RESEARCH PAPER

Hospital-Wide Patient Safety Risk Mapping Using NABH-Aligned FMEA in a Resource-Limited Tertiary Care Teaching Hospital

Dr. Vishnu Sunil[1], Dr. Sharanya Mohan[2*], Zichen Sherpa[3], Ritu Pal[4]

[1]Associate Professor, Department of Hospital Administration, All India Institute of Medical Sciences, Rajkot, Gujarat, India.

[2*]Senior Resident, Department of Hospital Administration, All India Institute of Medical Sciences, Kalyani, West Bengal, India.

Email: drsharanyamohan81@gmail.com

[3]Nursing Officer, All India Institute of Medical Sciences, Kalyani, West Bengal, India.

[4]Nursing Officer, All India Institute of Medical Sciences, Kalyani, West Bengal, India.

Received: 15th Jul, 2026 | Revised: 25th Jul, 2026 | Accepted: 5th Aug, 2026 | Available Online: 12th Aug, 2026

ABSTRACT

Background: Maintaining patient safety is a foundation of quality health care. Structured risk evaluations with evidence-based tools like Failure Mode and Effects Analysis (FMEA) have the potential to identify hidden safety risks throughout the healthcare environment.

Objectives: To identify, classify, and rank patient safety risks in 25 departments of a tertiary care teaching hospital based on NABH-compatible checklists and FMEA principles.

Methods: A cross-sectional observational survey was carried out in March 2025 among 25 inpatient and service departments, including ICUs, OPDs, procedural suites, and support services. A NABH-based validated patient safety checklist was utilized for focused data collection. Results were evaluated using FMEA methodology to assign scores to severity, occurrence, and detection of every risk.

Results: Major system-wide hazards were non-emergency equipment availability (80% of departments), sub-standard infection control SOPs (72%), fire extinguishers outdated and fire drills missing (92%), and calibrated equipment delayed (84%). ICU and OT-specific hazards were unmonitored HVAC systems and non-existent microbiological surveillance. Psychiatry wards did not have anti-ligature fixtures, surgical areas did not have zoning and dirty corridor separation, and most departments did not have organized fall risk assessment, patient identification procedures, and Code Blue readiness.

Conclusion: There are important gaps in patient safety in more than one department, particularly in emergency preparedness, infection control, and infrastructure safety. It is advised to use an active, system-based risk management strategy like FMEA, as well as institutionalizing a multidisciplinary patient safety committee and periodic audits.

Keywords: Patient safety, risk assessment, FMEA, quality in hospitals, NABH, infection control, fire safety, equipment calibration.

How to cite this article: Sunil V, Mohan S, Sherpa Z, Pal R., Hospital-Wide Patient Safety Risk Mapping Using NABH-Aligned FMEA in a Resource-Limited Tertiary Care Teaching Hospital. Int J Drug Deliv Technol. 2026;16(76s): 526; DOI: 10.25258/ijddt.16.76s.47

INTRODUCTION

Patient safety is among the most essential responsibilities of any health-care organization. The World Health Organization (WHO) finds that in high-income nations, an estimated 1 out of every 10 inpatients suffers a bad event, a rate likely to be greater in low-resource countries.[1] A study from AIIMS found that about 5.2% of hospitalized patients in a sample experienced adverse events, of which nearly 70% were preventable. [2] Understanding these hazards and addressing them in a systematic fashion is key to obtaining safe, high-quality care.

Indian hospitals are increasingly embracing the standards of the National Accreditation Board for Hospitals and Healthcare Providers (NABH) ,which focuses on leadership, patient participation, safe clinical processes, environment of care, and continuous learning.[3] The Failure Mode and Effects Analysis (FMEA) is one tool that also identifies weaknesses by determining the severity, frequency, and detectability of probable failures.[4]

Although increased awareness, even many large tertiary teaching hospitals find it difficult to manage uniform patient safety practices across their diverse departments and services. There is a requirement for formalized risk assessments that not only spot hazards but also order interventions according to risk scale.

This research was conducted in a 1000-bed developing tertiary care teaching hospital in West Bengal to perform an exhaustive patient safety risk assessment in 25 priority departments by utilizing NABH-compatible checklists. The results were classified based on FMEA scoring methodology to determine high-priority safety risks and guide evidence-based rectifications.[5]

OBJECTIVES

Primary Objective:

• To recognize and classify patient safety hazards in 25 departments of a teaching tertiary care hospital with the help of a structured checklist as per NABH standards.

Secondary Objectives

• To score identified risks by Failure Mode and Effects Analysis (FMEA) scoring.

• To suggest corrective measures based on the severity and extent of identified risks.

METHODOLOGY

A cross-sectional, observational hospital-based study was conducted in West Bengal, India, in a tertiary care teaching hospital with 1000 beds. The institution was in the development phase when the research was undertaken, and the various processes of operation, clinical guidelines, and administrative procedures were still in the process of formulation. A risk assessment of patient safety hospital wide was conducted in all 25 clinical and support departments. The evaluation was carried out within one month by a three-person team, using standardized NABH (National Accreditation Board for Hospitals & Healthcare Providers) patient safety checklists. Data were collected through direct observation and non-structured interviews with frontline health care staff to determine possible safety hazards in every department. The identified risks were evaluated employing the Failure Mode and Effects Analysis (FMEA) approach. For every failure mode, the Risk Priority Number (RPN) was determined by rating severity, occurrence, and detectability on an ordinal scale. The risk stratification and identification of high-priority areas were done based on RPN values. Heat maps were created to visually represent the risk

distribution in departments to facilitate priority for corrective actions.

RESULTS

25 departments were evaluated for patient safety hazards, of which 10 were inpatient wards, 3 were ICUs, and 12 were support and procedural areas. The observations were scored on the principles of FMEA.

There were a total of 158 unique patient safety hazards identified in all the departments. These patient safety hazards were later grouped into 8 most frequent repeated hazards which included fire safety violations, absence of emergency equipment, infection control non-compliance, delays in equipment calibration, and failure to have fall risk assessments.

Table 1: Most Frequently Occurring Risk Categories

Risk Category	No. of Departments Affected	% Coverage (n=25)
Expired/Absent Fire Safety	23	92%
Unavailability of Emergency Equipment	20	80%
Equipment Calibration Pending	21	84%
No Fall Risk Assessment	18	72%
No Infection Control SOP	18	72%
Lack of ACLS/Staff Training	19	76%
Lack of Code Blue Protocol	15	60%
Missing Wristbands/ID Errors	12	48%

These risk categories then underwent risk prioritization by calculating the RPN or risk priority number using FMEA tool.[6]

Table 2: Risk priority number (RPN) for identified hazards

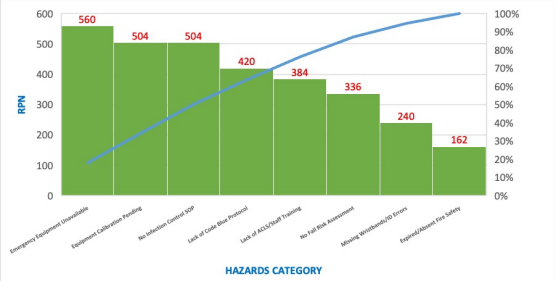
Hazard	Severity(S)	Occurrence(O)	Detectability(D)	RPN
1. Expired /Absent Fire Safety	9	9	2	162
2. Unavailability of Emergency equipment	10	8	7	560
3. Equipment Calibration Pending	8	9	7	504
4. No Fall Risk Assessment	8	7	6	336
5. No Infection Control SOP	9	8	7	504

6. Lack of ACLS/ Staff Training	8	8	6	384
7. Lack of Code Blue Protocol	10	6	7	420
8. Missing Wristbands/ID Errors	8	5	6	240

Note: Severity, occurrence, and detection were scored on a 1–10 scale based on consensus of the assessor team

A pareto chart was created using the above data to categorise the priority of the hazards

Figure 1 : Pareto chart



The Pareto chart clearly highlights that " Unavailability of Emergency Equipment " (RPN 560) is top priority hazard, followed closely by "Equipment Calibration Pending" and "No Infection Control SOP" (both RPN 504), represent the issues that account for the majority of the total risk.

Hazards with RPN > 500 were categorised under high-priority and require immediate corrective action while those with RPN between 300–500 are moderate risks, requiring planned interventions and hazards below RPN 300 are still important but may be addressed as part of a long-term safety plan. Based on this prioritization , immediate and corrective actions were formulated and action plan was created to be implemented.

Table 3 : Action plan

S. No.	Hazard (RPN)	Corrective Action (CA)	Preventive Action (PA)	Time line	Responsible Unit
1	**Emergency Equipment Unavailable (RPN 560)**	Procure and install defibrillators/crash carts where missing. Ensure accessibility in all high-risk areas.	Monthly checklist audits. Biannual training on equipment use. Create minimum equipment standard per unit.	**Immediate**	Biomedical + Nursing + Procurement
2	**No Infection Control SOP (RPN 504)**	Draft department-specific SOPs. Train staff on hand hygiene, HAI prevention, disinfect	Implement HAI monitoring, audit compliance monthly, and revise SOPs yearly.	**Immediate**	Infection Control Team (ICT) + Dept. Heads

S. No.	Hazard (RPN)	Corrective Action (CA)	Preventive Action (PA)	Time line	Responsible Unit
		ion protocols.			
3	**Equipment Calibration Pending (RPN 504)**	Calibrate all biomedical equipment. Maintain calibration logbooks. Tag equipment with calibration due dates.	Implement digital alerts for calibration due. Schedule preventive maintenance every 3–6 months.	**Immediate**	Biomedical Engineering + QA Cell
4	**Lack of Code Blue Protocol (RPN 420)**	Implement Code Blue SOP. Mark activation points. Train all staff in emergency response. Conduct	Annual refresher training. Include Code Blue in new staff orientation. Month	**Short-Term**	Medical Admin + Quality + Nursing Heads
5	**Lack of ACLS/ Staff Training (RPN 384)**	mock drills. Identify untrained staff. Conduct ACLS/BLS workshops. Create training calendar.	ly Code Blue audit (response time). Integrate ACLS into onboarding. Issue certifications valid for 2 years. Track compliance digitally.	**Short-Term**	Training & HR + Departmental In-charges
6	**No Fall Risk Assessment (RPN 336)**	Introduce fall risk screening tools at admission. Place signage for high-risk patients. Use bed rails and	Conduct incident audits monthly. Train staff on fall prevention protoc	**Mid-Term**	Nursing + Patient Safety Officer

S. No.	Hazard (RPN)	Corrective Action (CA)	Preventive Action (PA)	Time line	Responsible Unit
		call bells.	ols. Include fall metrics in quality dashboard.		
7	**Missing Wristbands/ID Errors (RPN 240)**	Implement patient ID bands in all critical units. Educate staff on 2-identifier policy (name + MRD).	Periodic ID audits. ID band SOP reinforcement. Use color coding (e.g., allergy, fall risk).	**Mid-Term**	MRD + Nursing + IT/Software
8	**Expired/Absent Fire Safety (RPN 162)**	Replace expired extinguishers. Verify that evacuation maps and fire exit signs are present.	Create fire safety SOPs. Schedule 6-monthly mock drills. Maintain extinguisher	**Immediate**	Engineering + Safety Officer

S. No.	Hazard (RPN)	Corrective Action (CA)	Preventive Action (PA)	Time line	Responsible Unit
			inventory logs with expiry dates.		

Discussion

Our findings align with existing FMEA-based studies in India that emphasize infection control and equipment reliability as key risk domains. For instance, a 2022 study analyzing Indian hospital risk inventories identified infection control among the top hazards contributing to adverse events, alongside sentinel events and cybersecurity risks. [7]Similarly, another Indian study on occupational hazards using FMEA noted a high RPN (144) for needle-stick injuries—underscoring weaknesses in infection prevention and safety protocol.[8]

Our identification of No Infection Control SOP (RPN 504) closely mirrors these Indian findings. Infection prevention has consistently emerged as a priority, particularly in environments with nosocomial infection rates between 7–10% . This reinforces the urgency of formalizing standard operating procedures and emphasizing staff training and surveillance, as observed in Indian healthcare settings.

Our research highlights wider infrastructural and emergency-response dangers, in contrast to studies that solely focused on clinical or trash management (e.g., hospital waste FMEA studies that reported waste-handling RPNs >100).[9]

The prevalence of Emergency Equipment Unavailable (RPN 560) and Expired/Absent Fire Safety (RPN 162) indicates systemic deficiencies in hospital safety infrastructure, especially in Indian institutions with limited resources.

An FMEA study in ICUs and emergency departments in Southern India revealed moderate RPNs (112–135) for delays in drug delivery and patient preparation. [10]While those concerns are process-specific, our analysis stresses infrastructure and calibration failures with far higher RPNs, indicating more acute systemic vulnerabilities.

Internationally, infection control often leads FMEA analyses (e.g., RPNs ~127–270 in neonatal/sepsis care), underscoring their cross-contextual importance . Yet, our data uniquely highlight fire safety and emergency readiness as high-stakes issues—factors that, in India, may be exacerbated by outdated infrastructure and inconsistent safety audits.

By comparison, studies such as those focused on catheter-related bloodstream infections demonstrated successful RPN reductions ($\sim 100 \rightarrow 25$) through targeted interventions [11]This supports our recommendation for immediate correctional actions on high RPN hazards, with the expectation of similar improvements.

Strengths and Limitations

Strengths:

This study employs a structured FMEA framework with a Pareto analysis to pinpoint the most significant hazards—facilitating evidence-based prioritisation. By benchmarking against both Indian and global FMEA studies, we highlight unique systemic vulnerabilities, reinforcing the applicability of our findings to similar resource-limited healthcare settings.

Limitations:

The analysis is constrained by its reliance on expert judgment for severity, occurrence, and detection ratings, which may be subject to bias. The study is also conducted in a single healthcare facility, limiting generalisability. Additionally, interdependency among failure modes—such as equipment calibration and emergency readiness—was not quantitatively modelled. Finally, while corrective action efficacy is anticipated, it remains untested within this study period.

Conclusion.

In conclusion, this FMEA investigation identified four high-RPN hazards—fire safety lapses, unavailable emergency equipment, pending calibration, and absence of infection control SOPs—as primary contributors to organizational risk. These findings are consistent with Indian literature on infection prevention and highlight infrastructure-related hazards that have received less attention. Implementing targeted, immediate corrective actions will likely yield meaningful reductions in risk. Broader application and future studies should assess intervention effectiveness and explore interdependencies to enhance safety management in similar healthcare settings.

Authorship

All authors contributed substantially to the conception, design, data collection, analysis, and drafting of the manuscript. All authors have reviewed and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

Ethics Approval

This study involved observational, non-interventional risk assessment based on institutional safety protocols and did not involve human subjects, identifiable patient data, or clinical interventions. Hence, it was exempt from formal ethics committee review as per the institutional guidelines.

Acknowledgment

The authors would like to express their sincere thanks to the administrative and clinical teams at AIIMS Kalyani, West Bengal, for their cooperation during the data collection process. We are also grateful to the Infection Control and Engineering teams for their valuable inputs during risk evaluation.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

References:

1. WHO Patient Safety Standards.pdf [Internet]. [cited 2025 Jul 4]. Available from: https://qai.org.in/ALLDOCS/WHO%20Patient%20Safety%20Standards.pdf
2. Haukland EC, Mevik K, von Plessen C, Nieder C, Vonen B. Contribution of adverse events to death of hospitalised patients. BMJ Open Qual. 2019 Feb 13;8(1):e000377.
3. Home - NABH [Internet]. [cited 2025 Jul 4]. Available from: https://nabh.co/
4. Saputra PD, Fansuri MH, Laksmi AA, Ragil M, Simbolon MNB. Construction Safety Risk Assessment for Underground Structures in Military Hospital Projects Using Activity-Based Failure Mode and Effects Analysis (FMEA). Eng Proc. 2025;84(1):33.
5. Identification of key risk areas and failure modes using the FMEA method for the prevention and control of major infectious diseases in a stomatology department | BMC Oral Health | Full Text [Internet]. [cited 2025 Jul 4]. Available from: https://bmcoralhealth.biomedcentral.com/articles/10.1186/s12903-024-05321-3
6. Ghoushchi NG, Ahmadzadeh K, Ghoushchi SJ. A New Extended Approach to Reduce Admission Time in Hospital Operating Rooms Based on the FMEA Method in an Uncertain Environment. J Soft Comput Decis Anal. 2023 Aug 29;1(1):80–101.
7. Fidelis JS, Joseph L, Souza KD, Sankaranarayanan K, Agarwal V. Development of risk inventory for hospitals in India. J Patient Saf Risk Manag. 2023 Feb 1;28(1):21–30.
8. A K, A B, Kathiresan S. Assessing the Risk of Occupational Hazard Using the FMEA Tool Among Hospital Staff at Multispecialty Hospital. Int J Exp Res Rev. 2023 Nov 30;35:43–53.
9. Bayat N, Nabizadeh R, Yaghmaeian K, Askari M, Alimohammadi M. A Survey on the Status of Hospital Waste Management Using Two Methods of Risk Assessment of Failure Modes and Effects Analysis and Preliminary Hazard Analysis. Int J Environ Health Eng. 2025 May;14(2):16.
10. Suji U. FAILURE MODE AND EFFECT ANALYSIS (FMEA) WITH SPECIAL REFERENCE TO ICU,

EMERGENCY DEPARTMENT AND BIO-MEDICAL ENGINEERING DEPARTMENT IN ONE OF THE LEADING HOSPITALS IN COIMBATORE. 2022;09(05).

11. Li X, He M, Wang H. Application of failure mode and effect analysis in managing catheter-related blood stream infection in intensive care unit. Medicine (Baltimore). 2017 Dec 22;96(51):e9339.