Risk Management in the Clinical Laboratory - High Need of Time

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Dear Editor,

Risk is characterized as a measurement of the possibility or probability that harm to one's life, health, property, and/or environment will arise from a particular danger. Risk in a clinical laboratory is defined as the likelihood of an error occurring in the laboratory that could affect both the patient and the laboratory[1]. Mistakes have the potential to arise during the stages of pre-analytical, analytical, or post-analytical processes. Risk management involves assessing potential scenarios that might result in errors and taking measures to address and prevent them[2]. Risk management has been done in other fields, and its importance in clinical laboratories cannot be ignored; especially during the COVID-19 times, this concept gained utmost importance. Risk management is essential to medical laboratories' Quality Management System (QMS). ISO 1497:2007 International Organization for Standardization Demands that risk management be applied to medical devices. Monitoring and adjustments are crucial to ensure risks are within acceptable clinical limits.

Risk management is essential because, despite the advanced machines, certain risks remain prevalent in this modern era. Concerning clinical laboratories, risk management serves as a vital quality enhancement endeavour. If not appropriately managed. The medical laboratory's information can impact the patient's decision-making, diagnosis and treatment. Wrong or incorrect knowledge can direly affect the patients' health and inevitably affect the laboratory's reputation. The ISO 15189:2012 standard, outlining the need for excellence and proficiency in medical laboratories, also affirms that laboratories must assess how their work processes and possible failures may influence examination outcomes, particularly concerning patient safety. Furthermore, they should adapt these processes to mitigate or eradicate recognized risks while thoroughly documenting the decisions and steps taken[3].

Risk management can be accomplished by mapping the testing process or tracking a sample through the pre-analytical, analytical, and post-analytical stages of testing and inspecting each step for potential dangers.

According to CLSI document EP18, there are two risk analysis approaches: the step-up approach FMEA (failure modes and effects analysis) and the step-down approach FTA (fault tree analysis)[2,5]. FAMEA studies the sources or the root causes of failure and determines how the system is affected. At the same time, FTA follows a top-down methodology, commencing with the presumption of a significant hazard and subsequently uncovering the fundamental source of that hazard. Employing both Failure Modes and Effects Analysis (FMEA) and Fault Tree Analysis (FTA) in conjunction is advisable to comprehensively evaluate all conceivable pathways through which a laboratory system could encounter failures and devise strategies for minimizing the likelihood of such failure.

In clinical laboratories, risk management is a continuous process of preventive measures, including risk identification, evaluation, prioritizing, mitigation, and continual monitoring through quality assurance activities[3,4]. By tackling each element individually and collectively, we can minimize the risk and bring the best health care to the patient.

An essential tool for risk evaluation is the severity occurrence analysis table[6]. It considers two significant aspects of a potential negative outcome: its severity and probability. A graph is made between the likelihood of an event occurring on one Y-axis and the seriousness of the consequences on the other X-axis. The area between the graph is divided into cells. The risk rating or priority level is then applied to each cell, and it might be color-coded or labeled to show the level of importance attached to that level of risk. These QA operations must be evaluated as part of a continuous improvement project, and the necessary steps must be planned, carried out, and documented.

Hence, proactive risk management is imperative for clinical laboratories to protect patient safety, maintain regulatory compliance, ensure quality, preserve reputation, manage financial risks, maintain business continuity, safeguard data, protect employee safety, and promote cost-efficiency and continuous improvement. It helps laboratories identify, assess, and mitigate risks to ensure the delivery of accurate and reliable test results while maintaining the highest standards of quality and safety.

REFERENCES

1. Kobo-Greenhut A, Sharlin O, Adler Y, Peer N, Eisenberg VH, Barbi M et al. Algorithmic prediction of failure modes in healthcare. Int J Qual Health Care. 2021; 33(1): mzaa151. doi: 10.1093/intqhc/mzaa151.
2. Njoroge SW, Nichols JH. Risk management in the clinical laboratory. Ann Lab Med. 2014; 34(4): 274-8. doi: 10.3343/alm.2014.34.4.274.
3. Jayamani J, Janardan CC, Appan SV, Kathamuthu K, Ahmed ME. A Practical Tool for Risk Management in Clinical Laboratories. Cureus. 2022; 14(12): e32774. doi: 10.7759/cureus.32774.
4. Schneider F, Maurer C, Friedberg RC. International organization for standardization (ISO) 15189. Ann Lab Med. 2017; 37(5): 365-70. doi: 10.3343/alm.2017.37.5.365.
5. Chiozza ML, Ponzetti C. FMEA: A model for reducing medical errors. Clin Chim Acta. 2009; 404(1): 75-8. doi: 10.1016/j.cca.2009.03.015.
6. Powers DM. Laboratory quality control requirements should be based on risk management principles. Lab Med. 2005; 36(10): 633-8.

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