods specifically related to occupational health. The authors of these articles explored the intersection between quality management and occupational health through practical examples, emphasizing their essential role in creating safer and more efficient working environments.

Despite a targeted literature search, many articles reviewed did not meet the study's requirements. Some materials presented quantitative estimates of occupational exposures, biological monitoring indicators, or analysis of laboratory test parameters. Others addressed topics like environmental management in the energy sector, safety and energy efficiency practices, specific occupational health practices, risk analysis, food value chain studies, and ergonomic analysis and design. While these articles aimed to enhance the quality and credibility of health information, they were excluded from the final analysis because they did not align with the specific objectives of the research.

The literature shows a growing trend of organizations adopting integrated quality management systems (ISO 9001), environmental management systems (ISO 14001), and occupational health and safety management systems (OHSAS 18001). The integration of these systems aims to optimize resources and reduce operating costs, meeting regulatory and market requirements, and promoting a more comprehensive and efficient business approach. This integration is expected to improve organizational performance (Bonato & Caten, 2015; Vitoreli & Carpinetti, 2013; Cardozo & Santos, 2009; Campos & Medeiros, 2009; Pombo & Magrini, 2008).

The limited number of texts found made it challenging to draw significant conclusions, indicating a clear need for further research and analysis in this area. The integration of quality management systems, environmental management systems, and occupational health and safety management systems offers numerous advantages, including enhanced efficiency and competitiveness. However, the lack of empirical studies on the nexus of these systems in the energy sector highlights a significant gap in the existing literature.

Given the limited number of documents identified, it is recommended to expand the search strategy to include other databases and broader search terms. The findings indicate a growing interest in integrated management systems, but much remains to be explored regarding their implementation and effectiveness in the energy sector. The emphasis on international standards, such as ISO 9000 and OHSAS 18001, underscores the importance of standardized guidelines for achieving excellence and organizational safety.

Below is a table detailing the material analyzed.

Table 2 - Comparative Analysis of Identified Articles

	Integrated Total Quality Management: Beyond Zero Defects Theory and Towards Innovation	**Implementing Integrated Management Systems Using a Risk Analysis Based Approach**	**Improvements of Global Performance System (GPS) Software Applied to HSEQ Management System in an Oil and Gas**
Language	English	English	English
Authors	Matias, JCO; Coelho, DA.	Labodová, A.	Méxas, MP; Drumond, GM; Alcantara, LS.
Document Type	Article	Article	Conference Paper

Publication	Total Quality Management & Business Excellence v. 22, n. 8, p. 891–910, Sep. 2011.	Journal of Cleaner Production v. 12, n. 6, p. 571 – 580. Aug. 2004	Revista Gestão & Tecnologia v. 21, n. 4, p. 111-134, dez. 2021.
Main Objective	The document discusses the importance of integrating quality management, environmental management, and health and safety systems within organizations. It highlights the historical development of quality management systems and the role of international standards such as ISO 9000. It also examines the lack of internationally certifiable standards for occupational health and safety management systems (OHSMS) and the development of national standards in this area. The article emphasizes the need for compatible systems to ensure the effectiveness of integrated management systems. It also provides insights into the ways in which corporate management systems can be integrated and the benefits of implementing an integrated management system directly. The article concludes with a discussion of the ongoing development of national standards for OHSMS, particularly in the Czech Republic.	The text presents a study aimed at evaluating the implementation effects of a Health, Safety, Environment and Quality (HSEQ) management software in an oil and gas service company. Using an applied, descriptive, exploratory, research-based methodology with both quantitative and qualitative approaches, the study found that the absence of an electronic management system in the HSEQ department led to nonconformities at Superior Energy Services. Users identified benefits such as conservation of environmental resources, improved information transfer and processing, reduced need for physical document storage, and improved process implementation. However, barriers such as limited knowledge of certain functionalities, insufficient user training, and software synchronization issues with Outlook were identified. Suggestions for improving the GPS DataStation software were made, with potential benefits for other organizations considering similar systems. The originality of the study was emphasized, as no practical results regarding computerization or digital transformation of the HSEQ management system could be found in the existing literature.	The text presents a study aimed at evaluating the implementation effects of a Health, Safety, Environment and Quality (HSEQ) management software in an oil and gas service company. Using an applied, descriptive, exploratory, research-based methodology with both quantitative and qualitative approaches, the study found that the absence of an electronic management system in the HSEQ department led to nonconformities at Superior Energy Services. Users identified benefits such as conservation of environmental resources, improved information transfer and processing, reduced need for physical document storage, and improved process implementation. However, barriers such as limited knowledge of certain functionalities, insufficient user training, and software synchronization issues with Outlook were identified. Suggestions for improving the GPS DataStation software were made, with potential benefits for other organizations considering similar systems. The originality of the study was emphasized, as no practical results regarding computerization or digital transformation of the HSEQ management system could be found in the existing literature.

Methodology	Theoretical review and conceptual analysis on the integration of management systems and the introduction of an IMS.	Case study using a risk analysis-based approach to integrate management systems.	Applied, descriptive, and exploratory research with a quantitative and qualitative approach, using questionnaires to collect data from GPS software users.
Main Findings	The integration of management systems can result in significant improvements in efficiency, performance, and competitiveness. The inclusion of an IMS is crucial for fostering innovation.	Risk analysis is essential for the effective implementation of integrated management systems, improving safety and compliance.	The implementation of GPS software improved efficiency and reduced non-conformities in HSEQ management. Users reported benefits such as agility in information transfer and reduced need for physical document storage.
Quality Management Tools	Integration of management systems (ISO 9001, ISO 14001, OHSAS 18001) and addition of an IMS.	Risk analysis as the basis for integrating management systems (ISO 9001, ISO 14001, OHSAS 18001).	Implementation of GPS software for HSEQ management, with functionalities such as unsafe conditions auditing, change management, and performance reporting.
Common Points	Discussion on the importance of integrating management systems. Use of international standards such as ISO 9001, ISO 14001, OHSAS 18001. Emphasis on continuous improvement and operational efficiency.	Need for integration and continuous improvement in management systems. Importance of systematic methods to ensure effectiveness. Use of risk analysis as a fundamental tool.	Implementation and challenges of integrating multiple management systems. Importance of digitization and information technology for process optimization.
Differences	Introduction of the IMS concept as an additional component. Greater focus on total quality theory and innovation.	Specific approach based on risk analysis. Detailed discussion on risk assessment methodologies.	Practical analysis of the impact of specific software (GPS) on HSEQ management. Results based on field research and user feedback.

Contributions to Occupational Health Quality Management	Integration of management systems can lead to improvements in efficiency and competitiveness. The inclusion of an IMS can bring innovation and new approaches to quality management.	Risk analysis is crucial for the effective implementation of integrated management systems. Risk-based methodologies can improve safety and compliance in occupational health.	Digitization and implementation of HSEQ management software can optimize processes and reduce non-conformities. User feedback provides insights for continuous improvements in the HSEQ management system.

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CONCLUSIONS

The research revealed a significant shortage of material on occupational health with an emphasis on quality management in the energy sector. This gap can be attributed to several factors. Firstly, the traditional approach to occupational health and safety, which focuses primarily on managing industry-specific risks such as workplace accidents and occupational illnesses, often overshadows broader health aspects of workers. Additionally, documents analyzing the energy sector predominantly focus on technical issues and regulatory compliance, leaving little emphasis on comprehensive occupational health programs.

Implementing occupational health programs and integrating them into quality management practices requires significant investments of time and financial resources, which may deter some companies. Moreover, some organizations might choose not to publish their results, contributing to the scarcity of knowledge about the adopted practices and their impacts on workers' health.

As awareness of occupational health issues grows and more research is published, it is anticipated that companies will increasingly recognize the benefits of integrating occupational health with quality management practices. Factors such as regulatory pressure and rising employee demands for healthier working environments are likely to drive this change.

The study also identified a notable lack of literature on the dissemination of management models tailored to the integration of occupational health and quality management in the energy sector. This highlights an urgent need for comprehensive studies to promote the sharing of effective management practices and knowledge adapted to the complexities of organizations in this specific sector.

Future research should broaden the range of databases used to gather a more comprehensive collection of material. Expanding the scope of search descriptors may help capture a wider variety of studies, even those not directly related to the energy sector, as long as they present healthcare quality management tools in the corporate world. Additionally, future studies should employ mixed-method approaches to provide a more holistic understanding of the topic. Combining quantitative data from surveys and performance metrics with qualitative insights from interviews and case studies can offer a deeper analysis of how integrated management systems affect organizational performance and employee well-being.

Researchers should also explore the development and implementation of specific tools and frameworks tailored to the unique challenges of the energy sector. These tools could include customized audit protocols, risk assessment methodologies, and performance measurement systems that integrate aspects of quality management and occupational health.

In conclusion, addressing these gaps requires a concerted effort to expand the research base, adopt comprehensive methodologies, and develop practical tools. By doing so, future research can significantly contribute to improving occupational health and quality management practices in the energy sector, ultimately enhancing both organizational performance and employee well-being.

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Integrating Sustainability into Excellence Models

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STRUCTURED ABSTRACT

Purpose

This paper aims to explore the intersection of excellence models and sustainability, analyzing their impact on organizational behavior and practices. It investigates the effectiveness of Multi-Criteria Decision-Making (MCDM) techniques in evaluating sustainability criteria within excellence models.

Design/methodology/approach

The study utilizes a comprehensive literature review approach to gather insights from existing research on excellence models, awards, and their relationship with sustainability. It synthesizes findings from diverse sources to provide a nuanced understanding of the subject matter. Additionally, the proposal outlines planned case studies and empirical data collection to illustrate practical applications of MCDM techniques in assessing sustainability within organizational frameworks.

Findings

The findings are anticipated to highlight the importance of integrating sustainability considerations into excellence models and organizational practices. The comparative analysis is expected to reveal the strengths and limitations of various excellence models in addressing sustainability criteria. Moreover, the application of MCDM techniques is projected to enhance the rigor and comprehensiveness of sustainability assessment, facilitating informed decision-making processes.

Originality/value

This proposal contributes to the existing literature by offering a comprehensive examination of the relationship between excellence models and sustainability. By incorporating MCDM techniques, it introduces innovative approaches to evaluating sustainability criteria within organizational frameworks. The findings are expected to provide valuable insights for organizations seeking to enhance their sustainability practices and align with global sustainability goals.

Keywords: Excellence models, Sustainability, Multi-Criteria Decision-Making (MCDM), Organizational behavior, Comparative analysis, Quality Management, Stakeholder Value, Literature Review, Data Analysis.

Paper type: Project Proposal.

1. INTRODUCTION

In today's rapidly evolving global economy, sustainability has emerged as a critical consideration for organizations across various industries. With increasing pressure to optimize performance while minimizing environmental impact and maximizing social responsibility, organizations are turning to excellence models and awards for guidance. These models, such as the Malcolm Baldrige National Quality Award (MBNQA), the European Foundation for Quality Management (EFQM), and others, provide frameworks for assessing and improving organizational practices. However, there remains a lack of comprehensive research examining how different excellence models address sustainability and how they influence sustainability practices within organizations. This paper seeks to address this gap by conducting a comparative analysis of excellence models and awards, with a specific focus on their approach to sustainability assessment. By integrating Multi-Criteria Decision-Making (MCDM) techniques, the study aims to enhance the rigor of sustainability evaluation within these models, offering valuable insights for organizations striving to integrate sustainability principles into their operations.

In addition to the comparative analysis, this study will employ MCDM techniques to evaluate and weight sustainability criteria across different excellence models. MCDM provides a systematic framework for analyzing complex decision problems involving multiple criteria. By incorporating MCDM, the study aims to enhance the rigor and comprehensiveness of the comparative analysis, providing a nuanced understanding of how different excellence models address sustainability. This integration of MCDM underscores the importance of rigorous decision-making processes in evaluating sustainability within organizational frameworks.

2. LITERATURE REVIEW

The literature review explores existing research on excellence models, awards, and their intersection with sustainability. Numerous studies have examined individual excellence models and their impact on organizational performance. For example, research by Vokurka et al. (2000) found a positive correlation between MBNQA principles and improved sustainability practices, highlighting the model's influence on organizational behavior. Similarly, Medne et al. (2020) explored EFQM's approach to sustainability, revealing a comprehensive integration of sustainability-focused criteria. However, despite these individual studies, there remains a lack of comprehensive research comparing various excellence models in terms of their sustainability assessment. Asif et al. (2011) emphasized the need for integrating sustainability indicators into core business processes using existing excellence model structures, advocating for a more holistic approach to sustainability assessment. Furthermore, Russo and Harrison (2005) highlighted the importance of understanding how different excellence models evaluate and prioritize sustainability, particularly within specific industries such as electronics. By scrutinizing the criteria employed by excellence models in assessing sustainability, organizations can gain valuable insights into how to integrate sustainable practices into their operations effectively. Additionally, Feng et al. (2006) emphasized the comprehensive nature of the Singapore Quality Award (SQA) criteria for sustainability assessment, which includes dimensions such as environmental stewardship, social responsibility, and ethical business conduct. Evans and Lindsay (2011) also provided insights into the Canadian Awards for Excellence (CAE), which emphasize sustainability, corporate social responsibility, and ethical business practices. Overall, the literature review highlights the importance of considering sustainability within the context of excellence models and awards, underscoring the need for further research in this area.

This literature review aims to explore existing research on excellence models, awards, and their impact on sustainability, providing a foundation for the proposed comparative study. MCDM will be integrated into the review to analyze how different studies have employed decision-making tools in evaluating sustainability criteria within excellence models.

2.1. Excellence Models and Awards

2.1.1. Malcolm Baldrige National Quality Award (MBNQA)

The MBNQA, a cornerstone of organizational excellence in the United States, has been a focus of several studies examining its influence on sustainability (Vokurka et al., 2000). Figure 1 illustrates the key criteria of the MBNQA and their intersection with sustainability practices (Ford, 2022).

(Politis and Grigoroudis, 2022) found a positive correlation between MBNQA principles and improved sustainability practices, indicating the model's impact on organizational behavior.

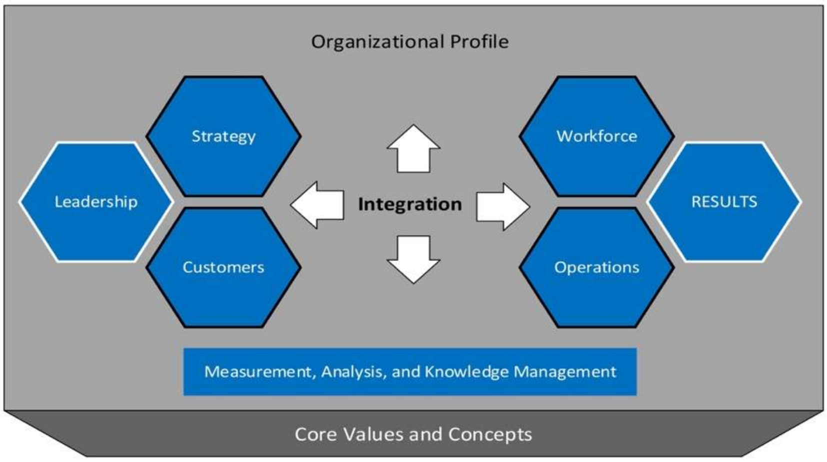

Figure 1. The key criteria of the MBNQA (Ford, 2022).

2.1.2. European Foundation for Quality Management (EFQM)

In Europe, EFQM stands as a holistic framework for organizational excellence. Medne et al. (2020) explored EFQM's approach to sustainability, revealing a comprehensive integration. Figure 2 outlines the sustainability-focused criteria within the EFQM model (Turisová et al., 2021).
The study emphasizes the need for organizations to align sustainability initiatives with EFQM criteria for enhanced performance (Medne et al., 2020).

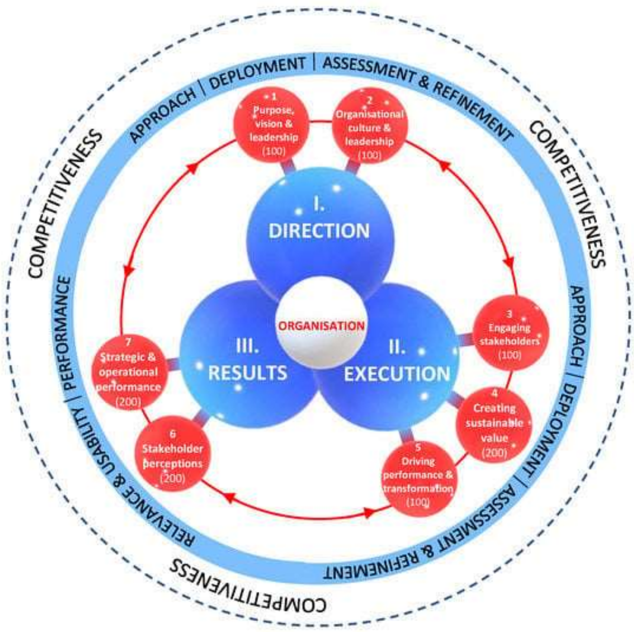

Figure 2. The sustainability-focused criteria within the EFQM model (Turisová et al., 2021).

2.2. Sustainability Assessment in Excellence Models

While excellence models have been integral to organizational success, their approach to sustainability assessment requires scrutiny. Limited research has explored how these models evaluate and prioritize sustainability (Russo and Harrison, 2005). Asif et al. (2011) focusing on the EFQM and the Baldrige Criteria for Performance Excellence (BCPE), reveals that while these models partially address triple bottom-line considerations, sustainability issues are not comprehensively covered, with economic prosperity taking precedence. Suggestions for enhancing the EFQM and BCPE models are discussed, and an integrated quality-sustainability framework is proposed, advocating the incorporation of sustainability indicators into core business processes using existing business excellence models structures.

Russo and Harrison, (2005) delve into the relationship between organizational design and environmental performance, shedding light on the intricacies of sustainability within the electronics industry. Understanding the criteria employed by different models in assessing sustainability is crucial for organizations striving to integrate sustainable practices into their operations.

In the pursuit of organizational excellence, the assessment of sustainability within the frameworks of renowned models and awards plays a pivotal role. This section delves into the specific criteria and considerations related to sustainability within two prominent excellence models: the Singapore Quality Award (SQA) and the Canadian Awards for Excellence (CAE). By scrutinizing how these models evaluate and prioritize sustainability, we gain a deeper understanding of their influence on organizational practices and strategies.

2.2.1. Singapore Quality Award (SQA)

Feng et al. (2006) research focused on the SQA, revealing its significant impact on sustainability practices.

The SQA's criteria for sustainability assessment are comprehensive, reflecting a holistic approach to organizational excellence. These criteria often include the following key dimensions (Lasrado et al., 2018):

Environmental Stewardship: Organizations are evaluated on their commitment to environmentally sustainable practices. This may involve initiatives to reduce carbon footprint, waste reduction, and adherence to eco-friendly standards.

Social Responsibility: The SQA places a significant emphasis on social responsibility, considering factors such as community engagement, corporate philanthropy, and contributions to societal well-being.

Ethical Business Conduct: A cornerstone of the SQA criteria is the promotion of ethical business conduct. This includes transparent and fair business dealings, adherence to ethical standards, and the establishment of a corporate culture that values integrity.

2.2.2. Canadian Awards for Excellence (CAE)

Turning our attention to the Canadian context, Evans and Lindsay (2011) investigation into the CAE provides insights into how this model fosters sustainability. The subsequent subsection uncovers the specific criteria of the CAE that emphasize the incorporation of sustainability considerations into the fabric of organizational excellence.

The Canadian Awards for Excellence sets forth criteria that extend beyond traditional benchmarks, seeking to acknowledge organizations that exemplify excellence in sustainability, corporate social responsibility, and ethical business practices. Through an exploration of these criteria, organizations gain valuable insights into the holistic expectations embedded within the CAE framework.

Through a focused analysis of these excellence models, we aim to discern the nuances in their approaches to sustainability assessment, thereby contributing to a comprehensive understanding of the interplay between organizational excellence and sustainable practices.

2.3. Impact of Excellence Models on Sustainability Practices

Jankalová and Jankal, (2020) conducted a recent comparative analysis using secondary data on business excellence models to explore and validate their fundamental principles, aiming to comprehend the correlation between excellence practices and sustainability. The study emphasizes core values such as customer and market focus. Meeting and surpassing customer expectations requires proactive competition analysis and flexible, timely responses. Enhanced competitiveness hinges on strategic customer satisfaction. Another pivotal core value is visionary leadership, where organizations with outstanding performance possess leaders who foresee the future, identify environmental trends, and translate them into reality through effective management.

The growing emphasis on corporate sustainability has led organizations to align strategies with economic, environmental, and social goals. Business Excellence Models (BEMs), recognized for optimizing organizational performance, face scrutiny for potential limitations in adequately addressing sustainability. Recent iterations of major BEMs show acknowledgment of sustainability but fall short of standardized implementation and measurement. To enhance their efficacy, BEMs should integrate comprehensive sustainability indicators aligned with Global Reporting Initiative (GRI) standards (Politis and Grigoroudis, 2022).

2.4. ISO Standards and Sustainability

2.4.1 ISO 9004

While not exactly a model, ISO 9004 is relevant for its broader reach compared to regional awards like Singapore's. It provides guidelines for organizations to achieve sustained success by addressing quality management and improving overall performance, including sustainability aspects.

2.4.2. ISO 26000, ISO 50001, and ISO 14001

These standards, although not specifically designed as excellence models, have a significant practical impact on sustainability practices. ISO 26000 offers guidance on social responsibility, ISO 50001 focuses on energy management, and ISO 14001 sets out criteria for environmental management systems. These standards act as de facto models for many companies, influencing their sustainability strategies and actions, often more so than specific sustainability-focused models like the SDGs.

2.5. Evolution of Sustainability and Excellence Models

As sustainability challenges evolve globally, the literature review explores how excellence models have adapted over time to address these changes (Jabbour and Santos, 2008; Prajogo and Olhager, 2012). Jabbour and Santos (2008) emphasize the central role of green issues in organizational responsiveness to stakeholders, providing insights from large companies in Brazil. Prajogo and Olhager (2012) contribute to the understanding of supply chain integration and performance, emphasizing the effects of long-term relationships and logistics integration. Additionally, Bansal and Roth (2000) delve into why companies go green, presenting a model of ecological responsiveness.
The excellence models such as EFQM model's adaptability renders it universally applicable to companies across sectors and sizes, embodying a philosophy encompassing principles, practices, and tools (Dean Jr and Bowen, 1994). Central tenets include customer focus, continuous improvement, and fact-based decision-making. Exceptional organizations feature leaders with foresight, capable of navigating evolving environmental trends through effective management, serving as role models due to shared values and ethics. Leadership influence extends beyond internal spheres, impacting society

(Jankalová and Jankal, 2020). The study explores additional core values, with emphasis on sustainable development, well-being, and inclusion. Excellently managed organizations positively influence society by enhancing performance across the three dimensions of sustainable development, surpassing legal requirements to exhibit commitment to the environment, transparency, and ethics (Jankalová and Jankal, 2020). Quality, as elucidated by Jankalová and Jankal, (2020), is fostered by acknowledging stakeholders, particularly employees, emphasizing that a well-supported workforce contributes to organizational benefit. Education and preparation of personnel for navigating business changes are deemed crucial. The organization prioritizes staff needs to ensure satisfaction. As a strategic management approach, organizational excellence seeks to fulfill the expectations of all stakeholders, aligning with widely recognized international excellence models (EFQM, Deming, Malcolm Baldrige, and the Ibero-American model). These models outline excellence principles as criteria applicable to diverse organizations, serving as self-assessment tools. Research affirms that positive sustainable development can be achieved through the implementation of excellence models, exemplified by the EFQM model (Aryanasl et al., 2016; Rocha-Lona et al., 2015).

2.5.1. Methodological Approaches in Studying Excellence Models

(Jankalová and Jankal, 2018) reviewed Business Excellence Models, seeking to enhance their sustainability assessment by considering environmental, economic, and social aspects. Through extensive literature review and analysis, the proposed model introduces seven non-results criteria and criterion results, with The Singapore Business Excellence Framework identified as the closest match. Figure 3 illustrates a categorical breakdown of research methodologies utilized in the study. It provides a comprehensive overview, detailing the approaches such as surveys, interviews, and document analysis employed in the research process.

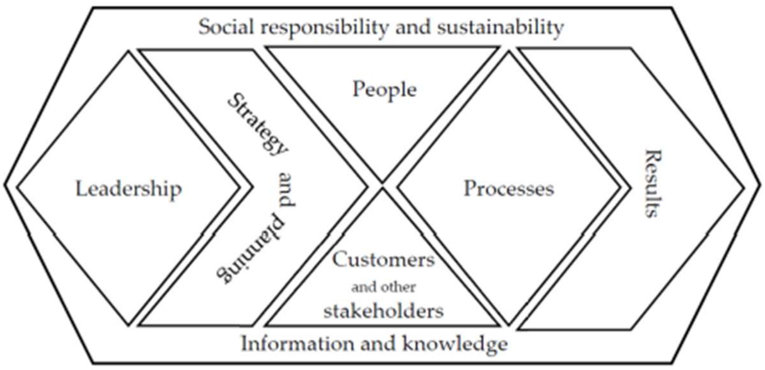

Figure 3. Methodological Approaches Overview: Surveys, Interviews, and Document Analysis.

Their work aids researchers in selecting effective methods for studying the impact of excellence models on sustainability.

2.5.2. Multi-Criteria Decision-Making Tools

MCDM is a systematic approach utilized in various fields to evaluate and prioritize alternatives based on multiple criteria or objectives. Unlike traditional decision-making methods that focus on single criteria, MCDM considers a diverse set of factors, each with its own importance and trade-offs. MCDM techniques provide decision-makers with structured frameworks to navigate complex decision problems, incorporating qualitative and quantitative inputs to facilitate informed choices. By synthesizing diverse perspectives and considering competing objectives, MCDM enhances the rigor and comprehensiveness of decision-making processes, leading to more robust outcomes. Common MCDM methods include Analytic Hierarchy Process (AHP), Technique for Order Preference by Similarity to Ideal Solution (TOPSIS), and the Stepwise Weight Assessment Ratio Analysis (SWARA) approach, each offering unique advantages depending on the specific decision context. In the context of quality management and organizational optimization, MCDM tools offer valuable insights into the prioritization of criteria and the identification of optimal strategies to achieve desired outcomes.

The MCDM tools play a crucial role in various fields, including quality management and healthcare systems optimization. The application of MCDM techniques enables researchers and practitioners to prioritize criteria and make informed decisions based on multiple factors. Hariri et al. (2024) proposed an integrated model utilizing the Stepwise Weight Assessment Ratio Analysis (SWARA) approach and the refined Kano model to classify and rank customer requirements in the automotive industry. By employing SWARA, the authors categorized customer requirements into main categories, including technical, quality, delivery, sustainability, and cost, highlighting the importance of considering sustainability concerns alongside traditional quality and technical aspects. Similarly, in the context of healthcare systems, Hariri et al. (2022) demonstrated the effectiveness of integrating the Fuzzy Analytic Hierarchy Process (FAHP) and Quality Function Deployment (QFD) to optimize hospital services. Through the adaptation of FAHP to determine the weights of patient requirements, the authors achieved more precise rankings of technical requirements, thereby improving the quality of hospital services. These studies underscore the value of MCDM tools in addressing complex decision-making challenges and enhancing organizational processes across diverse domains.

This addition emphasizes the significance of MCDM tools in addressing complex decision-making challenges and optimizing organizational processes in various contexts, aligning with the broader themes of the literature review.

3. METHODOLOGY

The methodology section outlines the research approach employed in this study, including data collection methods, analysis techniques, and the integration of MCDM. Data will be collected through surveys, interviews, and analysis of official documents and reports from organizations that have implemented excellence models. The selection of organizations will be based on their diversity in terms of industry, size, and geographic location. Surveys will be distributed to organizations that have received awards such as the MBNQA, EFQM, and others, while in-depth interviews will be conducted with representatives from selected organizations to gain deeper insights into their experiences with excellence models and their impact on sustainability. Data analysis will involve comparing the approaches of different excellence models towards sustainability and evaluating the impact of these models on the sustainability performance of organizations. MCDM techniques such as AHP and TOPSIS will be utilized alongside traditional data analysis methods to enhance the rigor of the comparative analysis. The expected outcomes of the study include informed decision-making for organizations, policy recommendations for policymakers, scholarly advancements in the fields of quality management and sustainability, and improved sustainability practices within organizations. In conclusion, the literature review provides valuable insights into the relationship between excellence models and sustainability, setting the stage for the proposed comparative study. The next sections will delve into the methodology, data collection, and analysis, aiming to contribute further to the scholarly discourse on sustainable organizational practices.

The project aims to address crucial questions at the intersection of excellence models, sustainability, and organizational behavior. By focusing on the following objectives, we endeavor to contribute novel insights and approaches to the field:

1. **Comprehensive Literature Review:** The literature review encompasses an extensive analysis of academic papers, industry reports, and case studies related to excellence models and sustainability. Key models such as the MBNQA, EFQM, SQA, and CAE are examined to understand their approach to sustainability assessment.

2. **Comparative Analysis:** The study conducts a comparative analysis of the identified excellence models to evaluate their strengths and limitations in addressing sustainability criteria. This analysis helps to highlight best practices and areas for improvement.
3. **Methodological Innovation:** Develop methodological approaches to enhance sustainability assessment within excellence models. Integrate comprehensive sustainability indicators aligned with GRI standards. Propose novel frameworks for incorporating sustainability considerations into core business processes using existing excellence model structures. Aim to advance the state of the art in sustainability assessment methodologies.
4. **Application of MCDM Techniques:** Although detailed methodological steps are minimized in this article, the project proposes the use of MCDM techniques to enhance the assessment of sustainability criteria within excellence models. This will be further elaborated upon in the project's detailed research phase.
5. **Innovative Research Methods:** Employ innovative research methods, such as qualitative and quantitative analyses, to explore the relationship between excellence models and sustainability. Utilize case studies, surveys, and interviews to gather insights from diverse perspectives and contexts. Aim to generate empirical evidence to support theoretical frameworks and practical recommendations.

Outcomes:

The anticipated outcomes of this project include the following:

1. **Identification of Best Practices:** The project aims to identify best practices for integrating sustainability into excellence models, highlighting effective strategies and approaches used by various organizations.
2. **Development of Recommendations:** Based on the comparative analysis, the project will offer actionable recommendations for organizations seeking to enhance their sustainability practices. These recommendations will be tailored to different industry contexts and organizational sizes.
3. **Enhanced Understanding of Excellence Models:** The study will contribute to a deeper understanding of the strengths and limitations of various excellence models in addressing sustainability criteria. This will help organizations make informed choices about which models best align with their sustainability goals.

4. **Application of MCDM Techniques:** By incorporating MCDM techniques, the project will demonstrate how these methods can enhance the rigor and comprehensiveness of sustainability assessments within organizational frameworks.
5. **Practical Insights:** The inclusion of planned case studies and empirical data will provide practical insights into the application of MCDM techniques, showcasing real-world examples of how organizations can effectively evaluate and improve their sustainability practices.

These outcomes will be detailed and elaborated upon completion of the project, providing valuable insights and guidance for organizations aiming to align with global sustainability goals.

4. CONCLUSION

In conclusion, this paper provides a comprehensive analysis of the intersection between excellence models and sustainability, offering insights for organizations striving to integrate sustainability principles into their operations. By conducting a comparative analysis of excellence models and awards and integrating MCDM techniques, the study aims to enhance the rigor of sustainability evaluation within these frameworks. The expected outcomes include informed decision-making, policy recommendations, scholarly advancements, and improved sustainability practices. Overall, this paper contributes to a nuanced understanding of the relationship between excellence models and sustainability, offering valuable insights for researchers, practitioners, and policymakers alike.

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Tool for assessing the degree of maturity in process management in the Brazilian electrical sector

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STRUCTURED ABSTRACT

This work proposes a business process management tool for the electricity sector in light of existing methodological alternatives. The importance of ESG (Environmental, Social, and Governance) and BPM (Business Process Management) for organizations and their stakeholders remains a suitable management practice. It has become essential for business, and the concept associated with quality must be understood as a critical factor that unifies and enhances these two practices. Bibliometric research was carried out to prove this conjecture, identifying the five main process management tools cited in the specialized bibliography, evoking a quality tool developed by the National Quality Program, now commonly used in Brazil. Treated and unified by the conceptual similarity between the dimensions of the investigated approaches, an alternative tool, BPM-BES (Business Process Management in the Brazilian Electric Sector), was designed and validated to analyze critical processes related to the difficulties of organizations in combating losses caused by failures in management processes. Prioritizing the consensus filter criteria used by already established approaches and adapting them to the functional characteristics and analysis criteria previously validated for the Brazilian business environment, the appropriate alternative proposed showed the potential to improve the operational efficiency of inherent critical electrical sector management processes. The work results show that understanding the level of maturity still constitutes one of the main obstacles to implementing effective management of essential processes, suggesting the need for more knowledge about process management. The proposed alternative tool is based on five dimensions of knowledge: knowledge management, corporate governance, technology and information, strategic alignment, and people management. After going through a pre-test process involving interviews with experts from the organization studied, the functions established as sampling

criteria in the investigation conducted in the procedures adopted by the Brazilian electricity sector regulatory agency (Aneel) were taken as a reference company.

Keywords: Management evaluation tool. Quality. Maturity of process management. Process Management. BPM. BPM-BES. Brazilian electrical sector.

INTRODUCTION

The national interconnected electrical system is an extensive network that spreads throughout the country, bringing together generation systems and an electricity transmission grid. Integrating a complex system transfers energy between public and private companies, including the concessionaires that generate, distribute, and commercialize electricity. While the independent national regulator controls the overall energy system, consumers benefit from the extensive energy infrastructure associated with the energy generation. Specialized studies confirm that Brazilian companies in the electricity sector face enormous challenges in combating energy losses, default on bills and difficulties in implementing actions to improve operational efficiency (Costa, 2005). Among the drawbacks identified, the lack of alignment between critical impacting sectors and failures in the information system stands out, compromising decision-making aimed at combating losses. In this context, the model's effectiveness in assessing the maturity of business process management must be understood as a determining factor in making energy companies more innovative, therefore more competitive and more profitable. In particular, process management is the strategic tool capable of inducing the necessary improvements to remain competitive, stimulate growth or market change. Despite the existence of a consensus on the relevance of process management, scholars in the area have different perceptions on the subject, as clearly characterized by their declared opinions documented in their literary productions, also reflected in the operational routine of the organizations in which they work (Paim, 2007). If, on the one hand, these differences of understanding enrich the debate, on the other, they reflect the lack of organizational culture, making it challenging to implement process management while inducing resistance from employees, who end up being seduced by the search for short-term results.

The interest in evaluating the effectiveness and maturity of management processes is also a result of a trend observed in large organizations, which have reduced their staff or made alliances with other organizations to make them more efficient and more innovative. Energy companies in the electricity sector are no exception to the rule.

This complex scenario explains the natural resistance by organizational attempts to assess the quality of management by processes, explained by four critical factors in the view of Gonzalez (2015): (i) the excess of functional thinking, which overshadows the institutional mission and its perception by employees; (ii) governance difficulties, due to the lack of perception that more efficient processes require more elaborate management actions; (iii) the lack of a sponsor to diagnose the quality of the processes, since any change process imposes internal resistance and breaks the current functional model (hence the absolute need to gain support from stakeholders and senior management to avoid failure); and finally, (iv) the natural resistance to any change management, either because of the discomfort of the change itself or because of the fear of loss of value, beliefs and communication noises.

Attempts to implement or improve the level of process management require overcoming communication challenges, among them, strategic alignment and diagnosis of the degree of maturity of the management of the organization's internal processes.

In essence, this is the purpose of this work, inspired by the multiplicity of analysis tools available in the specialized literature, to offer a diagnostic alternative in simple language and adapted to the specificities of Brazilian energy companies, thus contributing to assessing the maturity of the management of the company's business processes, more precisely, to evaluate if it is considered adequate to the culture of companies operating in the electricity sector. It is believed that the application of the proposed tool allows assessing the company's level of maturity, guiding it to achieve greater assertiveness in the dimensions to be worked on and efficient management of their internal critical processes.

THEORETICAL REFERENCE IN PROCESS MANAGEMENT

Theoretical background

According to Oliveira, Lobo, and Conceição (2018), process management is an organizational model oriented to managing organizations' business processes. Hence, it is also commonly called business process management and can be defined as a flow of activities that involve and integrate resources and the organizational structure to achieve a specific productive purpose, resulting in products, services, and information.

Pagliuso, Cardoso & Spiegel (2004) highlight that any process is associated with two milestones, a beginning and an end, and input and output data, known as process outcomes. For these steps to be integrated and applied orderly, the implementation of the process requires a logical routine divided into stages. Maturity models can be described as normative reference models. In general, they are applied in organizations to evaluate the current status quo of a set of capabilities, to derive improvement measures, and to prioritize them according to the strategy (Thordsen, Murawaki and Bick, 2020).

Although process maturity may vary from author to author, Kalinowski (2016) adopts the concept formulated by Humphrey. The latter associates process maturity with the degree of definition, management, measurement, control, and effectiveness associated with the process.

Among the alternatives documented in the specialized literature, Business Process Management (BPM) is gaining notoriety. This methodology uses process automation to improve and implement best practices.

Gabryelczyk (2016) proposed a managerial maturity indicator —the Business Process Maturity Indicator (BPMI)— associating maturity with the ability to manage and control processes efficiently.

The Association of Business Process Management Professionals (ABPMP, 2023) characterizes process management as a discipline that integrates an organization's strategies and objectives with customer expectations and needs through cutting-edge processes.

The Business Process Management managerial scheme handles end-to-end work by orchestrating activities across all business functions. This process management mainly deals with the 4W-1H analysis scheme (What, Where, When, Why, and How), whose answers are considered essential in information-gathering. In other words, maintaining customer focus treats management as a process that integrates and aligns business strategies to ensure that the organization can effectively improve its performance based on improvements in its function.

Applying this new management concept has proved successful, with a growing number of adepts of this methodology. The significant increase in members of the Association of Business Process Management Professionals (ABPMP) —an international association of Business Process Management professionals dedicated to promoting the concepts and practices of BPM— confirms the efficacy of the management tool. The number of adepts increased astonished, from 30 certifications in 2010 to 882 in 2017 (ABPM BRASIL, 2023).

Commonly, companies are "departmentalized", a way of organization that comes from the classic theory of Fayol; however, the structure needs to act in a matrix with process management. BPM is configured as a tool that places the process above the individual interests of sectors or departments, allowing individuals to perceive the whole and know their value chain.

Process management can be used to maintain or improve the quality of results. It is necessary to implement the classic PDCA process, which stands for Plan, Execute, Check, and Act.

Established tools for business management processes

This section concisely describes and characterizes the four tools identified by bibliographic research as the most effective and standard tools for assessing the maturity of business management processes.

The Control Objectives for Information and Related Technology (COBIT) —the management COBIT tool— is a framework initially developed for the Information Technology (IT) area but adapted for process management. It is recognised as a reference tool for the best IT and process management practices (management and maturity); it incorporates a differentiated logic. More specifically, based on governance, it aligns the process to the multiple needs of business administration and aggregates tools or security standards from other sources (Pagliuso, Cardoso & Spiegel, 2010). Alignment with management involves four domains: planning and organisation; acquisition and implementation; deliveries and support; and control and evaluations.

The Process and Enterprise Maturity Model (PEMM), or the HAMMER model, is widely used. The design (2002) and construction (2006) process are based on the BPM model. This model maps the characteristics necessary for the excellent performance of business processes and helps executives understand, plan, and evaluate process transformation initiatives (Mangueira, Gutierrez & Costa, 2014). The PEMM model uses the following facilitators: indicators, IT infrastructure and human resources, executors, projects, and their responsibilities.

Management Excellence Model (MEG). This evaluation process management scheme originated in the 1980s, based on the Malcolm Baldrige National Quality Award (MBNQA) criteria, created to increase the competitiveness of American companies threatened by Japanese companies, in line with internationally recognized practices, such as EFQM (European Foundation for Quality Management). Furthermore, the EFQM model adheres to the dimensions of the BPM tool, which shows how the evolution of process management and quality tools increasingly converge toward the search for efficient and sustainable results through people. The European EFQM (Silva & Sampaio (2012) quotes the following fundamentals from different perspectives:

- Results Orientation. Excellence is when the organization achieves results that delight all the organization's stakeholders.
- Customer Focus and Sustainability. Excellence is creating sustainable customer value.
- Leadership and Constancy of Purpose. Excellence is visionary and inspirational leadership coupled with constancy of purpose.
- Management by Processes and Systemic Vision. Excellence is achieved when the management of an organization is based on interdependent and interrelated systems, processes, and facts.
- People Development and Involvement. Excellence requires maximization of the contribution of employees through their development and involvement.

- Continuous Learning, Innovation, and Improvement. Excellence is challenging the status quo and effecting change by utilizing learning to create innovation and improvement opportunities.
- Partnership Development. Excellence is developing and maintaining value-adding partnerships.

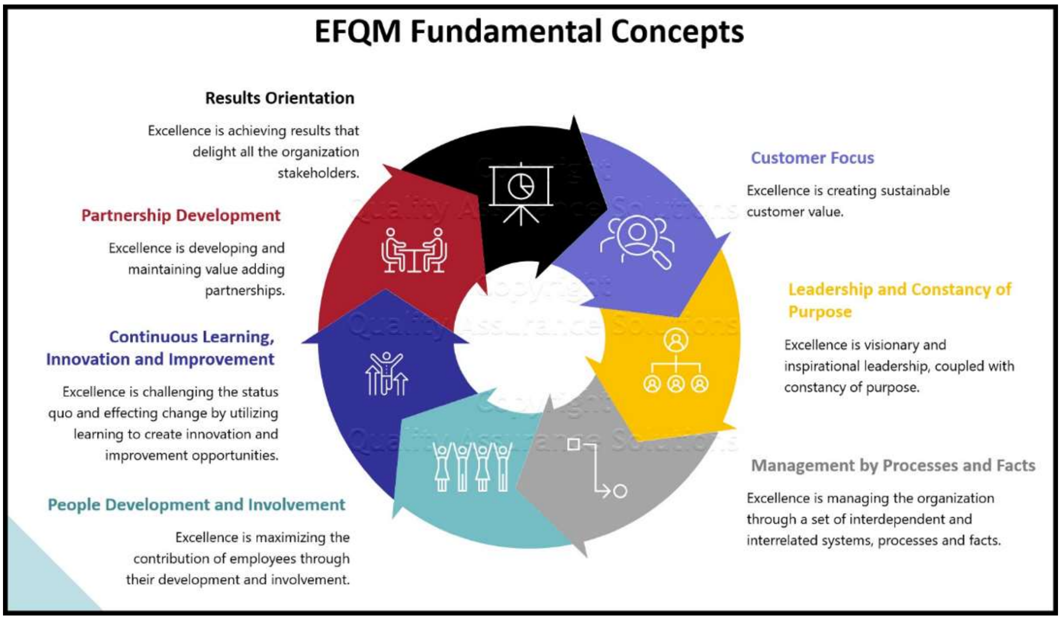

Figure 1: Management tools and their reference sources.
Source: EFQM (https://www.quality-assurance-solutions.com/EFQM.html).

According to the PDCL (Plan, Do, Check, Learn) cycle, MEG uses the principle of learning and continuous improvement. Even though it is not a specific maturity assessment tool in process management, the Management Excellence Model (MEG) has been used as it incorporates a maturity assessment model in management excellence.

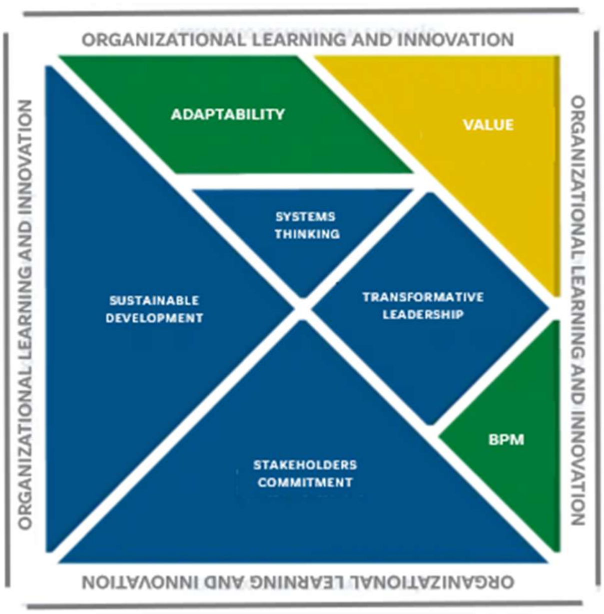

Figure 2: Model MEG (Brazil).
Source: MEG-FNQ.

It adheres to the basic concepts used in operational processes, which comprise the Fundamentals of Excellence (FNQ, 2016), thus reflecting internationally recognized ideas that world-class leading management organizations adopt. As evidence of the use of this assessment approach, the Competitiveness Award for Micro and Small Enterprises (MPE Brazil) adopted a questionnaire model for self-assessment based on the MEG, whose application allows an objective diagnosis of the degree of maturity of the management object of the assessment. In Brazil, the National Quality Foundation (FNQ, 2008) also adopts these concepts, which have been widely used since 2004, based on the review of the MEG method carried out in 2003. Based on eight dimensions (leadership, strategies and plans, customers, society, information and knowledge, people, processes, and results), the MEG assessment tool is intended to guarantee the survival and success of organizations.

The Project Management Maturity Model (MMGP) was developed in Brazil by Prado (2010), and this appraisal arrangement aligns international practices with local characteristics. Designed to assess the maturity of the organization and its ability to execute successful projects, this model is based on the principles of simplicity and universality. It adopts short and straightforward questionnaires, universally standardized, and therefore conveniently used by any interested organization to evaluate the effectiveness of their projects' management. Built based on the CMM model, their structures are very similar. They operate according to the following seven dimensions of analysis: contextual technical competence, methodology, informatization, organizational structure, alignment with strategies, behavioural competence, and core competence.

Maturity in Process Management

Process Management maturity assessment is a tool to evaluate how an organization manages its processes. Previous research proves that greater BPM maturity improves processes and organizational performance. However, its results according to maturity are not modular, and each organization has its level of maturity according to its area of activity and region. The results obtained by maturity are an essential part of the results, but they do not have exclusive responsibility (Dijkman, Lammers, and Jong, 2016).

Maturity models are a successful approach to improving a company's capabilities and business process management (BPM) capabilities. However, the number of corresponding maturity models is suggested to be so high that professionals and scholars risk losing control (ROGLINGER, POPPELBOß and BECKER, 2012).

Thordsen, Murawski, and Bick (2020) argue that the maturity of certain organizational processes is key to achieving improved performance. Furthermore, maturity models have several levels that indicate the path to be followed in developing organizational capabilities.

RESEARCH METODOLOGHY

This research can be classified according to two methodological aspects: (i) applied research, since it aims to assist in the solution of practical problems existing in organizations, with a focus on the intended area of study, and (ii) exploratory research, as it proposes the construction of an alternative tool for assessing the maturity of management processes, based on already consolidated tools. As for the objective, this study is classified as descriptive, as it sought to draw a picture of the level of maturity in process management (Gray, 2012). As for the means of data collection, the research was bibliographical, as it included a literature review through structured web search platforms (Scopus[1], ISI[2] and Scielo[3]), designed to identify books, theses and dissertations, therefore providing an adequate theoretical basis and the extraction of related critical themes capable of contributing to the analysis. The search for publications and other academic articles associated with the state of art used data mining web search webblionmining, which was censused in the ISI Web of Science/CAPES Sucupira databases[4].

The search in the indexed databases was based on the criterion "technical, scientific publications in English and Portuguese," filtered by topics related to process management, has revealed the following results (publications identified): (i) 7,767 references on "business process management"; (ii) 40 references on "business process management" and "maturity" and (iii) 40 references on "business process management" and "maturity" or "process management" or "model maturity bpm".

Table 1 summarizes the results of the careful literature review carried out on maturity models in process management.

[1] **Scopus** (Expertly curated abstract & citation database). Access: http://scopus.com
[2] **ISI** (International Scientific Indexing). Access: https://isindexing.com/
[3] **Scielo** (Scientific Electronic Library Online). Access: http://scielo.org. Twitter @RedeSciELO
[4] Sucupira.coleta@capes.gov.br

Table 1: Management tools and their reference sources.

YEAR	AUTHORS	SOURCE OF PUBLISHED	TOOL MATURITY
2017	PESOA ; KUZNECOVA & LATVIA	DE GRUYTER OPEN ; 2017, Vol 20; pp 74-78	CMM ; BPMM ; PEMM
2017	SILVA; GOMES & SILVA	Revista GEINTEC; 2017 , vol 7(3); v7i3.768	COBIT
2017	VUGEC & LOVRIC	Business Systems Research, 2017, Vol 8(1) pp60-70	BPMM ; SBPM
2016	NASCIMENTO; OLIVEIRA; LADEIRA & FILHO	Gestão e Produção; 2016; vol. 23 Epub 31-maio	CROSBY ; MEG
2016	KALINOWSKI	DE GRUYTER OPEN ; 2016, Vol 20; pp 87-98	CROSBY ; CMMI ; BPMMM
2016	GABRYELCZYK	DE GRUYTER OPEN ; 2016, Vol 62; pp 3-11	BPMM ; BPOMM ; PEMM BPMM ; PML ; BPMI
2016	TARHAN, TURETKEN & REIJERS	Information and Software Technology, 2016	BPMM
2016	DIJKMAN, LAMMERS & JONG	Information Systems Frontiers, 2016	BPMMM ; BPMM ; CMMI OMG
2015	MORAES, FORTE, OLIVEIRA & SOBREIRA	RAM. VER ADM MACKENZIE; 2015, vol. 16, pp 214-244	OPM3 ; CMM ; MMGP
2013	RADOMIR	Journal of Competitiveness; 2013, vol 5(4); pp 43-56	BPMM ; CMM
2013	NIEHAVES, PLATTFAUT & BECKER	Government Information Quarterly,2013, Vol 30(3), pp217-225	CMM ; OMG ; BPMMM PEMM
2013	SKRINJAR & TRKMAN	International Journal of Information Management, 2013, vol 33 , pp 48-60	BPM
2012	CARPES; INOMATRA; RADOS	GEPROS; 2012; nº 3, pp 57-74	Modelo APO
2011	ARAUJO; RODRIGUEZ	VII CNEG, 2011	BPMM ; CMM
2008	JANSEN	PUCRS; 2008, (/dspacel)	COBIT ; CMM
2008	TONINI; CARVALHO & SPINOLA	EPUSP; 2008; vol. 18, nº 2	TSP ; PMMM ; OPM3 SW-CMM ; PSP
2008	BEBER	PUCRS; 2008, (/dspacel)	P-CMM

Source: Souza, 2018.

The tools cited in the selected publications were grouped by a model of origin, respecting their variations. The BPMM group brought together the analysis models BPMMM, BPMM, BPM, BPMI, BPOMM, and SBPM, while the CCMI group included the reclassified models CMM, CMMI, SW-CMM and P-CMM. Table 2 ranks the identified models for assessing the degree of maturity of management processes by the number of citations in the specialized literature.

Table 2: Classification of the most cited business process management tool models.

Classification	Models (Grouped)	Qty of Citations	%
1 º	BPMM	15	36%
2 º	CMM	8	19%
3 º	PEMM	4	10%
4 º	COBIT	2	5%
5 º	OPM3	2	5%
6 º	OMG	2	5%
7 º	CROSBY	1	2%
8 º	MEG	1	2%
9 º	MMGP	1	2%
10 º	PMMM	1	2%
11 º	PSP	1	2%
12 º	TSP	1	2%
13 º	PML	1	2%
14 º	RPB	1	2%
15 º	APO	1	2%
TOTAL		**42**	**%**

Source: Souza, 2018.

Based on the research developed, the proposition of an alternative method for assessing the degree of maturity associated with business management processes sought to incorporate the concepts used in the four management models most cited in the specialised literature. They are the BPMM, CMM, PEMM, and COBIT, whose foundations were added substrates from the Brazilian MMGP and MEG models, thus adding regional adherence to the proposed alternative evaluation scheme.

According to Pagliuso, Cardoso and Spiegel (2010), of the 75 national and international business process management (BPM) models used at the time, about 80% incorporated the same essence, foundations, and evaluation criteria, as revealed by the study carried out by Global Excellence, named as Model Meeting (GEMM, 2006). Despite these models being intensively applied and showing an expressive superposition of concepts, the results of their applications did not converge within the expected expectations, indicating a gap between theory and practice. In other words, the models practiced did not converge in their ability to assess the degree of maturity of the management of the processes submitted to the assessment.

If, on the one hand, the BPMM management tool focuses on the dimensions of strategic alignment, governance, methods, information technology, people, and culture, lacking, however, clarity to assess knowledge management, on the other hand, the MEG tools insert leadership in culture and not in people management, as defended by Niehaves, Plattfaut & Becker (2013). The CMM tools incorporate knowledge management concepts, projects, controls, manuals, configurations, and agreements with suppliers aligned with governance as a strategy to guarantee processes and products, which can be defined as technology and information, but without neglecting a straightforward performance. On the other hand, the management schemes called PEMM, applicable to the assessment of IT and HR infrastructures, disregard the strategic alignment recommended by the different tools, while the MMGP, also built within the CMM model, does not prioritise people management. Similarly, CObIT, also designed for applications in IT processes, values something other than people management and knowledge management (Souza, 2018).

According to Mangueira, Gutierrez, and Costa (2014), some facilitators enhance the high performance of the company's process management, concentrating the focus of its organizational capacity in 4 well-defined areas: leadership, culture, knowledge, and governance.

Based on bibliometrics and the above analysis of best practices and business process management models, Figure 3 summarises the dominant characteristics associated with the 31 distinct critical issues identified in the main models studied, highlighting specificities and relevant attributes of each of the six tools analysed.

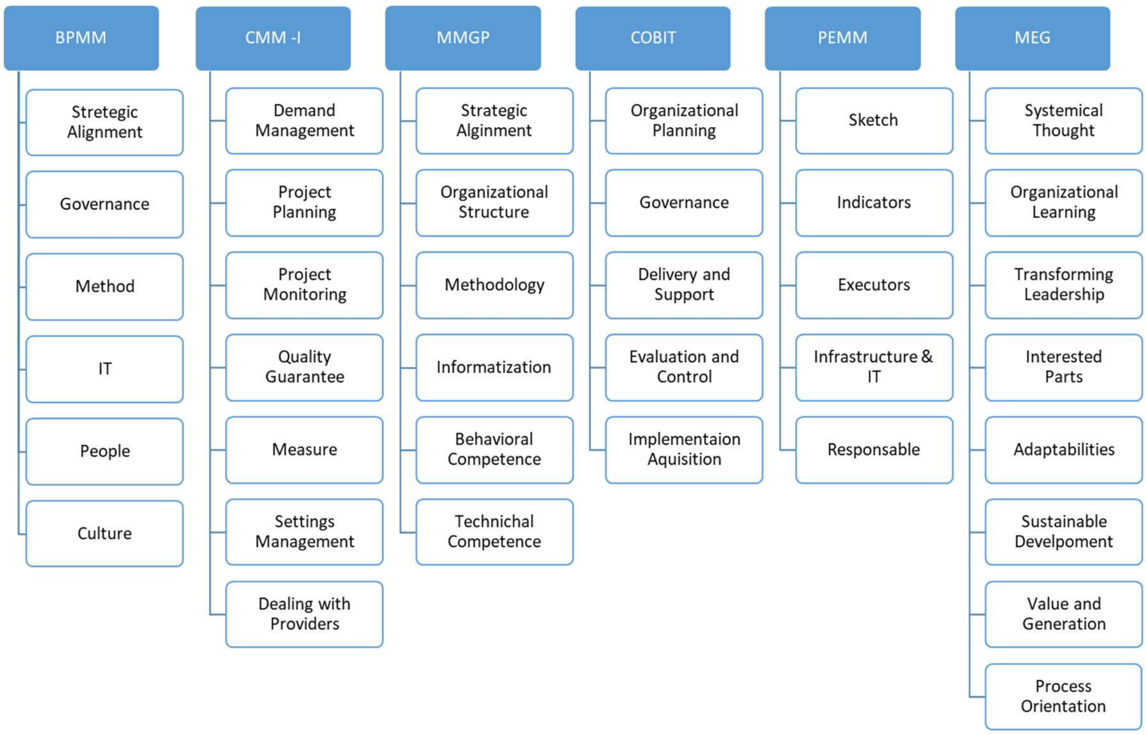

Figure 3: Selected management tools and their associated key issues.
Source: conception of the authors themselves.

As identified in the schematic presented in Figure 3, the six alternative business process management practices considered (BPMM, CMM-I, MMGP, CObIT, PEMM, and MEG) are based on 37 different vital assessment dimensions specified in this table for each of the assessment tools considered. Comparing this information makes it possible to verify a certain lack of homogeneity between the criteria used by these different process management tools. Based on this comparative analysis, 31 of the 37 key assessment dimensions were reorganized and reformulated to attribute greater homogeneity and coherence to the evaluation criteria used by the process management evaluation tools.

Data Collection Tool

The questionnaire is the most appropriate methodological data collection tool for obtaining data in large-scale research and case studies and can be associated with other tools. According to Gray (2012), the questionnaire is the best-known data collection tool and is considered by many researchers to be easy to design.

The strengths of the questionnaire are its low time and financial cost in the application, swift data flow, and respondents' greater comfort answering it. Data analysis of closed questions is simple and quickly coded, and anonymity can be preserved. It also reduces the influence of subjectivity and the interpersonal relationship between the interviewer and the interviewee, which can alter their answers (Gray, 2012).

The questionnaire design must ensure clear and objective instructions on questions and answer formats. Questions must be constructed in a standardized and transparent way, avoiding errors that, according to Arksey & Knight (Apud Gray, 2012, p. 276), can negatively influence the answer.

The questionnaire to be applied must have as a reference the customized organizational culture to, as pointed out by Gray (2012), write clear instructions, eliminate questions that may be misunderstood, imprecise and that are not part of the daily life of the organization where it will be applied, that is, that they remain only in the theoretical field.

Universe and Sample

For Gray (2012), it is vital to test before applying since "well-done testing reduces the incidence of non-response to the questionnaire." Gillham (2000 apud GRAY 2012, p 275) recommends testing at least 50% of the questions so that confusing questions can be discarded.

In this sense, the option was to create a pre-test group to test the instrument with the same configuration as the reference company ANEEL. As highlighted in Table 3, the composition of this group followed the 2015 sustainability report of one of the companies in the sector; this report is in the public domain, which, in addition to being aligned with ANEEL's reference company, details the distribution of professionals who make up a company in the electrical sector. The testing was designed so that the questionnaire tool was comprehensive enough to cover all functional levels of the Distribution and Commercial Directorates.

The importance of configuring the pre-test group sample for this study is the alignment to develop a tool to be applied in companies in the electrical sector; therefore, it can be used in different sectors with different levels of education and functions, but which are part of the structure of an energy company.

The pre-test group was then composed of 1 Electrical Engineer (Representative of the Professional position), 1 Technician (Representative of the Technical position), 1 Support Assistant (Representative of the Administrative position), 1 Manager (Representative of the Management position), and 1 Electrician (Representative of the Operational Position).

Table 3: Example of the Number of employees per activity performed.

Nature of the position	Grande Rio	Interior	São Paulo	Total	%
Administrative	1.031	129	0	1.160	27%
Managerial	220	11	2	233	5%
Operational	874	203	1	1.078	25%
Professional	763	35	5	803	19%
Technician	866	183	5	1.054	24%
Subtotal	**3.754**	**561**	**13**	**4.328**	**1**

Source: LIGHT 2015 Sustainability Report.

The instrument was applied to a company that we will call ALFA; this company is one of the largest energy companies in Brazil, with approximately 4 million customers. The research was carried out in three highly relevant sectors of the company ALFA: (i) the commercial sector, (ii) the operations and technology sector, and (iii) the asset management sector. These sectors were chosen. They are strategic for the business because they allow professionals to apply the tests in person and cover all professional levels listed in the reference company at ANEEL, as mentioned in Table 3.

Tool Preparation and Customization

To have greater cultural adherence and clarity in the questions and answers of the assessment tool, the methodology of this stage was to evaluate the understanding of the questions and answers.

The first step was to discuss the concepts of the questions presented to a manager who needed answers. Subsequently, the test was carried out in the pre-test and controlled by a control group encompassing 4 participants. The questions created for the Pre-Test questionnaire were read jointly by the first interviewee and researcher; at this stage, the interviewee interpreted the questions, which were later realigned to understand the semantics better. After the first interview, the questionnaire was updated, and the same method was repeated throughout the control group until the final version of the questionnaire was reached. During the questionnaire review process, the need for the twenty-fifth question was identified, referring to Organizational Communication, as it was found that the indicators of the researched sector are monitored by senior management and shareholders, and their results are highlighted even in the Report on Sustainability. Therefore, although the communication issue was not found explicitly in the six selected tools, it was included in the Strategic Alignment dimension as it has greater adherence to the topic in the literature.

Headings must be concise and indicate the distinction between the hierarchies of headings. The preferred format is for first-level headings to be presented in bold format and subsequent sub-headings in medium italics. Notes or Endnotes should be used only if necessary and must be identified in the text by consecutive numbers, enclosed in square brackets, and listed at the end of the article.

ANALYSIS OF RESULTS

Based on the consensuses of the five key assessment dimensions (specified above) and used by the six business process management practices considered (BPMM, CMM-I, MMGP, CObIT, PEMM, and MEG), it was possible to propose the bases of the proposed alternative tool to assess maturity process management of companies operating in the Brazilian electricity sector, called Maturity Assessment in Process Management in the Brazilian Electricity Sector. These five consensus key assessment dimensions are characterized individually, presented in Table 4 and below.

Table 4: Proposed five-dimension consensus tool.

TOOLS BPM SOURCE (MODELS)	CRITERIA (DIMENSION)	NEW DIMENSION
CMM (CMMM)	Requirements management (Documents and Models)	Knowledge Management
CMM (CMMM)	Project planning	Strategic Alignment
CMM (CMMM)	Project monitoring	Process Governance
CMM (CMMM)	Guarantee of process and product quality	Process Governance
CMM (CMMM)	Measurement and analysis	Process Governance
CMM (CMMM)	Configuration management (Manuals and prioritization)	Process Governance
CMM (CMMM)	Management of agreements with suppliers	Process Governance
COBIT	Governance	Process Governance
COBIT	Planning and Organization	Strategic Alignment
COBIT	Acquisition and Implementation	Process Governance
COBIT	Deliveries and Support	Information Tecnology
COBIT	Control and Evaluation	Knowledge Management
MMGP	Technical Competence	Knowledge Management
MMGP	Methodology	Process Governance
MMGP	Informatization	Information Tecnology
MMGP	Organizational structure	Process Governance
MMGP	Alignment with Strategy	Strategic Alignment
MMGP	Behavioral Competence	Knowledge Management
PEMM	Design	Process Governance
PEMM	Executors (Knowledge, Skills, Behavior)	Knowledge Management
PEMM	Responsible (Authority, Identity, activity)	People Magament
PEMM	Infrastructure (IT and HR)	Information Tecnology
PEMM	Indicators (Metrics)	Strategic Alignment
BPM (BPMM)	Strategic Alignment	Strategic Alignment
BPM (BPMM)	Governance	Process Governance
BPM (BPMM)	Method	Process Governance
BPM (BPMM)	Information Technology	Information Tecnology
BPM (BPMM)	People (Skill, Knowledge, Education)	People Magament
BPM (BPMM)	Culture	People Magament
MEG	Leadership	People Magament
MEG	Strategy and Plans	Strategic Alignment
MEG	Customers	Process Governance
MEG	Society	Process Governance
MEG	Information and Knowledge	Information Tecnology
MEG	People	People Magament
MEG	Law Suit	Process Governance
MEG	Results	Process Governance

Source: conception of the authors themselves.

- **Knowledge Management**. It is understood as one of the primary motivators of process management; it contributes directly to improving key processes in organizations to generating efficiency gains, either through the maintenance or strategic repositioning of their procedures or in the pursuit of continuous improvement and the generation of value for their products or services. The practical application of knowledge management in process management refers to its ability to support the process of continuous improvement, adding innovation and strategic updating of the organization. In contrast to the western culture that limits the vision of its products to the pragmatism of manuals, procedures and formulas, Takeuchi and Nonaka (2008) believe that the success of Japanese companies results from the company's ability to build, disseminate and diffuse its organizational knowledge, incorporating them into its processes, services and products. Conceptually, the following topics fall within the scope of the Knowledge Management concept: (i) Technical competence; (ii) Behavioural Competence; (iii) Competencies/Executors; (iv) Performance evaluation; (v) Requirements management; and (vi) Configuration Management.

- **Process Governance**. The Brazilian Institute of Corporate Governance (IBGC) defines Process Governance as the system by which organizations are directed, monitored and encouraged, involving the relationships between owners, the board of directors, directors and control bodies. Good corporate governance practices convert principles into objective recommendations, aligning interests to preserve and optimize the organization's value, facilitating its access to capital and contributing to its perpetuity (IBGC 2018, p. 22). The concept associated with Process Governance gained relevance with implementing the SOX-Sarbanes Oxley Act of 2002, created to restore investor confidence after the American stock market crisis. It made corporate governance widely known as an instrument that aims to provide more transparency to the information generated by organizations, allowing control and accountability. In the view of experts, the topic of governance should be part of the central topic of management by processes since governance is the main element in the proposal of its process management model, understood as the leading integrator between techniques, projects and strategies (Araújo, Garcia and Martines, 2017). Regarding the BPMM management tool, the critical dimensions of analysis act as strategic controls for monitoring the performance of processes and projects that guide preventive or corrective decision-making mechanisms. Thus, they provide inputs for improvements, but without incorporating the functions of norms and laws. In Brazil, governance is widely publicized, and best practices are discussed by the Brazilian Institute of Corporate Governance (IBGC). Recognized as a reference in publications and certifications in Brazil, the IBGC represents Brazil in other international reference bodies, including the Global Reporting Initiative (GRI), the Institute of Corporate Governance in Latin America (IGCLA) and the Global Network of Institutes Directors (GNDI). The following topics fall within the scope of Process Governance: (i) Policies and Laws; (ii) Methods / Design; (iii) Monitoring; (iv) Shareholders and (v) Organizational structure.

- **Information Technology and Innovation**. As a competitive strategy to implement improvements in their management and information production processes, organizations add technological tools to contribute to improving production efficiency. This investment in technology translates into a strategic repositioning of the company, generating greater efficiency in meeting its demands and increasing the technical capacity of its operators. According to Plachta (2014), Information Technology has evolved significantly in recent years, leading companies to perceive their integrated hardware and software systems as crucial strategic instruments for integrating their business management processes. Although companies are investing in new integrated systems and gaining more and more prominence among IT executives, investments in IT are primarily aimed at improving existing methods and providing legal support in integrating their business management processes (Sordi, 2018). In performing this leading and strategic role, the information technology and innovation assessment dimension includes the following key topics: (i) Information security; (ii) Technological Innovation (Investment in Technology); (iii) Automation; and (v) IT infrastructure.
- **Strategic Alignment**. This theme deals with an alignment between the dimensions of the organization (Human Resources; Information and Knowledge; Culture; Investment and Financial Resources) to ensure that the vision of the future and the strategic positioning of the organization converge in the same direction. According to Barakt, Boaventura & Polo (2017), strategic alignment observes the following conditions: (i) improvement of the competitive environment; (ii) choice of issues related to the Company's principal activity and (iii) dialogue between stakeholders and monitoring and management of results. To support the proposition of the proposed process management alternative, this analysis dimension "strategic alignment, incorporates the following themes: (i) Change Management (Flexibility / Adaptability); (ii) Alignment with the Company's strategy; (iii) Indicators (Metrics) and (iv) Organizational communication.
- **People Management**. Just like organizations, processes are made up of people. According to Araujo, Garcia & Martines (2017), it is necessary to understand that no one is competent in everything, but if they are properly stimulated, they are capable of seeking knowledge and ways of putting it into practice to bring results, preferably positive ones, because if the stimulus is contrary to the results they can be negative and harmful, as in a calm and controlled environment, it is possible to quickly identify the failure and the person responsible, whereas in turbulent environments or moments, the delay in identifying the failure and those responsible can put all efforts to waste. Nowadays, in the era of

organizations with open systems, moments of turbulence and pressure in the internal or external environment increasingly influence results, which makes the central themes: (1) Transformative Leadership (Visionary); (1) Responsible (Manager), (3)Human Resources Infrastructure, (4) Meritocracy and justice (Recognition), (5) Organizational Culture, and (6) Development and Continuing Education.

Finally, the tools evaluated in the literature review were extracted from articles listed in bibliometrics, considered the most relevant among publications on Process Management, and therefore suitable to support the construction of an alternative business process management tool. Figure 4 illustrates the key elements that make up the new analysis dimensions of the alternative process evaluation scheme conceived and called the Process Management Maturity Assessment Tool (identified by its Acronym in Portuguese: MBPM-SEB).

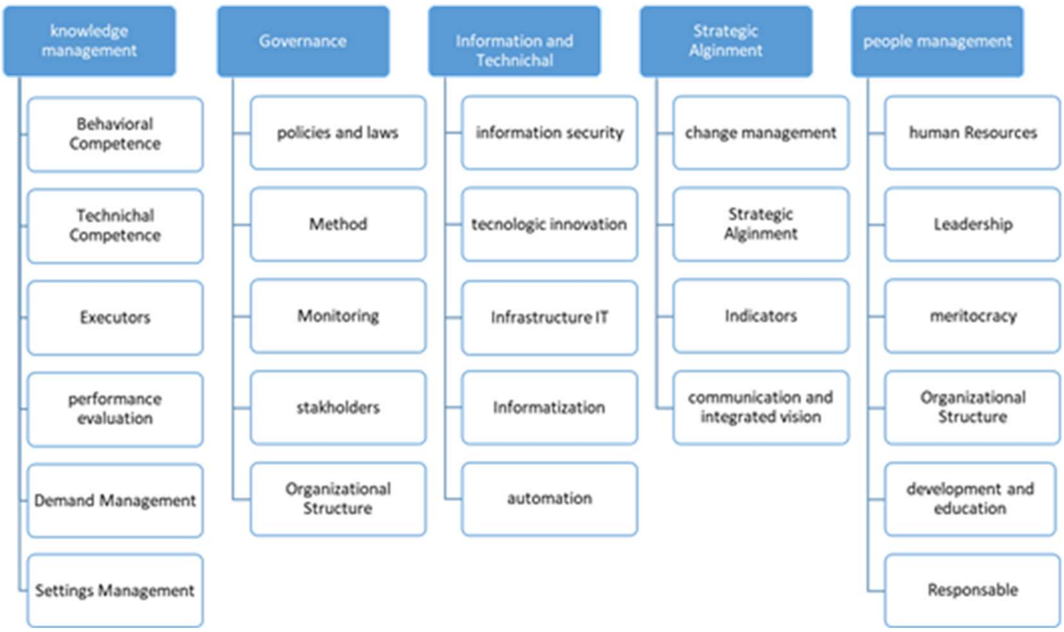

Figure 4: Dimensions of the proposed Process Management Maturity Assessment Tool.
Source: Authors' conception.

In addition to investments and public policies aimed at the constant innovation and modernisation of the electricity sector, it is understood that improving the operational efficiency of the companies operating in this business environment also requires the companies and organisations to use effective management of their business processes. Among the vulnerabilities of process management systems, they highlight the need for more knowledge in process management and the lack of self-knowledge of the organization's level of maturity.

Contributing to understanding the essence of the Company's management tools, it is recommended to use a more adherent system customised to the organisation's culture, which requires knowledge of the sector and its strategic importance for the region and country. Customization of the management practices and consciousness about the maturity of its strategic processes significantly contribute to the growth and strengthening of the organisation, reducing the natural resistance on the part of employees to any institutional change that might be promissory for upgrading the Company's values.

CONCLUSIONS

This research aimed to propose a tool to assess the level of maturity in the management of strategic business processes in the Brazilian electricity sector. Based on a critical analysis of careful bibliographical research that identified the most used tools to fulfill this purpose, an alternative proposal incorporating consensus criteria used in existing evaluation methodologies was formulated. Among the 23 process management assessment tools identified in specialized literature, variations of the CMMI and BPMM tools were grouped and condensed into 14 different tools. Special attention was paid to the four most cited tools internationally, namely BPMM (34%), CMMI (20%), PEMM (9%), and CObIT (5%). Two tools frequently used in the country were also included: MMGP and MEG, as it was found that the quality tools represented by MEG create integration between all other process tools. The study showed that the six tools analysed deeply incorporate different definitions and focuses. Among the analysis dimensions, 37 themes were identified and grouped by affinity, resulting in five questions related to knowledge (knowledge management; governance, people management, strategic alignment; and Technology and Information), subdivided into twenty-five themes. The alternative tool, the Process Management Maturity Assessment Tool (MBPM-SEB), was formulated based on these themes. It was found that the EFQM Quality tool used in Europe is highly adherent to MEG and is fully aligned with process management practices, and the new tool was created.

This tool was extensively tested in a control group to develop a customized tool with high cultural adherence to organizational reality. After testing and customization, the questionnaire was applied to a large energy distributor in the southeast region, thus validating its applicability.

This effort required compiling concepts in different process management schemes and information of interest to professionals from companies and organizations in the electrical sector.

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Advancing Quality Management:
Towards Artificial Intelligence capabilities to improve digital service quality

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STRUCTURED ABSTRACT

Purpose: In the competitive landscape of small and medium-sized enterprises (SMEs), the integration of artificial intelligence (AI) functions has emerged as a pivotal strategy to enhance customer service objectives. This study focuses on identifying AI functions that contribute to the improvement of digital service quality through a systematic content screening process, integrating concepts of quality management.

Design/methodology/approach: Employing a case study methodology aligned with the Critical Appraisal Skills Programme (CASP), the research delves into comprehensive aspects of AI functions impacting digital service quality. In collaboration with 12 management science experts, relevant research is categorized and evaluated, leading to the identification of dimensions within a multidimensional theoretical framework through content screening.

Findings: The findings, based on 18 selected studies, unveil four categories, eight components, and 34 conceptual themes encapsulated within an eight-dimensional theoretical framework. Furthermore, utilizing a system model grounded in input, process, output, and feedback, the study underscores the necessity for SMEs to strengthen individual and team capabilities to align with AI needs at the input stage. This enhancement enables these enterprises to attain maturity levels through information systems in the process stage, thereby fostering outputs such as social and competitive functions of AI development to enhance digital service quality.

Originality/value: This study improves the current understanding of Artificial Intelligence Capabilities to Digital Service Quality by A systematic review of theoretical literature, integrating concepts of quality management. Because the gap in existing theories has prevented the presentation of an integrated theoretical framework in this field. Therefore, this study can help to better understand the functions of Artificial Intelligence (AI) to improve Digital Service Quality.

Keywords: Artificial Intelligence Functions, Digital Servitization, Service Quality, Quality Management

1. INTRODUCTION

The current social change crisis calls on small and medium-sized enterprises (SMEs) to assume greater responsibility for transitioning to a more sustainable business model. To address this challenge, artificial intelligence (AI) has emerged as a crucial transformative force, making SMEs more sustainable and competitive through digital servitization (Sjödin et al., 2023). Digital servitization involves the transformation of processes, capabilities, and offerings within firms to create, deliver, and capture increased service value using digital technologies like the Internet of Things (IoT), big data, AI, and cloud computing (Sjödin et al., 2020 a). A critical aspect of this transformation is Quality Management, which ensures that digital services meet required standards and customer expectations.

Digital servitization fosters new capabilities that can be used to develop new business model offerings (Agarwal et al., 2021). For instance, these technologies can predict and prevent the failure of critical tools, enabling value-based services like uptime rather than merely selling a tool (Frank et al., 2019). Digital servitization thus represents a transition towards smart product-service-software systems that facilitate value creation and capture through monitoring, control, optimization, and autonomous function (Kohtamäki et al., 2019). Effective Quality Management practices underpin these benefits for both providers and customers.

However, the challenge remains: how can digital service platforms be more efficient in the competitive world, especially for SMEs? Researchers like Sjödin et al. (2020) suggest that AI is a key mechanism for improving the quality of digital service delivery in SMEs. Previous research lacks examples of data and AI-based servitization initiatives, prompting this study to address this gap through systematic screening. AI's development in digital servitization is seen as an emerging value that enhances the quality of services and products, particularly for SMEs.

AI enables companies to analyze market changes and customer needs rapidly through advanced algorithms and data processing, allowing more accurate market predictions and improved service quality. However, integrating AI with Quality Management principles is crucial to ensure that predictions and actions meet desired standards. Achieving this integration requires considering various factors, including company type, human resources functions, and structural strategies, to better fit with digital servitization.

Introducing digital technologies to support digital services often requires AI functions integrated with Quality Management processes to ensure consistent and reliable service delivery. This is especially true for SMEs, which need technological innovations to integrate capabilities and manage complex changes (Rajala et al., 2008; Franco and Haase, 2015; Saccani et al., 2014). Companies advancing in the market are recognized as key carriers of digital servitization for SMEs (Zhou et al., 2017). Yet, many aspects of this interplay remain underexplored (Rapaccini et al., 2020), particularly for minor businesses often excluded from mainstream research (Luoto et al., 2017). This study aims to illuminate how SMEs transform their business from traditional to digital services and the role of AI in enhancing digital servitization quality.

The study sets several research objectives (ROs) focused on AI functions within digital service strategies in SMEs. The first objective is to analyze existing studies' research profiles on this topic. The second objective investigates AI functions in digital service strategies within SMEs, emphasizing alignment with Quality Management principles. The third objective critically appraises emergent themes, highlighting gaps in the literature on AI functions in digital service strategies for SMEs. The fourth objective develops a comprehensive framework to help stakeholders understand AI functions in digital service strategies within SMEs.

To achieve these objectives, the study employs a systematic literature review with five main steps: defining the extraction method for congruent studies, conducting a research profiling exercise, performing manual content analysis, introducing a theoretical framework, and exploring theoretical and practical concepts uncovered during the study.

2. DIGITAL SERVITIZATION AND AI

2.1. Digital Servitization

Digital servitization blends digitization and servitization, using digital technologies to deliver advanced services innovatively (Kohtamäki et al., 2020; Paschou et al., 2020). It transforms analog information into digital formats (Ng and Wakenshaw, 2017) and combines digital technologies to create value (Svahn et al., 2017). Recent scholarship examines servitization and digitization together, defining digital servitization as developing or improving services using digital technologies (Paschou et al., 2020). It transforms services into digital and "smart" offerings (Allmendinger and Lombreglia, 2005) and makes business models more ecosystem-focused, emerging from co-creation among network actors (Kamalaldin et al., 2020). Digital servitization exploits data to generate knowledge and competitive advantages, enabling new digital business models (Paschou et al., 2020).

Despite interest in digital and traditional servitization, few studies discuss operational capability development mechanisms. Prior research focuses on strategic approaches to capability development for traditional and digital servitization (Chirumalla et al., 2023). For example, Behl et al. (2023) used a strategic reference matrix to examine differences between traditional and digital servitization, identifying quadrants based on capability development functions and service types. This study aims to build on such work, exploring the role of AI functions intertwined with Quality Management principles in digital service strategies within SMEs. The quadrants are shown in Table 1.

Table 1 - Strategic Reference Matrix, the difference between Traditional and Digital Servitization (Source: Author's own creation/work)

Type of servitization		
Digital	Artificial intelligence capabilities lead to servitization development, moderated by absorptive capacity (Abou-foul et al., 2023) Manufacturers realign their strategic capabilities to become smart solution providers (Huikkola et al., 2022) Servitization success within the digital economy depends on the interactions between dynamic capabilities (Zhan et al., 2022). Manufactures undergo phases concerned with digital service maturity of SMEs (Kolagar et al., 2021)	New opportunities for absorbing customer knowledge and engaging customer in value co-creation (Gremyr et al., 2022) Manufactures require external resource for IOT technology from different types of suppliers (Ferreira and Lind, 2022) Different factors such as customer involvement, technology strategy impact service innovation in hybrid offerings (Behl et al., 2023)
Traditional	Manufactures managers their internal ecosystems (the front and back office) to undertake capabilities development (Jovanovic et al., 2021) Capabilities evolve over time in a dynamic process of knowledge codification, transfer and integration (Valtakoski, 2017) Capabilities for each step of the servitization transition (Kanninen et al., 2017) Manufactures need to adapt and renew their existing capabilities and processes (Kindstrom et al., 2013)	Turning integrated solutions into modular (Rajala et al., 2019) The ability of firms to absorb external knowledge impacts their service capability development in collaborative partnerships (Xing et al., 2017). What operational capabilities are required to develop service networks to facilitate solution provision (Gebauer et al., 2013)
	Strategic	*Operational*
	Capability development functions	

2.2. Artificial Intelligence

Artificial Intelligence (AI) aims to create systems capable of tasks requiring human intelligence, using machine learning and deep learning techniques like classification, regression, and neural networks for pattern detection, image, and speech recognition, and decision-making. Since McCarthy introduced AI in the 1950s, the field has evolved into human-centered and rationalist approaches. Human-centered approaches rely on hypotheses and experimental validation, while rationalist approaches integrate engineering and mathematics. Mikalef and Gupta (2021) defined AI as systems that identify, interpret, infer from, and learn from data to achieve organizational and societal goals.

Despite extensive research, AI applications remain new and often overstated. Wirtz et al. (2018) categorized AI functions in business, including process automation, virtual agents, predictive analytics, cognitive robotics, intelligent digital assistants, security analytics, identity analytics, edge analytics, and machine vision. Sjödin et al. (2020) classified AI capabilities in digitally servitized manufacturing, including data pipeline, algorithm development, AI democratization, customer co-creation, and data-driven delivery operations enhancing social well-being.

AI is closely related to predictive analytics. AI involves creating systems that perform tasks requiring human intelligence, such as understanding natural language, recognizing data patterns, and making data-based decisions. Predictive analytics uses statistical algorithms and machine learning techniques to analyze data and predict future events or trends. Together, they help businesses make accurate predictions about customer behavior, market trends, and other critical factors (Božić, 2023). However, digital servitization, which integrates digital technologies into service offerings, is a relatively new research area needing further exploration, especially for SMEs developing necessary capabilities.

3. METHODOLOGY

To identify AI functions that enhance the quality of digital servitization, this study reviews existing literature, providing insights for future research. We employed the Systematic Literature Review (SLR) method, a secondary research approach now popular in human sciences and AI (Borges et al., 2020; Ali et al., 2023; Atkinson, 2023). A rigorous SLR should allow future researchers to replicate or extend the study (Kitsios and Kamariotou, 2021). Therefore, our report includes a detailed protocol for identifying and assessing relevant studies (Figure 1).

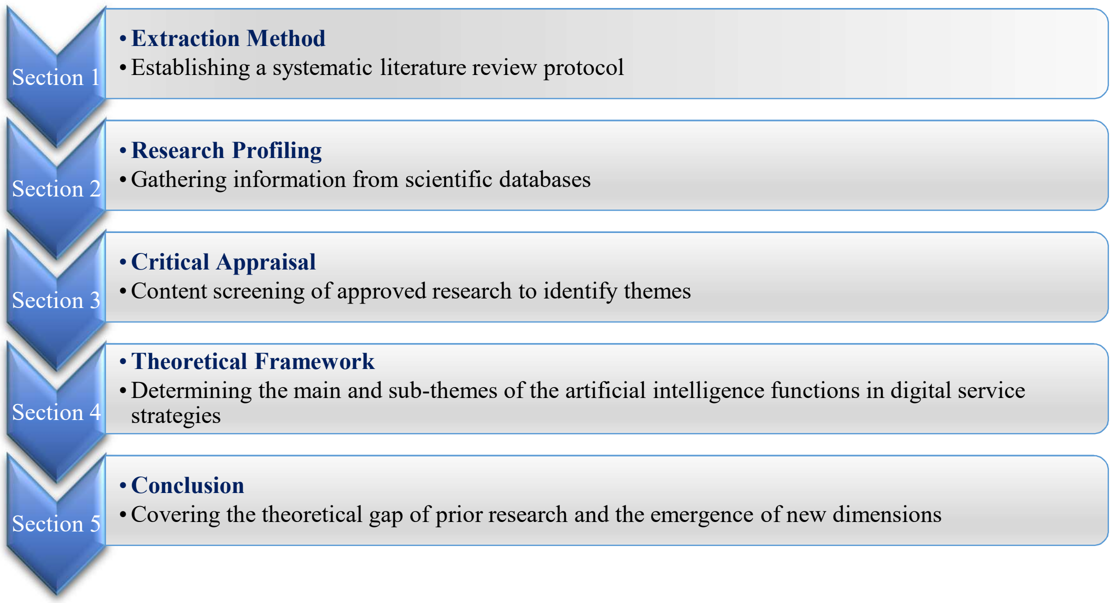

Figure 1 - Outline of the systematic literature review (source: authors' own creation)

To this end, it was necessary to select a larger number of participants based on the importance of fit criterion, considering their specialized training experience in the field of management theories, and conducting similar research. During this process, 20 people were invited to participate. This study relies on the participation of experts in various fields of management knowledge to systematically implement and evaluate research to provide a theoretical framework. The selection of these individuals is done through purposive sampling, and the process of identifying and persuading them to participate is based on the nature of research expertise proposed by Patton (1990), which emphasizes criteria such as:

- ❖ importance of fit: the expert's knowledge and experience should be relevant to the research topic;
- ❖ power of differentiation: the expert should be able to provide unique insights into the research topic;
- ❖ awareness of the research context: the expert should be familiar with the research literature and methods;

❖ in-depth interpretation: the expert should be able to provide in-depth interpretations of the research findings.

According to the researchers, these individuals had a better fit in terms of understanding the nature of the research topic. Out of the 20 people, 15 responded positively. In the following step, the 15 initial participants were re-evaluated based on their sensitivity to the research context. This was done by conducting a semi-structured interview with each participant. The interview questions focused on the participant's understanding of the research topic, their research experience, and their willingness to participate in the study. Based on the results of the interview, 12 participants were selected to participate in the study. These participants were considered to have the necessary expertise and sensitivity to the research context. Therefore, the step-by-step implementation process of the study can be illustrated in Figure 2.

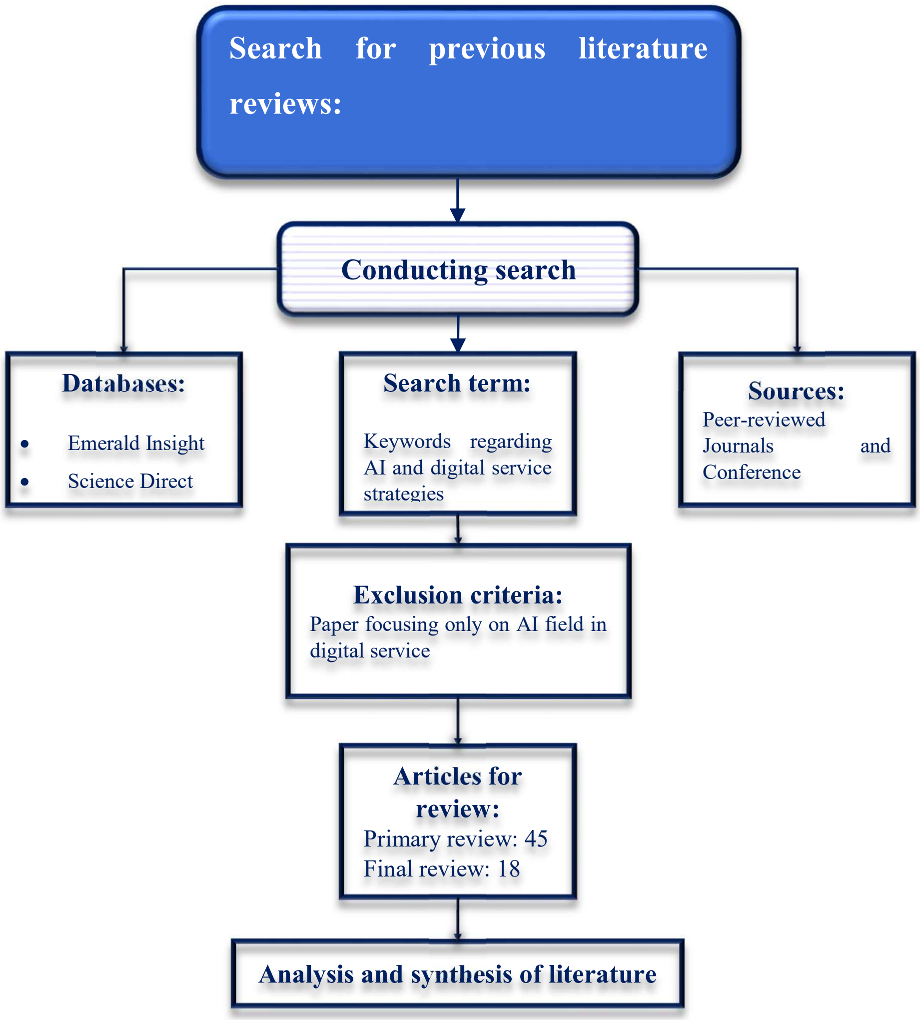

Figure 2 - Step-by-step methodology phases

4. SLR IMPLEMENTATION AND FINDINGS

First, it was necessary to identify the theoretical literature related to the AI functions in digital service strategies in SMEs; accordingly, we defined an initial set of keywords for use in searching the studies to be reviewed (Table 2).

Table 2 - Keywords for AI functions in digital service strategies (source: authors' own creation)

Key words	Case description	References
Servitization Maturity	It refers to the competitive capabilities in providing digital services that can guide the development capacities of companies towards sustainability.	Kimita et al. (2022); Adrodegari and Saccani (2020).
Information Systems of Digital Servitization	It refers to the system capabilities in providing digital services that can strengthen the sustainable development capacities of companies by creating decision support systems.	Ralyté et al. (2013)
Cloud Digital Servitization	It is a service that takes place in the virtual space and provides online services by creating a network of computer systems.	Schiavone et al. (2022)
Ecosystems of Digital Servitization	The formed digital services ecosystem is based on a group of actors (organizations, people and things) that work together on standard digital platforms to achieve mutual goals that benefit the stakeholders.	Kolagar et al. (2022); Kohtamäki et al. (2019)
Retraining of Digital Servitizations staff	Revision of human resource training policies can help to increase the capacities of Digital Servitizations.	Momeni et al. (2023); Tronvoll et al. (2020).
Marketing of Digital Servitization	It is a level of marketing that, based on digital capabilities, helps companies to gain a larger share of the competitive market.	Hosseinzadeh et al. (2023)

As seen in this process, various aspects of the effective functions of AI in advancing the goals of digital servitization were identified as keywords from theoretical literature, which are used to search for similar studies. We searched for these keywords on Google Scholar, Science Direct, Emerald, Francis and Taylor, Wiley and we analyzed the first 45 results to update the keywords list in the period 2018-2023. Choosing a limited period (2018-2023) leads to the emergence of newer literature in relation to the AI functions in digital service strategies. Therefore, with the aim of achieving more similar research, in the next step, it should be compared to the initial three-stage screening including title; theory and analysis screening were carried out. For this purpose, 45 primary studies were evaluated based on figure 3.

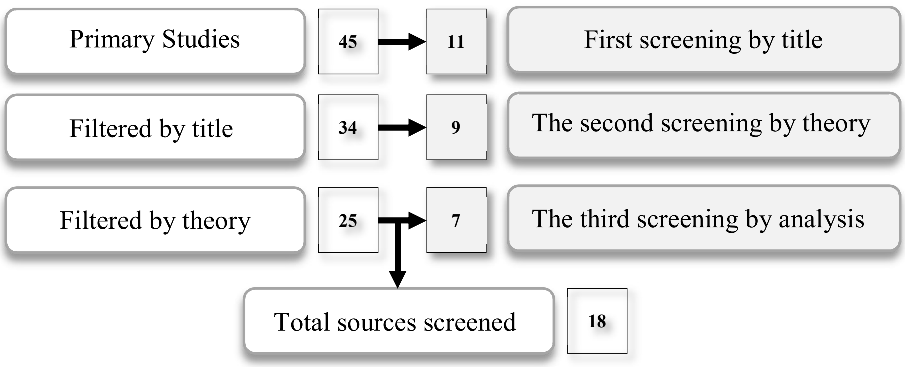

Figure 3 - Screening process of primary research

The purpose of such a process is to prevent dispersion and focus on the main criteria for evaluating the AI functions in digital service strategies in SMEs. Therefore, at this stage, the 18 identified studies should be examined based on the Critical Appraisal Skills Programme (CASP) checklist. Figure 4 depicts the Critical Appraisal Skills Program (CASP) criteria. This process includes the following 10 criteria, which are examined based on a minimum score of (1) and a maximum of (5). The total score based on the 10 criteria can be 50, if a research scores 30 or more, it enters the next step. In the following, we present the research profile of the retrieved congruent studies concerning descriptive statistics, such as publication year, publication source, publication frequency and publication sources. The year-wise publications indicate that only eighteen were published studies on the AI functions in digital service strategies in SMEs. The next step is to proceed with systematic content screening (Table 3).

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Table 3 - Critical Appraisal Process

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
	Concealed researches	Wirtz et al. 2023	Sjödin et al. 2023	Hajipour et al. 2023	Kim. and Seo 2023	Schiavone et al 2022	Kinita et al. 2022	Kolagar et al 2022	Vrontis et al. 2022	Kitsios and Kamariotou 2021	Truby & Brown 2021	Iphofen & Kritikos 2021	Borges et al. 2020	Adrodegari and Saccani 2020	Wamba-Taguimdje et al 2020	Kohtamäki et al 2019	Jin et al 2019	Yeung 2018	Crowley et al. 2018
Critical appraisal criteria	Purpose	4	2	2	4	2	3	3	4	3	3	1	2	4	2	3	3	4	3
	Method	3	3	3	3	1	3	2	3	2	5	2	2	3	1	3	3	3	4
	Plan	3	4	2	5	2	3	3	4	3	4	3	2	4	2	4	3	4	3
	Sampling	3	3	1	4	3	5	3	4	2	3	3	3	4	3	3	4	4	3
	Data collecting	5	2	2	3	2	5	5	3	2	3	2	2	4	4	3	3	3	4
	Generalization	4	3	1	3	3	3	5	4	3	3	3	1	4	3	3	4	4	5
	Ethical	3	4	2	3	3	5	3	4	4	2	1	3	4	2	4	4	4	4
	Analyze	3	5	2	4	3	4	3	3	2	3	2	3	4	3	4	3	3	3
	Theoretical	3	4	2	5	2	3	3	4	1	3	3	2	3	2	3	4	4	4
	Value	4	4	2	4	2	3	4	4	3	4	2	3	4	2	4	4	4	3
	Total	**35**	34	19	38	23	**37**	37	37	25	32	22	23	37	**26**	**34**	34	37	**36**
	Confirm ☑	☑	☑		☑		☑	☑	☑		☑			☑		☑	☑	☑	☑
	Elimination ☒			☒		☒				☒		☒	☒		☒				

The critical appraisal process showed that, out of the 18 initial studies reviewed, 6 studies were excluded because they had a total score of less than 30. According to the instructions for this analytical process, studies that score 30 can proceed to the content screening process (Ghorbaniyan et al. 2023). Therefore, based on this result, the 12 approved studies in this stage enter the content screening process based on the frequency distribution index. In this process, the main criteria, as identified themes in the similar studies, must be evaluated to determine which criteria can generalize the functions of AI to improve the quality of digital services. For this purpose, the main criteria in this section are approved if they are selected based on the highest frequency distribution. In other words, criteria are selected that have been repeated in more than half of the approved studies in the previous stage of critical appraisal (Mohammadi et al., 2023). Therefore, during this process, the results are presented in Table 4.

Table 4 - Content screening process

Concepts	Articles (see Table 3)												
	Wirtz et al. 2023	Sjödin et al. 2023	Kim. and Seo 2023	Kimita et al. 2022	Kolagar et al 2022	Vrontis et al. 2022	Truby & Brown 2021	Kohtamäki et al 2019	Adrodegari and Saccani 2020	Jin et al 2019	Yeung 2018	Crowley et al. 2018	Sum
Educational Function of Artificial Intelligence Development	-	R	R	-	R	-	R	R	-	R	-	R	7
The function of the artificial intelligence development ecosystem	R	-	-	R	-	R	-	-	-	-	-	-	3
Adaptive functions of artificial intelligence development	-	R	-	-	-	-	-	-	-	-	-	R	2
Structural functions of artificial intelligence development	R	-	R	R	R	R	-	-	R	R	-	-	7
Financial infrastructure functions of artificial intelligence development	-	-	-	R	-	-	R	-	-	-	R	-	3
Social functions of artificial intelligence development	-	R	R	-	R	-	R	R	-	R	R	R	8
Institutional functions of artificial intelligence development	R	-	-	-	-	R	-	-	R	-	R	-	4
Process functions of artificial intelligence development	R	-	-	-	-	-	-	R	-	R	-	-	3
Competitive functions of artificial intelligence development	-	R	R	R	R	-	R	-	R	-	-	R	7

Based on the 9 main criteria that determine the dimensions of the expansion of AI functions to improve the quality of digital services, it was determined that 4 criteria (defined in Table 5) – repeated in more than half of the 12 studies entered in this process – could be considered the basis for identifying the dimensions of the phenomenon under investigation. Defining these four main categories helps improve the level of shared understanding of the nature of the identified dimensions and create a basis for identifying components and themes in the content screening.

Table 5 - Definitions of the Main Categories Identified (Source: Author's own creation/work)

Categories	Definitions	References
Educational function of the development of artificial intelligence	Developing effective AI functions for digital service delivery relies on the capabilities of AI system users, including their knowledge, skills, and information sharing. This enhances participatory decision-making. SMEs must align human resource capabilities with system structures to achieve individual and collective goals. Due to their size, SMEs should review job descriptions and qualification requirements to support digital service delivery strategies. This process helps increase organizational learning and create inclusive values through effective skill and communication needs assessments.	Sjödin et al. 2023; Kim. and Seo 2023; Truby & Brown 2021; Kohtamäki et al 2019; Kolagar et al 2022; Jin et al 2019; Crowley et al. 2018
Structural function of the development of artificial intelligence	SMEs aim to align strategic functions with stakeholder expectations by strengthening information systems for digital service delivery. This enhances structural maturity, market adaptability, and customization, reducing service costs and increasing productivity. Appropriate resource allocation to digital structures is key to achieving these goals.	Kimand Seo 2023 Kimita et al. 2022 Kolagar et al (2022) Vrontis et al. (2022) Adrodegari and Saccani 2020 Jin et al 2019 Wirtz et al. 2023
Social functions of the developme nt of artificial intelligence	The social functions of AI in SMEs focus on sustainability, respecting customer and environmental rights, and enhancing entrepreneurial activities. This helps shorten the time to market entry, growth, and profitability. SMEs use AI to design and market products that uphold social values for stakeholders.	Sjödin et al. 2023 Kim and Seo 2023 Truby & Brown 2021 Kohtamäki et al 2019 Jin et al 2019 Yeung 2018 Crowley et al. 2018 Kolagar et al 2022
Competitive functions of the development of artificial intelligence	The competitive functions of AI in SMEs involve using AI and machine learning to quickly address customer needs, service quality, and market entry, enhancing digital marketing capabilities and capturing market share. This helps SMEs achieve competitive advantages in digital service delivery.	Sjödin et al. 2023; Kim. and Seo 2023; Kimita et al. 2022; Kolagar et al 2022; Truby & Brown 2021; Adrodegari and Saccani 2020; Crowley et al. 2018

In the following step, and with the provision of definitions for each of the identified categories, a deeper content screening of the phenomenon under investigation must be conducted to enable the identification of components and themes in the second and third rounds of this process. Based on this, according to Table 6, as can be seen, a combination of categories, components, and themes identified for the functions of AI to improve the quality of digital services is presented.

Table 6 - Dimensions of AI functions to improve the quality of DS

Categories	Components	Themes
Artificial Intelligence Development Training Function	Individual empowerment in the context of digital services	• Developing Needs Assessments for Digital Services Users Training • Develop technical skills required by users of digital services • Development of personal motivation for individual innovation in the effectiveness of digital services • Developing organizational and individual learning levels in creating inclusive values for digital services
	Team orientation in the context of digital services	• Developing people's participation in participatory decision making of • digital services • Development of interpersonal communication channels in digital services • Developing information feedback for collaborative decision making of digital services • Development of material and spiritual incentives to strengthen the base of participation in digital services
Structural Function of Artificial Intelligence Development	Structural Maturity in the Digital Services Platform	• Development of technological awareness of system users in digital • service structures • Developing technological innovations in digital service structures • Developing technological service customization in digital service structures • Development of Technological Allocation Resource Assessment in Digital • Service Structures
	Information system in the context of digital services	• Development of decision support systems (DSS) in digital service structures • Development of Transaction Processing Systems (TPS) in Digital Service • Structures • Development of Information Management System (MIS) in Digital Service Structures • Developing Big Data Capacities in Digital Service Structures • Development of Administrative Information Systems (EIS) in Digital Services Structures
Social Functions of Artificial Intelligence Development	Social Responsibility of Digital Services Platform	• Developing artificial intelligence robots to answer customer questions • Development of artificial intelligence technologies in environmental risk assessment • Developing artificial intelligence to protect customers' privacy • Development of artificial intelligence technologies in environmental pollution assessment • Developing artificial intelligence in designing and manufacturing environmentally friendly products
	Entrepreneurship ecosystems in the context of digital services	• Developing the Role of Digital Actors in Strengthening the Entrepreneurial Ecosystem • Developing customer knowledge in strengthening the digital • entrepreneurship ecosystem • Synergistic development of knowledge of the digital entrepreneurship ecosystem • Developing startups in strengthening the digital entrepreneurship ecosystem
Competitive Functions of Artificial Intelligence Development	Marketing in the Digital Services Platform	• Cloud Systems Development in Digital Marketing • Development of Metaverse Simulation Systems in Digital Marketing • Development of GPT Chat in Digital Marketing • Developing chatbot tools in digital marketing
	Learning Capabilities in Digital Services	• Development of Machine Learning in Quality of Service • Development of Deep Learnings in Evaluating Entry to New Markets • Development of Convolutional Neural Network in Market Data Processing • Transfer Leverage Development in Forecast of Market Conditions

By determining these dimensions to present a coherent theoretical framework, Figure 4 in the form of an 8-D model, AI functions are presented to evaluate digital service strategies.

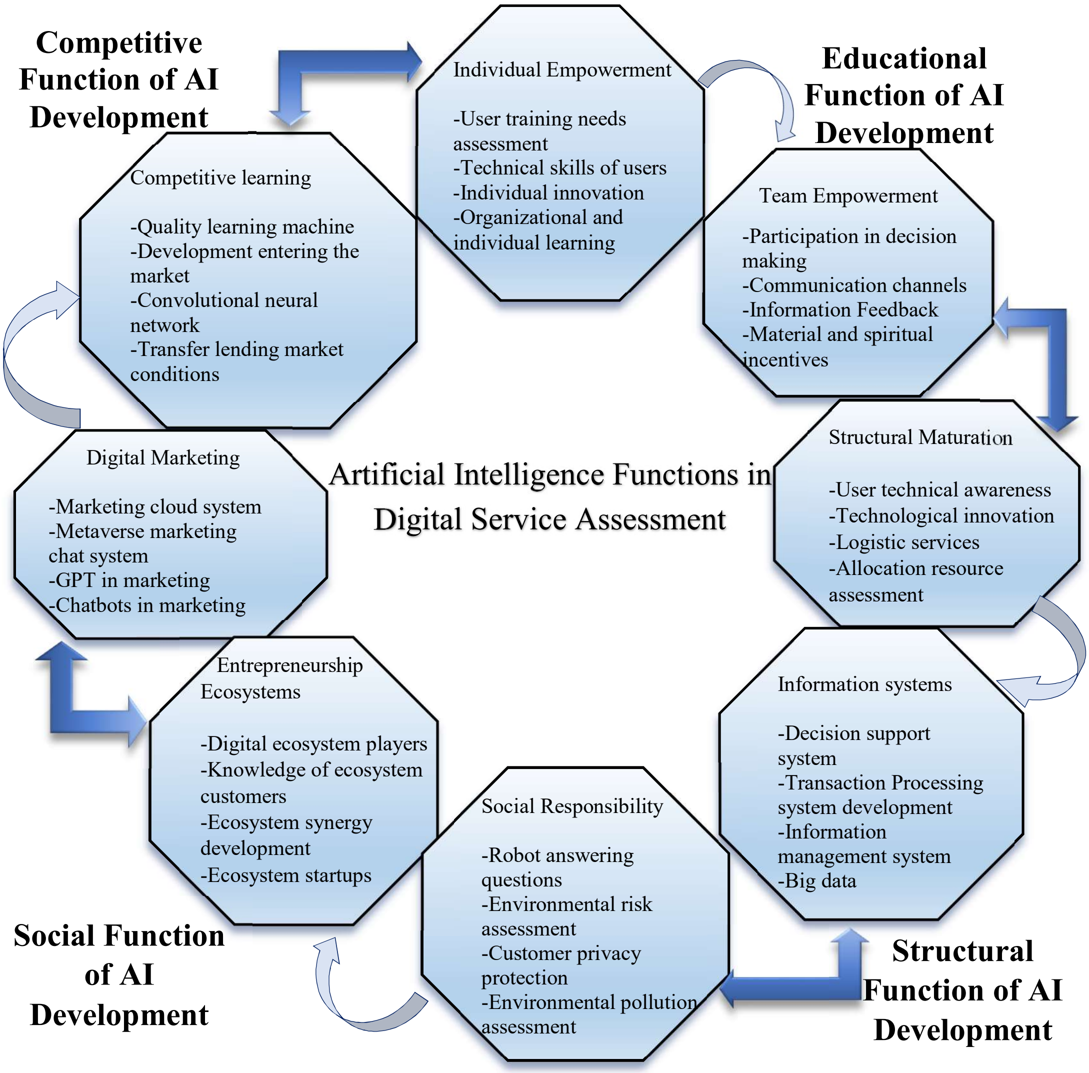

Figure 4 - Conceptual Framework (Source: Author's own creation/work)

5. DISCUSSION AND CONCLUSIONS

The purpose of this study is to provide a framework for moving towards the functions of artificial intelligence (AI) to improve the quality of digital services at the level of small and medium-sized enterprises (SMEs). This study, through the process of systematic content screening and the critical appraisal tool, sought to examine the different aspects of the functions of AI to improve the quality of digital services. In this process, first, through the initial evaluation of similar studies, research was identified for content screening in the period from 2018 to 2023. In the next step, with the participation of 12 experts in management science and the use of scoring checklists to assess critical appraisal as a tool for the analytical process, the most relevant research was identified. During three phases of content screening, analytical actions were taken to identify categories, components, and themes. As the process followed in Section 4 of the present article shows, 4 categories, 8 components, and 34 conceptual themes were identified in this regard and presented in the form of a theoretical framework to improve the level of conceptual understanding of the phenomenon under investigation. As argued in the section on providing definitions, the identified categories show a level of AI functions from focusing on individual capabilities to structural, social, and competitive functions. To achieve greater theoretical coherence beyond the theoretical framework presented, the dimensions in question can be analyzed in the form of a systematic cycle.

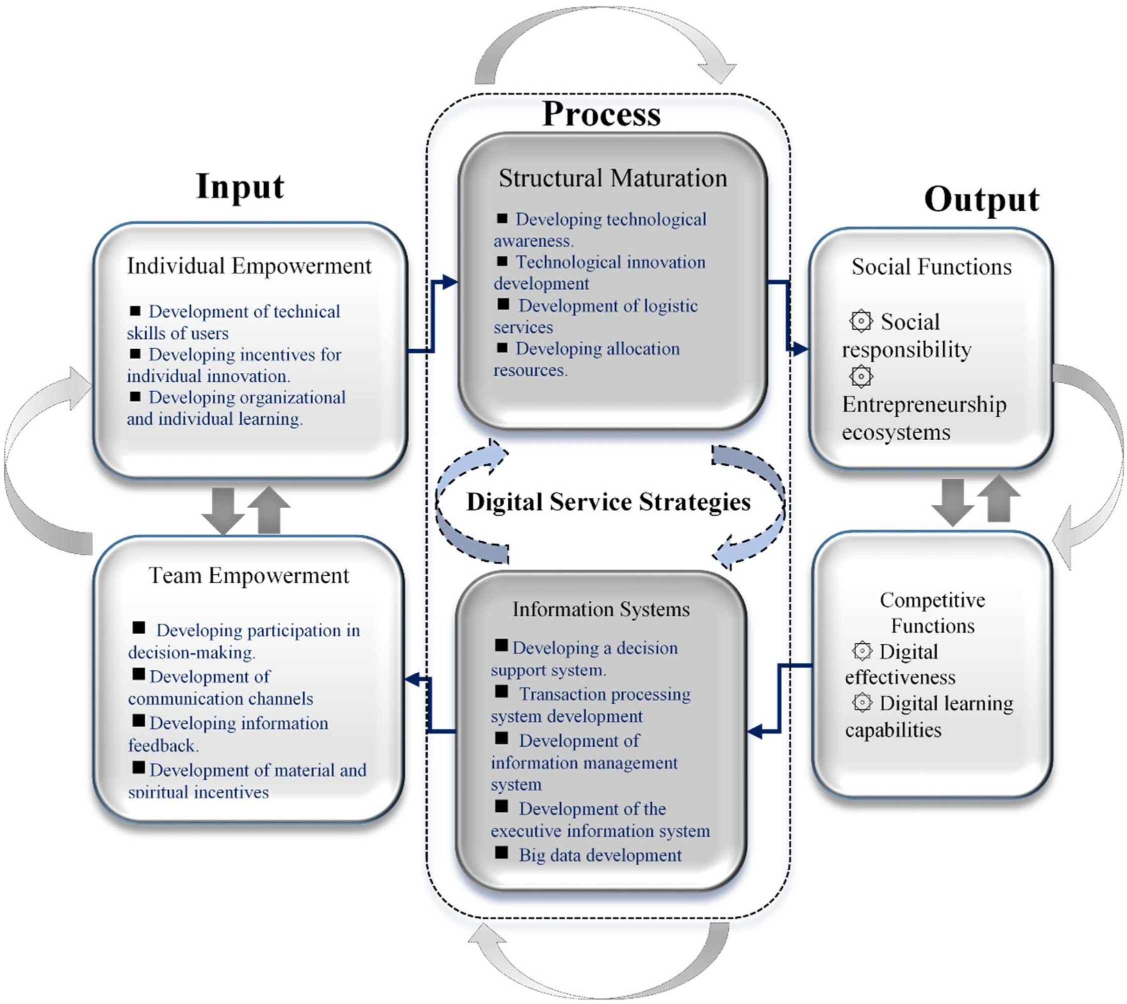

Figure 5 - Evolutionary cycle of artificial AI to improve the quality of digital services

Integrating Quality Management (QM) into the systematic cycle enhances the framework's coherence and applicability, ensuring digital services meet customer expectations and industry standards. By incorporating QM practices like process optimization, performance measurement, and continuous improvement, SMEs can enhance the reliability, effectiveness, and quality of their digital services. Embedding QM provides a comprehensive approach to leveraging AI for digital service quality enhancement, fostering organizational excellence and competitiveness.

SMEs must initially strengthen human resource capabilities to interact effectively with AI, enhancing technical skills and decision-making. This stage fosters structural maturity through prompt feedback and motivation reinforcement. Additionally, integrating QM practices from the outset ensures digital services meet quality standards and customer expectations, laying a foundation for excellence.

In the second stage, companies optimize internal processes, harnessing higher productivity to institutionalize technological innovations and allocate resources optimally. This enables systemic processes to achieve effective outcomes, helping SMEs capture a larger market share. Creating entrepreneurial ecosystems stimulates competitive innovations and essential capabilities, facilitating effective digital marketing through AI and expanding customer bases.

5.1. Theoretical Implications

The findings highlight the importance of developing capabilities for digital service offerings and increasingly using AI. This study identifies aspects of digital capabilities that play an effective role in servitization, providing theoretical contributions to the digital servitization literature. SMEs face unique challenges in commercializing digital service offerings, such as liability of smallness and newness (Gimenez-Fernandez et al., 2020). They often adopt restrictive strategies focusing on digital service maturity or ecosystem involvement to conserve resources (Jovanovic et al., 2021). While larger firms may adopt broader strategies, the insights from this study are valuable for coping with digital servitization paradoxes and organizational inertia (Sjödin et al., 2020b).

Systematic attention to AI and QM functions gives SMEs the opportunity to move through the business cycle quickly, gaining a competitive advantage over larger companies. Developing AI functions and implementing QM is crucial for enhancing the digital servitization literature stream. This study also facilitates the trajectory of SMEs toward digital servitization by smoothing the differentiation of internal structural, process, and external structural aspects, improving strategic development capabilities (Nicoletti and Appolloni, 2023; Robayo-Pinzon et al., 2023).

5.2. Limitations and Future Research

While offering novel insights, this study's empirical findings are limited by the small number of cases examined. Future research could employ quantitative methods, such as distributing questionnaires among SME participants, to generate more reliable results and explore correlations between these variables. Further research could also delve into management processes, sub-activities, and cultural aspects of SMEs implementing digital servitization strategies. The concept of digital servitization is still in early exploration, presenting opportunities for future research to deepen understanding of its relationship with digitalization and QM, and to develop a contingency model guiding academics and practitioners in this evolving field.

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Beyond Taylor (clientocracy) management methodology as a tool to enhance corporate culture and improve business process efficiency through flexible approaches

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STRUCTURED ABSTRACT

This paper addresses the challenge of managing organizations faced with complex tasks, requiring management tools and methods integrated within a flexible management methodology. It highlights the relevance and opportunities for transforming organizational management. The study hypothesizes that one of the flexible management methodologies, the Beyond Taylor or clientocracy, is suitable for managing organizations and organizational change. The aim of this paper is to explore and demonstrate the feasibility of transitioning to clientocracy within organizations. The methodological foundation discussed is the clientocracy management methodology — a management structure where hierarchy and processes are constructed around customer values. This paper introduces for the first time the experience of training quality experts under the clientocracy methodology and briefly discusses the training content. It highlights the research findings on factors that facilitate and impede an organization's transition to clientocracy. The intended audience includes leaders of organizations, quality management experts, and heads of innovation teams.

Keywords: clientocracy, Beyond Taylor methodology, quality management.

INTRODUCTION

Today's ambitious innovation challenges necessitate new management tools and methods that are integrated into a flexible methodology [6, 8, 9, 10, 12]. The Beyond Taylor or clientocracy (C2) methodology is one such approach. Clientocracy is a management structure where the organizational hierarchy and processes are derived from customer values. Consequently, the organization is perceived as a dynamic entity aimed at unleashing human potential to maximize benefits for the end-users (society). The research hypothesis asserts that the clientocracy methodology is applicable to managing organizations and implementing organizational changes across various sectors [2, 3].

The clientocracy methodology in Russia at the federal level is supported by the autonomous non-profit organization “Russian System of Quality” (Rusquality) — the national institute of quality of the Russian Federation. Rusquality conducts diagnostics of business processes across various sectors in Russian organizations, based on a model of quality and business excellence that is harmonized with the best international practices. Additionally, it shares experiences and developments through international collaboration with leading quality alliances [1].

The clientocracy methodology is disseminated and advanced across various economic sectors — including healthcare, education, small business, service industries, and industrial production — as well as within governmental bodies and state organizations. To further develop and promote this methodology, Rusquality became a founding member of Beyond Taylor.

The Beyond Taylor (C2) methodology, also known as clientocracy, was developed by Russian theorists Andrei Krivenko, Valera Razgulyaev, and Nikolai Popovich. It is operationalized in management practice through the advisory services of the Beyond Taylor innovation group (https://beyond-taylor.com/) [2, 3]. What exactly is the Beyond Taylor methodology, or clientocracy?

BEYOND TAYLOR METHODOLOGY AND THE CONCEPT OF CLIENTOCRACY

The principles of clientocracy that can be applied to organizational management and change include [4]:

For organizations:

- Optionality. Instead of rigidly adhering to one approach in every situation, we allow for flexibility and the exploration of alternative directions.
- Redundancy. Rather than solely pursuing efficiency and standardization, we allocate resources for launching new projects and swiftly adapting to new directions.
- Experimentation. Rather than focusing on planning long-term projects, we engage in extensive experimentation and allow all company employees to participate.

For employees:

- Trust. Rather than requiring constant approvals, we empower each employee to make decisions, granting them both rights and responsibilities.
- Autonomy. Instead of reinforcing hierarchical structures and expanding administrative roles, we provide teams with self-management tools and encourage team-driven motivation.
- Humanity**.** Instead of coercion and work until burnout, we cultivate creative synergy, inspire employees with an evolutionary purpose, and integrate diverse perspectives into a unified whole.

There is an additional principle: not to treat these six principles as indisputable [4]. The purpose of these established principles is to keep them in focus when making various decisions. The transition to clientocracy can be described as an algorithm that unfolds in steps (see Figure 1):

- Identify teams that generate value and those that provide support.
- Allocate the necessary rights and resources to deliver value to customers, thereby achieving autonomy.

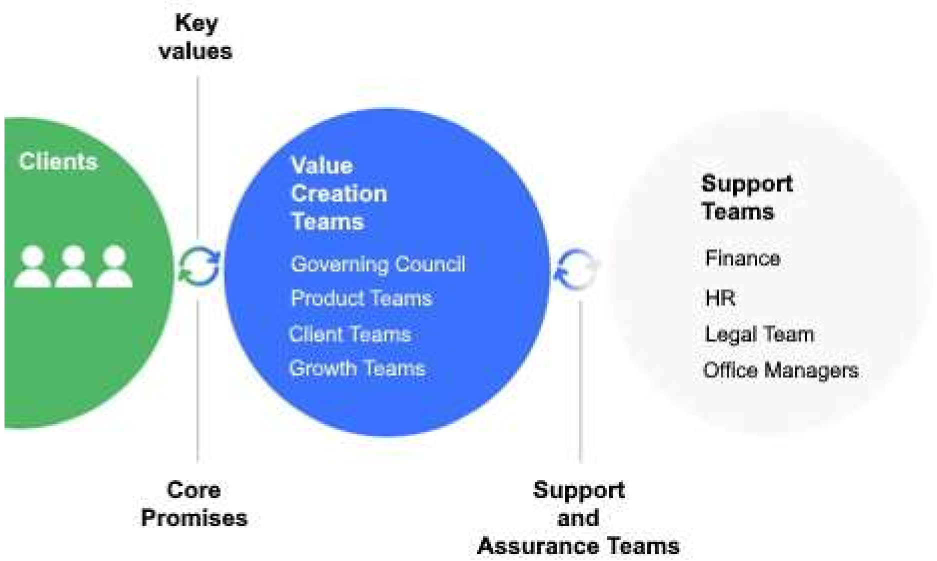

Figure 1 – Scheme of Interactions and Management under the Clientocracy Methodology.

SOME IMPLEMENTATION OUTCOMES

As previously mentioned, the clientocracy concept is centered around developing an organizational management system and business processes based on customer values. This C2 methodology aligns closely with the quality and business excellence model developed by the European Foundation for Quality Management (EFQM).

This model includes criteria and components that can assess clientocracy approaches, notably under the categories: 5e «Customer relationships are managed and enhanced», 6a «Customer's perceptions», and 6b «Customer's performance indicators» (see Table 1).

Table 1 – The relationship between EFQM criteria and clientocracy approaches.

EFQM Criteria definition	Clientocracy approaches
5e «Customer relationships are managed and enhanced» - Segment customers, in line with the organization's strategy, and adopt appropriate policies and processes for effectively managing the relationship. - Determine and meet customers' day-to-day and long-term contact requirements. - Build and maintain a dialogue with customers, based on openness and transparency. - Continually monitor and review the experiences and perceptions of their customers and ensure processes are aligned to respond appropriately to any feedback. - Ensure customers are clear on their responsibilities with regards to the use of products and services.	In a clientocracy, the needs and interests of both external and internal clients are more important than formal corporate orders and regulations.
6a «Customer's perceptions» Measures could include perceptions of: - Reputation and image - Product and service value - Product and service delivery - Customer service, relationship and support - Customer loyalty and engagement 6b «Customer's performance indicators» Measures could include performance indicators on: - Product and service delivery - Customer service, relationships and support - Complaints handling - Involvement of customers and partners in the design of products, processes, etc.	Companies can use clientocracy for their benefit, for example: - to satisfy customers — when the company focuses on the desires of customers, and it leads to increased loyalty of the target audience and sales growth; - a better understanding of the market by involving customers in the decision-making process, it allows to see new trends and consumer preferences; - product and service improvements based on customer feedback analysis; - continuous business development

Rusquality, the operator of the national competition for business process improvement (the Russian Federation Government Quality Award) [5], conducts diagnostics of business processes across all economic sectors using the EFQM model. This includes evaluating company interactions with customers and their outcomes. Rusquality also actively contributes to the development of an expert community, holding master classes, training sessions, and professional development courses for quality and business process improvement professionals.

In March 2024, expert training on applying clientocracy approaches within the business process diagnostic model was conducted. Over 100 experts were trained, demonstrating significant interest in clientocracy. Topics covered included:

- The relationship between clientocracy and ISO 9000 standards;
- Key areas for product development (clientocracy);
- Establishing a system for the distribution of authority and responsibility;
- Informal leadership;
- Employee engagement;
- Developing a corporate culture based on clientocracy.

An essential aspect involves studying the factors that hinder and facilitate successful implementation of the clientocracy methodology within organizations. In 2024, Beyond Taylor conducted an internal study to identify the success factors for implementing clientocracy and the aspects requiring special attention during its implementation. The chosen personnel were the project managers of Beyond Taylor, who accompany the implementation of the methodology in commercial organizations of various profiles. These personnel served as experts, possessing experience in implementation and a knowledge base on the clientocracy model.

The study was conducted through interviews, where responses to questionnaire questions were recorded and analyzed. The questions comprised three sections:

- Introduction (3 questions, determining the status/expertise of the respondents);
- Main section (9 questions, aimed at identifying the studied factors);
- Additional section (3 questions, ensuring the consistency of the answers);
- Conclusion (a question related to the overall final opinion).

The study conducted allowed for the formalization of accumulated experience in the form of several factors, specifically:

- Resistance within companies;

- Challenges during implementation;
- Factors influencing the successful transition to the clientocracy model;
- Implementation mistakes.

Here are some results of the conducted research. The following implementation challenges have been identified:

- Outdated information on business processes and team roles.
- Lack of tools for measuring metrics that evaluate the fulfillment of an employee's commitments.
- Absence of client analytics within the company (lack of knowledge about who their clients are).
- More than five levels of hierarchy within the company.
- Poor delineation of responsibility areas (overlaps, duplications) and authority (insufficient authority).
- Lack of clarity on resource distribution, leading to internal competition for resources.
- Reluctance to explore or poor quality of understanding client pains and values.

Factors Influencing Successful Transition to Clientocracy:

- Ability to work in a team and prioritize group goals over individual ones.
- Capability to negotiate and engage in "healthy conflicts" that lead to better outcomes.
- Leadership in the change process by the owner.
- A company structure that enhances departmental independence (easier transition in a matrix structure).
- High level of self-reflection and openness to change in management.
- Robust systems for record-keeping (culture of data management and usage).
- Proficiency in modern tools for data gathering and analysis.
- Advanced expertise in marketing, sales, analysis of customer journeys, product management, data handling, business analytics, and IT skills.
- An organizational culture receptive to change, typically entrepreneurial or research-oriented.
- A learning culture within the company, with employees and managers eager to adopt new tools and approaches.

DISCUSSION

Within the clientocracy model, the organization is seen as a living mechanism for unlocking people's potential, with the goal of maximizing benefits for the end consumer. The recognition of this approach can be observed in commercial enterprises and governmental organizations [6, 7, 8, 10, 11, 14].

In the clientocracy model, the primary focus is shifted to the values of citizens, clients, and customers, which are ensured by a system of promises from employees to the recipients of these values [2, 3, 6, 10, 14]. The management model is adjusted to collaborate with the client and meet their needs [2, 3]. For this purpose, value-creating and support teams are designated, and rights and resources are allocated to deliver value to customers, thereby creating autonomy. It is important to establish how the customer evaluates the performer and to build a market structure of the customer and performer [2, 3]. In this case, relationships self-regulate, and those who do not deliver value are compelled to evolve [2, 3, 10, 12].

In the course of development of the clientocracy methodology, experience has been accumulated in modernizing management tools and implementing the methodology in management practices, which can be formalized into a knowledge base. This was confirmed by Beyond Taylor's internal study, the selective results of which are presented in this article. For example, the analysis of implementation experience highlighted several advantages of implementing the clientocracy methodology (C2) [2, 3]:

An analysis of the implementation experience has identified several advantages of adopting the clientocracy (C2) methodology:

- Accelerated task completion due to reduced process bureaucratization;
- Employee autonomy leads to rapid development and facilitates scaling;
- Cost reduction and budget savings accompanied by improved quality;
- Increased efficiency and speed in interdepartmental collaboration;
- Reduction in process load on personnel.

It can be concluded that implementing the clientocracy methodology enhances the overall level of management culture and production efficiency while also increasing public trust [2, 3, 10, 11, 13, 14].

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Six Sigma and Data Mining to Improve Production Processes

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STRUCTURED ABSTRACT

Purpose - Six Sigma includes traditional tools that are usually difficult to give a full understanding of the manufacturing data. Data mining is usefully applied in industries; some algorithms generate significant information to serve the industrial fields. Data mining algorithms enhanced DMAIC to extract relevant knowledge about the process.

Design/methodology/approach - In the defining step, three weeks were spent outlining the main problems by studying and evaluating the job shop processes. Data were collected during the measuring step to evaluate the baseline process and build a reliable plan to make the change in the process. In analyzing, two data mining algorithms were applied to analyze and select the most important predictors. Worker efficiency was evaluated carefully to be applied as output in the dataset; 12 technical variables were carefully screened and filtered from huge datasets to extract significant relationships. In the improving step, the results have been applied to make the changes by adding lean principles and agile projects. Finally, five months waited to get the impact on business, so this was confirmed by the management in the control step.

Findings - The productivity of the weaving department has improved from 58% to 92%, lead time has been reduced from an average of 35 days to an average of 20 days, and the capability process has improved from 0.77 to 1.7.

Originality/value - The value lies in the systematic approach to problem-solving, the use of statistical methods to analyze data, and the application of scientific principles to improve the processes.

Keywords: Six Sigma, Data Mining, Worker Efficiency, Features Selection.

Paper Type: Case Study

INTRODUCTION

Six Sigma is a reliable technique in process improvement and quality management in recent years. It has acquired wide popularity in different business fields since the 1990s. Most fortune 500 companies have applied Six Sigma (Vicente et al., 2024). Rich anecdotal evidence shows that Six Sigma can help companies get a high performance of the improvement. For example, Motorola has reported $16 billion benefits from applying Six Sigma for the period from 1986 to 2001 (Swarnakar et al., 2023); (Salah et al., 2011) and therefore, the improvements to be implemented are determined by their impact on customer satisfaction and value (Vicente et al., 2024). Other companies like General Electric (GE), Honeywell, and 3M reported the same results (Jirasukprasert et al., 2014); (Kaswan et al., 2023); (Reed and Neubert, 2011); (Cui et al., 2022). The benefits of Six Sigma are included, but it is limitless in the cost reduction, sales revenue growth, and customer satisfaction improvement (Patmawati et al., 2023).

Six Sigma is a sequencing tool for improving the process of transforming inputs into outputs where quality excellence can be gained using statistical methods and techniques (Tsarouhas and Sidiropoulou, 2024). In Six Sigma, two methodologies can be considered to solve problems, DMAIC and DMADV (Kovach et al., 2024). Both methodologies have the same goal to reduce defects to reach the highest six-sigma level. The study is established to improve the quality of the current system based on this, DMAIC was applied to identify and eliminate causes of defects, defined as anything that may lead to customer dissatisfaction or failures in the business processes by focusing on outputs that are critical to the customers (Saad, 2018); it applies the normal distribution and a strong relationship between failure product, and product yield, cycle time, reliability schedule, and inventory (Escobar et al., 2022). Six Sigma has been widely applied in different industries as a proven management innovation methodology to produce high-quality products and reduce costs at all levels of an organization (Juran and De Feo, 2010); (Samanta, and Gurumurthy, 2023). DMAIC movement has gained acceptance in marketing, healthcare, financial, engineering, and legal service organizations, in addition to achieving high benefits in the production and manufacturing fields (Klimecka et al., 2021). Many studies have been conducted regarding the implementation of the methodology in big companies (Samanta, and Gurumurthy, 2023). Nevertheless, a few studies reported on the successful application of Six Sigma in Small and Medium companies (Ronowicz et al., 2015).

DMAIC methodology utilizes old and new quality tools to find out the main causes and solve problems. However, complicated relationships and interactions among the variables cannot be identified successfully with those tools. Although the six-sigma DMAIC framework is the best-known approach for process improvement, it has some limitations when the complicated process needs to be improved using a large number of variables. Furthermore, conducting some techniques such as Design of Experiments with a large number of variables in a running industry is almost infeasible. Data mining has emerged as a useful tool to extract quality from the process variables.

While Six Sigma can be a powerful tool for process improvement (Widiwati et al., 2024), however, there are some potential drawbacks to consider before delivering projects of Six Sigma or lean Six Sigma, it can sometimes focus too much on statistical analysis and not enough on practical problem-solving. Six Sigma is primarily focused on process improvement and may not address broader organizational issues. Implementing Six Sigma can be expensive, especially for smaller organizations. Delivering projects of Six Sigma can be time-consuming and may take several months or even years to complete. Six Sigma in many scenarios requires a high level of buy-in and support from leadership and employees, which can be difficult to achieve. Six Sigma can sometimes create a culture where belts are seen as the only ones who can drive improvement, rather than empowering all employees to make changes, and that is why many training levels of Six Sigma were offered to tackle culture and communication problems. Six Sigma with limited information can sometimes focus too much on incremental improvement and not enough on innovative solutions. It's important to be aware of these potential drawbacks and to approach Six Sigma implementation with a balanced perspective. Six Sigma and data mining can be integrated by using data mining techniques to identify areas for improvement in a process, and then using Six Sigma methodology to implement changes to address those areas. For example, data mining can be used to identify trends in customer complaints, and then Six Sigma can be used to implement changes to address those complaints. This study proposes an integration of data mining and DMAIC that utilizes data mining techniques to analyze and improve worker efficiency by extracting knowledge under the most regular problem-solving in DMAIC cycle. A case study is performed in a Middle East company. The focus of this study is to eliminate defects in the final preparation unit. The study utilizes nonlinear, nonparametric tree-based data mining approaches, called (Interactive Tree with the model building method is (Classification and Regression Trees, CART) (Kono et al., 2024) and Feature Selection (Alirezapour et al., 2024) to identify the ‘vital few’ impacting process variables affecting the elimination defects. The results showed the effectiveness of the approach in reducing the defects. Algorithms of data mining will be applied in the

Analyze step to extract meaningful knowledge from a dataset based on which input variables have a significant impact on the output to build changing in the process (Goh, 2010).

RESEARCH METHODOLOGY

Many studies have presented the Six Sigma methodology since introduced in the late 1980s and have specified many success attributes which are essential for implementation. Six Sigma defines as a management system to achieve customer requirements by improving the processes with the support of data and facts (Goh, 2010). The basic idea of utilizing the Six Sigma process is to increase profit margins by improving customer needs (Ronowicz, 2015). It is a business system that focuses on customers; facts and data drive the process of improvement activities that require active management involvement and professional teamwork.

The study focuses on applying the DMAIC methodology to improve product quality by reducing defects in complicated processes (Prado et al., 2024). DMAIC in current study is a powerful tool in Defining and Measuring steps, but in Analyzing step, we defined more professional tools that can extract the relationships and get the knowledge to know how the process is developed. We spent 3 weeks defining the main problems, identifying necessary information, managing people and resources, assessing the baseline process, and collecting convenient and reliable data. We evaluated a few data mining algorithms to confirm the best algorithms that can understand industrial datasets. Interactive trees (CHAID Chi-square Automatic Interaction Detector and CART Classification and Regression Trees) provided high-accuracy prediction to choose in Analyzing step to find the relevant variables associated with the worker efficiency (Ronowicz et al., 2015). Based on the information that was extracted in the Analyzing step, we are ready to start preparing the roadmap for changes. In the improvement step, we assessed the significant variables that were outlined in the Analyze step to improve the job shop processes. In control, we waited for 5 months to measure the impact of the application that was confirmed by the third party. Figure 1 defines the methodology of the study.

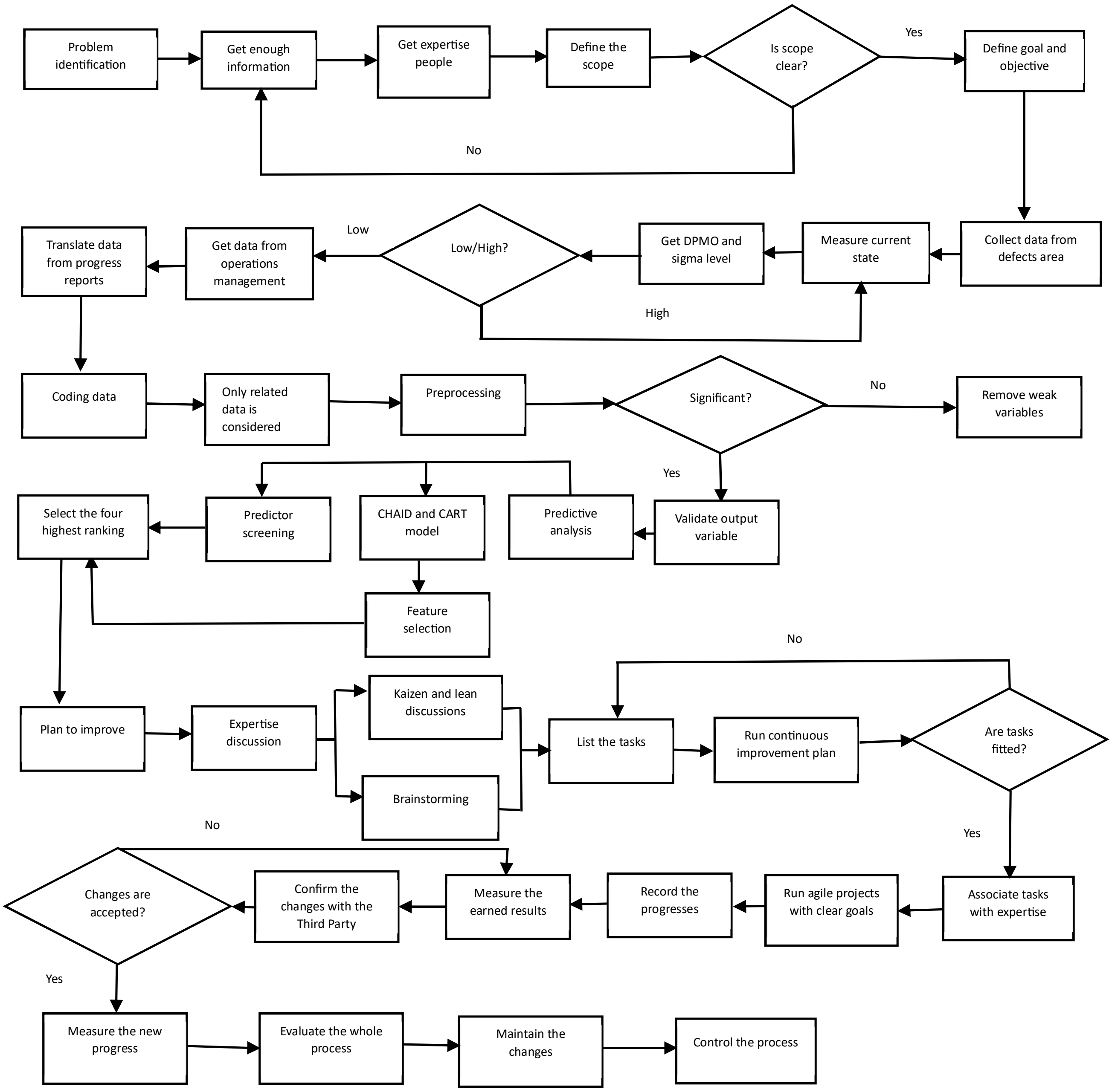

Figure 1 – Methodology development.

SIX SIGMA APPLICATION

DMAIC process (Define). At the first step in applying Six Sigma in an industrial company, there are many essential points that can draw the roadmap for a study such as a problem statement, business case, project charter, key people, and more necessary information. The problem may occur in the sub-system, but it can affect the entire system if the problem is not solved on time. To find a problem or abnormal work at the job shop, we followed all processes of production, starting with the sorting process and finishing at the final preparation process to get the main problems.

Many defects were found in the final product due to a few skilled workers and weak supervision; many skilled workers had lost in the company due to late salaries or bad incentives especially the company had lost potential customers. Hiring new people costs the company a lot of money to provide relevant training, whether inside or outside the company. However, the company pays salaries according to the work efficiency of each worker; if the worker's efficiency was %80 and his/her starting salary is $1000, then the salary will be only $800 per month or less. This problem directly affected the weaving department because it requires a lot of skilled workers to operate the machines and check product quality. We evaluated the process of production through sorting, washing, blending, dying, spinning, weaving, to final preparation, and the problems that were found are that a few skilled workers and long lead time.

Critical to quality tree (CTQ). It is one of the tools that is used in defining step, and it is a useful technique to understand the needs for a system problem. Critical to Quality, are the key characteristics of a process that have a significant impact on the quality of the output. In Six Sigma, CTQs are used to identify the most important aspects of a process that need to be controlled and improved to achieve the desired quality levels. CTQs are typically identified through a process called Quality Function Deployment (QFD), which involves mapping customer requirements to process characteristics and identifying the most critical ones. Needs are what does customer require and expect (Goh, 2010). In quality drivers, we need to look for how to gain these needs. Moreover, at critical to quality or quality requirements, we need to measure and evaluate these drivers (Juran and De Feo, 2010). Critical to quality tree is described in figure 2.

There are two needs to solve or optimize the problem for the entire system. The company spent much money preparing workers who operate the specific machines; some workers on machines need to get hard skills because most of the machines in the job shop are Computer Numerical Control (CNC) and other machines need regular skills to fit the standardized work. There are four drivers in the Critical To Quality (CTQ), but the most remarkable driver is the long lead time that we need to optimize it, as well as provide special soft and hard skills training for the workers who were hired by the company at the weaving department.

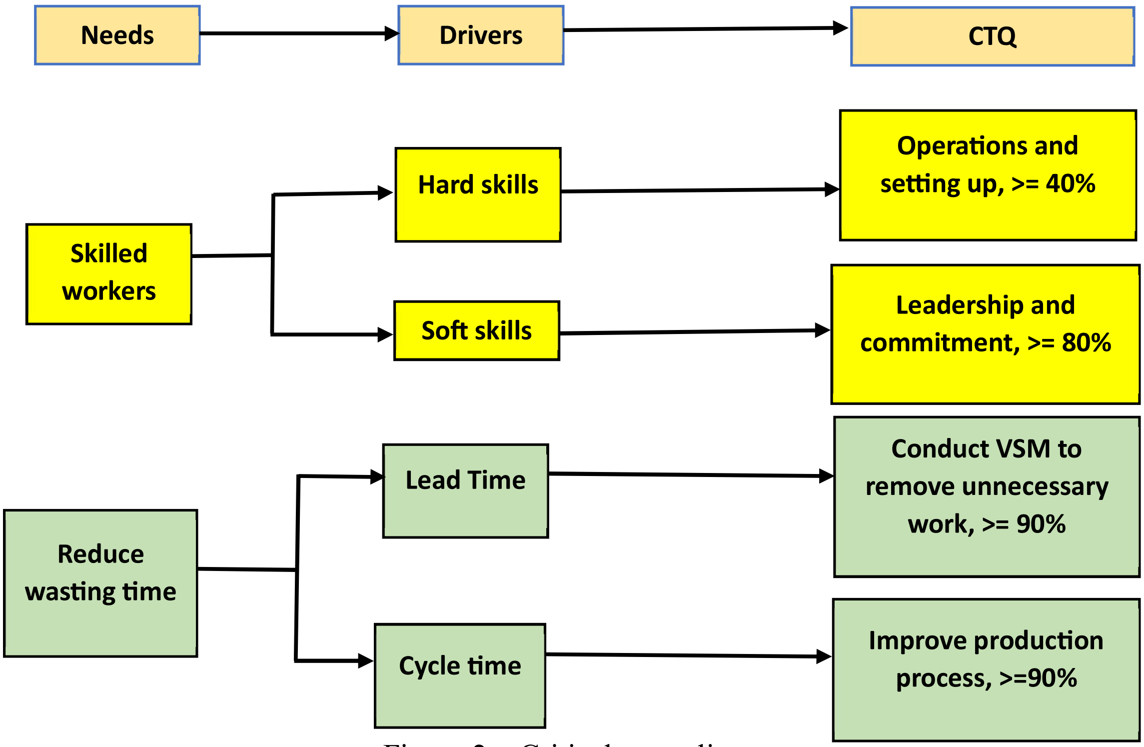

Figure 2 – Critical to quality tree.

DMAIC process (Measure). At the measuring step, we got close enough to estimate and evaluate the baseline process by getting relevant information, which helps to extract meaningful knowledge about the process. To understand the process, we estimate the process performance in its current state to figure out the gap. Critical success factors and process capability process applied in measuring step to conduct the understanding of the current process.

Critical success factors (CSFs). The critical success factor is required to make sure a company has achieved its target. The term critical success factor is universally used in data analysis and business strategies. We considered several steps to select the most important factors that fit the project scope by defining what we need to be achieved. Many elements have been chosen by the management, and based on the project goal, we confirmed only the critical elements that will impact the achievement of the (key performance indicators) KPIs and goals. The management has ranked the CSFs in order of importance and impact. To keep strategy developing, we created a plan to address each factor, including allocating resources and assigning responsibilities. By catching any impact, we can regularly track and measure progress towards each factor. Afterward, we build the continuous improvement plan by reviewing and updating the CSFs and strategy to ensure they remain relevant and effective. In production process, many factors affect the process, but which factor had an impact more than others? By following the processes and evaluating all offers from management and production supervisors, we found that skilled workers in the weaving department are the most principal factor that needs to improve. Another factor wasting time is the most critical factor, but also this occurs from the real problem in the weaving department. We intended to rank the training as the high priority of Critical Success Factor (CFS), but the management was not ready to train new employees due to financial problems. The training factor has ranked in the medium based on the suggestions of the management. This ranking of the factors was confirmed by the Company.

Table 1 – The critical success factors for different targets in production.

Ref #	CSF	Priority Ranking	Description
1	Skilled workers	High	The weaving department includes 16 weaving machines. Each machine has a skilled worker who is responsible for the daily operations. Already, the company provided highly professional training that found many skilled workers, but right now, it cannot provide the same training and is unable to pay the same salaries due to the loss of important customers. Current efficiency is around 58%, so, we need to improve this percentage by applying some changes to the company.
2	Wasted time (and lead time)	High	Inaccurate estimation to lead time and wait long time for raw materials. At the final process, the workers got a lot of products that did not meet the requirements and needed to spend more time to fix the problems. The current wasting time is so high, and we need to improve the process and build accurate prediction to > 90% by applying relevant changes.
3	Raw materials and supply chain	Medium	Only virgin wool is provided from the same city, but the rest of the materials need to be ordered from overseas with high quality. This factor has ranked as a medium because the company plans to order high quantities to avoid any abnormal stops in production due to a shortage of raw materials. We need to improve the sales strategy, improve supply chain processes, and make sure the company did not miss raw materials.
4	Internal and external training	Medium	In industry, training is highly recommended to follow updates on manufacturing, but training needs to be scheduled and included in the annual plans, especially some workers need to update hard skills. However, the company currently is interested in changing some rules and modifying some strategies to improve the quality and

	attract more customers. We highly recommend them get training for lean Six Sigma, leadership effectiveness, supply chain mitigation, and marketplace strategies.

All data of study has collected from Libya, Germany, and India. All results and findings have been confirmed by the community of research. The community names and contacts have been validated by a community of lean Six Sigma at SUNY at Binghamton.

Process capability analysis. To measure the baseline of the process, we requested specific data for number of defects, total opportunities, and defect per unit to evaluate the current state. Based on the given data, the total number of defects for specific shift loads = 337 defects. Table 2 presents all the required data to calculate defect per million opportunities and sigma value for the current process.

Table 2 – Defect per million opportunities.

Term	Description	Measurement
D	Defects	337
TO	Total of Opportunities	1625
U	Units	65
D/U	Defect per Units	5.184

Defect Per Million Opportunities (DPMO) = (337/1625) * 1,000,000 = 207384.6

The standard table for Defects Per Million Opportunities (DPMO) in table 3 is a widely used metric in Six Sigma to measure process performance. We clearly defined the process that we are measuring and the opportunities for defects. In table 2, we gathered data on the number of defects and opportunities and used the formula DPMO = (Total Defects / Total Opportunities) x 1,000,000 = 207384.6. Then, we used a sigma level conversion table to determine the corresponding sigma level based on the DPMO value, as shown in table 3. The sigma level in the current system is between 2 and 3 sigma, which is very far from 6 sigma.

We found that 207384.6 is equivalent to 2.315530 sigma and the Yield is 79.26% and C_p (Process Capability) = 0.77. Then, the measured baseline sigma value of the current process = 2.3

Table 3 – Sigma value vs. DPMO.

Sigma level	DPMO	Yield
1	691462	30.85%
2	308538	69.15%

3	66807	93.32%
4	6210	99.38
5	233	99.98%
6	3.4	100%

The current sigma level is between 2 and 3 sigma as shown in table 3.

Process capability analysis. Poisson process capability Defect per unit (DPU) has no stability, and Binomial plots are not on the straight line. The chart of sample count per unit has no stability as well, and there are a number of points that are out of the control limit.

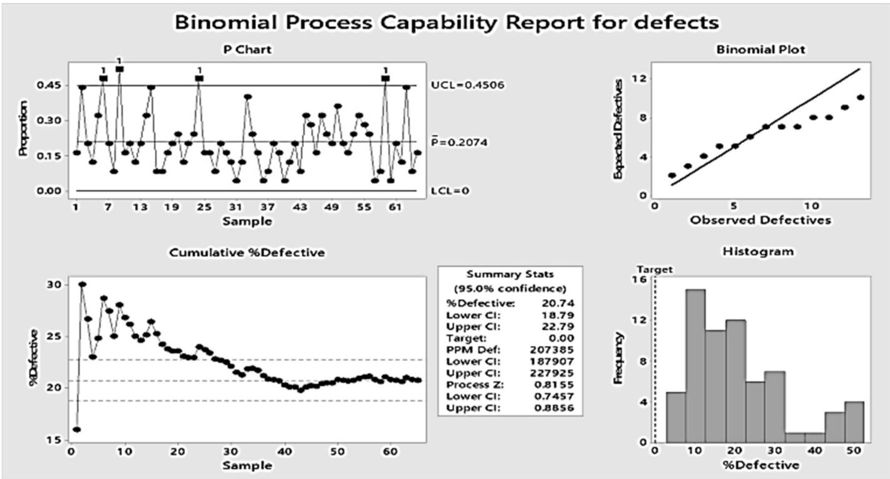

Figure 3 – Binomial process capability.

Data Collection. The study is conducted based on the data collected from the company and focused on producing kinds of carpets daily. The data collection activities are taken in June 2023 and November 2023. The defect data used in this study was taken from the archive of operation management and defects data collected in June 2023, September 2023, and November 2023. There are two types of data used in making this study: sample and progress report data. The sample data is the data that is obtained from observations, historical, and data sampling. On the other hand, progress reports data is the data that is obtained from the operation management to predict what affected the efficiency of workers by using data mining. The 12 variables were screened from over 62 variables including missed data, unclear variables, and inappropriate observations that are completely modeled to use in data mining to find highly significant variables that affect the worker efficiency to reduce the variations in the process. The samples were collected in the same weaving process in different periods to measure the progress. Data was collected from Libya, India, and Germany (German and Indian data were used to validate Libyan data that included many unclear variables recorded by the operation management in the company). The dependent variable was worker efficiency. Elapsed time was also considered as an output, but it did not get confirmation because insignificant results that gained using it.

The following predictors were used to predict what affects worker efficiency.

- Base production: The minimum of production should be achieved to get a full salary.

- Production achieved: Real production quantity has been produced.

- Progress evaluation: Final score provided by direct supervisors to follow employee's progress.

- Job Title: Type of job designed for each process.

- Badge no: Identification number given to the worker by the operation and production department.

- Cycle time: The desired time to produce a specific quantity.

- Operator (shift worker): Specialist who manages the machine and production operations.

- Incentive wages: Rewards provided if a worker's productivity exceeded base production.

- Production rate: The ratio between base production and achieved production.

- Type of product: Data collected based on the 6 kinds of products that are produced by different machines.

- Production unit: Production that is passed from unit to unit until completion.

- Machine model: Old and new machines.

So, one variable has been applied as a dependent called Worker Efficiency.

- Worker efficiency: Percentage rate was evaluated by the responsible supervisors connected with the production lines.

DMAIC process (Analyze). In the analyzing step, we used data that had already been collected in the measuring step based on the problem that was identified in the defining step by applying suitable data mining algorithms to understand the main causes. Two algorithms from data mining have been applied: interactive tree-based CART tree model and feature selection (predictor screening).

Note: CART stands for Classification and Regression Trees. It supports both categorical targets (classification) and continuous targets (regression). CHAID stands for Chi-squared Automatic Interaction Detection. It is suited for classification problems with categorical target variables (Demir., 2024). (GCHAID) stands for General Chi-squared Automatic Interaction Detection, and GCART stands for General Classification and Regression Tree.

Data Mining. It has a fundamental role in predicting the roadmap of manufacturing and production data. Many companies entered data mining as a tool to solve problems and extract knowledge from vast and vague data. The manufacturing processes are overly complicated to understand by traditional techniques, so statistical analysis and quality tools are unable to manage huge daily data. Therefore, data mining is an appropriate technique used to extract essential knowledge to build the relationship between variables and take the right decision to improve and diagnose the quality of product (Saad, 2018). This study is related to the production process for predicting the worker efficiency of each industrious worker based on input variables. The industrial data of the case study is overly complicated to understand by conventional algorithms of data mining because finding the best algorithm that can realize this data must be considered before doing any analysis process.

Interactive trees use classification and regression trees as a model building method. The primary purpose of the interactive trees (CHAID and CART) models is to build interactivity and entire control over the tree-building process. It conducts ("grows") regression and classification trees as well as CHAID trees according to automatic (algorithmic) techniques, rules, and criteria defined by the user-specified through a highly interactive graphical user interface, or combinations for both. The aim of the module is for providing a highly interactive environment for building regression or classification trees (through classic CHAID and CART) to enable analyzers to try various input predictors and split criteria in combination with almost all functions for the automatic tree building established in General CHAID models (GCHAID) and General classification and regression tree (GCART). All these choices of algorithms and techniques can be obtained when using the Statistica program.

The algorithm of the interactive tree is not known enough because it applies popular algorithms like CHAID, CART, and Exhaustive CHAID to build a tree. Furthermore, this algorithm has two models of the solution that can be regression or classification. Regression is used when the output is numerical, and classification is applied when the output is categorical. The interactive tree follows techniques of CHAID and CART. The algorithm is different from random forests and boosted trees. In this case, the algorithm of the interactive tree is applied based on the CART tree for regression because this selection provided robust results (Saad, 2018).

CART algorithm: CART is one of the most straightforward decision tree algorithms utilized to construct successive binary decision trees, by splitting the entire dataset into subsets and then again splitting each of the subsets into two sub-subsets to create two child nodes repeatedly, using all the input variables (Ronowicz et al., 2015). The best predictor is chosen using a variety of impurity measures. In the case of classification trees with the categorical response, 'Gini' and 'Towing' impurity measures are used. In the case of regression trees with a continuous response, the 'Least-squared deviation' measure is used as a splitting criterion. Results of the application of the interactive tree based on the CART model are presented in table 4.

Table 4 – Error estimation.

Run	Risk estimate	Standard error
Train	0.000932	0.000573
V-fold	0.000053	0.000020

Based on the results in table 4, the algorithm of data mining gave a sophisticated prediction because there was an exceedingly small value in RMSE (Standard error) and MSE (Risk Estimate).

Table 5 – Variables ranking from CHAID+CART algorithm results.

Input Variables	Variable rank	Importance
Operator (Shift worker)	100	1.000000
Reported Evaluation	72	0.717938
Production rate	70	0.704598
Incentive Wages	43	0.430169
Base Production	22	0.223547
Job Title	22	0.217376
Production Achieved	12	0.115748
Badge No.	8	0.075904
Type of Product	7	0.067224
Elapsed time	4	0.042903
Production Unit	2	0.020909
Machine model	0	0.001120

We can see in table 5 the relevant variables which have a significant impact on the worker efficiency; Operator (people on machines), Reported evaluation, Production rate, and Incentive wages.

Predictor screening (feature selection). The objective of the predictor screening model is to select a set of input variables from many candidates allowing them to focus on a more manageable set for more analysis. The predictor screening model optimally fits continuous and categorical predictors. It estimates their predictive power associated with the output variable. The model in Statistica software constructs the optimal fitting using the algorithm of Classification and Regression Tree.

Predictor screening in data mining is selecting and ranking features that affect the output with different importance levels. Some software like Weka has different algorithms for feature selection, but variables in that program are ranked in the sequence numbers based on the importance of each feature without giving details for F-statistic, R-square, and P-value. In Statistica software, results have been modified to get the best four essential variables based on R-square and F-value results. Impurity measures play a crucial role in feature selection to improve the model performance. Impurity measures applied to evaluate the quality of splits in decision trees and other tree-based models like (CHAID and CART) models. We used these measures to provide a way to assess the purity of nodes in a tree and finding the best features to split on. We conducted the analysis process by considering Gini impurity, entropy, and variance reduction. By minimizing impurity measures, feature selection algorithms worked well to identify the most relevant features that contribute to the purity of nodes and improve model performance. We considered the feature selection from both algorithms to provide good selection to build the improvement.

Table 6 – The best four variables in the dataset.

Input variables	**R-square**	**F-statistic**	**Variable position in origin dataset**
Operator (Shift worker)	0.919139	443.3076	1
Reported Evaluation	0.732531	161.5866	13
Production rate	0.602840	89.5549	7
Incentive Wages	0.307944	52.9515	6

DMAIC process (Improve). From the analyzing step, four variables have impacted worker efficiency. By changing the input variables, the efficiency of the worker will be changed to reduce variations in the process. However, variables of the operator, reported evaluation, and production rate rely on the performance of the workers, and this would be difficult to change if the company did not consider reliable plans to retain qualified workers. We built the continuous improvement plan by conducting three Kaizen event sessions, and the attendees were from different departments. They were interested in developing the company's efficiency. The roadmap plan in table 7 has been confirmed by the top management of the company.

Table 7 – Continuous improvement plan.

Issue	**Possible solution**	**Expected impact**	**Ease of implementation (1 hard, 10 easy)**	**Cost benefits (1 low, 10 high)**	**Rank (Effect)**	**start**	**Finish**	**Who**
Final product quality issue	Reduce defects	Reduce variation	6	10	60	Jun 10th	Jul 7th	Quality manager
Productivity issue	Provide skilled workers	Improve productivity	5	9	45	Jun 9th	Jul 11th	Production manager
Worker's skills	Internal training	Skilled workers	7	10	70	Jul 2nd	Aug 15th	Business development manager
Huge Bottlenecks	Standardized work	Work flexibility	8	6	48	Jul 7th	Aug 21st	Operations manager
Salary and rewards	Increase sales	Company Benefits	5	10	50	Jul 9th	Aug 15th	Financial manager and company director
Accurate measurement	Get bet devices	Accuracy	7	7	49	Jul 12th	Jul 27th	Quality assurance specialist

Reworks	First time quality	Reduce costs	7	10	70	Jun 28th	Jul 13th	Quality manager, Operations manager
Machines efficiency	Lean Layout	Increase productivity	3	9	27	Nov 15th	Nov 27th	Operations manager, Quality Manager, Production manager
Advanced quality tools and techniques	Designed training	Quality control	7	8	56	Jul 2nd	Nov 3rd	Business development manager

There is a discrepancy in the performance of workers, which has affected productivity and increased production problems due to the company's failure to maintain employees due to delayed salaries and low benefits. This type of production requires proper training to deal with multifunctional and fast production machines. The company is always hiring those who accept the low benefits of the company without focusing on high-performance workers who are eligible to deal with different production scenarios. Through the four variables that we extracted from data mining; we can build an improvement plan. Focus on supervisors and provide them with appropriate training. Focusing on customer demands and building a system that responds to the customer in a proper manner. Reducing lead time by organizing work and creating a flexible system in production that will respond to abnormal work. Redistribute workers in production and connect an appropriate evaluation of their performance based on quantity and quality. Reorganizing work and machines to make the production process more flexible and with zero or small variations.

DMAIC process (Control). In control, the team needs to make sure that the changes in the process by the management will make a change in the product quality. A long-term control plan needed to be conducted in this step to restrict the improved process from drifting back to the earlier steps. To measure the improvement, 5 months waited to evaluate the progress in the process. We evaluated the team's work after 5 months and started by reviewing their progress towards their goals and objectives. We looked at metrics such as productivity, quality of work, and customer satisfaction to get a sense of their performance. We identified areas where they're excelling and areas where they need improvement. We provided specific, objective, and actionable feedback to help them grow and develop. Based on the evaluation, we set new goals and objectives for the team to work towards, and continuously monitor their progress after 5 months to develop the process more. We were open to adjusting our evaluation process as needed based on feedback from our team and changes in the organization. The full details of teamwork progress after 5 months are written in table 8.

Table 8 – Continuous improvement plan evaluation.

Issue	Possible solution	Who	Time delays	Achievement	Achievement percentage after 5 months waiting
Final product quality issue	Reduce defects	Quality manager	On time	Standardized work. Skilled workers have controlled the process.	100%
Productivity issue	Provide skilled workers	Production manager	One month late	Retain employees. Got hired thirteen skilled employees.	100%
Worker's skills	Internal training	Business development manager	On time	Providing soft and hard skills. The training has been scheduled for 5 months.	50%
Huge Bottlenecks	Standardized work	Operations manager	Two months late	Satisfy only the actual demands based on the priority customers. Reduce rejection in final products.	90%
Salary and rewards	Increase sales	Financial manager and company director.	Ongoing	Increase salary using reliable marketing strategies.	70%

Accurate measurement	Get best devices	Quality assurance specialist	On time	Skilled workers can measure the process using the right tools. provide what customer needs.	100%
Advanced quality tools and techniques	Designed training	Business development manager	On time	Many quality tools and techniques have been added in measurement processes.	100%
Machines efficiency	Lean Layout	Operations manager Quality Manager Production manager	45 days late	Add new advanced machines in a new job shop layout.	54%
Reworks	Source of the Quality	Quality manager Operations manager.	5 weeks late	Skilled workers have managed the entire process.	85%

The process is continuously monitored for 5 months to define the process behavior after the actions have been taken by the management based on the previous findings. Management provides specific years. We measured the Six Sigma for those years and compared it with what improved in this year. Table 9 was used to compare current state and future state using indexes of sigma, process capability, yield, and defect per million opportunities to catch the success in project. We started with determine the current state by calculating the current sigma level, process capability, and defect per million opportunities (DPMO) using data from the past 5 months. Next, we determine the future state by setting goals and objectives for each metric. For example, we may want to improve the sigma level from 2.3 to 5, increase process capability from 0.77 to 1.7, and reduce DPMO from 207384.6 to 159. The compare for the current state to the desired future state for each metric is presented in table 9. This can help to identify areas where they need to improve and by how much. Based on the comparison, we offered a plan to help company improve its performance and achieve its desired future state. This may include training, process changes, or other initiatives. Finally, continuously monitor the company progress towards the desired future state and make adjustments to the plan as needed. We used the year of 2012 to show the company was in good progress, but it lost this progress because it failed to retain qualified people. Miss qualified people means miss the opportunities! When unqualified individuals are in leadership positions, they may not have the skills or expertise to make informed decisions, which can lead to missed opportunities and poor outcomes as what happened to the company.

Table 9 – Calculate sigma values and Cp in real process.

Year	DPMO	Sigma Value	Process Capability C_p	Yield
1/1/2012	337	4.9	1.63	99.97%
06/15/2023 (Baseline Process)	207384.6	2.3	0.77	79.26%
09/30/2023	6523	4	1.5	99.35%
11/20/2023	159	5.1	1.7	99.9%

The process will keep improving because the management has confirmed a reliable system to manage and improve production processes. Moreover, the time has been optimized by reducing the defects in the weaving department, so these defects have been eliminated by skilled workers who retained or hired by the company. All steps of this study showed that the main impact could be made by improving worker efficiency and retaining qualified workers. In table 10, some improvements in the production processes have been observed and measured by the company.

Table 10 – Improvements in the process.

Factor	June 2023	November 2023	Process status
Skilled Worker	7	15-17 and still improving	Improved
Wasted time	Average of 2.5 hrs. per shift	Less than 1 hrs. per shift	Improved
Quality	Improved	Improved	Improved
Sigma level	2.3	5.1 and still improving	Improved
Lead time	Months	Few Days	Improved
Sales	Limited	Increased	High domestic sales
Investment	16 old machines	Added new 3 advanced multifunction machines	19 machines

CONCLUSION

Six Sigma and data mining are both powerful tools that can help industries improve their processes and make better decisions. By combining the two, organizations can leverage the strengths of both methodologies to achieve even greater improvements. Any production process needs human resources to standardize work and build quality, and this will not take place without providing qualified employees. The company cannot retain qualified employees if it does not provide sufficient benefits to retain them, and this needs challenging work by the company to increase sales by following advanced marketing strategies. Traditional quality tools help a lot, but the addition of data mining helped us identify the most important variables that affect the efficiency of workers and production. Data mining succeeded in outlining where we can start to make improvements in the process and providing a reliable strategy to build continuous improvement in the company. We provided Kaizen sessions to build the roadmap to change management at the scheduled times with the required milestones, deliverables, and targets. Agile projects with lean principles have been applied to get the changes in the management and job shop processes. By providing highly skilled workers, we improved productivity, quality, and sales after 5 months. The capability process has improved from 0.77 to 1.7, productivity has improved from 58% to 92%, and lead time has been reduced from an average of 35 days to an average of 20 days.

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Validation of a conceptual model of service quality for Direct-to-consumer telemedicine consultation: preliminary results of the 1st round of a Delphi study

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STRUCTURED ABSTRACT

Purpose: A conceptual model to assess service quality of DTC telemedicine consultation was developed by the authors. The objective of this study is to validate and further refine this model. **Methodology:** A Delphi study will be used to develop consensus and appraise the model with the participation of 10 patients, 10 teleconsultants, and 3 service quality academics. In round 1 conducted in November-December 2023, participants rated the initial 15 items and made suggestions, which will be incorporated in round 2. All panelists evaluated each service dimension (item) based on its potential positive and significant impact on service quality and its degree of relevance for the scale content validity. Consensus was defined a priori, as items that reach the pre-established cut-off (interquartile score of 1 or less, minimum of >70% of participants with a level of agreement ≥ 4 and an I-CVI of 0.78 or above).

Findings: In round 1 of the Delphi, 14 out of the 15 initial items met the consensus criteria. A lack of consensus was recorded for the Website design subdimension. The panel also identified some overlapping items (Website design/Ease of Use) and (Waiting time/Accessibility), indicating the need to reevaluate those subdimensions for Round 2.

Value: Results from Round 1 are encouraging in suggesting that a majority of the items will achieve consensus and the overall scale significant content validity. To the best of the authors' knowledge, this study is the first to aim at gaining consensus on a set of service quality for DTC telemedicine consultations.

Keywords: Direct-to-Customer (DTC) telemedicine, Service quality, Scale validation, Delphi study.

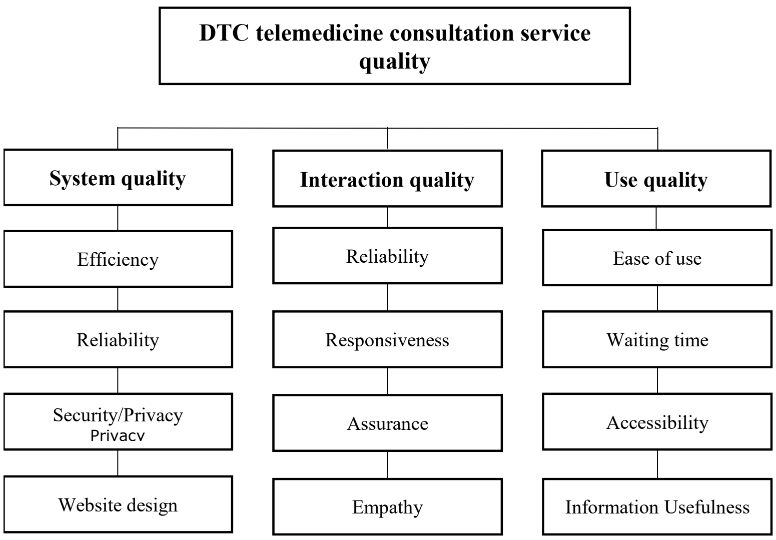
INTRODUCTION

Direct-to-consumer (DTC) telemedicine can be defined as *"the delivery of health care services through the use of information and communications technology (ICTs), where patients initiate the care and patients and healthcare professionals are separated by distance for the treatment of mainly low-acuity conditions"*(Preaux, Casadesús and Bernardo, 2023, p. 3). In other words, it enables the provision of on-demand online medical consultation services to patients.

Although service quality in the health industry (Fatima *et al.*, 2019) and online sector (Ladhari, 2010) has been extensively investigated, there has been little research done to measure e-health service quality in the context of DTC telemedicine consultation (Preaux, Casadesús and Bernardo, 2023). Thus, the creation of a new conceptual industry-specific service quality model by the authors to support DTC telemedicine providers in understanding whether their service meets the needs of the patients using it (Juran *et al.*, 1999).

Service quality (SQ) in general, and its conceptualization and measurement in particular, have been considerably explored since the 1980s. The best-known scale to measure service quality which has been used across a wide range of service industries is SERVQUAL (Parasuraman, Zeithaml and Berry, 1988). Based on the disconfirmation paradigm which originated from the customer satisfaction literature, SERVQUAL measures the customer´s perceived service quality by confronting the customer´s perceptions and expectations of a service (Parasuraman, Zeithaml and Berry, 1985). According to Parasuraman et al., 5 generic service dimensions are essential and influence how customers evaluate service quality, namely, tangibles, reliability, responsiveness, assurance, and empathy (Parasuraman, Zeithaml and Berry, 1988). Despite the extensive use of the SERVQUAL multi-dimensional service quality model, the instrument has been criticized (Martínez and Martínez, 2010). Some authors have for example argued that service quality was not only multi-dimensional but also multileveled to reflect the complexity of the service quality evaluation process (inclusion of primary and sub-dimensions of service) (Dabholkar, Thorpe and Rentz, 1996; Brady and Cronin, 2001). In addition, others advised against the use of a single universal scale across all service industries and advocated for the creation of industry-specific service quality models (Carman, 1990; Philip and Hazlett, 1997). The literature indicates service quality measurement instruments need to be sector specific (composed of industry-specific service dimensions) in order to properly assess and understand the customer perception of service quality. For example, service dimensions that may be valid for the measurement of service quality in the hospitality or banking sector may not be equality relevant to the healthcare industry. Hence, the development over the decades of several health service quality models. Among them, (Zineldin, 2006) created the 5Qs model and uncovered 5 dimensions of health service quality: quality of object (technical quality), quality of process (functional quality), quality of infrastructure (hospital resources), quality of interaction (doctor/patient communication), and quality of atmosphere (hospital environment). (Aagja and Garg, 2010) proposed PubHosQual with five dimensions, admission, medical service, overall service, discharge process, and social responsibility. to measure patient's perceived SQ for public hospitals. In 2017, (Lee, 2017) developed HEALTHQUAL to measure healthcare SQ and identified 5 dimensions : empathy, tangibles, safety, efficiency, and degree of improvements of care service. With the development of information and communications technology, a digital transformation of the health sector occurred and a technological growth in e-health services was observed. To measure quality of e-healthcare services, (Hadwich et al., 2010) identified three primary dimensions: potential quality, process quality, and outcome quality. In 2014, (Lerouge, Garfield and Hevner, 2014) proposed a hierarchical model to measure telemedicine SQ with 4 dimensions, namely: system, information, service, and use quality attributes.

In view of the foregoing, a review of models related to health, e-service, and e-health service quality was conducted during Jan-Dec 2021 and led to the identification of 12 subdimensions of DTC telemedicine consultation services, classified under 3 primary dimensions (system, interaction and use quality) (Preaux, Casadesús and Bernardo, 2023) (see Figure 1).



Source: (Preaux, Casadesús and Bernardo, 2023)

Figure 1 - Proposed conceptual service quality model for DTC telemedicine consultation (dimensions and subdimensions)

The purpose of the study is to refine and validate the conceptual model by establishing consensus among the stakeholders involved in the teleconsultation on the service dimensions to measure service quality of DTC telemedicine consultation.

MATERIALS AND METHODS

Phase one: Study design and expert selection

To develop consensus and validate the model, the Delphi method was selected. It is a popular interactive and iterative technique to build consensus on a topic by collecting the opinions of a panel and which allows participants to revise their initial judgments upon receipt of the aggregated position or feedback of the group (Linstone and Turoff, 1975; Hasson, Keeney and McKenna, 2000; Landeta, 2006). The authors relied on published practical Delphi guidelines to ensure the relevancy of the results (Boulkedid *et al.*, 2011; Diamond *et al.*, 2014). This consists of a clear indication of the study objective, a meaningful panel composition, and a clear definition of consensus and criteria to include an item, defined a priori (Boulkedid *et al.*, 2011; Diamond *et al.*, 2014; Preaux, Casadesús and Bernardo, 2022).

In line with (Upadhyai *et al.*, 2021) Delphi study to validate a hospital service quality model, 10 patients, 10 teleconsultants, and 3 service quality academics were invited to participate in the survey to get both feedback from the caregivers and care receivers (Ziglio, 1996). All participants were required to (1) be fluent English readers and (2) be aged over 18 years old. For the patients and teleconsultants, purposive sampling was used to ensure:

- Patients had at least one teleconsultation in the previous 12 months.
- Medical practitioners had at least 1 year of experience as a teleconsultant.

While some Delphi surveys invite participants to brainstorm on a topic and generate inputs and information as the starting point of the investigation, in this study the panel will be requested to share their opinion and add their inputs on the conceptual model that originated from a previous targeted literature review. The protocol for this Delphi study was presented at the 5th International Conference on Quality Engineering and Management in July 2022 (see Figure 2 for the Delphi design and progression).

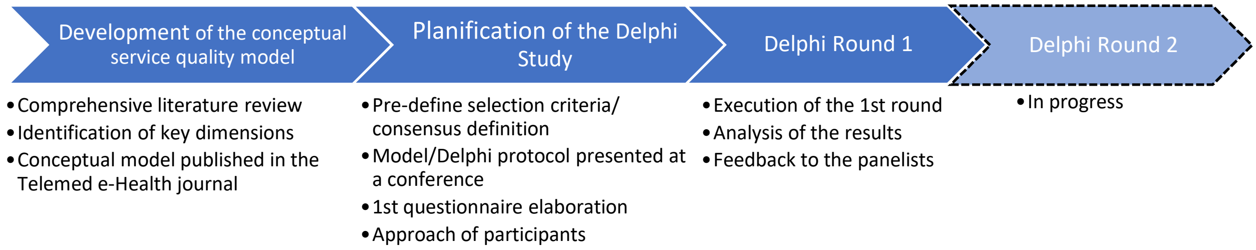


Figure 2 - Delphi design and progression

Phase two: Survey process and a priori consensus criteria

A maximum of 4 rounds will be held with the purpose of reaching consensus. Several drafts of the questionnaire were tested a priori among the research team, and successive modifications made to optimize its clarity. The study protocol was approved by the Ethical Committee of the University of Barcelona on 31/05/2023. To ensure confidentiality, all collected data was aggregated and anonymized. Microsoft Forms was used to develop the survey, and the link to the 1st online questionnaires was distributed by email. Reminder emails were sent to non-respondents every 7 days to encourage the questionnaire completion.

For each Delphi round, the panelists will rate on a 5-point Likert scale (with 1 being the lowest level and 5 the highest):

- their level of agreement that each dimension significantly and positively impacts patients perceived service quality of telemedicine consultations (with 1= strongly disagree; 2= disagree; 3=neutral; 4= agree; 5= strongly agree).
- the degree of relevance of the subdimensions for the measurement of the primary dimensions in order to test the scale content validity (with 1 = absolutely irrelevant; 2 = not relevant; 3=neutral; 4=relevant; 5 =highly relevant).

For all ratings, the panel was encouraged to justify their responses (free-text boxes). During the first round, participants were also invited to suggest additional service dimensions *(Is there a component of service quality that you believe has been missed in this model?)* and ways to simplify the model (*Is there any way that you would suggest simplifying the existing model or any of its components?*).

As recommended by published practical Delphi guidelines, consensus criteria for inclusion of an item into the final framework were defined a priori (Boulkedid *et al.*, 2011; Diamond *et al.*, 2014) and developed by a two-step process. First, in line with other studies, at least 70% of the participants must agree or strongly agree that an item should be included, and the group interquartile score equals or falls below 1.0 (Mao, Loke and Hu, 2020). Secondly, the scale content validity is calculated per item and any I-CVI of 0.78 or higher would be considered statistically significant (Mao, Loke and Hu, 2020). Ratings of 1 or 2 are combined as not relevant and ratings of 4 or 5 as relevant (Upadhyai *et al.*, 2021). Scale developers are expected to test and provide evidence that their instrument has good content validity. Content validation is a crucial element of the instruments development process as it measures "*the degree to which a scale has an appropriate sample of items to represent the construct of interest—that is, whether the domain of content for the construct is adequately represented by the items*" (Polit, Beck and Owen, 2007, p. 3). There are different methods to assess content validity and the index of content validity (CVI) is the one used in this study.

Thus, items that reach the pre-established cut-off (interquartile score of 1 or less, minimum of >70% of participants with a level of agreement ≥ 4 and an I-CVI of 0.78 or above) after 2 rounds are included in the final framework.

Table 1 – Definitions of the primary dimensions and their subdimensions

Dimensions	Subdimensions	Definition	
System quality The patient's perception of the website technology quality/ characteristics enabling the telecommunication between the parties.	*Efficiency*	*The degree to which the DTC telemedicine platform is:*	easy to access and provide fast-loading, processing time to support information sharing (sound quality and image resolution).
	Reliability		dependable over time, functions as designed to perform the promised service accurately and consistently.
	Security/Privacy		safe and protects the health information provided to and by the patients.
	Website design		easy to use and aesthetic due to its clear layout and visually pleasing design.
Interaction quality The patient's perceived quality of interaction with the doctor	*Reliability*	*The patient's perception of the doctor:*	delivering the promised service in an accurate and dependable manner.
	Responsiveness		being willing to assist and help him promptly.
	Assurance		inspiring confidence by demonstrating courtesy, expertise and ability.
	Empathy		focusing on his best interest and showing personal attention.
Use quality The patient's perceived efficient and informed usage of communication, service management and technology to achieve the desired outcome.	*Ease of use*	*The patient's perceived:*	ease of understanding and operating the technology and all website, consultation features.
	Waiting time		timeliness to connect to a doctor
	Accessibility		ability to connect to a doctor at anytime ability from anywhere
	Information Usefulness		quality of information received during and at the end of the remote consultation.

Source: (Preaux, Casadesús and Bernardo, 2023)

Round 1 was conducted in November-December 2023, and along with the first online questionnaire, each participant received an introduction letter outlining the aim of the study, a short video presentation of the model and its components (definition of primary and subdimensions) (see Table 1), and an explanation of the Delphi process.

FINDINGS

The main objective of this study is to establish consensus among the stakeholders involved in teleconsultations on the service dimensions to measure service quality of DTC telemedicine consultation. The authors initially developed a conceptual service quality model consisting of 3 primary dimensions (system quality, interaction quality and use quality) and 12 subdimensions. All service dimensions were identified a priori through a comprehensive literature review. This study used a Delphi consensus approach to refine and validate the conceptual model.

Table 2 – Delphi participants' profile

	Teleconsultants	Patients	Academics
Number of participants	6	10	3
Gender			
Male	3	3	3
Female	3	7	-
Age (yrs)			
20-30	1	6	-
31-40	2	1	-
41-50	2	1	2
51-60	1	2	-
>60	-	-	1
Country of residence:			
Indonesia	-	1	-
Italy	-	1	1
Philippines	1	-	-
Spain	2	7	2
UK	-	1	-
USA	3	-	-
Avg Work experience (yrs)	4.7 years	***	***
Recency of latest teleconsultation (months)			
<3	***	7	***
4-6	***	3	***
>6	***	-	***
Number of teleconsultations over the past year			
1-3	***	4	***
4-6	***	3	***
7-9	***	2	***
>10	***	1	***

Out of the twenty-three panelists who were invited to participate, nineteen panelists (6 doctors, 10 patients, and 3 academics) completed Round 1 (a 82.6% response rate). Panelist characteristics are summarized in Table 2. For this Delphi study, a minimum of two rounds is needed to ascertain whether items meet the pre-established consensus criteria. The preliminary results reported after the first Delphi round (see Table 3) are promising, as all 15 items but one (Website design) met the consensus criteria (inter-quartile score of 1 or less, a minimum of >70% of participants with a level of agreement ≥ 4 and an I-CVI of 0.78 or above).

The "Interaction quality" primary dimension and its subdimensions achieved the highest level of agreement (between 89.5 and 94.7%), I-CVI score (0.95 for all items), and the lowest interquartile range (between 0 and 0.50). In addition, the "Reliability", "Responsiveness", "Assurance" and "Empathy" subdimensions have also secured the largest percentage of panelists strongly agreeing with their impact on service quality. Other items, "Security/Privacy" (89.5%, IQR 0.50), "Waiting time" (88.9%, IQR 0.50), and "Information Usefulness" (94.8%, IQR 1), also reached an important consensus level.

While the "Website design" subdimension obtained a score ≥ 4 in 73.7% of the panelists and an I-CVI score above 0.78, the interquartile range was above 1 (1.50), indicating more variability and a greater lack of consensus for this item. Participants suggested that if the aesthetic of a website can be pleasant for patients, its impact on service quality is lower than other dimensions identified in the model. Those lowest scores are supported by additional remarks from the panel pointing out some overlaps between the "Website design" and "Ease of Use" dimensions. Feedback from the panel indicates those dimensions could be combined to reflect both the aesthetic and the user-friendliness of the platform, thanks to its well-organized, designed, and intuitive architecture.

Similar remarks were formulated on the "Waiting time" and "Accessibility" dimensions. To simplify the model, participants recommended to combine those overlapping components. The following two items ("Website design" and "Accessibility") are consequently the ones with the lowest level of agreement, median, and I-CVI score and/or largest interquartile range. Thus, the need for the research team to reevaluate those items and build upon this feedback in Round 2 to improve the overall reliability of the scale.

Finally, participants also suggested additional service dimensions to be included in the second-round survey. The first new dimension could be categorized under the term "website features" to improve the overall user/patient experience, such as easy appointment scheduling, payment processing, and notification, prescription management. The second one, “connectivity”, involves all wearable medical devices or medical information/history that can be linked to the platform or sent to the physician to enhance remote health care. The last suggested dimension, “continuity of care”, focuses on the telemedicine provider´s ability to ensure a smooth transition and effective follow-up between virtual consultations and in-person care.

Table 3 – The level of agreement, median, interquartile range, and I-CVI of items in the first Delphi round.

The below items positively and significantly impact perceived service quality of DTC telemedicine consultation….	Round 1								
	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Agree*	Disagree†	Median (IQR)	I-CVI
1. System quality	5.3%	0%	15.8%	5.3%	73.7%	**79%**	5.3%	5 (**0.50**)	**0.89**
1.1. Efficiency	5.3%	0%	10.5%	26.3%	57.9%	**84.2%**	5.3%	5 (**1**)	**0.89**
1.2. Reliability	0%	0%	15.8%	21.1%	63.2%	**85.3%**	0%	5 (**1**)	**0.95**
1.3. Security/privacy	5.3%	0%	5.3%	15.8%	73.7%	**89.5%**	5.3%	5 (**0.50**)	**0.89**
1.4. Website design	5.3%	0%	21.1%	26.3%	47.4%	**73.7%**	5.3%	4 (1.50)	**0.84**
2. Interaction quality	5.3%	0%	5.3%	0%	89.5%	**89.5%**	5.3%	5 (**0**)	**0.95**
2.1. Reliability	0%	0%	5.3%	10.5%	84.2%	**94.7%**	0%	5 (**0**)	**0.95**
2.2. Responsiveness	0%	5.3%	5.3%	15.8%	73.7%	**89.5%**	5.3%	5 (**0.50**)	**0.95**
2.3. Assurance	0%	0%	5.3%	15.8%	78.9%	**94.7%**	0%	5 (**0**)	**0.95**
2.4. Empathy	0%	0%	5.3%	0%	94.7%	**94.7%**	0%	5 (**0**)	**0.95**
3. Use quality	5.3%	0%	5.3%	21.1%	68.4%	**89.5%**	5.3%	5 (**1**)	**0.95**
3.1. Ease of use	0%	0%	10.5%	21.1%	68.4%	**89.5%**	0%	5 (**1**)	**0.89**
3.2. Waiting time	0%	5.3%	5.3%	15.8%	73.7%	**88.9%**	5.3%	5 (**0.50**)	**0.84**
3.3. Accessibility	0%	5.3%	15.8%	31.6%	47.4%	**79%**	5.3%	4 (**1**)	**0.79**
3.4. Information usefulness	0%	0%	5.3%	31.6%	63.2%	**94.8%**	0%	5 (**1**)	**0.95**

% in bold serves to highlight 70% consensus was achieved; *Agreement ≥ 4 (Agree or Strongly agree); †Disagreement ≤ 2 (Disagree or Strongly disagree).

Strengths and limitations

This study, as with any research, has a number of strengths and limitations. First, the use of the Delphi technique allowed participants to anonymously express their opinions freely (influence of dominant personalities reduced (Landeta, 2006), no fear of embarrassment (Linstone and Turoff, 1975)). Additionally, the absence of physical scheduled meetings enables the research team to include participants from different continents to permit a consortium of perspectives on the topic being discussed.

On the other hand, several limitations need to be acknowledged. In fact, the Delphi technique is often criticized for its lack of scientific robustness (inconsistent approach in defining and measuring consensus (Boulkedid *et al.*, 2011). While academics recognize Delphi findings have value to gain insights where empirical evidence is sparse, the validity and credibility of consensus studies remain disputed (Powell, 2003). To address those weaknesses, a rigorous protocol to conduct this Delphi study was created and documented. It consisted of a clear indication of the study objective, a meaningful panel composition, and a clear definition of consensus defined a priori (Preaux, Casadesús and Bernardo, 2022).

Finally, although purposive sampling was used to recruit patients and doctors worldwide and who used/work for different telemedicine providers, the opinions of the participants in this study may not be representative of all patients/telemedicine consultants. The purpose of the study is to create a universal service quality model for Direct-to-Consumer telemedicine consultation that can be used globally by DTC telemedicine providers. While the study aimed at collecting opinions from a wide range of cultural backgrounds, no participants from Africa, South America, the Middle East, and Oceania were involved.

CONCLUSION

The service management literature suggests health services organizations should seek to deliver high service quality as it positively impacts patient satisfaction (Bowers, Swan and Koehler, 1994; Choi *et al.*, 2005; Dagger, Sweeney and Johnson, 2007), loyalty (Kesuma *et al.*, 2013; Fatima, Malik and Shabbir, 2018), behavioral intentions (Dagger, Sweeney and Johnson, 2007; Amin and Zahora Nasharuddin, 2013); and conversely, may lead to patient losses when service quality is deficient (Pohwah, Pui-Mun and Dhanjoo, 2006). However, there is a lack of consensus on the measurement and conceptualization of service quality (Brady and Cronin, 2001).

Thus, the aim of this study, through the Delphi method, is to validate which service dimensions patients consider when assessing service quality of DTC telemedicine consultations.

Following the 1st round of rating, the results reported here are encouraging in suggesting that a majority of the initial dimensions and sub-dimensions will achieve consensus and the overall scale significant content validity. Given this, this research can provide valuable insights and direction for

DTC telemedicine providers, academia, and others who are looking to understand, monitor, and improve the quality of teleconsultation services delivered to patients.

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Quality Management strategies for small-scale 3D printing

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STRUCTURED ABSTRACT

Purpose – The article aims to discuss the importance of implementing quality strategies in small-scale FDM 3D printing.

Approach – For creating a ground base study, the approach is mainly focused on the basics of the FDM 3D printing process, good practices and failure avoidance.

Findings – Through the scientific literature there are studies regarding risks encountered through the process, the influence of equipment and printing parameters on the part properties and improvements of the quality of resulted products. Moreover, the 3D printing community is contributing too, with information, practical examples and discussions on topics of interest.

Research limitations/implications – As stated in the purpose, the environment is a small-scale one, so the budget and resources are limited.

Practical implications – The article highlights the main principles of FDM 3D printing and provides a structured set of quality strategies that must be addressed throughout the process to increase the manufacturing quality.

Social implications – Socially, the adoption of quality management strategies empowers small businesses and hobbyists to provide efficient custom services while encouraging innovation despite resource limitations.

Originality/value – Despite the numerous studies found in the scientific libraries, the literature primarily focuses on large-budget industries, as well as on the development of additive manufacturing technologies and new material options, this article addresses the needs of the small-scale segment of the industry, opening new perspectives for desktop 3D printer users.

Keywords: FDM 3D printing, 3D printing quality management, small-scale 3D printing, 3D printing optimization.

Paper type: General review.

INTRODUCTION

Importance of quality management strategies into small-scale FDM 3D printing

Additive manufacturing, in particular Fused Deposition Modeling (FDM) 3D printing, has revolutionized the industry of prototyping and small-scale production. This technology is utilizing thermoplastic filaments that are heated to a fluid melting point and extruded layer by layer to create three-dimensional objects. FDM 3D printing is characterized by accessibility, affordability and versatility making it a popular choice for hobbyists and small-scale producers, empowering their capabilities of bringing ideas to life with unprecedented ease. (Zapciu and Constantin, 2021)(Jianu et al., 2020)

In recent years, FDM 3D printing has shifted its initial role as a rapid prototyping tool, evolving into a viable solution for low-volume production and customized manufacturing technology. Despite these newly discovered possibilities, this opportunity comes with the responsibility of upholding quality standards and ensuring the reliability of 3D printed products. (Lait et al., 2017)

Taking in account the fact that most of these hobbyist and small-scale producers don't benefit of a large budget, development of a set of tailored quality management practices that can be easily implemented into the manufacturing process, from design and material selection to 3D printing optimization and post-processing is needed. For these users to adopt good methodologies, the practices should be Do It Yourself (DIY) and accessible so that the manufacturers can implement them easily and deliver products that meet and exceed customer expectations. (Antić et al., 2023)

Moreover, the development and adoption of quality management principles not only enhances the reputation and credibility of individuals and businesses operating in the 3D printing sector, but also contributes to the overall improvement and advancement of the industry. Implementing standardized quality protocols, sharing best practices, and embracing a continuous improvement mindset, hobbyists and small producers can elevate the quality benchmark for FDM 3D printing. (Ciocoiu and Ilie, 2010)

Basic understanding of FDM technology

To begin thinking of quality management strategies, at first the basics of FDM 3D printing concepts must be understood together with the functioning mode of a FDM 3D printer.

The manufacturing of a 3D printed object starts from the idea, transposed into a brief blueprint that is followed by adding dimensions that respect the requirements of the part. At this point the material is chosen for the specific application. Once the blueprint is finished, it is modeled into a digital 3D object using a CAD (computer aided design) software and the resulted file is exported in .STL format (STL – Stereolithography – "language" that the 3D printer reads). This .STL file is afterwards imported into a slicer software where the printing parameters are established. From this slicer software a .gcode (file extension for 3D printers) file is resulted for the 3D printer. The equipment is checked and prepared so that the 3D manufacturing can begin. After the 3D printer is finished the resulted object gets through a couple post processing stages to have an end product. (Jianu et al., 2020)

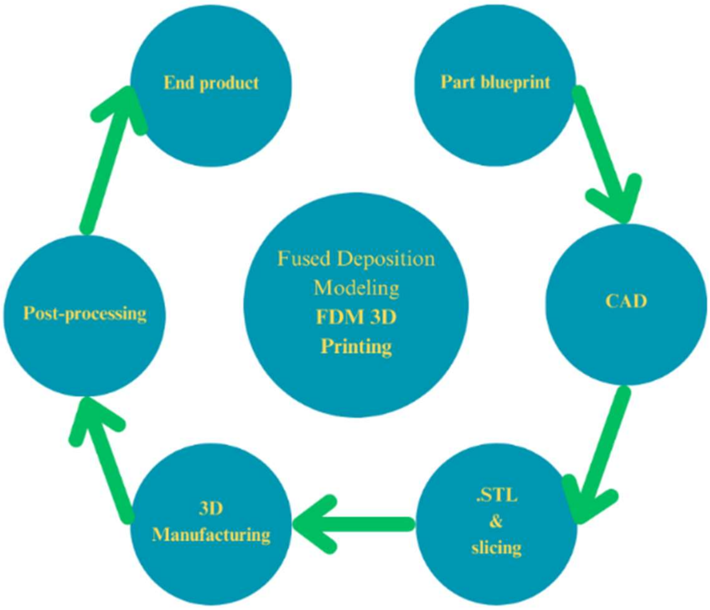

Figure 1 - FDM 3D printing process diagram

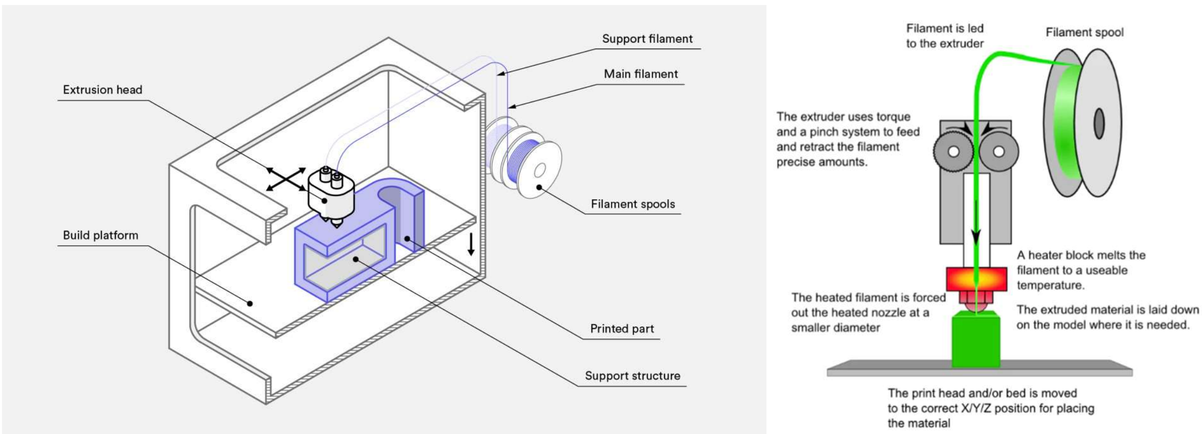

Figure 2 - FDM 3D printer components

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Quality management strategies (6M Ishikawa diagram)

In the following paragraphs a quality management strategy will be detailed listing the procedures and good practices that must be implemented throughout the process from part request to end product. These quality strategies will be followed by the actual manufacturing of the part, to ensure and prove that by implementing these practices, the end result will be satisfying.

The basis of the quality management strategies for FDM 3D printing is the Ishikawa diagram, that was designed to prevent the potential factors that are causing an overall effect. For this case study, regarding the manufacturing of a 3D printed object the 6M model will be used, addressing "manpower", "machine", "material", "method" (process), "measurement" and "medium" (environment). (Ciocoiu and Ilie, 2010)(Agrawal, 2023)

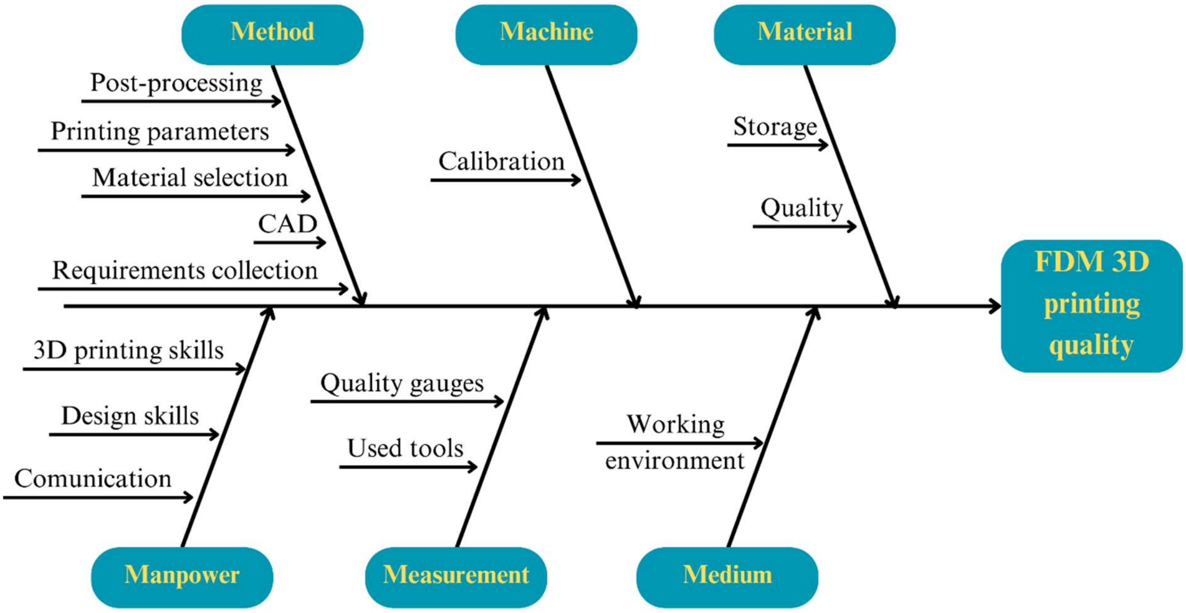

Figure 3 - 6M Ishikawa diagram for FDM 3D printing

It is important to understand that most of the causes presented are linked together, depending on one another, and despite their representation in the Ishikawa diagram split in the 6M's, throughout the quality strategies implementation they might be addressed differently, based on the order of the steps of the 3D printing process.

Table 1 – Ishikawa good practices for FDM 3D printing

6M Ishikawa	Cause	Good practices
Manpower (Antić, 2023)	Communication	Structured protocols; regular update meetings; communication trainings; open communication environment.
	Design skills	Specific 3D printing design trainings; access to design software/tools; collaboration; continuous development.
	3D printing skills	Trainings on operation, maintenance and safety; standardized procedures; regular competency assessments; knowledge sharing culture.
Method (Parada et al., 2019) (Zapciu and Constantin, 2021) (Sawant et al., 2023)	Requirements collection	Systematic data collection; standardized templates; regular reviews and updates.
	CAD (computer aided design)	Standardized design rules; CAD software training; version saved designs in libraries.
	Material selection	Research and testing; selection matrices; approved materials databases.
	Printing parameters	Standardized parameters; settings optimization; documented parameters.
	Post-processing	Standardized techniques; training on methods and safety; quality control checks.
Machine (Kun, 2016)	Equipment calibration	Regularly schedule; documented records; training.
Measurement (Sawant et al., 2023)	Quality gauges	Standardized tests; documented records.
	Measuring tools	Handling, storage and maintenance procedures; tool inspection and inventory management.
Material (POPA et al., 2024) (Milovanović et al., 2024) (Nagaraju et al., 2023)	Storage	Controlled storage areas; labeling inventory system; regular inspections; first in first out management.
	Quality	Supplier research; documented performance monitoring.
Medium (Antić et al., 2023)	Working environment	Clean and organized workspace; waste management protocols; safety inspections.

In retrospect, the FDM 3D printing process is complex and involves many factors that can interfere with the end product. Most of the defects can be mitigated by following this set of quality strategies, but each fault can have its specific cause that can be identified easily following the process backwards, from where it failed to the beginning and addressing the problem directly or the cause might be unknown, and the identification process requires a trial-and-error procedure to deep dive at the core of the problem. (Agrawal, 2023)

By following the quality management strategies presented previously, the failures during the process are minimized and the overall quality of the manufactured parts is enhanced.

RESEARCH METHODOLOGY

The information in this article were structured in 2 sections, a theoretical discussion of quality management strategies developed by using an Ishikawa diagram, followed by the implementation of good practices in the manufacturing process of a given product.

As discussed in the introduction, the production environment is a low budget one, so the strategies were developed to be implemented DIY easily by anyone.

Implementation of quality management strategies

Human factor (Ishikawa – Manpower)

Considering that the producer has a decent amount of knowledge about FDM 3D printing, being able to collect product requirements and communicate possibilities and limitations, 3D design, operate the equipment, handle the material, post process, the following quality strategies were implemented to achieve a satisfying end product.

3D printer calibration (Ishikawa – Machine)

The quality of each manufactured product relies at first on the capability of the equipment that is 3D printing so to assure a satisfactory production the 3D printer is prepared for proper functioning.

The calibration process refers to:

- checking the sturdiness of the gantry by checking that all the bolts are tight;
- carrier belts that allow movement on the axis are tensioned;
- electrical connection
- moving parts are working smoothly;
- material flow is unrestricted;

- nozzle and printing surface are heating properly;
- the printing surface is aligned with the nozzle.

Material testing (Ishikawa – Material)

It is recommended to use only materials from certified producers validated by quality standards and tested by the 3D printing community. Usually, a certified material (filament) producer will provide a technical datasheet with useful information regarding properties, printing parameters and storage.

Each material comes with recommended printing parameters that serve as ground base for tests that will reveal the optimal settings for specific material and machine pair.

These tests consist of:

- printing surface adhesion (test performed by printing on layer of material on the 4 corners and the center of the printing surface);
- flow calibration (test that determines the amount of material that has to be pushed through the nozzle so that the printed wall to match the set dimension);
- temperature test (geometrical sections printed one on top of the other at different temperatures);
- retraction test (test performed to establish at what distance and speed the filament must be retracted when the nozzle moves from one printing area to another);
- speed test (test that establishes what is the optimal printing speed for the specific material).

For better testing and more accurate results these tests can be performed a couple of times trying different combinations of settings that are obtained after each individual test. One final test that can be performed is a XYZ cube (20mm side) which is made to check dimensional accuracy and surface quality on all axis.

CAD, STL slicing and post-processing (Ishikawa – Method)

Designing parts for FDM 3D printing imply understanding the manufacturing limitations, first of all, taking in account that the part requires a flat surface that will serve as base on the printing surface, the 2nd consideration must be a low amount of hanging geometries that will require support structures and a 3rd factor is the thin wall dimensions that must not go bellow the value of wall thickness.

A properly designed model requires consideration of the position in which the part will be printed. This position is made in accordance with the strength requirements of the part knowing that the length of layers is much more resistant to fracturing than layer over layer geometry which offers more resilience at sustaining weight.

With the 3D model designed, and the optimal printing parameters resulted from material testing the 3D printing slicing settings are established in accordance with the parts requirements to obtain the .gcode file that will be introduced into the equipment for 3D manufacturing.

At the end of the 3D printing manufacturing the part is removed from the printing surface and the producer post process the part removing the support structures if it's the case and by using manual or motorized sanding paper or files, the producer rectifies rough surfaces.

Quality control (Ishikawa – Measurement)

The quality of a 3D manufactured part is determined by analyzing dimensional accuracy, aesthetics, functionality. To measure the dimensional accuracy in this low budget context, the traditional tools are used such as rulers and calipers. For the aesthetics of the product a visual inspection is performed, at first to see if the aspect is satisfying and afterwards the part is compared to the quality gauges that are the successful results of the previous material testing. The functionality is checked by assembling the part in the intended location to see if it fits.

To assure proper quality control the used tools must be calibrated regularly and to keep a documented record of service information.

Working environment (Ishikawa – Medium)

The entire 3D printing process requires attentive handling and clean and organized working environments. Each interference in the process can produce a failure so that is mandatory to work in a ventilated, dust free environment with a stable temperature that minimizes humidity.

For safety reasons the workspace must be organized due to sensitive or sharp tools used in the process and equipment must be attentively handled and inspected due to its highly operating temperatures.

RESULTS

By following these quality strategies, the part that was intended for manufacturing was produced successfully. Throughout the 3D printing process each step was addressed according to the information provided above and the product resulted can be seen in the below figure.

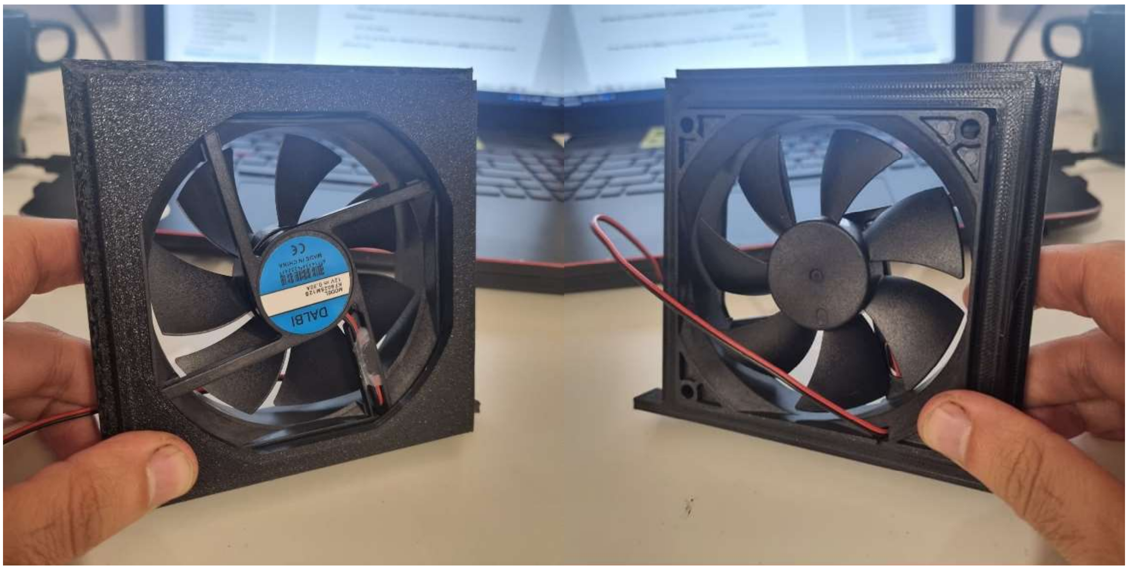

Figure 4 – Manufactured part

CONCLUSIONS

In small-scale FDM 3D printing environment failures can be encountered often due to lack of resources and rigorous quality controls seen in larger manufacturing settings. However, the introduction of quality management strategies is crucial to ensure a consistent and reliable process. This does not only enhance product quality but also raises customer satisfaction and trust in using products manufactured by 3D printing.

In this article there were discussed several key quality management strategies fit for specifical needs of small scale FDM 3D printing. These strategies include meticulous material testing, calibration and maintenance of printers, rigorous process monitoring, thorough post-processing techniques, and ongoing staff training. Implementing these strategies can significantly mitigate common quality issues associated with FDM printing.

This article serves as a guideline of how quality management strategies can influence small-scale FDM 3D printing settings. By meticulously following the outlined strategies, the manufacturing of high-quality FDM 3D printed parts, with minimal defects and deviations from the desired specifications can be achieved.

Through the adoption of quality management strategies, small-scale FDM 3D printing businesses can achieve consistent quality and reliability in their output. This is essential for meeting customer expectations, reducing waste, and ultimately enhancing competitiveness in the market.

Quality management in small-scale 3D printing is not a one-time effort but a continuous journey of improvement. It requires a commitment to ongoing monitoring, evaluation, and refinement of processes to adapt to changing technologies, materials, and customer requirements.

As 3D printing technology continues to evolve, there will be further opportunities to enhance quality management strategies in small-scale FDM printing. This may include the integration of advanced monitoring and control systems, the development of new materials with improved properties, and the implementation of automated quality assurance processes.

In conclusion, by prioritizing quality management strategies in small scale FDM 3D printing, users can achieve high results and reliability withing their restrictive budget.

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1. Teaching Tech 3D Printer Calibration (https://teachingtechyt.github.io/calibration.html) (last accessed at 28th of April 2024) – a good source of information regarding 3D printer calibration

2. CHEP @FilamentFriday YouTube channel (https://www.youtube.com/@FilamentFriday) (last accessed at 28th of April 2024) – helpful videos regarding 3D printers

3. All3DP (https://all3dp.com/2/how-to-calibrate-a-3d-printer-simply-explained/) (last accessed at 28th of April 2024) – a great source for information about 3D printing

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ANNEX I – DETAILED ISHIKAWA GOOD PRACTICES

MANPOWER

Communication

- Establish structured communication protocols within the team and with external stakeholders;

- Conduct regular meetings to facilitate information exchange and address project-related issues;
- Provide training on effective communication techniques and documentation standards;
- Cultivate an environment encouraging open communication and constructive feedback.

Design skills

- Offer targeted training programs focusing on design principles for manufacturability in 3D printing;
- Provide access to design software, tools, and resources for skill enhancement;
- Foster collaboration between designers and engineers to optimize designs for 3D printing;
- Encourage continuous professional development through participation in relevant courses and events.

3D printing skills

- Develop comprehensive training modules covering machine operation, maintenance, and safety protocols;
- Implement standardized operating procedures for consistent printing processes;
- Conduct regular competency assessments and provide targeted training as needed;
- Promote a culture of experimentation and knowledge sharing among operators.

METHOD

Requirements collection

- Employ systematic methods, such as interviews or surveys, to gather comprehensive requirements from requesters;

- Utilize standardized templates or checklists to ensure all relevant requirements are documented;
- Conduct regular reviews and updates of requirements throughout the project lifecycle to accommodate changes or new insights.

CAD

- Implement standardized CAD practices and templates to maintain consistency and efficiency in design;
- Provide training and support for CAD software to enhance proficiency among design team members;
- Establish version control mechanisms to manage design iterations and revisions effectively.

Material selection

- Conduct thorough research and testing to evaluate the suitability of materials for specific printing applications;
- Develop criteria or decision matrices to facilitate informed material selection based on performance requirements and cost considerations;
- Maintain a database or library of approved materials, along with their properties and performance characteristics;

Printing parameters

- Establish standardized printing parameters based on material properties, printer capabilities, and desired outcomes;
- Conduct calibration and optimization procedures to ensure consistent print quality and dimensional accuracy;

- Document printing parameters for each project or material type, including settings for layer height, infill density, print speed, etc. .

Post-processing

- Define standardized post-processing techniques to enhance surface finish, strength, and dimensional accuracy of printed parts;
- Provide training on post-processing methods and safety precautions for handling post-processing equipment and materials;
- Develop quality control checks to verify post-processing results and identify opportunities for improvement.

MACHINE

Equipment calibration

- Establish a regular calibration schedule based on manufacturer recommendations and industry standards;
- Document calibration procedures, including reference standards, measurement techniques, and acceptance criteria;
- Train designated personnel in calibration procedures and ensure competency through regular assessments;
- Maintain accurate records of calibration activities, including dates, results, and any adjustments made;
- Implement a system for tracking equipment status and scheduling future calibration activities to prevent lapses in calibration.

MEASUREMENT

Quality gauges

- Standardize the selection and use of quality gauges based on industry best practices and specific measurement requirements;
- Establish calibration procedures for quality gauges to ensure accuracy and reliability of measurements;
- Train personnel in the proper use and maintenance of quality gauges, emphasizing techniques for accurate and consistent measurements;
- Conduct regular inspections and verification checks of quality gauges to identify and address any deviations from calibration standards;
- Document gauge calibration and usage records to track performance over time and facilitate traceability in quality assurance processes.

Used tools

- Implement a tool management system to track the usage, condition, and calibration status of all tools used in the 3D printing process;
- Define standard operating procedures for tool handling, storage, and maintenance to ensure longevity and reliability;
- Provide training to operators on proper tool usage techniques and safety precautions to minimize the risk of errors or accidents;
- Conduct periodic inspections and preventative maintenance of tools to identify and address any signs of wear, damage, or deterioration;
- Maintain a comprehensive inventory of tools, including serial numbers, purchase dates, and maintenance history, to facilitate effective tool management and replacement planning.

MATERIAL

Storage

- Establish designated storage areas with controlled environmental conditions (e.g., temperature, humidity) to preserve material integrity;

- Implement proper labeling and inventory management systems to track material usage, expiration dates, and replenishment needs;
- Train personnel on proper handling procedures to prevent contamination, moisture absorption, or degradation of materials during storage and handling;
- Conduct regular inspections of stored materials to identify and address any signs of damage, spoilage, or deterioration;
- Rotate stock systematically to ensure FIFO (First In, First Out) inventory management and minimize the risk of using expired or degraded materials.

Quality

- Define quality specifications and acceptance criteria for materials based on performance requirements and industry standards;
- Establish supplier qualification processes to ensure the consistent quality and reliability of material sources;
- Implement incoming inspection procedures to verify material quality upon receipt, including visual checks, dimensional measurements, and material testing;
- Monitor material performance throughout the printing process, conducting periodic quality checks to detect any deviations or defects;
- Document material-related issues, such as defects, inconsistencies, or failures, and initiate corrective actions to address root causes and prevent recurrence.

MEDIUM

Working environment

- Maintain a clean and organized workspace conducive to safe and efficient operations;
- Establish protocols for housekeeping, waste management, and hazardous material handling to ensure compliance with health and safety regulations;

- Conduct regular inspections of the working environment to identify and address potential hazards, such as trip hazards, electrical risks, or chemical exposures;
- Provide appropriate personal protective equipment and training to employees to mitigate risks associated with the working environment;
- Promote a culture of safety awareness and proactive hazard reporting among all personnel to prevent accidents and injuries.

Risk management in a forensic genetic laboratory in the Central Region of Brazil

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STRUCTURED ABSTRACT

Purpose - Present how risk management was implemented in a forensic genetic laboratory in the Brazil.

Design/methodology/approach - The first stage was the identification of risks. A brainstorming session was conducted with the laboratory team to identify threats. The second stage involved organizing these threats into categories, ensuring that all items from the ISO/IEC 17025 standard were considered. The third stage involved prioritizing these risks. To determine the level and priority of risk in activities, threats were evaluated regarding their probability of occurrence and impact on results. An action plan to mitigate risk in the chain of custody of evidence was proposed.

Findings - Twelve risks were identified, including five low-level risks, five moderate-level risks, and one high-risk. Threats identified included impartiality risks, equipment malfunction, lack of supplies, contaminations, low proficiency testing performance, and chain of custody issues. Immediate actions were proposed for all of threats.

Research limitations/implications - The research was limited to one case of risk management implementation in the laboratory, not allowing generalization of results.

Social implications - There are implications for the laboratory team in which the case was applied, who can determine which activities require careful execution and how to manage problems during forensic activities, as well as allowing the method to support application in other laboratories.

Originality/value - The significance of the study is presenting a case of risk management in a forensic laboratory, which directly impacts in criminal investigation processes.

Keywords: ISO/IEC 17025, risk, Forensic laboratory, Brazil

Paper type: Case study.

INTRODUTION

Forensic science aims to provide objective and impartial scientific evidence for the criminal investigation process, enabling the elucidation of crimes, identification of perpetrators, and exoneration of suspects in order to assist the judicial system. Forensic laboratories are responsible for analyzing evidences, primarily collected at the crime scene and from victims' bodies (Houck et al., 2022). Among the various fields of forensic science, genetics has gained significant importance in recent years. Forensic genetics is the science that uses molecular biology techniques for criminal investigation and the search for missing persons (Ataide et al., 2023).

Ensuring the quality of results issued by forensic genetics laboratories is imperative, as errors in analyses can lead to errors throughout the justice system, including unjust convictions (McAndrew et al., 2023). Preventing errors in laboratory analyses and establishing actions in case of occurrences that minimize the impact generated is of paramount importance. Nevertheless, the third version of the ISO/IEC 17025 standard has included risk-based thinking. ISO/IEC 17025 is a specific standard for testing and calibration laboratories that brings competency requirements. Compliance with these requirements, which must be assessed by a competent external body, ensures the quality of the products and services generated. The standard requires the laboratory to consider the risks and opportunities associated with laboratory activities, aiming to ensure that the management system achieves the intended results, enhances opportunities to achieve purposes and objectives, prevents or reduces undesirable impacts and possible failures in activities, and achieves improvement. (ISO, 2017).

Risk management is fundamental for the continuous improvement of any quality management system, including forensic laboratories. It allows for the identification of threats that may adversely affect the quality of the service provided. These risks can be identified proactively by the team or after the occurrence of a problem that may or may not have caused a non-conformity (Heavey et al., 2023).

Understanding the importance of the topic, as well as the need to comply with the requirements of ISO/IEC 17025 to demonstrate the laboratory's competence, this study aimed to describe the implementation of the risk management process in a forensic genetic laboratory located in the state of Goiás, in the central region of Brazil.

RESEARCH METODOLOGHY

The risk management used in the work was that proposed in the ISO/IEC 31000:2018 standard, which includes risk identification, analysis, evaluation, treatment, monitoring, and review, as well as risk communication (ISO, 2018).

The risk management implementation process involved four stages. The first one was the identification of threats. A brainstorming session was conducted with the laboratory team to identify threats. The team comprises 32 people, covering all positions, including forensic experts, forensic assistants, administrative assistants, and interns. The brainstorming session was conducted by the quality manager, guided by the requirements of ISO/IEC 17025. For each item in the standard, the risks involved in the process of obtaining reliable results by the forensic laboratory were identified. Items 4, 5, 6, and 7 of the ISO/IEC 17025 were evaluated, which are related to impartiality, confidentiality, structure, resources, and processes. These items are directly associated with laboratory activities, which is the objective that ISO/IEC 17025 mandates for analysis.

The second stage involved organizing these risks into categories. The main risks identified during the brainstorming session were categorized by the processes involved. With this categorization, it became easier to identify the existing control measures in the laboratory and determine whether they are indeed effective. This organization was done to ensure that all items of the ISO/IEC 17025 standard were considered. They are: general requirements, structure, resources, process and management. After this categorization for better system organization, the risks identified by the team were evaluated by the laboratory management for their relevance and applicability. The primary basis for selecting the risks to be monitored was the previous occurrence of the event in routine operations or the difficulty in managing the activity or process. Thus, 12 risks were chosen as priorities for monitoring to control their occurrence. As the last step, immediate actions were proposed for all of threats. Figure 1 presents the summarized process.

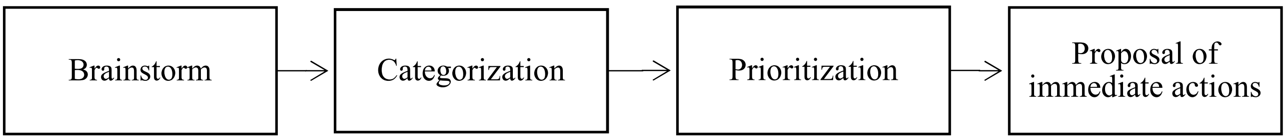
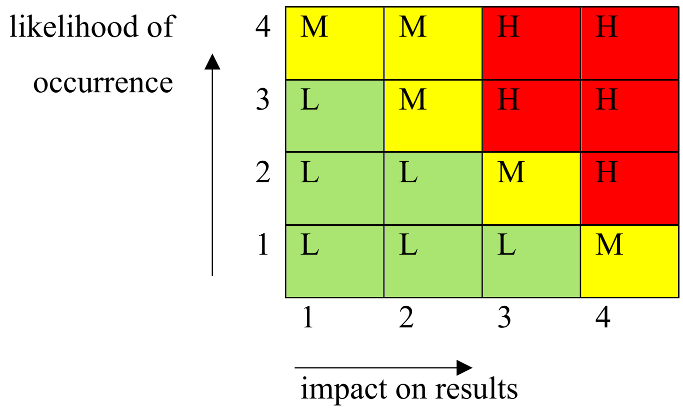


Figure 1. Method used for risk assessment.

The risks were evaluated regarding their likelihood of occurrence and impact on results to determine the level of risk in the laboratory's activities. Risks matrix used for evaluation risks and issue criteria represented in Figure 2.



Likelihood of occurrence	Description
1	Rare
2	Unlikely
3	Probable
4	Likely

Impact on results	Description
1	Minor
2	Moderate
3	Major
4	Severe

Risk level	Description
High	Must be treated
Medium	Should be treated
Low	Do not need to be treated

Figure 2. Risk matrix and issue criteria.

For the risk assessment, the laboratory team was reconvened. Based on group consensus, each of the twelve prioritized risks was evaluated according to their probability and impact on the results produced by the laboratory.

RESULTS

Risk assessment

As a result of the empirical research, twelve risks were identified, including five low-level risks, five moderate-level risks, and one high-risk.

Risks identified for the laboratory in the first stage included impartiality, equipment malfunction, lack of supplies, contaminations, low proficiency testing performance, and chain of custody issues. Chain of custody is chronological record of the handling and storage of an item from its point of collection to its final return or disposal. Chain of custody is one element that contributes to the integrity of an item (ISO, 2018). As a forensic laboratory, it is imperative to consider chain of custody errors as a threat due to their critical importance in the outcome products. The chain of custody should allow tracking of the entire history of the evidence, including records of possession, storage, and activities conducted.

As the last step, immediate actions and control mechanisms were proposed for all of threats (Table 1). The risks are continuously being reassessed concerning immediate actions in the event of occurrence and their risk level (likelihood of occurrence x impact on issued results). This evaluation of immediate actions is done continuously upon the event's occurrence. Meanwhile, risk level is review frequently based on observed occurrences and their impacts.

The research was limited to the risk management implementation process in the laboratory, requiring reassessments and continuous monitoring of actions and associated risk levels. The identified risks, control mechanisms, and actions in case of occurrence are presented in Table 1.

Table 1 - Risks identified in the Forensic Biology and DNA Laboratory

N.	Risks	Control Mechanisms	Immediate Actions
1	Forensic analyst acting with bias in an examination requested by themselves while being the responsible forensic expert at the crime scene in the past.	The involved forensic expert is prohibited from conducting and reviewing examinations in the laboratory.	Removal of the expert from the case
2	The expert fails to perform all internal quality assurance mechanisms before releasing the report.	Avoid direct communication between clients and the analyst expert responsible for the case. Refrain from disclosing analysis results before the report is released. Implement peer review.	Discontinuation of the analyses and returning the case for further review
3	Lack of reagents.	Inventory assessment and procurement planning at the beginning of the current year for the following year.	Notify immediate supervisor. Request loan from another laboratory Carry out emergency purchase. Halt analyses related to the missing reagent(s). Assign personnel to tasks unrelated to the use of the missing material
4	Error in custody records that may lead to the inability to locate the trace	Unique and unequivocal identification of traces.	Correct the accurate information on the packaging as soon as the error is identified.

N.	Risks	Control Mechanisms	Immediate Actions
	or sample in the custody unit.	Two-step identification (must contain at least two pieces of sample identification information).	
5	Storage of the sample in the wrong location leading to the inability to locate the trace or sample.	Organize the samples in sequential order according to their registration. Record simultaneously with the registration in the forensic system. Preferably, perform storage with double-checking.	Store in the correct location as soon as the error is identified. Inform coordination and quality management to decide on the next steps (examples: assess the possibility of conducting the examination with other samples from the case, possibility of new collection, etc.). Notify the client of the non-performance of the analysis for the sample not found.
6	Unqualified or unauthorized personnel performing an activity.	Training and capacity control through the Quality Management System. Evaluation before authorization is granted. Conducting competence monitoring through intralaboratory testing. Peer review of reports. Restriction of access to analysis software until competence.	Interruption of the analyst's activities.
7	Contamination.	Collection of DNA samples from laboratory staff, crime scene investigators, forensic physicians, and other personnel involved in evidence collection. Adherence to good laboratory practices. Biosafety guidelines. Proper sanitization of the environment and workbenches.	Investigation of the origin, cause, impact, and frequency to assess non-conformity treatment. Repeat the analyses whenever possible. Notify the stakeholders. Conduct cleaning and decontamination of the environment. Do not accept non-conforming work. Report the result without quality in the impossibility of rework.
8	Failures in refrigeration units.	Daily checking of the operation of custody units.	Relocation of samples or reagents to another custody unit. It is not possible to assess the damage of the malfunction on the samples, only on the reagents due to the lack of sample standards.

N.	Risks	Control Mechanisms	Immediate Actions
			In case of failures in units containing critical reagents, verify the stored reagents.
9	Failure in critical equipment.	Implementation of preventive and corrective maintenance contracts. Use of uninterruptible power supply (UPS).	Interruption of equipment activity until the assessment of non-conforming work is conducted.
10	Use of critical reagents and solutions that have not been verified.	Visual identification of verified and approved reagents and solutions.	Retention of results until assessment of non-conforming work.
11	Pipetting errors.	Automation and use of multichannel pipettes	Rework
12	Low performance in proficiency testing activities.	Testing conducted independently in pairs. Results reviewed by the technical supervisor.	Suspension of activities until a new evaluation with satisfactory results is conducted.

Action Plan

An action plan to mitigate risk in the chain of custody was proposed and is being implemented. The objective of the action plan is to reduce the likelihood of custody errors occurring. The action plan was: (1) automate the identification of traces, (2) acquire a new cold chamber to replace the existing freezers, and (3) change the procedure for forwarding traces so that they are packaged in definitive storage containers. This action plan was proposed by three team members, one of whom was the quality manager.

To automate the identification of traces (action 1), it was necessary to create a functionality in the sample and request management system. The system needed to have a tool for generating identification labels, containing a code and sample identification. It was also necessary to define which information could be printed and the ease of doing so.

To acquire a new and larger cold storage room (action 2), it was necessary to conduct a preliminary study and describe the product and service to be executed. It was required to define the space, the engineering service needed for installation and operation, technical study for the elaboration of the equipment description and acceptance criteria for the supplier, cost estimate, and impact on the involved activities. And finally, it was necessary to set up a bidding process for the public service.

To change the procedure for packaging the traces to be forwarded (action 3), it was necessary to convince the management to standardize the change as a forwarding requirement. In this sense, it was important to understand the experience of the requesting customer (crime scene investigator) in order to facilitate their adherence. It was also necessary to adapt these packages to the legal requirements in Brazil regarding the topic. It would be advisable to acquire samples for testing and evaluate their suitability for routine use before their definitive implementation.

For the implementation of these actions, the team requested a two-year period from the laboratory management. For the effectiveness assessment of the action plan, it is advisable for the laboratory to measure the quantity of custody errors identified and continuously monitor the process for a sufficient period to allow for this evaluation (at least one year).

To the discussion of work in the literature, we emphasize that laboratory activities were assessed based on the ISO/IEC 17025 standard. Since the risk approach should at least cover laboratory activities (according to the document itself), the standard can be used as a guide for this, as was done in this work. However, it is important that the monitoring of actions and control measures, as well as their reassessment, be done continuously (ISO, 2018). Furthermore, other risks should be identified over time, resulting from non-conformities, complaints, internal and external changes to the laboratory (ISO, 2017).

According to Santana and Loureiro (2022), implementing a risk-based thinking is more about creating a culture of prevention than just writing procedures. For a risk-based thinking to be effective, all individuals involved in laboratory activities need to reflect on the risks associated with each process. Everyone should have the ability to assess the potential risks involved and make the best decisions regarding their actions.

In this sense, the brainstorming session conducted in this study proved to be an interesting tool, as it allowed the entire laboratory team, with different roles, to identify the threats they consider in their activities that may affect the results, as well as the existing control measures and how to improve them. Actions like this help to create the risk mindset that ISO/IEC 17025 demands. After analyzing the level of each risk, the entire team was aware of each threat, control, and immediate actions in case one event related to the risks occurs.

A similar method to the one applied in the Forensic Biology and DNA Laboratory was also implemented in a laboratory at a public university in Brazil. In the study, the brainstorming technique, semi-structured interviews for risk analysis, and the probability x impact matrix tool for risk level assessment were used. In the article, the authors consider that the method was suitable for managing their risks, as it allowed the identification and execution of future actions necessary to mitigate or eliminate the risks. However, the authors considered that the risk matrix that evaluated probability x impact brought subjectivity to the interpretation of risk levels (da Silva et al., 2021).

The subjectivity that Silva et al., 2021 reported is inherent in any content analysis. It refers to personal feelings, the influence of opinions, individual perspectives, and interpretations of people on a particular topic (Cardoso et al., 2021). The view that a collaborator has on the impact of a risk occurrence will directly influence its level and, consequently, its treatment. To manage subjectivity in risk analysis, it is advisable to gather as many individuals as possible, performing different functions, to establish a common consensus in the laboratory. This was the strategy chosen in this work.

It's important to acknowledge this limitation of risk analysis: the employee's perspective on a particular threat. This limitation was also observed in this work. However, more important than a procedure and a risk management method is to cultivate a risk mindset within the organization's team. Identifying threats and predicting actions to control and minimize their effects should be part of the laboratory routine (Santana and Loureiro, 2022).

In a forensic environment, some inherent risks in its activities must be considered due to the importance in producing forensic evidence. Threats involving the chain of custody of evidence are of great importance and should be considered in risk management in a forensic laboratory. Chain of custody failures can invalidate forensic evidence within the justice system (Wilson et al., 2020). Chain of custody records detailing each person or organization that had possession of the evidence must be maintained and must encompass from receipt of items or samples, storage process, and, where applicable, return to the client or disposal. The definition and procedures adopted must be in accordance with legal provisions. Any transfer of material must be recorded, detailing each person responsible for its possession or, alternatively, its location when archived (ILAC, 2014).

Wilson et al. (2020) reported that risk management in forensic science should be addressed at a strategic level in conjunction with the Quality Management System to help organizations achieve their objectives and continuously improve their capacity. The implementation of strategic risk management systems in forensic science allows the development of treatment activities that help prevent critical system failures that may result in judicial errors. Among the risks to be considered that directly involve forensic laboratory activities, the authors suggest chain of custody, contamination, analysis failures, lack of competence, and bias in analysis. This analysis aligns with this article, as these same risks were identified in the Brazilian forensic laboratory addressed.

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The authors express thanks to the team of the Forensic Biology and DNA Laboratory of the State of Goiás, Brazil, whose contribution was essential in the execution of actions.

CONCLUSIONS

Risk management for impartiality and laboratory activities is a mandatory requirement of ISO/IEC 17025. It's essential that the laboratory adopts a risk mindset across all its processes, as it's crucial to ensure greater safety, regulatory compliance, accident prevention, optimal resource utilization, and result quality assurance. Preventive measures against errors must be in place, and knowing how to react to them is fundamental. In a forensic laboratory, all analyses must be carefully considered due to the importance and implications of the results issued within the criminal prosecution process.

Twelve risks were proactively identified by the team at the Forensic Biology and DNA Laboratory located in Brazil. Immediate actions were proposed in the event of occurrence for all identified risks. Risk levels were established empirically by combining likelihood of occurrence and impact on results. For the risk related to errors in the chain of custody (testing items), an action plan was proposed to attempt to minimize the risk by reducing the probability of occurrence. Chain of custody is very important within forensic science, and continuous improvement should always be evaluated to prevent errors. Mistakes in the chain of custody can invalidate the entire investigation.

As part of future study, it is necessary to monitor these risks as well as the action plan developed to mitigate the risk of errors in the chain of custody. After implementing the action plan, effectiveness analysis should be conducted. It is suggested that the effectiveness analysis be conducted over the long term, due to the forensic examinations backlog to be performed by the laboratory, which may hinder this activity.

In addition to monitoring these twelve identified risks, it is necessary for the laboratory to continue identifying new risks and define the appetite for each risk, analyzing the possibility of process improvement and delivery of results with risk acceptance. Some risks are inherent to the work, and it is the organization's responsibility to define the acceptable limit accordingly.

The laboratory should also consider risks by analyzing non-conformities that may arise in the laboratory, especially those related to non-conforming work. Additionally, it is important to consider the effectiveness of the proposed actions in response to the occurrence of the event. This analysis represents a good performance indicator of the management system. The effectiveness of the system in preventing errors demonstrates the quality and efficiency of the laboratory.

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Integrating Quality 4.0 and 5.0 with Organisational Learning: Shaping the Future of Quality and Organisational Excellence

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STRUCTURED ABSTRACT:

Purpose: This is a conceptual paper that aims to synthesise and demystify the existing links between the key concepts of Quality 4.0, 5.0, organisational learning and organisational excellence to make sense of the perceived relationships. Considering that the pivotal literature of quality stems from Deming's work and especially the 14 Points, the authors attempt to answer a central question i.e., Can Deming's 14 points be a vital resuscitator for Quality Management in the era of AI?

Design/methodology/approach

This conceptual paper builds on several key research studies to synthesize the authors' argument for developing an integrative, learning-driven framework. This framework aims to address the advancement of Quality 4.0, Quality 5.0, and Organizational Learning. It continues the discourse from previously published works by Garad and Gold (2019 and 2021), Kannan and Garad (2020), and Huq (2017a and 2017b).

Findings:

Organisational learning, Quality 4.0, and Quality 5.0 are critical elements that significantly influence the success and sustainability of any organization. When effectively integrated, these components can drive continuous improvement, enhance performance, and provide a competitive advantage, thereby serving as enablers of business excellence. The authors advocate for the development of a comprehensive, learning-driven excellence framework that accommodates the needs of all industries and stakeholders.

Research Limitations:

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As this is a conceptual paper, it brings up the author's stand towards the discussed topics hence it is not yet validated and has no empirical evidence, however, it builds on a solid body of knowledge and practice i.e., Quality, Empowerment, Excellence and Organisational Learning.

Practical and Research Implications:

As Quality 4.0 employs cutting-edge technologies, such as artificial intelligence and computer vision, to streamline operations and facilitate digital transformation, it sets the stage for the emergence of Quality 5.0. This forthcoming iteration should aim to humanise technological processes in manufacturing and service sectors, enhancing customer experiences by leveraging organisational learning mechanisms to foster a culture of continuous learning across the enterprise. This conceptual paper scrutinises the integration of Quality 4.0 and 5.0 with organisational learning and endeavours to chart an agenda for a new quality and learning-driven excellence roadmap. It underscores the significance of technological advancements, process optimisation, and a strategic focus on customer satisfaction and continuous improvement as vital drivers for fostering organisational excellence in a rapidly changing business environment.

Keywords: Quality 4.0, Quality 5.0, Organisational learning, Business Excellence, Learning-Driven Organisations, Deming's 14 Points, Leadership, Employee Empowerment.

Paper Type: Conceptual paper

1.0 - Introduction

The industry is witnessing a significant transformation in quality management practices, which is marked by the advent of Quality 4.0 and the emerging concept of Quality 5.0. These concepts represent the progressive integration of advanced technologies and human-centric approaches, redefining the paradigms of quality control and management. Quality 4.0 integrates the principles of Industry 4.0, leveraging cutting-edge technologies like the Internet of Things (IoT), Big Data Analytics, Cloud Computing, Artificial Intelligence (AI), and Machine Learning. This approach focuses on enhancing quality management through data-driven decision-making, real-time monitoring and control, predictive maintenance, automated quality inspections, and ensuring traceability and transparency throughout the production process. Manufacturers can make informed decisions by harnessing data from connected devices and systems, proactively addressing maintenance needs, and maintaining stringent quality standards through automated inspections and end-to-end traceability. This leads to reduced downtime, improved product quality, and a more streamlined production process.

Building upon the foundations of Quality 4.0, Quality 5.0 emphasises the harmonious collaboration between humans and intelligent systems. This concept aims to balance technological advancements with human-centric approaches, fostering a synergistic environment where human skills are enhanced by AI and other advanced technologies. Key aspects of Quality 5.0 include fostering human-machine collaboration, empowering workers through training and AI-assisted decision support systems, enabling personalization and customization of products, incorporating sustainability and ethical considerations into quality management, and developing adaptive and flexible quality systems. By integrating these elements, Quality 5.0 seeks to create more efficient, sustainable, and customer-centric quality management practices, ultimately leading to a more resilient and responsive manufacturing industry. The transition from Quality 4.0 to Quality 5.0 represents a pivotal shift towards a future where technology and human expertise coexist and complement each other, driving innovation and excellence in quality management.

2.0 - Review Deming’s 14 points

How can organisations pursuing quality management ‘intelligently embrace’ Deming’s 14 points for quality improvement in the changing world environment, keeping it human-centric and in the context of Artificial Intelligence (AI)? With the advent of Artificial Intelligence (AI) and the transformative era of digital innovations, there are important questions that need to be raised about quality management. Perhaps there is a need to chart a global agenda for a new quality and learning roadmap. However, this raises several questions about the future of quality in organisations and how a new quality and learning roadmap can be created, keeping in principle the teachings of the predecessors of quality gurus, such as Deming. This conceptual paper examines these challenges and attempts to encourage conversations and recommendations on how organisations can move forward by learning and un-learning and working in parallel with AI and data-driven technology.

2.1 - Is quality management dead? How can Deming's 14 points be a vital resuscitator for quality management in the era of AI?

Reflecting on the long-debated question: 'How can organisations improve quality?', this paper aims to explore quality guru Deming's 14 points and how it can be a vital resuscitator for quality management within the context of Artificial Intelligence. Deming described his 14 points as a 'System of Profound Knowledge for Transformation from the present management style to one of optimisation.' (Deming, 1986), and to this day, it is considered the foundation for quality management. How can we build on this foundation of knowledge and co-create a path to move forward in keeping with the quality philosophy and principles? Is quality management dead, and is there a danger that the principles of quality may be neglected in the dense use of AI? These are crucial questions that need to be discussed. Can Deming's 14 points be a vital resuscitator for quality management in this scenario?

2.2 Revisiting Deming's 14 points.

With the advent of AI and the transformative era of digital innovations, there are important questions that need to be raised, how can we intelligently embrace quality and in what format, and most importantly, keeping the teachings of past Quality Gurus at the forefront of quality initiatives in organisations, whilst moving with the times. Deming's 14 points are great reminders to understand the purpose of quality improvement and why we are doing what we are doing. This paper argues that amidst the turbulence of global competition, Deming's 14 points (Deming, 1986); below, could be a vital resuscitator for quality management, keeping the human side of quality alive, and in usage with AI in organisations.

2.2.1 - Create constancy of purpose to improve product and service.

Creating a purpose for improvement forces organisations to address these questions: 'Why do organisations exist?' and 'What can they do to constantly improve quality?' These questions may have been asked before, and organisations need to be careful not to arrive at the same answers. How to improve quality needs to be considered in the light of AI and must consider data-driven facts and figures.

2.2.2 - Adopt a new philosophy for the new economic age by managing learning responsibilities and taking leadership for change.

When organisations know their purpose, the vision becomes clear, as the realisation sinks in that quality needs to be embraced throughout the organisation. Deming talked about the new economic age in 1986, and it is still relatable now, with the advent of AI. This demonstrates that managing change is always a vital part of organisational life and the need for management to take responsibility in leading change. The challenge is to inject new ideas with the help of AI and digital technologies, side by side with people bringing their human intelligence, and ways to implement the new philosophy, designing products and services to meet the needs of the customer, including the impact on society and environment. Adopting AI involves organisations being clear about governance and compliance procedures, responsibly managing and implementing these, and making sure that employees have clarity, and do not get too caught up with data and digital technologies.

2.2.3 - Cease dependence on inspection to achieve quality; eliminate the need for mass inspection by building quality into the product.

Quality organisations must move away from the need to inspect, and opt for quality improvement, rather than quality inspection. The methods for improving quality should replace inspection, and this is where AI and digital tools can help. With data-driven technology and help from AI, inspection will be an outdated practice. When everybody takes responsibility for quality and builds it into the process from start to finish, there should not be any need for inspectors. The goal is to constantly improve and get better, the road to continuous improvement. Facts and figures derived from the data and AI should facilitate design, manufacturing, quality planning, process improvements, and everything related to quality in a fast and efficient way.

2.2.4 - End awarding business on price; instead minimise total cost and move towards single suppliers for items.

In a world where the markets are constantly changing, suppliers are also changing. A single supplier might prove to be difficult with the changing times, hence organisations should globally collaborate with all their suppliers and potential suppliers and keep in constant touch to make sure all their suppliers also improve quality at their end, and that they meet all quality standards. It will be important to constantly source quality suppliers, to combat less variation and maintain consistency. AI could assist in the sourcing of suppliers with speed and efficiency, and organisations could take this advantage.

2.2.5 - Continuously and forever improve the production and service system to improve quality and productivity and decrease costs.

AI could potentially free up time so that everyone in the organisation can get training and education, take responsibility for improving quality, and own their jobs. Organisations that do not pay attention to constant and continuous improvement will be unable to sustain themselves. Continuous improvement in systems, processes, and communication is crucial. Constantly improving quality, and upscaling employee skills not only helps to reduce waste but can also eliminate waste, thus improving effectiveness and safety.

2.2.6 - Institute training on the job.

Training and education are vital, otherwise, there is a danger that quality will be compromised. It enables knowledge sharing at work, which helps build trust and good teamwork. It is important that training and education focus not only on maintaining consistency and reducing variation but also on leadership education and equipping leaders with people skills, empowerment, and good communication. These skills can help to build trust and good teamwork, encouraging employees to share knowledge and learn from one another.

2.2.7 - Implement leadership; supervision should be to help do a better job; overhaul supervision of management and production workers.

Organisations cannot deliver without a leader who understands the philosophy of quality and has the capacity, ability, and willingness to embrace quality. Implementing and recruiting a leader who can lead in the age of AI is going to be crucial for organisations. This is a radical shift for leaders, away from 'command and control'(Block, 1987); to a more empowered culture (Huq, 2017b). How leaders shape their attitudes, behaviour, and interaction with people, and incorporate kindness, empathy, and respect for others, in the best way possible, will be the future challenge.

2.2.8 - Drive out fear so that all may work effectively for the organisation.

When employees are empowered (Conger, and Kanungo, 1988); and work in an environment where they are not afraid to express their ideas and put forward suggestions, they are more productive, happy, and willing to go the extra mile to give service to customers and fulfil the needs of the customer. Leaders need to create a culture of empowerment, where open, honest, and authentic communication helps to get rid of fear in organisations ((Huq, 2017b). When employees are not afraid to speak up, suggest some innovative ways of doing things, or improve quality, psychologically, this raises their self-esteem, self-efficacy, and self-confidence, with a positive result that makes employees feel valued (Bandura,1977; Baron and Greenberg, 1990).

2.2.9 - Break down barriers between departments; research, design, sales and production must work together to foresee problems in production and use.

Breaking down barriers can help share the vision of the organisation, understand the purpose better, and move towards achieving the goals. It enables better teamwork and helps to solve problems collectively. It also enables collaboration, and more understanding and builds trust.

2.2.10 - Eliminate slogans, exhortations and numerical targets for the workforce, such as 'zero defects' or new productivity levels. Such exhortations are diversory, as the bulk of the problems belong to the system and are beyond the power of the workforce.

Slogans can be confusing and often end up in lip service, which must be always avoided.

Mission statements must be simple and clear so that everybody in the organisation understands it, knows what it means and has clear strategies in how it is to be achieved. Everybody must be trained to understand how to analyse and utilise AI's data and figures and respond quickly to meet customer needs or solve a complaint.

2.2.11 - Eliminate quotas or work standards, and management by objectives or numerical goals; substitute leadership.
Achieving targets is an objective, but without compromising quality. Having low-quality products or services, and achieving targets is not a quality equation. Leaders must make sure that employees are given support to understand how to use data, and that adequate resources are provided so that quality is maintained.

2.2.12 - Remove barriers that rob people of their right to pride of workmanship; hourly workers, management, and engineering; eliminate annual or merit ratings and management by objective.
Everyone has a right to take pride in workmanship, no matter what the job entails, and leaders must make sure that AI doesn't rob people of this right, to be proud of their achievements as human beings. Even in teamwork situations, employees can be applauded, rewarded, and praised, sometimes individually, if someone has contributed on their own, or the whole team and every individual within the team. Psychologically, reward, praise, and appreciation make everyone want to improve constantly, thus making quality management more human-centric.

2.2.13 - Institute a vigorous education and self-improvement programme.
Education and self-improvement programmes are often ignored in organisations. The skills of employees must constantly be upscaled and encouraged to learn new skills, such as AI. This will help to prepare for challenges and find areas to achieve improvements and excel. An ongoing continuous education also needs to include self-improvement and self-education, of leaders and employees in the organisation.

2.2.14 - Put everyone in the company to work to accomplish the transformation.
It cannot be emphasised enough, that to improve quality, leaders must include everyone, and empower everyone to their capacity, so that each person in the organisation can take the necessary steps needed to improve quality and deliver on promises made by the organisation (Bowen and Lawler III, 1992); (Huq, 2017b). It will be important to keep the human voice alive somewhere in the organisation, amidst the AI-enabled conversation, to help customers.

2.3 Responding to the Paradigm Shift, Enabling Change, and Empowering Employees.
Considering Deming's 14 points to be the foundation, the challenge is how leaders can respond to the paradigm shift, enable change, and empower employees, in the new wave of disruption. Quality management is no longer just a strategy for quality, it is the core of organisational transformation alongside AI; how an organisation conducts its business, responds to ethics, and sustainability and contributes to the benefit and good of society. Each of Deming's 14 points is a valuable learning curve for all organisations, large or small, including SMEs. Leaders must consult with employees,

creating a culture of inclusiveness, on how these can be applied to all departments to provide a great customer experience and for the survival of organisations, including the impact on society and the environment. By studying these 14 points, leaders can also prepare themselves for managing change, adapting their leadership style to one that is empowering and finding ways to empower the culture of the organisation, so that everyone can take part in decision-making, (Huq, 2017a); feels empowered to do their jobs, with self-confidence, alongside AI. Without employee empowerment, innovation and creativity are thwarted in organisations, (Huq, 2017a), and people lose the spark, the *joie de vivre*.

This paper poses the question of how a new quality and learning roadmap can be created, keeping in principle the works and teachings of the predecessors of quality gurus, such as, Deming. It provides a space, and an opportunity to discuss how organisations can create various strategies for quality management from the learning emanating from Deming's 14 points, which will be very helpful to the research community on leadership, quality, and organisational development. Considering Deming's 14 points as the foundation of knowledge for quality management, the challenge is how organisations can continue to improve quality and accommodate the paradigm shift in the new wave of disruption. By embracing AI, organisations can augment their existence as a force for good in society. To survive in the competitive market, organisations cannot afford to do just 'better', they will have to innovate and seek new ways of doing things for survival, achieving business excellence, and making a positive impact on society and sustainability.

If organisations do not pay attention to how they can 'intelligently embrace' quality management, they will be doing it solely through 'artificial intelligence', without the human touch or the human side of leadership. This over-reliance on AI may be detrimental to the people side of quality management and customer experience. Leaders have a responsibility to ensure that everyone in the organisation understands the importance of quality management and the dynamics of AI. One way to do this is to empower employees to reach their full potential, which in turn motivates them to give their best (Hill and Huq, 2001; 2004). Deming's 14 points are a great enabler to open the conversation and can be a good starting point for organisations to help them with their quality management initiatives, and to think for the future how the organisation can operate by adding value to what they do.

Quality management creates challenges and opportunities for organisations, and there is a need to have a better perspective of AI and the management of quality. This is highly necessary, as without guidance on quality management, the organisation will flounder, and there is a danger that the old teachings will be lost forever. As we look upon Socrates, Plato, and Aristotle to be the fathers of philosophy and give them respect to this day, their teachings adorn philosophy, psychology, literature, arts, and poetry, similarly, leaders need to pay it forward and be the guardians of quality management and make sure that the teachings of the quality gurus are followed, and applied in the organisation, keeping it human-centric alongside embracing AI and modernism.

3.0 - Organisational Learning and Quality Management: An Intertwined Relationship

Organisational learning and quality management are two vital components that significantly impact the success and sustainability of any organisation. When these two concepts are effectively integrated, they can lead to continuous improvement, enhanced performance, and a competitive advantage. This article explores the interconnectedness of organisational learning and quality management, highlighting their symbiotic relationship and mutual benefits. Organisational learning refers to the process through which organisations develop, enhance, and transfer knowledge and capabilities. It involves the continuous creation, acquisition, and dissemination of knowledge, which ultimately leads to improved organisational performance (Argote, 2013). Key aspects of organisational learning include:

1. **Knowledge Acquisition:** The process of obtaining information and skills from various sources, such as training, experience, and research.
2. **Information Distribution:** The dissemination of acquired knowledge across the organisation to ensure that all members can access and use it.
3. **Information Interpretation:** The process of making sense of the distributed information and integrating it into organisational practices.
4. **Organisational Memory:** The storage and retrieval of knowledge to ensure it is retained and can be used in the future.

Quality management systematically ensures that an organisation's products or services meet or exceed customer expectations. It encompasses principles and practices, including Total Quality Management (TQM), Six Sigma, and ISO standards. The core principles of quality management include:

1. **Customer Focus:** Understanding and meeting customer needs and expectations.
2. **Leadership:** Establishing a clear vision and direction to foster a quality-oriented culture.
3. **Engagement of People:** Involving all employees in quality improvement efforts.
4. **Process Approach:** Managing activities and resources as processes to achieve efficient results.
5. **Continuous Improvement:** Making ongoing efforts to enhance products, services, and processes.

6. **Evidence-Based Decision Making:** Using data and analysis to inform decisions.
7. **Relationship Management:** Building strong relationships with stakeholders to enhance performance.

Organisational learning and quality management are deeply intertwined, with each reinforcing and supporting the other. This relationship can be understood through several key points:

1. **Continuous Improvement through Learning:** Organisational learning is essential for continuous improvement, a core principle of quality management. By fostering a culture of learning, organisations can continuously identify and implement improvements in processes, products, and services. For example, Six Sigma and TQM rely heavily on data collection, analysis, and the dissemination of best practices, all of which are elements of organisational learning (Deming, 1986; Marquardt, 2011).
2. **Knowledge Sharing and Quality Enhancement:** Effective knowledge sharing within an organisation leads to the standardization of best practices, reducing variability and enhancing quality. When employees share their insights and experiences, it helps in identifying the root causes of quality issues and developing solutions. This collaborative learning environment supports the implementation of quality management initiatives (Senge, 2006; Gherardi, 2019).
3. **Employee Empowerment and Engagement:** Quality management emphasizes the engagement and involvement of all employees in quality initiatives. Organisational learning contributes to this by providing opportunities for training, development, and participation in problem-solving activities. When employees are empowered with knowledge and skills, they are more likely to contribute to quality improvements (Juran, 1988; Senge, 2014, Huq, 2017b).
4. **Adaptability and Innovation:** Organisations that prioritize learning are better equipped to adapt to changing environments and innovate. Quality management frameworks often require organisations to be flexible and responsive to customer feedback and market trends. Organisational learning fosters an adaptive mindset, enabling organisations to make data-driven decisions and innovate to maintain quality standards (Nonaka & Takeuchi, 1995; Garvin et al., 2018).
5. **Building a Quality-Oriented Culture:** A culture of quality is built on shared values, beliefs, and practices that prioritize quality in every aspect of the organisation. Organisational learning plays a crucial role in shaping this culture by promoting a mindset of continuous improvement, openness to feedback, and a commitment to excellence. Leadership's role in fostering a learning culture is instrumental in embedding quality management principles across the organisation (Garvin, 1993; Chiva & Alegre, 2009).

Recent studies and case examples illustrate the practical implications of integrating organisational learning with quality management. For instance, Toyota's application of the Toyota Production System (TPS) showcases how continuous learning and improvement principles lead to superior quality outcomes and operational efficiency (Liker, 2004). Similarly, companies like General Electric (GE) have leveraged Six Sigma methodologies in conjunction with robust learning mechanisms to drive significant quality enhancements and innovation (Gehani, 2013). Moreover, digital transformation and technological advancements are reshaping how organisations approach learning and quality management. The use of big data analytics, artificial intelligence, and machine learning is enabling more precise and predictive quality control measures while also facilitating real-time knowledge sharing and continuous learning across organisations (Srai & Lorentz, 2019).

In a nutshell, the integration of organisational learning and quality management creates a powerful synergy that drives organisational excellence. By fostering a continuous learning and improvement culture, organisations can enhance their quality management efforts, leading to sustained success and a competitive edge. As organisations navigate the complexities of today's business environment, the intertwined relationship between organisational learning and quality management will remain a cornerstone of their strategic initiatives.

4.0 Excellence as a product of quality and learning

Garad and Gold (2019), proposed a model for organisational learning that can transform organisations into learning-driven entities. It considers the entire ecosystem and emphasises the importance of technology, digitalization, and dataism in fostering a culture of continuous learning and improvement. The authors argue that strategic learning should be embedded at all organisational levels—individual, team, and organisation-wide—to achieve excellence and meet stakeholder needs effectively. The authors argue that organisations should look into learning as an enabler of creativity and innovation, which should ultimately lead to excellence and fulfil the needs of all stakeholders. Organisations should be consciously aware of their emerging intangible assets and proactively encourage their people toward more creativity. Learning can be institutionalised, and the organisation transforms into an LDO.

In the rapidly evolving landscape of the 21st century, achieving business excellence has become a crucial goal for organisations worldwide. This objective is increasingly seen as the product of integrating quality management and organisational learning. These two components, when effectively combined, foster a culture of continuous improvement, innovation, and adaptability, which are essential for sustaining competitive advantage in the post-pandemic era. This essay explores how business excellence emerges from the synergistic relationship between quality and organisational learning, drawing on recent research and practical insights.

4.1 - The Role of Quality Management

Quality management involves the systematic processes and practices aimed at ensuring that an organisation's products or services meet or exceed customer expectations. Traditionally, quality management has focused on methodologies such as Total Quality Management (TQM), Six Sigma, and the ISO standards, which emphasize defect reduction, process improvement, and customer satisfaction (Oakland, 2014). In the context of Industry 4.0, the integration of advanced technologies such as Artificial Intelligence (AI), the Internet of Things (IoT), and big data analytics has transformed quality management practices, making them more precise and efficient (Ivanov & Dolgui, 2020).

4.2 - The Importance of Organisational Learning

Organisational learning refers to the process through which organisations develop, enhance, and transfer knowledge and capabilities. This continuous process of learning is critical for adapting to changes, solving problems, and innovating (Argote, 2013). In the modern business environment, where the pace of change is unprecedented, the ability to learn and adapt quickly is a significant competitive advantage. Organisational learning involves acquiring new knowledge, sharing it across the organisation, and applying it to improve processes and outcomes (Garad & Gold, 2021).

4.3 - Synergizing Quality Management and Organisational Learning

The integration of quality management and organisational learning creates a powerful synergy that drives business excellence. This relationship can be understood through several key dimensions:

1. **Continuous Improvement and Innovation:** Quality management provides a structured framework for continuous improvement, which is enhanced by the dynamic capabilities fostered through organisational learning. By continuously acquiring and applying new knowledge, organisations can refine their quality management practices, leading to innovative solutions and improved performance (Garvin et al., 2018).

2. **Enhanced Adaptability:** In an environment characterized by rapid technological advancements and shifting market demands, adaptability is crucial. Organisational learning equips employees with the skills and knowledge to adapt to new challenges and opportunities. This adaptability is further supported by quality management practices that emphasize responsiveness and flexibility (Vial, 2019).

3. **Employee Empowerment and Engagement:** Quality management and organisational learning both stress the importance of involving employees in improvement initiatives. Empowering employees with the tools and knowledge to contribute to quality improvements fosters a sense of ownership and engagement, which is essential for achieving business excellence (Juran, 1988; Garad & Gold, 2018).

4. **Strategic Use of Emerging Technologies:** The adoption of emerging technologies such as AI and data analytics enhances both quality management and organisational learning.

These technologies enable more precise quality control and provide insights that drive learning and innovation. For example, predictive analytics can help identify potential quality issues before they arise, while AI can support decision-making processes (Brynjolfsson & McAfee, 2017).

Recent research underscores the importance of integrating quality management and organisational learning. For instance, Kannan and Garad (2020) highlight the need for quality professionals to develop digital competencies to effectively manage quality in the era of Industry 4.0. They argue that a balanced set of technical and soft skills is essential for fostering a culture of continuous improvement and innovation.

4.4 - Future Directions

As organisations continue to navigate the complexities of the post-COVID-19 world, the integration of quality management and organisational learning will be crucial for achieving business excellence. Future directions for research and practice include:

1. **Embedding Quality Education in Curricula:** To build a foundation for future excellence, quality education should be integrated into school and university curricula. Teaching students about quality management principles and practices from an early age can instil a culture of excellence and continuous improvement (Sallis, 2014).
2. **Updating Training and Development Programs:** Organisations should regularly update their training programs to reflect the latest industry practices and technological advancements. This ensures that employees remain competent and competitive in the evolving job market (Meister, 2020).
3. **Leveraging Digital Transformation:** Organisations must continue to invest in digital technologies to enhance their quality management and learning capabilities. This includes adopting advanced AI, IoT, and big data analytics solutions to drive efficiency and innovation (Vial, 2019).

Business excellence in the post-COVID-19 era is the product of a strategic integration of quality management and organisational learning. By fostering a culture of continuous improvement, adaptability, and innovation, organisations can achieve sustained competitive advantage. The future of business excellence lies in embracing emerging technologies, updating educational and training programs, and embedding quality education in curricula. As organisations continue to evolve, the synergistic relationship between quality and organisational learning will remain a cornerstone of their success.

5.0 - The Future of Organisational Excellence Post-COVID-19: Integrating Learning, Quality, and Emerging Technologies

The COVID-19 pandemic has profoundly reshaped the business landscape, underscoring the need for agility, resilience, and continuous improvement. In this context, the integration of organisational learning and quality management is more crucial than ever. To achieve sustained organisational excellence, it is essential to update and upgrade existing theories and practices. This article explores how organisations can achieve this by leveraging emerging technologies, updating educational programs, and embedding quality education in curricula. Kannan and Garad (2020) argue that the advent of Industry 4.0 necessitates a new set of competencies for quality professionals, emphasizing the integration of digital technologies such as IoT, AI, and data analytics into quality management practices. They identify that alongside technical skills, quality professionals must also possess strong soft skills like adaptability, problem-solving, and critical thinking, and maintain a commitment to continuous learning. The authors stress the importance of interdisciplinary knowledge and advocate for organisations to invest in comprehensive training programs. Additionally, they highlight the need for educational curricula to evolve, incorporating digital competencies to prepare future professionals for the challenges and opportunities presented by Industry 4.0.

5.1 - The Evolution of Organisational Learning and Quality Management

Organisational learning involves the acquisition, sharing, and application of knowledge to adapt to changing environments (Argote, 2013). Quality management focuses on meeting or exceeding customer expectations through systematic processes and continuous improvement (Deming, 1986). The integration of these fields can lead to sustained excellence by fostering a culture of continuous learning and improvement.

5.2 - Post-COVID-19 Challenges and Opportunities

The pandemic has highlighted the necessity for organisations to be both agile and resilient. Key areas to focus on for future organisational excellence include:

1. **Immediate Customer Service and Action:** Traditional customer service methods, such as chatbots, are often inadequate for addressing immediate customer needs. Advanced AI and machine learning technologies can provide real-time, personalized responses, improving customer satisfaction and loyalty (Huang & Rust, 2018). AI-driven customer service platforms can analyze customer queries and provide instant, accurate responses, reducing wait times and enhancing user experience.
2. **Smart Use of Emerging Technologies:** The adoption of AI and data analytics should be strategic. Organisations must implement solutions that provide actionable insights and drive decision-making processes. Predictive analytics can help anticipate customer needs and optimize supply chain operations, leading to more efficient and responsive business practices (Brynjolfsson & McAfee, 2017).

3. **Updated Educational and Training Programs:** The rapid pace of technological advancements necessitates continuous learning and skill development. Educational and training programs must be regularly updated to include the latest industry practices and technologies, ensuring employees remain competent and competitive in the evolving job market (Meister, 2020).

4. **Embedding Quality Education in School Curricula:** To build a foundation for future organisational excellence, quality education should be embedded in school curricula. Teaching students about quality management principles and practices from an early age can instill a culture of excellence and continuous improvement (Sallis, 2014).

5.3 - Implementing Advanced Organisational Learning and Quality Management Practices

Organisations must embrace a holistic approach to learning and quality management. Here are some strategies:

1. **Developing a Learning-Driven Culture:** Leaders should foster a culture that encourages continuous learning and knowledge sharing. Regular training sessions, workshops, and platforms for collaborative learning are essential (Garad & Gold, 2019). Organisational leaders must also promote an environment where mistakes are seen as learning opportunities, encouraging innovation and experimentation.

2. **Leveraging Technology for Quality Improvement:** Implementing advanced technologies like AI, IoT, and blockchain can enhance quality management practices. For instance, AI can detect defects in real-time, while blockchain ensures transparency and traceability in supply chains (Ivanov & Dolgui, 2020).

3. **Employee Empowerment and Engagement:** Engaging employees in quality improvement initiatives and empowering them with the necessary tools and knowledge is crucial. This not only enhances their performance but also fosters a sense of ownership and accountability (Juran, 1988).

4. **Continuous Monitoring and Feedback:** Establishing mechanisms for continuous monitoring and feedback ensures that quality standards are maintained and improved over time. Regular audits, customer feedback surveys, and performance reviews are essential (Oakland, 2014).

5.4 - Recent Developments and Future Directions

Recent studies and practical implementations provide insights into the future of organisational excellence:

- **The Learning-Driven Business:** Garad and Gold (2021) emphasise that organisations must transform into learning-driven entities. This involves creating an ecosystem where learning is embedded at all levels—individual, team, and organisational. Their model suggests that learning should be a strategic priority, integrated into the organisation's core operations (Garad & Gold, 2021).
- **The Learning-Driven Leaders:** To embed learning at all levels, leaders must learn how to empower employees. Huq's Employee Empowerment Model can enable leaders to learn and implement an employee empowerment culture in organisations through her Employee Empowerment Framework: (Huq, 2017b).
- **Digital Transformation:** The digital transformation of businesses has accelerated due to the pandemic. Companies like Microsoft and Amazon have demonstrated how leveraging cloud computing, AI, and data analytics can enhance operational efficiency and customer satisfaction (Vial, 2019). Organisations must continue to invest in these technologies to stay competitive.
- **Sustainability and Social Responsibility:** Post-pandemic, there is a growing emphasis on sustainability and social responsibility. Companies are increasingly being held accountable for their environmental impact and social practices. Integrating sustainability into quality management practices can lead to long-term benefits and enhance corporate reputation (Elkington, 2018).

6.0 Conclusion

The future of organisational excellence hinges on the strategic integration of organisational learning, employee empowerment, and quality management, all amplified by emerging technologies of Quality 4.0 and 5.0. In the post-COVID-19 era, organisations must be agile, resilient, and committed to continuous improvement. By updating educational programmes, embedding quality education into curricula, and leveraging advanced technologies, organisations can achieve sustained excellence and meet the evolving needs of their customers and other stakeholders. Achieving successful organisational outcomes necessitates adept management across various domains, including information dissemination, structural alignment, people engagement, employee empowerment, incentive systems, learning modalities, and process optimisation. Future strategies should especially prioritise Small and Medium-sized Enterprises (SMEs), recognising their critical role and providing them with accessible, practical tools to implement quality and excellence with manageable investments.

In the aftermath of COVID-19, revitalising the skill sets of quality professionals has become imperative. Reevaluating Deming's 14 Points and the lessons learned from the industry during this period is crucial for shaping a collaborative research and practice agenda in business excellence and organisational learning. These components, along with an enriched learning and excellence culture, underscore the inseparable link between excellence and learning, the foundational elements of organisational success. The authors advocate for the development of an integrative, learning-driven excellence framework that addresses both current and future needs and challenges.

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Smart agriculture for enhancing quality: the firms' perspective

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STRUCTURED ABSTRACT

Purpose- The purpose of this study is to investigate the multifaceted impact of AI and IoT technologies in the agriculture industry, highlighting their main contributions as well as their limits and opportunities related to quality and productivity.

Design-Methodology-Approach- A bibliometric analysis was realised to unfold the directions of the research field, focusing on the connection between technology and agriculture. The literature search was developed during the second week of February 2023. A total amount of 124 papers were obtained from the Scopus database. VosViewer software was used for the bibliometric analysis. Then, a qualitative survey (July to November 2023) was developed to investigate the impacts of AI and IoT on agriculture companies, focusing on benefits and challenges and potential implementation strategies, involving a panel of eight companies that were users or not of the new technologies.

Findings - The survey's main results should be considered preliminary due to the few respondents, but they provide valuable insights that go beyond the surface of technological adoption. They showed significant achievements of AI and IoT in agriculture, facilitating precision farming, resource optimization, operations, and supply chain movements. However, the results evidence the need to put emphasis on staff training, technical assistance, technology resilience, socio-technical integration, and stakeholder involvement, balancing the transformative potential of AI and IoT with long-term benefits, cost reductions, and production improvements.

Originality/value – By showing the state of the art of the literature on AI in the agri-food sector, the authors point out that this topic should be further investigated mainly with empirical studies.

Keywords: Artificial Intelligence, agricultural sector, quality improvement, smart agriculture.

Paper type: Research Paper

INTRODUCTION

The United Nations predicts that by 2050, there will be 9.7 billion people on the planet, a 26% increase from current estimates. These projections have significant consequences for sustainable development (UN 2019). The agriculture sector is one of those that is being severely impacted. While the demand for agricultural products has increased due to global population growth and demographic shifts, agricultural systems are also under tremendous pressure from the growing effects of climate change, including extreme weather events, water scarcity, and temperature fluctuations (FAO 2017). To feed the world's expanding population, it is imperative to both meet food demand and achieve significant reductions in greenhouse gas emissions. The agriculture industry needs to adjust and adopt sustainable techniques as climate change continues to have an impact to lessen its adverse effects. Collaboration among researchers, policy makers, and stakeholders is vital to provide novel approaches that improve resilience, boost production, and reduce environmental impacts. Considering the difficulties brought on by climate change, these initiatives are essential for guaranteeing food security and sustainability. The agriculture industry is in a unique position to embrace innovation as a vital driver for sustainable growth, considering the growing global population and the unprecedented challenges posed by climate change. Farmers used to evaluate crop conditions and make decisions based on their combined knowledge by going on field visits. But given the changing parameters that will determine the direction of agriculture in the future—efficiency, sustainability, and accessibility to farming methods for a larger population—this conventional strategy is no longer viable (Saiz-Rubio and Rovira-Más, 2020). Through the adoption of innovative agricultural techniques like precision farming, intelligent irrigation systems, and drone surveillance, farmers may maximize their output while reducing their environmental effect. Precision agriculture has been adopted very slowly, especially in lower-income countries, despite the fact that it has enormous potential to mitigate the environmental and economic issues connected with farming (Lowenberg-DeBoer and Erickson 2019; Aune et al. 2017). It might be difficult for many farmers, especially those with little financial means, to cover these initial expenses. Furthermore, farmers are discouraged since they think utilizing these technologies calls for highly skilled technical knowledge. In order overcome over these challenges, the emphasis must be on offering extensive training and support programs that can demystify the technology and give farmers the confidence they need to successfully apply precision agricultural techniques on their farms. However, since many conservation strategies have long payoffs and farmers may be reluctant to abandon long-standing practices, government grants and incentives can be crucial in persuading them to adopt these practices (FAO, 2011; Sanz et al. 2017; Climate Science, 2022). With their transformational powers, artificial intelligence (AI) and the internet of things (IoT) can be the driving forces behind bringing in a new era of data-driven decision-making, resource efficiency, and precision farming.

The purpose of this study is to investigate the multifaceted impact of AI and IoT technologies in the agriculture industry, highlighting the main contributions as well as limits and opportunities of these technologies related to the quality and productivity.

Our study is structured in two main steps: a) a bibliometric analysis was realised to unfold the directions of the research field focusing on the connection between technology and agriculture; b) a qualitative survey was developed (July to November 2023) to investigate the impacts of AI and IoT on agriculture companies, focusing on benefits and challenges and potential implementation strategies, involving a panel of ten companies that were users or not of the new technologies.

The present paper is organized as follows. First, the methodological approach is presented, then the main results of the study both for the bibliometric analysis and the qualitative survey are shown, and then, conclusions are provided.

METODOLOGHY

To achieve the research, aim and analyse the impacts of AI and IoT technologies in the agriculture industry two methodology were used: the bibliometric analysis (a) and the qualitative survey (b).

a) Bibliometric analysis: methodological approach

In the first phase, the Scopus and WoS databases were used to conduct a bibliometric analysis of the literature using the methods suggested by Donthu et al. (2021). The goal was to synthesize all of the available evidence on AI and IoT and agriculture Using the four-step process recommended by Donthu et al. (2021), the analysis was conducted as follows: a) establish a broad purpose and objective for the research; b) decide which type of analysis technique to apply; c) define the keywords to be used, select the database, collect the data, and set up the final dataset; d) conduct the bibliometric analysis and report the results. In this paper the co- occurrence analysis is provided.

To reveal the paths taken by the field of study concentrating on the relationship between technology and agriculture, bibliometric analysis was implemented. In the Scopus and WoS database, keywords related to the subject of the analysis were searched to develop the literature search during the second week of February 2023. Assuring rigor and clarity for the researched topic, these databases offer pertinent publications (Paré et al., 2015). The Boolean operators "OR" and "AND" were used to restrict the keywords search to "Abstract, Title, and Keywords"; no other filters were used. The search query that was used to carry it out was TITLE-ABS-KEY "Internet of Things" AND "Artificial Intelligence" AND "Agriculture 4.0" OR "Smart agriculture." from the Scopus database, a total of 124 papers were acquired. 48 papers were found eligible for bibliometric analysis following the screening and eligibility phase (Pizzi et al., 2020; Dabic et al., 2020; Caputo et al., 2018; Marzi et al., 2018). According to Donthu et al. (2021), Shi et al. (2022), and Van Eck & Waltman (2010), the "visualization of similarities" (VOS) technique is the distinctive foundation of the bibliometric analysis. Van Eck & Waltman (2010) using VosViewer software to conduct a bibliometric analysis.

b) Qualitative survey: design

A qualitative survey was realized to investigate the effects of AI and IoT on agri-food sector involving a panel of ten firms that either used or were not using those technologies. The topic guide focused on the advantages and disadvantages of the technologies as well as possible implementation techniques that those companies encounter on their daily activity and possible impact on their staff. Considering there were a small number of respondents, the survey findings should be viewed as preliminary, but they still offer insightful information that goes beyond the obvious implications of technology usage. The target companies were: agrifood companies, plant nurseries, farms, wineries, agricultural machineries producers operating in Europe.

RESULTS

In the present section, the results of the analysis and their discussion are presented. First, a description is made of the results obtained from the bibliometric analysis (a), and then the results that emerged from the qualitative analysis are described (b).

a) Bibliometric analysis of the literature: results

The themes that describe the phenomenon under examination and are of primary importance to the scientific community were identified using the co-occurrence analysis, which was built considering the keywords provided by the authors. Consequently, it is possible to identify the most discussed subjects in the literature during the last years by using keyword analysis.

Specifically, the authors identified three main clusters:

i. *Smart Agriculture and IoT:* grouped under this theme are the keywords that relate to the themes of IoT and Smart Agriculture.

ii. *Artificial Intelligence and Agriculture:* This cluster includes articles focused on the study of the AI in the agriculture field.

iii. *Machine Learning and climate change:* This group includes keywords that refer to the learning system of technologies and sustainability.

The cluster are described in the network visualization map (Figure 1). It represents the clusters and the relationships between them. The size of the word indicates the number of publications in which it appears, while the colour indicates the cluster to which it belongs. The lines connecting the terms in the figure serve to represent co-occurrence relationships and the smaller the distance between two words, the greater there is the relationship.

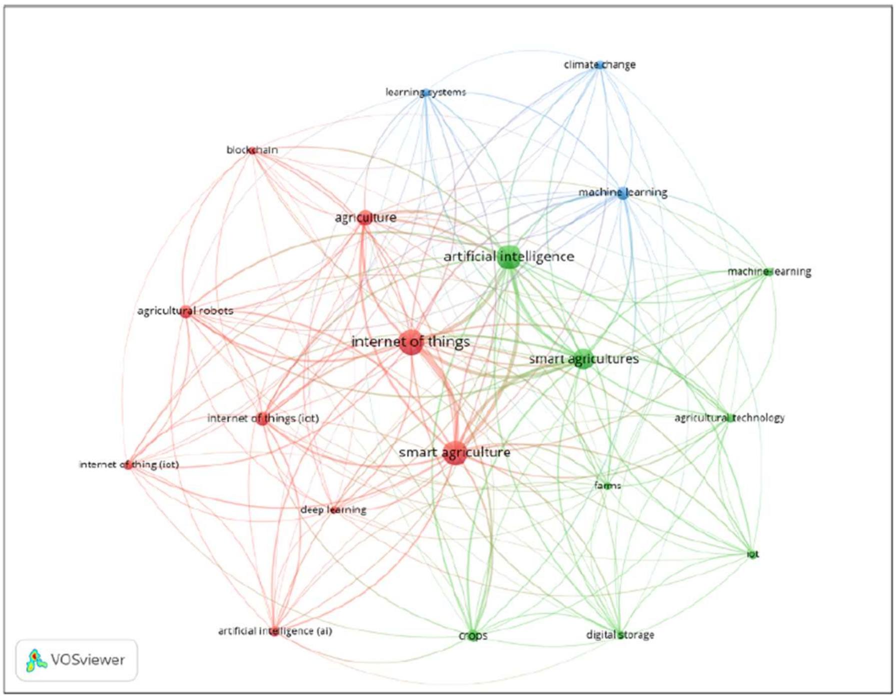

Figure 1. Network visualization.

Overlay visualisation map on the other hand indicates the temporal development of the topics by highlighting through colours the average year of publication of the articles in which the term appears. It makes it possible to see how particular components have changed or become more significant over time, giving researchers a visual depiction of the temporal dynamics in their data. An analysis of Figure 2 shows that the words appearing most recently in the literature are those coloured in yellow including for example climate change, machine-learning, farms.

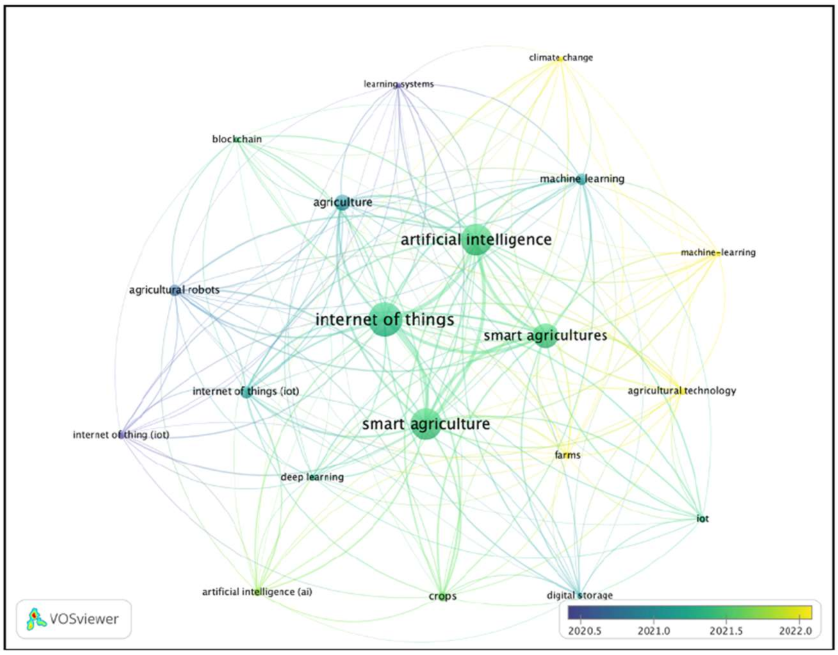

Figure 2. Overlay visualization.

Finally, the density map (Figure 3) illustrates the strength or frequency of occurrences among various items by visualizing the density of links or linkages between elements (such as keywords).

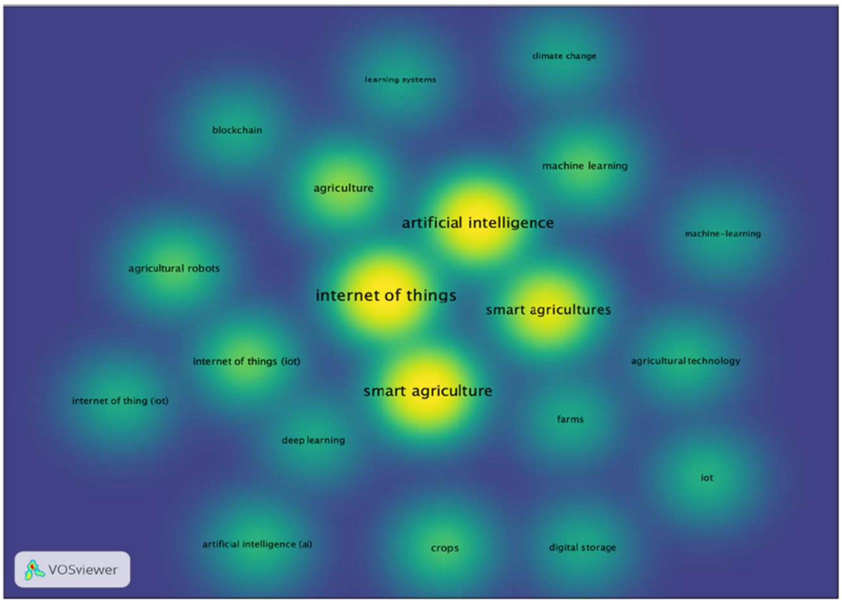

Figure 3. Density map

b) Qualitative survey: results

Through the qualitative survey it was possible to analyze the impact of AI and IoT on agricultural companies, with a focus on challenges, benefits, and implementation strategies. Specifically, four companies (HP Hydraulics, Kulto, Tomato+, Cooko) that integrate AI and IoT and four companies (Vivai Margheriti, Vallesina Bio, Arrigoni, Az. Agricola Milazzo) which not integrate new technologies in their processes were interviewed. The survey was realized under the collaboration of Federunacoma. A description of the companies is provided in Table 1.

Table 1 – Companies information.

Name	Headquarter	Employees	Interviewee's job title
HP Hydraulics (Bondioli & Pavesi)	Italy	50	CEO
Kulto	Italy	5	CEO and COO
Tomato+	Italy	10	Management and Robotic Engineer
Cooko	Germany	10	Chief of Staff
Vallesina Bio	Italy	15	Founder & Project Manager
Vivai Margheriti	Italy	104	CEO
Arrigoni	Italy	13	CEO
Az. Agricola Milazzo	Italy	51	CEO

Starting from the companies which integrate the new technologies (AI and IoT) in their production systems it was possible to highlight that the main benefits identified by the respondents are the significant reduction in water use (up to 95%), the reduced production lifecycles, the increased energy efficiency and the enhanced quality and productivity. While the companies underline that the main challenges encountered in integrating technology into business processes are the difficulty in explaining AI/IoT benefits due to limited industry openness, the high initial investment, but potential cost savings over time, the lack of specific ROI figures, not enough research and support within the sector and by policymakers. Moreover, the startups face dual challenges: tech understanding and establishing client loyalty. Following some examples of quotations from respondents:

"Artificial intelligence was the easiest solution to standardize our production and make the business scalable." Kulto
"The current mentality and philosophy in the industry are some of the difficulties we have encountered in promoting our product. The fact that we are a new and young company has also been a stumbling block." Tomato+
(…)

Considering the four companies that do not adopt the technology, it was possible to identify the main issues, the blocking factors and the possible strategies for the AI implementation. Specifically, the main issues for these companies are the bureaucratic hurdles and sector resistance slowed technology integration and the difficulty finding precise tech solutions for specific needs. Among the factors blocking the adoption of IoT and AI in the field are highlighted the need for accurate data and hardware systems resilient to climate change events, the lack of recognition of long-term competitive benefits, the absence of tailored solutions and strategic partnerships which ensures technology adoption for better operations. Finally, possible strategies which have been identified as enablers for the integration of the new technologies there are the collaboration with educational institutions to bridge readiness gaps, the focus on customized solutions through partnerships and continuous tech assessment, the emphasis on accuracy, resilience, and employees training in tech adoption and the need for supportive policies.
Example of quotations are provided:

"There is a lack of support from trade unions, which are not yet in line with the innovation required by Europe and the rest of the world, which is why it is difficult, when innovating in our sector, to find funds and know-how." Vallesina Bio
"At the moment, we have not found a key solution to help us with the main issues: extreme weather events, assessing the health of plants and their water requirements." Vivai Margheriti

CONCLUSIONS

Our study primary purpose was to examine if and how AI and the IoT are affecting the agriculture industry while taking into account the always evolving surroundings. By using bibliometric analysis, it was possible to highlight significant gaps in the body of research and define the state-of-the-art for AI and IoT applications in agriculture. This insightful analysis gave our study a more focused and knowledgeable orientation in addition to offering a broad overview and acting as a cornerstone for guiding its development. Expanding upon this basis, we combined our views derived from the literature with those gathered from the field. We conducted eight strategically comprehensive interviews that included perspectives from businesses who have already begun integrating AI and/or IoT technology as well as those that have not yet done so. By combining best practices with current issues that businesses at different levels of technology adoption are facing, this dual approach ensured a comprehensive awareness of the adoption landscape. Our research has highlighted the incredible advancements in AI and IoT in the field of agriculture. These technologies have opened up revolutionary possibilities ranging from resource efficiency and predictive analytics to precision farming, crop monitoring, and predictive analytics. Increased productivity, environmentally friendly methods, and adaptable agricultural systems that can adjust to changing conditions are among the objectives set forth for the industry. Notwithstanding the significant progress, our analysis has revealed enduring obstacles. The paucity of tailored solutions, industry readiness, and bureaucratic barriers have been identified as barriers to the smooth integration of AI and IoT technology. These problems are complex and emphasizes the necessity for a flexible and thoughtful approach to technology adoption. The gaps that have been found include the need for additional research on the long-term socioeconomic effects, the functions of startups in the digital economy, and the efficacy of reskilling initiatives. Filling in these gaps will help us comprehend Industry 4.0's effects on agriculture from a broader perspective. The study acknowledges the interaction between human factors and technological integration, highlighting the significance of staff development programs and a sensible reliance on outside technical assistance. The effective application of IoT and AI technologies is a socio-technical undertaking that calls for consideration of both the technical and human aspects, in addition to being a technological problem. Businesses and other stakeholders in the agriculture industry should think about the strategic implications this study has identified. A careful balancing act is necessary to fully realize the revolutionary potential of AI and IoT, considering the long-term competitive advantages, cost savings, and production lifecycle improvements that may be attained through their wise application.

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