Original Article

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Biochemistry Section

Evaluation of Risk Management Parameters for Quality and Safety in a Clinical Biochemistry Laboratory of a Tertiary Health Care System: A Cross-sectional Study

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ABSTRACT

Introduction: Clinical laboratory results play a crucial role in medical decision making and patient management. Accuracy and reliability of laboratory findings require systematic risk assessment and management across all phases of laboratory testing. Laboratory processes are broadly classified into pre-examination or pre analytical, examination or analytical and post examination or post-analytical phases. Failure Mode and Effect Analysis (FMEA) is a risk assessment tool that helps identify potential failures, prioritise risks and improve quality management system in accordance with the standards of International Organisation for Standardisation (ISO) 15189: 2022.

Aim: To evaluate risk management parameters affecting quality and safety in a Clinical Biochemistry Laboratory and prioritise them using FMEA assessment tool.

Materials and Methods: The present cross-sectional study was carried out over a period of 12 months from January 2024 to December 2024 at the clinical biochemistry section, Central Diagnostic Laboratory Services, RL Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College Kolar, Karnataka, India. Laboratory incident reports were retrieved from audit logs and categorised into pre-examination, examination and post-examination phases. FMEA scoring based on severity, occurrence and detectability was applied to calculate Risk Priority Numbers (RPN). Corrective and Preventive actions (CAPA) were aligned with ISO 15189: 2022 guidelines.

Results: A total of 14 incident events were identified and recorded. In the pre-examination phase, errors related to improper labelling, inadequate samples and delay in transport accounted for 3 (21.4%) of reported incidents. The examination phase accounted for the highest proportion of incidents 7 (50%) majorly due to Quality Control (QC) failures and equipment downtime that showed the highest RPN values. These risks were mitigated using Westgard QC rules, standby analysers and vendor service agreements. In the post-examination phase, Laboratory Information System (LIS) failures and delays in reporting contributed to 4 (28.6%) of the total incidents affecting Turnaround Time (TAT).

Conclusion: Errors were identified across all the phases of the laboratory testing cycle. Implementation of an National Accreditation Board for Testing and Calibration Laboratories (NABL)-accredited quality system, combined with rigorous risk assessment through FMEA and CAPA, significantly contributes to improved patient safety and reliability of laboratory reporting.

Keywords: Diagnostic laboratory, Failure mode and effect analysis, Risk priority number

INTRODUCTION

Laboratory based investigations form an integral component of modern health care system supporting diagnosis, patient treatment and monitoring patient outcomes. Ensuring accuracy and reliability of laboratory results requires controlled quality management and risk mitigation strategy within laboratory processes [1]. Risk management involves systematic identification, assessment and reduction of potential errors throughout the testing process. Despite advances in laboratory technology and automation, diagnostic errors remain a significant concern in clinical laboratory [2].

The laboratory testing process involves three phases namely pre-examination or pre-analytical phase, examination or analytical phase and post-examination or post-analytical phase. Errors occur at any stage of these processes affecting the patient safety and clinical decision making. Earlier studies have shown that around 60-70% of laboratory errors occur during the pre-examination phase, primarily due to issues such as improper sample collection, labelling errors and transport delays of samples [3,4]. Analytical errors are comparatively less frequent and may arise due to equipment malfunction, calibration issues, reagent instability or QC failures [5]. Transportation from long distances further requires robust logistics and QC systems [6].

According to ISO 15189: 2022 standards, it emphasises the implementation of risk-based approaches in Laboratory Management Systems [7]. According to ISO 15189:2022 standards, laboratories should establish defined sample acceptance and rejection criteria to ensure the quality and reliability of test results. Samples may be rejected due to patient identification errors (missing or mismatched patient information), improper labelling, inadequate sample volume, incorrect collection containers, haemolysed, lipemic or clotted specimens, improper transport or storage conditions, contamination, leakage, damaged containers, or expired/improperly collected specimens. These criteria form an important component of quality assurance and risk management in clinical laboratories [7].

The FMEA tool provides a structured approach to identifying potential failures in the testing process, evaluating their severity and likelihood and implementing preventive measures.

The FMEA aims to reduce errors before they occur and improve overall safety and quality. In this method each possible failure mode

is analysed in terms of its severity, occurrence and detection. All these are used to calculate the RPN, which helps prioritise which risks need immediate attention. Therefore, FMEA is an important tool for risk management and quality improvement [8,9].

Regular evaluation of risk parameters within individual laboratories is therefore necessary for maintaining compliance with ISO Standards and improving overall diagnostic reliability. Most of the existing studies focus on isolated errors or single phases of the testing process rather than evaluating the entire total testing cycle. Moreover, there is a lack of integration of risk assessment findings with standardised quality frameworks such as ISO 15189:2022 [10,11].

The present study addresses this gap by identifying and prioritising risk parameters across pre-examination, examination, and post-examination phases using the FMEA approach. It also links the identified risks with CAPA aligned to ISO 15189:2022 standards. This provides a structured, practical model for risk-based quality improvement thereby enhancing patient safety and reliability of laboratory services. Hence, the present study was undertaken to evaluate risk parameters affecting quality and safety in clinical biochemistry laboratory and to prioritise corrective measures using the FMEA risk assessment framework. The objectives of the study were to identify common risk parameters across pre-analytical, analytical and post-analytical phases, to quantify risk for each parameter using FMEA and calculating RPN, to analyse incident reports and identify patterns of process failures across the total testing cycle.

MATERIALS AND METHODS

The present cross-sectional study was conducted over a study period of one year (January 2024-December 2024) in Clinical Biochemistry laboratory, RL Jalappa hospital and Research Centre, attached to Sri Devaraj Urs Medical College Kolar, Karnataka, India. The Central Ethics Committee of Sri Devaraj Urs Academy of Higher Education and Research, Kolar has examined the research project proposal and the detailed work plan on 17th November 2025. The Institutional Ethics Committee (IEC) was obtained from the Institution's ethical committee. Ref: SDUAHER/R&D/CEC/ SDUMC-PG/264/NF/-2025-26.

Inclusion criteria: All laboratory incident reports recorded during January 2024 and December 2024 in the NABL-accredited clinical biochemistry laboratory were included. Incidents from all phases of the total testing process: pre-examination, examination, and post-examination were considered. Only documented and verifiable incidents available in internal audit logs were included for analysis.

Exclusion criteria: Incomplete audit logs were excluded.

Study Procedure

Data collection: Laboratory incidents reports were retrieved from internal audit logs and categorised according to different phases of the laboratory testing process, pre-examination, examination and post examination phase.In the pre-examination phase, the parameters included billing errors, improper labelling, improper sample collection, improper container usage, needle stick injuries, and delays in sample transport.In the examination phase, the assessed parameters were QC failure, equipment failure, temperature fluctuations, calibration issues, and the use of expired reagents.

In the post-examination phase, the parameters included delay in reporting, LIS breakdown, Sample/Reagent spills and typographical errors.

Blood and body fluid spills during sample collection were classified under the pre-examination phase, whereas sample/reagent spills occurring after completion of analysis during reporting, storage, or disposal were classified under the post-examination phase.

CAPA were implemented for each identified failure mode. The identified risks were derived from internal audit records and incident reports and analysed using the FMEA method. For each failure mode risk identification was performed by reviewing incident record logs and non-conformities, categorising errors into pre-analytical, analytical, and post-analytical phases and assigning Severity (S) xOccurrence (O)xDetection (D) scores based on FMEA criteria. Calculating RPN to prioritise risks.

Risk scoring was adapted from standard FMEA guidelines {Automotive Industry Action Group (AIAG) / Verband der Automobilindustrie (the German Association of the Automotive Industry) (VDA)}, LSI and customised for the study. Risk assessment was performed using the FMEA risk matrix. Each identified risk parameter was scored based on the criteria, that is Severity(S) which impacts the patient's safety, Occurrence(O) the likelihood of occurrence and Detection (D) is the probability of detecting error before affecting the patient.

Standard FMEA risk matrix scores on a scale of 1-10 were used, where '1' indicates severity (no effect), occurrence (remote), and detection (almost certain detection), while '10' indicates severity (hazardous), occurrence (almost certain), and detection (almost impossible to detect).The RPN was calculated using the formula RPN=severityxoccurrencexdetectability. RPN of 1-40 identified as low-risk, 41-100 as moderate-risk, 101-200 as high-risk and >200 as critical risk [12,13]. CAPA were implemented based on the identified risks and failures and mapped to relevant clauses of ISO 15189: 2022 Standards [3,14].

For the preliminary risk assessment, each incident was assigned Frequency and Severity scores. The criticality score was calculated as the product of frequency and severity (Criticality=Frequency×Severity). Higher criticality scores indicated greater potential risk and were used for initial prioritisation of laboratory incidents.

The preliminary severity score was assigned by the multidisciplinary laboratory quality team based on the potential impact of each reported incident on patient safety, test quality, and laboratory workflow, using the predefined severity scale. A severity score of 2 was considered a very minor impact.

Preliminary risk assessment: Initially, all laboratory incidents were screened using a preliminary risk assessment matrix based on frequency of occurrence, severity of impact, and criticality. This assessment was used to identify and prioritise incidents requiring further evaluation. Incidents identified as significant were subsequently subjected to a detailed FMEA-based risk assessment.

The severity scores were assigned according to the FMEA methodology by a multidisciplinary laboratory quality team, considering the potential impact of each failure mode on patient safety, test accuracy, TAT, and clinical decision-making.

The severity scale [7,15]:

1-Negligible: No effect on patient care or laboratory performance.

2-Very Minor: Minimal impact with no significant effect on test quality.

3-Low: Minor reduction in laboratory efficiency or service quality.

4-5-Moderate: Noticeable impact on workflow or TAT.

6-7-High: Major impact that may influence clinical interpretation or patient management.

8-9-Critical: Severe consequences causing major patient harm or service disruption.

10-Catastrophic: Extremely serious failure with potential for permanent harm or death.

For the preliminary risk assessment, the criticality score was calculated as Frequency×Severity. For the detailed FMEA assessment, the RPN was calculated as Severity (S)×Occurrence (O)×Detection (D).

The preliminary risk assessment presented in [Table/Fig-1] was based on frequency, severity, and criticality scores to identify laboratory incidents. Subsequently, a detailed FMEA was performed, and Severity (S), Occurrence (O), and Detection (D) scores were assigned for each failure mode to calculate the RPN as presented in [Table/Fig-2]. Therefore, the severity scores in [Table/Fig-1,2] represent different assessment frameworks and are not directly comparable.

Parameters	Frequency	Severity	Criticality
Improper labelling	1	2	2
Improper sample	1	2	2
Delay in transport	1	2	2

[Table/Fig-1]: Risk assessment in pre-examination phase.
Severity represents the initial severity assessment based on the predefined severity criteria described in the methods section

Phases	Failure mode	Severity (S)	Occurrence (O)	Detection (D)	RPN (S×O×D)	Risk level	Corrective / preventive actions
Pre-examination phase	Improper labelling	3	2	2	12	Low	Barcode labelling system, regular staff training
	Improper sample	3	2	2	12	Low	Phlebotomy training and adherence to Standard Operating procedure (SOP)
	Delay in transport	3	2	2	12	Low	Defined sample transport protocol
Examination phase	QC failure	7	6	3	126	High	Implementation of Westgard QC Rules
	Equipment failure	6	6	3	108	High	Preventive maintenance and standby analyser
Post-examination phase	Delay in reporting	2	3	3	18	Low	Turnaround Time (TAT) Monitoring Inventory Management System
	LIS breakdown	7	3	3	63	Moderate	Backup LIS and Manual Reporting
	Reagent spills	2	3	3	18	Low	Biosafety SOPs and Spill Management protocols

[Table/Fig-2]: Failure Mode and Effect Analysis (FMEA) risk prioritisation.
Severity (S) represents the FMEA severity score used for RPN calculation and is based on the detailed FMEA assessment

STATISTICAL ANALYSIS

The collected data were entered in Microsoft Excel and descriptively analysed. Frequency of incidents was recorded for each risk parameter. Criticality was calculated as Frequency×Severity. Based on the calculated RPN values, risks were classified as low-risk (RPN 1-40), moderate risk (RPN 41-100), high-risk (RPN 101-200), and critical-risk (RPN >200) [12,13].

RESULTS

During the study period, a total of 142,169 patient samples corresponding to 905,975 laboratory parameters were processed. Overall, 14 laboratory risk incidents were recorded during the study. Three incidents in pre-examination phase 21.4%, seven incidents in examination phase 50% and four incidents in post-examination phase 28.6%.

Pre-examination phase: The pre-examination phase accounted for 3 (21.4%) of reported incidents. The issues included improper labelling, inadequate sample collection and delay in sample transport [Table/Fig-1].

Examination phase: The examination phase accounted for 7 (50%) of reported incidents, representing the highest proportion of risk events. Major issues included equipment failure and QC failures [Table/Fig-3]. QC failures showed the highest RPN value (RPN 126), followed by equipment downtime (RPN 108).

Parameters	Frequency	Severity	Criticality
QC failure	2	3	6
Equipment failure	5	3	15

[Table/Fig-3]: Risk assessment in examination phase.

Post-examination phase: The post-examination phase contributed to 4 (28.6%) of reported incidents. The most common issues included LIS failures and delay in reporting results mainly due to reagents exhausted and non availability of reagent kits as the indent was not procured on time by the laboratory leading to variations in TAT [Table/Fig-4].

CAPAs implemented based on identified risks are shown in [Table/Fig-2]. Implementation of barcode labelling systems and staff training for labelling errors, Phlebotomy training and adherence to SOPs for improper sample collection, defined transport protocols for delay-related issues, implementation of Westgard QC rules for analytical errors, preventive maintenance and standby analyser support for equipment failures.

DISCUSSION

In the present study, laboratory incidents across the pre-examination, examination, and post-examination phases were evaluated using a FMEA based approach. A total of 14 incidents were identified with the examination phase accounting for the highest proportion of reported incidents. QC failures and equipment-related issues

Parameters	Frequency	Severity	Criticality
Delay in reporting	2	2	4
LIS breakdown	1	7	7
Sample and Reagent spills (post-examination handling/disposal)	1	2	2

[Table/Fig-4]: Risk assessment in post-examination phase.

emerged as the most significant risks, while improper labelling, inadequate sample collection, transport delays, reporting delays, and LIS breakdowns were identified as important contributors to laboratory errors. The application of FMEA facilitated systematic risk prioritisation and supported the implementation of targeted CAPAs to improve laboratory quality and patient safety.

The present study evaluated laboratory risks across the pre-examination, examination, and post-examination phases using a FMEA-based approach in a NABL-accredited clinical biochemistry laboratory. A total of 14 incidents were identified during the study period, with the examination phase accounting for the highest proportion of reported incidents, followed by the post-examination and pre-examination phases. QC failures and equipment-related issues emerged as the most significant risks, whereas improper labelling, inadequate sample collection, transport delays, reporting delays, and LIS breakdowns contributed to errors in other phases. The application of FMEA facilitated systematic risk prioritisation and supported the implementation of targeted CAPAs aimed at improving laboratory quality, operational efficiency, and patient safety.

Calibration issues, reagent availability were managed through routine calibration schedules and inventory monitoring protocols [14].

Backup reporting workflows and manual verification procedures minimised the impact on clinical decision making [5]. Biosafety operating procedures ensured safe handling of occasional blood and reagent spills [16]. Overall, this study demonstrates that laboratory errors may occur at any stage of the diagnostic testing

cycle. However, the pre-analytical phase continues to contribute the largest proportion of errors, particularly those related to improper sample identification and collection.

Strict sample acceptance and rejection criteria along with biosafety protocols minimised the clinical impact of the recorded incidents in the pre-analytical phase. These findings are in alignment with previous studies reporting that the majority of laboratory errors occur during the pre-analytical phase [17,18].

During the analytical phase, equipment malfunction and QC failures represent critical risks due to their direct impact on analytical accuracy. Preventive maintenance schedules and vendor collaboration play a vital role in minimising these risks [19].

Post-analytical errors, especially delay in reporting caused by LIS failure or reagent shortages may significantly affect clinical decision-making. Establishing backup information systems and efficient inventory management systems can significantly reduce such errors [2].

Implementation of a planned and structured risk management programs, involving monitoring, root cause analysis and corrective action planning is therefore essential for improving laboratory quality and patient safety [20].

Based on the study findings, the following measures are recommended: Regular robust risk assessment using structured tools such as FMEA. Continuous staff training and competency testing in sample collection, labelling and biosafety procedures. Scheduled preventive maintenance and calibration of laboratory equipment.Strengthening LIS backup and contingency plans. Periodic monitoring of key quality indicators across all phases of testing. Future multicentre studies with larger sample sizes are warranted to validate these findings and evaluate the long-term impact of FMEA-based risk management on laboratory quality and patient safety.

Limitation(s)

The study was conducted in a single NABL-accredited clinical biochemistry laboratory, which may limit the generalisability of the findings to other healthcare settings. Additionally, the number of recorded incidents was relatively small due to the presence of established QC procedures within the laboratory. Future multicentre studies with larger datasets would provide broader insights into risk management practices in clinical laboratories.

CONCLUSION(S)

Errors were observed across all phases of the Laboratory testing cycle. However, the implementation of a robust NABL accredited quality management system combined with proactive risk assessment through FMEA and CAPA significantly enhanced the patient safety and laboratory reliability. QC failures, equipment downtime and LIS breakdown were identified as critical risks with moderate priority for intervention due to high detection ability. Integration of structured risk management approaches within laboratory workflow is essential for continuous quality improvement and compliance with ISO 15189 Standards.

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