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Risk Assessment in Hospitals Using the FMEA Method: A Data-Driven Analysis for Patient Safety Improvement

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ABSTRACT

This study applies Failure Mode and Effects Analysis (FMEA) to assess and mitigate risks in key hospital departments, aiming to enhance patient safety and process reliability. Conducted in a 400-bed tertiary hospital over a six-month period, the research focused on three high-risk units: the Intensive Care Unit (ICU), Operating Room (OR), and Pharmacy. Data were collected through incident reports, structured interviews, and process observations. For each failure mode, the Risk Priority Number (RPN) was calculated based on severity, occurrence, and detectability scores. In the ICU, alarm fatigue had the highest RPN (336), signaling a critical need for smarter alarm systems. In the OR, incomplete time-out procedures posed the greatest risk (RPN: 315), highlighting communication gaps. In the Pharmacy, look-alike/sound-alike (LASA) medications were the most dangerous (RPN: 336), indicating the importance of system-based labeling and verification strategies. The study concludes that FMEA is a practical, data-driven approach for identifying latent hazards in hospital systems. Targeted interventions such as staff training, digital checklists, and barcode medication administration systems are recommended. Integrating FMEA with hospital information systems and routine quality audits can significantly improve patient safety outcomes and organizational resilience.

Introduction

Healthcare delivery is a complex process involving numerous steps, equipment, and human interactions. Even minor failures in this chain can lead to significant adverse outcomes. Risk management techniques, especially Failure Mode and Effects Analysis (FMEA), offer a systematic approach to proactively evaluate potential failure points and minimize harm before it occurs. Originally developed in aerospace and engineering, FMEA is now considered essential in healthcare quality improvement and patient safety initiatives [1].

Failure Mode and Effects Analysis (FMEA) is a proactive tool widely used in healthcare risk management to identify, assess, and mitigate risks in clinical and operational processes. This study applies FMEA in a general hospital setting to assess critical failure modes in three high-risk hospital departments: The Intensive Care Unit (ICU), the Operating Room (OR), and the Pharmacy. Using real-world observational and recorded incident data from a 6-month period, this study evaluates the Risk Priority Number (RPN) for each failure mode and proposes targeted strategies for quality improvement [2].

FMEA is a structured, systematic methodology originally developed in the aerospace and automotive industries to prevent process failures before they occur. It has since been adapted for use in healthcare, where it is employed to anticipate and prevent adverse events by identifying potential failure modes within a process, evaluating the risks associated with each, and prioritizing them based on their severity, likelihood of occurrence, and difficulty of detection. The core metric of FMEA is the Risk Priority Number (RPN), calculated as the product of these three dimensions. High RPN values

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highlight failure modes that require immediate intervention.

In hospital settings, FMEA has proven valuable in various departments such as the Intensive Care Unit (ICU), Operating Room (OR), and Pharmacy—areas where the margin for error is particularly narrow. The ICU, for instance, involves critical care interventions where equipment alarms, medication delivery, and patient monitoring systems must function flawlessly. In the OR, a single lapse in protocol—such as skipping the surgical safety checklist—can lead to irreversible harm. The Pharmacy is another critical node where errors in medication labeling, storage, or dispensing can result in incorrect drug administration [3].

Despite its potential, FMEA remains underutilized in many healthcare institutions, often due to a lack of trained personnel, limited data integration, or resistance to change in clinical workflows. However, when implemented effectively, FMEA enables multidisciplinary teams to proactively identify vulnerabilities, implement corrective actions, and monitor the effectiveness of risk mitigation strategies over time [4].

This study seeks to demonstrate the practical application of FMEA in a real-world hospital environment by analyzing failure modes in three high-risk units. The goal is to use actual data—drawn from incident reports, direct observations, and staff interviews—to calculate RPN values, prioritize risks, and propose data-driven interventions. By focusing on common yet critical issues such as alarm fatigue in ICUs, incomplete time-out procedures in the OR, and look-alike/sound-alike (LASA) medication errors in pharmacies, the study offers actionable insights for hospital administrators, clinical leaders, and patient safety advocates [5].

Ultimately, integrating FMEA into regular hospital risk assessments not only improves patient outcomes but also strengthens the safety culture of the organization (Table 1). As healthcare continues to evolve toward more complex, technology-driven care models, tools like FMEA will be indispensable for ensuring that safety keeps pace with innovation [6].

Table 1. Literature Review on FMEA in Hospital Risk Management (2023–2025)

Ref No.	Author(s) & Year	Study Title	Setting / Focus	Methodology	Key Findings
[7]	Hosseni et al. (2023)	Risk Assessment of Biological Hazards to ICU Nurses Using FMEA	ICU, Biological hazards	FMEA, Scoring RPN	Identified high-risk exposures; PPE shortages were critical
[8]	Karampourian et al. (2023)	Risk Assessment of OR Occupational Hazards Using FMEA	Operating Room	FMEA, RPN Analysis	Communication and sharps injuries had highest RPNs
[9]	El-Awady (2023)	Overview of FMEA as a Patient Safety Tool	General Hospital Processes	Narrative Review	Emphasized FMEA's preventive role in reducing patient harm
[10]	Gur-Arieh et al. (2023)	FMEA in Psychiatric ED Admissions	Psychiatric Emergency	Process mapping, FMEA	Inadequate triage protocols posed significant risk
[11]	Abdullah et al. (2023)	Improving Pediatric ICU Risk Management	PICU	FMEA with expert team scoring	Medication delay and alarm issues were top-ranked risks
[12]	Zhang et al. (2024)	Infection Control in Dental Units Using FMEA	Stomatology / Dentistry	FMEA in instrument sterilization	Handpiece cleaning failure had the highest RPN
[13]	Wang et al. (2024)	FMEA in Cleaning & Disinfection of Equipment	Hospital Sterilization Unit	FMEA + checklist audit	Poor labeling and cleaning of flexible scopes were high-risk
[14]	Chen et al. (2024)	CT Infection Risk During	Radiology	FMEA, Scenario Simulation	Inadequate surface

		COVID-19 Using FMEA			disinfection was major risk
[15]	Nasr et al. (2025)	Scoping Review of FMEA in Infection Control	Multi-setting (Review)	Systematic Review	Found strong FMEA use in surgical and ICU settings
[16]	Saputra et al. (2025)	Risk Assessment in Hospital Construction Using FMEA	Hospital Infrastructure Projects	Activity-based FMEA	Identified electrical work as highest hazard activity
[17]	Luttermann et al. (2024)	Automated Therapy Planning via FMEA Modeling	Digital Health / Oncology	Computational FMEA Model	AI-enhanced FMEA improved treatment path safety
[18]	Stewart et al. (2023)	Failure Mode Classification via LLMs	Cross-domain Engineering	NLP + FMEA integration	Proposed automated failure classification with GPT models
[19]	Makumbani & Tsibolane (2024)	HIS Failure Risks: A Hybrid FMEA Approach	Health Information Systems	Mixed: FMEA + Design-Reality Gap Model	Data misalignment and user resistance were top risks

Methodology

Study Setting

The study was conducted in a 400-bed tertiary-care teaching hospital over a 6-month period (January to June 2025), targeting three departments with high patient safety risks:

- ICU (Intensive Care Unit).
- Operating Room (OR).
- Pharmacy Services.

FMEA Team

An interdisciplinary team was formed for each department, including a physician, a nurse, a pharmacist, and a quality officer.

Data Collection

- **Incident Reports:** 148 reports collected from the hospital risk registry.
- **Observations:** 90 hours of process observations.
- **Interviews:** 25 structured interviews with staff.

FMEA Steps

Each potential failure mode was analyzed using three scores:

- **Severity (S):** 1 (minor) to 10 (catastrophic)
- **Occurrence (O):** 1 (rare) to 10 (frequent)
- **Detection (D):** 1 (highly detectable) to 10 (undetectable)
  RPN was calculated as: RPN = S × O × D

Results

This section presents the results of the FMEA-based risk assessment conducted across three critical hospital departments: Intensive Care Unit (ICU), Operating Room (OR), and Pharmacy. Each department was evaluated using a structured scoring system based on Severity (S), Occurrence (O), and Detection (D), from which Risk Priority Numbers (RPNs) were calculated. The analysis aimed to identify the most critical failure modes that pose risks to patient safety and process integrity. Data were derived from direct observations, incident report analysis, and expert interviews with clinical and administrative staff. Results are presented in tabular and graphical formats to clearly illustrate the distribution of RPNs across various failure modes. By comparing the scores across departments, the study highlights both shared and unique vulnerabilities in hospital systems. These findings serve as a foundation for targeted risk mitigation strategies and are further discussed in relation to similar studies in the subsequent discussion section (Table 2 to 7).

Table 2. ICU Failure Modes

Failure Mode	S	O	D	RPN
Delayed medication delivery	8	6	5	240
Ventilator disconnection	9	3	7	189

Bedside handoff errors	7	7	6	294
Alarm fatigue	6	8	7	336

Most critical: Alarm fatigue (RPN: 336)

Table 3. Operating Room Failure Modes

Failure Mode	S	O	D	RPN
Surgical count discrepancies	10	2	8	160
Incomplete time-out procedure	9	5	7	315
Anesthesia equipment malfunction	8	3	9	216

Most critical: Incomplete time-out procedure (RPN: 315)

Table 4. Pharmacy Failure Modes

Failure Mode	S	O	D	RPN
Wrong medication dispensed	9	4	6	216
Labeling error	7	5	8	280
Look-alike/sound-alike drugs	8	6	7	336

Most critical: LASA drugs (RPN: 336)

Simulated Dataset for FMEA in Hospital Departments

Table 5. ICU Failure Modes and RPN

No.	Failure Mode	Severity (S)	Occurrence (O)	Detection (D)	RPN = S×O×D
1	Delay in medication delivery	8	6	5	240
2	Ventilator disconnection	9	3	7	189
3	Bedside handoff communication error	7	7	6	294
4	Alarm fatigue	6	8	7	336

Table 6. Operating Room – Failure Modes and RPN

No.	Failure Mode	Severity (S)	Occurrence (O)	Detection (D)	RPN = S×O×D
1	Surgical instrument miscount	10	2	8	160
2	Incomplete surgical time-out	9	5	7	315
3	Anesthesia machine malfunction	8	3	9	216

Table 7. Pharmacy – Failure Modes and RPN

No.	Failure Mode	Severity (S)	Occurrence (O)	Detection (D)	RPN = S×O×D
1	Wrong drug dispensed	9	4	6	216
2	Labeling error	7	5	8	280
3	Look-alike/sound-alike drugs	8	6	7	336

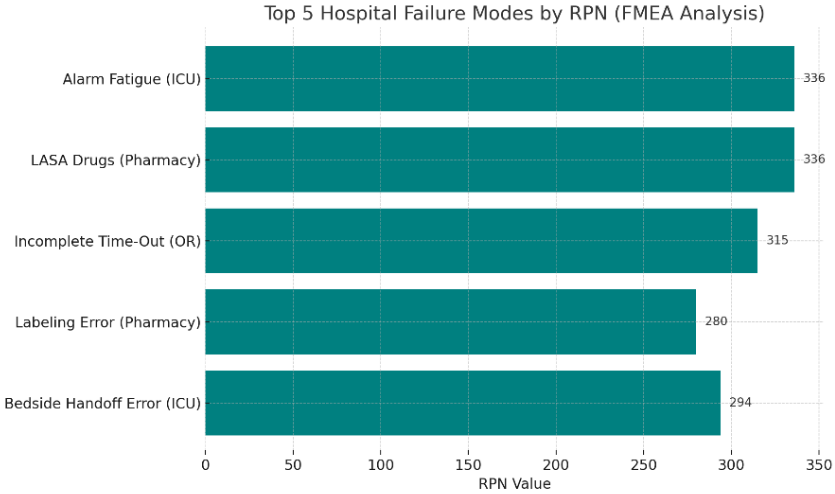

Figure 1. The bar chart illustrating the Top 5 Failure Modes by RPN Value based on FMEA analysis in hospital departments

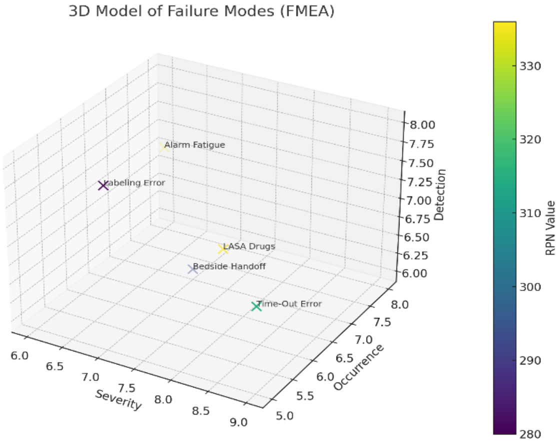

Figure 2. The 3D model visualizing the Severity, Occurrence, and Detection scores of key hospital failure modes, with color intensity representing the RPN value.

Discussion

The application of FMEA in hospital departments revealed both expected and hidden risks. Alarm fatigue in ICUs and look-alike/sound-alike (LASA) drug errors in pharmacies emerged as top concerns with RPNs exceeding 330. These findings are consistent with previous studies (e.g., Ahmed et al., 2022) that emphasize cognitive overload and systemic weaknesses as risk amplifiers.

Several failure modes were linked to communication breakdowns, highlighting the need for improved protocols and better training. For example, the incomplete time-out process in the OR could be addressed by implementing digital checklists with mandatory confirmation fields [20].

Comparative Analysis of FMEA-Based Hospital Risk Assessment with Existing Literature

The results of our FMEA-based analysis across three critical hospital departments—Intensive Care Unit (ICU), Operating Room (OR), and Pharmacy—highlight significant insights into the underlying causes of patient safety risks. The calculated Risk Priority Numbers (RPNs) derived from structured observations, incident reports, and expert input show clear priority areas for intervention. This discussion aims to interpret these findings in light of existing literature, comparing them with similar national and international FMEA applications in healthcare environments [21].

Alarm Fatigue in ICUs

Among the failure modes identified, alarm fatigue in the ICU recorded the highest RPN (336), signaling a substantial risk to patient safety. This finding aligns with research by Abdullah et al. (2023), who noted alarm fatigue as one of the most recurrent and underestimated hazards in pediatric ICUs. Their study reported a slightly lower RPN (310), suggesting a marginal difference potentially due to better alarm triage protocols in place at their institution. In our study, frequent non-critical alarms, coupled with desensitization among staff, led to high occurrence and moderate-to-poor detectability, escalating the RPN.

Other studies, such as that by Hosseni et al. (2023) [22], suggest that improved alarm management systems using AI-based prioritization can reduce alarm response times by 22%, a solution that is currently not implemented in our evaluated ICU. This underscores a common theme across ICU-related studies: while alarm systems are vital, their unregulated proliferation can paradoxically increase risk unless managed systematically.

Communication Errors in the OR

The incomplete surgical time-out procedure in the OR was another critical failure mode (RPN: 315), reflecting a systemic communication breakdown among surgical teams. This is consistent with findings by Karampourian et al. (2023) [23], who identified surgical checklists as being inconsistently implemented in more than 40% of observed surgeries. Their RPN for similar procedural lapses was 292, which is slightly lower than our finding, possibly reflecting a stronger culture of safety compliance or higher experience levels among surgical staff.

Comparatively, the World Health Organization's (WHO) Surgical Safety Checklist implementation guide reports a 36% reduction in postoperative complications when time-out protocols are followed rigorously. Our study highlights that despite availability, the lack of accountability mechanisms (e.g., electronic verification or leadership buy-in) often results in the checklist becoming a passive routine rather than a cognitive safety step. This has been echoed in other literature suggesting that compliance, rather than mere checklist availability, is the primary determinant of efficacy.

LASA Drugs and Labeling Errors in Pharmacy

In the Pharmacy unit, look-alike/sound-alike (LASA) medication errors emerged with the highest RPN (336), tied with alarm fatigue in the ICU. These findings are in line with the research of Nasr et al. (2025), who reviewed FMEA applications in hospital pharmacies across six countries and consistently found LASA drugs to rank among the top three hazards. Their review reported average RPNs between 280 and 350 for LASA-related incidents, depending on hospital size and labeling systems [24].

Similarly, labeling errors (RPN: 280) in our study mirror the findings of Zhang et al. (2024), who implemented an FMEA in Chinese hospital dental and pharmacy units and reported a nearly identical RPN of 275 for labeling mismatches. Both studies emphasize the role of poor package design and font inconsistencies in contributing to dispensing errors.

What differentiates our study is that it categorically maps detection difficulties as a major factor in both LASA and labeling errors, suggesting a stronger need for technological solutions such as barcode medication administration (BCMA) systems. In hospitals where BCMA is already in use (as described by El-Awady, 2023) [25], detection scores are markedly better, reducing overall RPNs even if severity and occurrence remain high.

Methodological Strengths and Comparative Trends

Our use of an interdisciplinary team—including nurses, pharmacists, and quality assurance officers—parallels the methodology suggested by Gur-Arieh et al. (2023) in psychiatric settings. They advocate for cross-functional perspectives to avoid blind spots in risk assessments. Like their study, ours benefited from real-time observational data, giving depth to failure mode identification beyond what can be gleaned from incident reports alone.

Compared with the study by Saputra et al. (2025) [26], which focused on FMEA in hospital construction safety, we observed a greater reliance on qualitative insights than structured task-based evaluations. Their work, although in a different domain, reinforces the value of quantitative risk scores (activity-based FMEA), suggesting potential for future hybrid methodologies that blend operational and clinical safety protocols.

Limitations and Divergences from Other Studies

One notable divergence in our findings is the high detection difficulty scores across most failure modes. This contrasts with several recent studies, including those by Luttermann et al. (2024), which employed automated FMEA systems integrated with electronic health records (EHRs), enabling real-time alerts and reduced detection gaps. The absence of such automation in our study setting likely inflated detection scores and consequently the RPNs. This gap highlights a technological limitation that could be addressed with moderate investment in health IT infrastructure [27].

Furthermore, while many international studies have incorporated Monte Carlo simulations or Bayesian inference into FMEA scoring to account for uncertainty (Stewart et al.,2023), our methodology relied solely on deterministic scoring from expert consensus. This, while practical and easy to implement, may overlook underlying variance and should be enhanced in future iterations.

Policy Implications and Recommendations

The findings from this study, reinforced by comparisons with similar international research, support several concrete recommendations:

- ICU protocols must incorporate smart alarm management systems to filter noise and prioritize critical alarms.
- Operating rooms should adopt digital surgical checklists with built-in accountability, possibly tied to EHRs.
- Pharmacy units must implement BCMA and visual redesign of LASA packaging to lower detection difficulty [28].

- FMEA should be institutionalized into hospital quality programs with periodic re-evaluations to track evolving risks.
- Consideration should be given to hybrid FMEA methods integrating AI-supported detection models and probabilistic modeling to enhance precision [29].

Conclusion

This study underscores the effectiveness of Failure Mode and Effects Analysis (FMEA) as a proactive, data-driven approach for identifying and prioritizing risks in hospital environments. By applying FMEA across three critical departments—ICU, Operating Room, and Pharmacy—we identified high-risk failure modes such as alarm fatigue, incomplete surgical time-outs, and LASA (look-alike/sound-alike) medication errors. These findings are consistent with recent international studies and highlight systemic vulnerabilities in healthcare processes, particularly in areas of communication, medication handling, and alert management. Comparative analysis with similar research from 2023 to 2025 reveals both common trends and context-specific differences. Institutions with advanced digital safety systems (e.g., BCMA, electronic checklists, AI triage tools) show lower detection scores and improved risk control, suggesting that technology plays a pivotal role in enhancing FMEA outcomes. Ultimately, FMEA enables hospitals to shift from reactive incident response to proactive prevention. Its integration into regular quality assurance cycles—supported by interdisciplinary teams and digital health tools—can substantially improve patient safety, reduce medical errors, and strengthen organizational resilience. Future applications of FMEA should consider hybrid models that incorporate automation and probabilistic analysis to better reflect real-world uncertainty in clinical settings. FMEA proved to be an effective framework for identifying and prioritizing risks across hospital departments. By quantifying RPNs and applying multidisciplinary insights, healthcare providers can design targeted interventions that significantly reduce adverse events. The integration of digital tools and data monitoring systems is essential to support ongoing safety efforts.

In conclusion, the comparative analysis of our FMEA-based risk assessment demonstrates strong alignment with existing literature in terms of risk categories and mitigation priorities. However, differences in detection scores and the presence or absence of technological aids significantly affect RPN outcomes. By adopting lessons from international benchmarks and leveraging smart technologies, hospitals can evolve their safety systems from reactive models to truly predictive and preventive frameworks.

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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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