Failure Modes Effects Analysis (FMEA) For Review of a Diagnostic Genetic Laboratory Process

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Abstract

Failure Modes effects analysis (FMEA) can be used as a process improvement tool to document steps of a process in detail, and interrogate potential failures before they occur. A cross functional team using ordinal scales ranks and prioritizes these risks - the validity of which has been questioned. Traditionally FMEA is viewed as a time consuming process. FMEA was used to analyse a laboratory process, 3 months after an initial quality improvement review. This study shows that FMEA can yield benefits, for prospective risk management and general process improvement within a laboratory setting where time and team input is restricted, and within a process considered during the initial review to have limited evidence of problems for continuous improvement. Findings, shortcomings and possible approaches to increase the utility of FMEA ranking activities are described.

Keywords: FMEA, Laboratory, Process Improvement, Risk Management, Quality Management.