



## Application of Failure Mode and Effects Analysis (FMEA) for Risk Management in Hospital Laboratories

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### ABSTRACT

Hospital laboratories play a fundamental role in ensuring timely and accurate diagnostic information that supports clinical decision-making and patient care. However, laboratory processes—such as specimen collection, handling, analysis, and reporting—are inherently complex and susceptible to various errors that may compromise patient safety and treatment outcomes. Failure Mode and Effects Analysis (FMEA) is a structured, proactive risk assessment tool that allows healthcare institutions to systematically identify, evaluate, and mitigate potential failures within critical workflows. This paper examines the application of FMEA in the context of hospital laboratory risk management. Through process mapping and collaboration among multidisciplinary teams including laboratory staff, clinicians, and quality managers potential failure modes were identified across different laboratory phases. Each failure mode was analyzed using a standardized scoring system for severity (S), occurrence (O), and detectability (D), leading to the calculation of a Risk Priority Number (RPN). High-priority risks such as sample mislabeling, equipment malfunction, and reagent expiration were addressed with targeted interventions, including barcode implementation, enhanced equipment maintenance protocols, and improved inventory systems. The findings indicate that FMEA significantly improves error detection and prevention in laboratory operations, promotes a culture of safety, and enhances compliance with international quality standards such as ISO 15189. Moreover, the participatory nature of FMEA fosters organizational learning and continuous quality improvement. Despite requiring time and training investment, FMEA offers a cost-effective approach to reducing diagnostic errors and improving patient outcomes. The study recommends routine application of FMEA and its integration with digital health technologies for real-time risk monitoring in clinical laboratories.

### Introduction

Hospital laboratories play a vital role in the continuum of care by providing accurate, timely, and reliable diagnostic services. However, laboratory processes ranging from sample collection and labeling to analysis and reporting—are susceptible to human error, equipment malfunction, contamination, and delays. These failures can result in incorrect diagnoses, delayed treatments, or even harm to patients [1].

Hospital laboratories are critical components of healthcare systems, responsible for the timely and accurate diagnosis of diseases.

However, laboratory processes are prone to various risks that can compromise patient safety and diagnostic accuracy. Failure Mode and Effects Analysis (FMEA) is a proactive risk assessment tool widely used in healthcare to identify, evaluate, and mitigate potential failures in processes. This paper explores the implementation of FMEA in hospital laboratories, focusing on identifying critical failure modes, calculating Risk Priority Numbers (RPNs), and developing corrective actions to enhance laboratory safety and efficiency [2].

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The study demonstrates that systematic application of FMEA significantly improves risk awareness and process control, thereby reducing the likelihood of adverse outcomes in clinical diagnostics [3].

To minimize these risks, structured risk management strategies are essential. Failure Mode and Effects Analysis (FMEA) is one such method, originally developed in the aerospace industry and now adapted across healthcare sectors. It allows multidisciplinary teams to proactively analyze potential failure points, assess their severity, and prioritize improvement measures before adverse events occur.

### **The Impact of Risk Management on Hospital Administration and Prevention of Critical Incidents**

Hospitals are complex organizations where numerous interrelated processes converge to deliver quality patient care. In such dynamic environments, effective risk management has become an indispensable component of hospital administration. It involves the systematic identification, evaluation, and mitigation of potential risks that could jeopardize patient safety, disrupt clinical workflows, or cause financial and reputational harm to healthcare institutions. The adoption of robust risk management practices enables hospitals to anticipate and prevent adverse events before they occur, thereby safeguarding patients, staff, and resources [4].

The healthcare sector faces unique challenges, including the high stakes of medical errors, unpredictable patient needs, and evolving regulatory requirements. Failures within hospital processes can lead to critical incidents such as medication errors, diagnostic inaccuracies, infections, or equipment failures all of which may result in significant morbidity, mortality, or legal consequences. Therefore, embedding comprehensive risk management frameworks within hospital operations is crucial to minimizing these adverse outcomes [5]. Risk management tools, such as Failure Mode and Effects Analysis (FMEA), Root Cause Analysis (RCA), and incident reporting systems, empower hospital administrators to proactively analyze vulnerabilities, prioritize risks based on their severity and likelihood, and implement corrective actions. These strategies foster a culture of safety, enhance organizational resilience, and support compliance with international accreditation standards [6].

In summary, risk management plays a pivotal role in hospital administration by enabling early detection of potential hazards and facilitating informed decision-making. By preventing critical incidents and promoting continuous quality improvement, risk management enhances patient outcomes, operational efficiency, and institutional credibility in an increasingly complex healthcare landscape.

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**Table:** Research Background on FMEA in Clinical & Hospital Laboratories

Author(s)	Year	Title of Study	Methodology	Key Findings	Relevance to Current Study
Al-Shammari et al. [12]	2021	<i>Using Failure Mode and Effects Analysis (FMEA) to Improve Laboratory Quality in a Tertiary Care Hospital</i>	Cross-sectional FMEA in a Saudi Arabian central laboratory; multidisciplinary team identified failure modes, scored S/O/D, calculated RPNs, and implemented corrective actions	High-RPN issues: sample mislabeling, delayed results, equipment downtime. Barcode implementation and updated protocols significantly reduced errors.	Core empirical support—demonstrates FMEA’s practical impact in a hospital lab akin to the current study’s setting.
Blaško et al., [13]	2023	<i>Application of the FMEA Tool in an Accredited Testing Laboratory in the Context of the ISO/IEC 17025:2017 Standard</i>	FMEA risk assessment in 8 key areas of an accredited testing lab; aligned with ISO/IEC 17025 requirements; identified and prioritized risks	The FMEA-based risk database improved error control and decision-making in compliance with accreditation standards.	Shows applicability of FMEA beyond clinical labs—supports cross-contextual relevance and standard compliance.
El-Awady [14]	2023	<i>Overview of Failure Mode and Effects Analysis (FMEA): A Patient Safety Tool</i>	Narrative review describing FMEA applications in various healthcare processes, with illustrative case studies	Emphasizes FMEA’s role in proactive error prevention, structured workflows, and patient safety enhancement across clinical settings.	

**Methodology**

The FMEA process for hospital laboratories generally follows these key steps:

**Process Mapping:** A detailed mapping of laboratory workflows is conducted from sample collection to test result reporting to identify each sub-process.

**Team Formation:** A multidisciplinary team is assembled, including laboratory technologists, quality managers, physicians, and risk managers, to ensure comprehensive insight.

**Identification of Failure Modes:** At each step, potential failure modes (e.g., mislabeled samples, reagent degradation, and equipment calibration failure) are listed.

**Risk Evaluation:** Each failure mode is scored based on:

- **Severity (S):** The impact on patient safety or service quality if the failure occurs.
- **Occurrence (O):** The likelihood that the failure will happen.

- **Detection (D):** The likelihood that the failure will be detected before it causes harm. Each parameter is rated on a scale of 1 to 10, and the Risk Priority Number (RPN) is calculated as:

$$RPN = S \times O \times D$$

**Prioritization and Action Planning:** Failure modes with the highest RPNs are prioritized for intervention. Action plans may include retraining staff, revising SOPs, introducing barcode systems, or preventive maintenance programs.

**FMEA + PDSA = powerful combo:** Embedding FMEA within iterative quality cycles strengthened risk control and fostered a proactive safety culture.

**Quantitative management:** The use of RPN metrics was crucial in prioritizing which risks to address and tracking progress afterward.

**Team & resource focus:** Clear assignment of tasks and resource allocation contributed to the success of mitigation efforts.

**Continuous improvement:** The reassessment step ensured that improvements were sustained, not one-off fixes.

**Results and Discussion**

**Key Findings:**

In a pilot FMEA conducted in a hospital laboratory, the following failure modes emerged as high-risk:

- Sample mislabeling (RPN: 280)
- Delay in sample transport (RPN: 216)
- Equipment malfunction due to lack of maintenance (RPN: 198)
- Reagent expiration oversight (RPN: 175)

**Corrective Actions Implemented:**

- **Sample Identification:** Barcode systems were introduced for improved tracking and reduced labeling errors.
- **Logistics Optimization:** A pneumatic tube system and electronic sample tracking reduced transport delays.
- **Equipment Monitoring:** A digital maintenance calendar was introduced with alerts for routine checks.
- **Inventory Management:** Automated alerts for reagent expiry dates were added to the lab management software [15].

**Table 1: Identified Failure Modes and Initial RPN Scores**

Laboratory Process	Failure Mode	Severity (S)	Occurrence (O)	Detectability (D)	RPN
Sample registration	Incorrect sample labeling	9	6	5	270
Sample transport	Delay in transferring sample to analysis	7	5	6	210
Equipment maintenance	Equipment failure due to poor maintenance	8	4	6	192
Inventory management	Use of expired reagents	6	4	7	168
Result reporting	Data entry error in LIS	8	3	5	120

This table presents the first step of the FMEA process identifying and evaluating potential failure modes across different laboratory activities:

- Each failure mode represents a specific risk-prone activity that could affect the accuracy, timeliness, or safety of laboratory services.
- The **Severity (S)** score reflects how serious the consequences would be if that failure occurred (scale: 1–10).
- **Occurrence (O)** indicates how frequently the failure is likely to happen.

- **Detectability (D)** refers to the likelihood that the failure would be detected before it causes harm.

- **RPN (Risk Priority Number)** is calculated by multiplying  $S \times O \times D$  and helps prioritize risks. For example, "incorrect sample labeling" had an RPN of **270**, making it the **highest-risk issue** needing urgent attention [16].

**Table 2: Corrective Actions and Responsibility Allocation**

Failure Mode	Proposed Corrective Action	Responsible Party	Implementation Timeline
Incorrect sample labeling	Introduce barcode system and automated scanners	Quality Control Officer	Immediate
Delay in sample transport	Install pneumatic tube system or dedicated courier	Technical Manager	Within 1 month
Equipment failure	Create digital preventive maintenance calendar	Equipment Coordinator	Within 2 weeks

Use of expired reagents	Implement automatic expiry alerts in inventory software	Laboratory Manager	Within 1 week
Data entry error in LIS	Retrain staff; add double-check validation in result submission system	Training Supervisor	Within 10 days

This table shows the **actions taken** to address the high-priority risks identified in Table 1.

- For each failure mode, a **specific corrective or preventive action** is proposed.
- A **responsible party** is assigned to implement the solution (e.g., lab manager, QC officer).

- A **timeline** ensures accountability and timely risk mitigation.

This step transforms theoretical analysis into **practical safety improvements**. For instance, barcode systems were introduced to minimize human error in sample labeling.

**Table 3:** Comparison of RPN Scores Before and After Intervention

Failure Mode	RPN (Before)	RPN (After)	Risk Reduction (%)
Incorrect sample labeling	270	90	66.7%
Delay in sample transport	210	84	60.0%
Equipment failure	192	96	50.0%
Use of expired reagents	168	63	62.5%
Data entry error in LIS	120	60	50.0%

The FMEA application resulted in a significant risk reduction across key laboratory processes. The average RPN decreased from 192 to 78.6, indicating substantial improvements in process safety, reliability, and operational efficiency.

This table demonstrates the impact of the corrective actions by comparing RPN scores before and after implementation.

- All five failure modes showed a significant reduction in RPN, often by 50% or more.
- The average RPN across all issues dropped from 192 to 78.6, showing enhanced safety and process reliability.
- This post-intervention evaluation confirms the effectiveness of FMEA as a continuous improvement tool.

For instance, the RPN for “delayed sample transport” was reduced from 210 to 84, a 60% decrease, following implementation of a courier or pneumatic transport system.

These tables collectively represent the core cycle of FMEA:

1. Identify the risks (Table 1),
2. Act on them (Table 2),
3. Evaluate improvements (Table 3).

They help hospital labs quantify risk, prioritize safety efforts, and monitor outcomes, all of which are essential for patient safety, regulatory compliance (like ISO 15189), and operational excellence.

## Discussion

FMEA provided a structured platform for identifying latent risks and implementing preventive measures. The involvement of cross-functional staff enhanced communication and buy-in for safety protocols [17-19]. While FMEA is resource-intensive, the long-term benefits include reduced

diagnostic errors, improved patient satisfaction, and compliance with international accreditation standards such as ISO 15189 [20].

One limitation is the subjectivity in scoring severity, occurrence, and detection, which can vary across institutions. Regular review of RPN scores and continuous quality improvement (CQI) cycles are necessary to maintain the effectiveness of risk mitigation strategies [3-21-23].

Hospital laboratories serve as critical nodes within healthcare systems, providing timely and accurate diagnostic information that informs clinical decision-making. Despite advances in automation and quality control, laboratory processes remain vulnerable to a variety of risks ranging from human errors to equipment malfunctions that may jeopardize patient safety and the quality of diagnostic results [24-26]. Effective risk management is therefore essential to minimize such errors, improve operational efficiency, and comply with international quality standards such as ISO 15189.

Failure Mode and Effects Analysis (FMEA) is a systematic, proactive risk assessment tool originally developed for high-reliability industries such as aerospace and manufacturing. In recent decades, FMEA has been adapted to healthcare environments, including hospital laboratories, as a means to identify potential failure modes, analyze their causes and effects, prioritize risks, and implement corrective actions before adverse events occur. The application of FMEA in hospital laboratories enables multidisciplinary teams to collaboratively map processes, quantify risks, and foster a culture of continuous improvement [27].

The initial phase of FMEA involves detailed process mapping to visualize every step involved in specimen handling, from patient preparation and sample collection to analysis and result reporting.

This comprehensive workflow analysis uncovers potential points of failure that might otherwise be overlooked. For example, sample mislabeling, one of the most frequent and high-risk failures identified in numerous studies, can lead to incorrect diagnoses and inappropriate treatments, posing serious risks to patient safety [28].

Once failure modes are identified, each is assessed using three key criteria: Severity (S), Occurrence (O), and Detectability (D). Severity reflects the seriousness of the consequences if a failure occurs; occurrence estimates the likelihood of the failure happening; and detectability measures the probability that the failure will be caught before reaching the patient. These parameters, typically rated on scales from 1 to 10, are multiplied to yield a Risk Priority Number (RPN). The RPN serves as a quantitative metric to prioritize risks and allocate resources effectively [29].

In a practical hospital laboratory setting, high RPNs often correspond to critical failure modes such as mislabeled samples, delayed sample transport, equipment breakdowns, reagent expiration, and data entry errors in laboratory information systems (LIS). Addressing these issues requires tailored interventions. For instance, the implementation of barcode scanning technology has significantly reduced sample identification errors by automating labeling and verification processes. Similarly, enhancing equipment maintenance schedules with digital reminders ensures optimal functioning of analytical instruments, thereby minimizing downtime [30].

The risk management process does not end with the identification and mitigation of failure modes. Continuous monitoring and reevaluation are essential to validate the effectiveness of corrective actions. By recalculating RPNs post-intervention, laboratories can measure risk reduction and identify residual or emerging threats. In successful implementations, such as the case study summarized earlier, RPN values dropped by more than 50% for major failure modes after corrective actions were applied. This demonstrates the effectiveness of FMEA not only as a diagnostic tool but also as a framework for continuous quality improvement.

Beyond technical interventions, FMEA promotes enhanced **interdisciplinary communication** and staff engagement. Risk analysis workshops and FMEA sessions involve laboratory technicians, quality managers, clinicians, and support staff, fostering a shared understanding of risks and encouraging collective responsibility. This inclusive approach is essential to overcoming resistance to change and ensuring adherence to new protocols and safety measures.

Moreover, integrating FMEA into hospital laboratory management aligns with the requirements of international accreditation standards such as ISO 15189, which emphasize risk management, process

control, and continual improvement. By systematically documenting risk analyses and corrective actions, laboratories can demonstrate compliance during audits and external evaluations, thereby enhancing institutional credibility and patient trust.

However, challenges exist in implementing FMEA effectively in hospital laboratories. The process can be resource-intensive, requiring dedicated time, trained personnel, and data collection efforts. Subjectivity in scoring severity, occurrence, and detectability may introduce variability in RPN calculation, which necessitates calibration and consensus-building among team members. Additionally, rapid technological changes and evolving laboratory workflows demand regular updates to FMEA analyses to remain relevant.

To address these challenges, some laboratories have begun integrating FMEA with digital health tools and predictive analytics. For example, software platforms can automate risk scoring, track corrective actions, and alert managers to deviations in real time. Artificial intelligence (AI) algorithms can analyze large datasets to predict potential failures before they manifest, enhancing the preventive power of FMEA frameworks.

In conclusion, Failure Mode and Effects Analysis provides hospital laboratories with a robust, structured methodology to proactively identify and mitigate risks. Its application leads to measurable reductions in diagnostic errors, improved patient safety, and compliance with international standards. By fostering interdisciplinary collaboration and continuous improvement, FMEA contributes significantly to enhancing laboratory quality management systems. Future advancements in digital integration and data analytics promise to further increase the efficiency and predictive capabilities of FMEA in healthcare settings. Hospitals and clinical laboratories that adopt and sustain FMEA practices position themselves at the forefront of patient-centered, risk-aware diagnostic service delivery.

### **Comparative Analysis of Failure Mode and Effects Analysis (FMEA) Applications in Hospital Laboratories**

The application of Failure Mode and Effects Analysis (FMEA) in hospital laboratories has been widely studied, revealing consistent benefits as well as variations in approach and outcomes across different healthcare settings. This comparative analysis synthesizes findings from several recent studies to highlight common themes, divergences, and lessons learned regarding the use of FMEA as a risk management tool in clinical laboratories.

A foundational study by Al-Shammari et al. (2021) investigated the use of FMEA in a tertiary care hospital laboratory in Saudi Arabia. The study identified critical failure modes such as sample

mislabeled, delayed sample transport, equipment downtime, and reagent expiration. These failure modes had high Risk Priority Numbers (RPNs), with sample labeling errors ranking the highest at an RPN of 280. Interventions focused on implementing barcode systems, improving equipment maintenance schedules, and enhancing inventory control. Post-intervention analysis showed substantial RPN reductions, indicating significant risk mitigation.

Similarly, a 2023 study by Blaško et al. conducted in an accredited testing laboratory emphasized the alignment of FMEA with ISO/IEC 17025:2017 standards. This study expanded the application of FMEA beyond clinical diagnostic laboratories to a broader testing environment, reinforcing its versatility. By integrating FMEA into their quality management system, Blaško et al. reported improved decision-making and error reduction across multiple test phases. This study's results highlight FMEA's adaptability to different laboratory contexts while underscoring the importance of compliance with international standards.

El-Awady's (2023) narrative review further contextualizes these findings by examining FMEA's role across various healthcare domains. The review stresses the proactive nature of FMEA, which contrasts with traditional reactive risk management approaches. It emphasizes multidisciplinary involvement and continuous improvement as key factors in successful implementation. These elements are echoed in empirical studies, which consistently demonstrate that engaging diverse staff in FMEA sessions enhances both risk identification and buy-in for corrective measures.

While these studies align in recognizing FMEA's effectiveness in reducing laboratory errors and improving patient safety, differences emerge in methodological details and resource requirements. For instance, Al-Shammari et al. utilized a cross-sectional FMEA approach with a clearly defined scoring system, enabling quantifiable risk prioritization. In contrast, some laboratories adopt a more iterative, Plan-Do-Study-Act (PDSA) integrated model, as reported in a Brazilian clinical biochemistry laboratory study. This approach couples FMEA with continuous quality improvement cycles, fostering an ongoing risk assessment culture rather than a one-time intervention.

Additionally, variability exists in how detectability is assessed. Some studies rely heavily on expert judgment, which introduces subjectivity, while others incorporate data-driven indicators such as error logs and audit findings to inform scoring. This variation impacts the precision of RPN calculations and highlights the need for standardization or calibration among teams.

Technological integration also differentiates contemporary FMEA applications. The Saudi Arabian and Brazilian studies illustrate successful incorporation of barcode scanning and digital maintenance scheduling to reduce human error and equipment failures. Meanwhile, emerging research advocates for embedding artificial intelligence (AI) and predictive analytics to enhance FMEA's predictive capabilities. This trend promises to transform risk management from primarily manual and qualitative processes into more automated, data-driven systems.

Despite the positive results reported, challenges remain. Resource intensity is a common concern, especially in low- and middle-income countries where staffing and training capacities may be limited. Time-consuming meetings and data collection can burden already stretched laboratory personnel. Moreover, sustaining momentum after initial improvements requires organizational commitment and continuous training to adapt to evolving risks.

In summary, the comparative literature suggests that FMEA is a valuable and versatile tool for risk management in hospital laboratories. Key success factors include multidisciplinary involvement, alignment with accreditation standards, incorporation of technological tools, and integration within continuous quality improvement frameworks. Differences in implementation strategies reflect contextual factors such as laboratory size, available resources, and institutional culture.

Future directions should focus on standardizing FMEA methodologies to reduce subjectivity and improve comparability of results. Integration with digital health platforms and AI-driven analytics represents a promising evolution, enabling real-time risk monitoring and more efficient allocation of mitigation resources. By learning from diverse international experiences, hospital laboratories worldwide can optimize FMEA application to enhance diagnostic safety, efficiency, and patient outcomes [30].

## Conclusion

The application of Failure Mode and Effects Analysis in hospital laboratories is a robust, proactive approach to managing clinical risks. By identifying and addressing high-priority failure modes, FMEA enhances the reliability and safety of diagnostic processes. Institutions adopting FMEA benefit from improved patient outcomes, reduced operational inefficiencies, and heightened readiness for accreditation. Future work should focus on integrating FMEA with digital health tools and AI-based predictive analytics to further improve laboratory risk management.

Effective risk management is a cornerstone of modern hospital administration, crucial for ensuring

patient safety and maintaining operational integrity. By systematically identifying, assessing, and mitigating risks, hospitals can significantly reduce the occurrence of critical incidents such as medical errors, equipment failures, and adverse patient outcomes. The integration of structured risk management tools, including Failure Mode and Effects Analysis (FMEA), enhances the ability of healthcare organizations to anticipate vulnerabilities and implement preventive measures proactively. Moreover, fostering a culture of safety and continuous quality improvement empowers hospital staff at all levels to participate actively in risk reduction initiatives. This collaborative approach not only improves patient care but also contributes to regulatory compliance and institutional reputation. As healthcare environments continue to grow in complexity, the role of comprehensive risk management in hospital administration will only become more vital. In conclusion, prioritizing risk management equips hospitals to navigate challenges effectively, safeguard patients, and deliver high-quality care. By embedding these practices into everyday operations, healthcare institutions can create safer environments and better health outcomes for the communities they serve.

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#### Authors' Contributions

All authors contributed to data analysis, drafting, and revising of the paper and agreed to be responsible for all the aspects of this work.

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