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ORIGINAL RESEARCH

# Exploring the Correlation Between Patient Safety Culture and Adverse Medical Events Using Failure Mode and Effect Analysis (FMEA)

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**Objective:** This study aimed to explore the correlation between medical safety adverse events and patient safety culture through the lens of Failure Mode and Effect Analysis (FMEA).

**Methods:** Sixty patients from a hospital were selected as the research subjects, alongside 440 medical staff members (including clinical, medical technology, and management personnel) who participated in the study. The general demographic characteristics of medical staff, patient safety culture, and adverse medical safety events were investigated. FMEA was employed to analyze the relationship between medical safety adverse events and patient safety culture, using the risk priority number (RPN) as a key metric.

**Results:** A comparison of RPN values before and after FMEA intervention revealed that the RPN values of each failure mode significantly decreased post-intervention. Correlation analysis showed significant relationships between medication errors and several factors: "incident reporting frequency" (OR=0.706), "manager expectations and actions to promote patient safety" (OR=0.733), and "management support for patient safety" (OR=0.755). Pressure ulcers were significantly correlated with "manager expectations and actions to promote patient safety" (OR=0.729) and "shift and transfer" (OR=0.707). Falls were notably associated with "interdepartmental cooperation" (OR=0.735), "feedback and communication about errors" (OR=0.756), and "shift and transfer" (OR=0.660). Additionally, a strong correlation was identified between adverse events and "management support for patient safety" (OR=0.701).

**Conclusion:** Utilizing FMEA to analyze the correlation between medical safety adverse events and patient safety culture is effective in identifying specific dimensions of these events related to safety culture. This enables the development of targeted interventions to mitigate adverse events and enhance patient safety.

**Keywords:** failure mode and effect analysis, healthcare, medication errors, correlation

## Introduction

Patient safety is central to healthcare quality and has garnered significant attention from health departments in both developed and developing countries. Medical safety adverse events, arising from both personal errors and systemic weaknesses, have become a global issue in healthcare, with their incidence serving as a key indicator of patient safety. A systematic review found that the incidence of medical safety adverse events ranged between 7% and 40%,[1] with the most common events involving complications related to infections, surgeries, and medications. Another systematic review indicated that approximately 10% of patients experienced adverse events, of which 43% were preventable and 7.4% resulted in fatalities.[2]

Medical incident reporting systems are vital tools for improving patient safety, providing customized feedback for healthcare quality. However, challenges such as decentralization, bias, and limited system interoperability hinder effective cross-regional learning and incident analysis. Additionally, Health Information Technology (HIT) issues like

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poor software design and user interface problems further complicate safety efforts, highlighting the need for more integrated safety frameworks.[3–5]

In hospitals, patient safety culture encompasses trust-based communication, effective information flow, recognition of the importance of safety, organizational learning, leadership commitment, and non-punitive error reporting. Research by Alrasheeday highlights the significant impact of patient safety culture on medical safety adverse events. Other safety frameworks, such as Root Cause Analysis (RCA), Hazard Analysis and Critical Control Points (HACCP), and Failure Mode and Effects Analysis (FMEA), are widely used to evaluate and improve safety processes in healthcare. While RCA focuses on identifying the underlying causes of incidents, HACCP is more frequently used in food safety and healthcare settings for assessing potential hazards in critical care.[6] FMEA, in contrast, focuses on identifying potential risks in processes before they lead to harm, helping organizations prioritize which risks to address first. These frameworks, along with FMEA, contribute to understanding and mitigating risks in healthcare systems, offering different approaches to safety improvement. Research by Alrasheeday[7] highlights the significant impact of patient safety culture on medical safety adverse events.

Failure Mode and Effect Analysis (FMEA) is a tool that identifies potential risk pathways within processes and refines them to minimize the occurrence of risks.[8] The composition of the team is critical for the effective implementation of FMEA. According to Institute for Safe Medication Practices (ISMP) guidelines, an FMEA team should consist of 3 to 8 members, including both front-line practitioners and managers. Research shows that involving front-line staff in discussion groups is crucial, as they possess extensive experience in addressing practical issues.[9] The ISMP guidelines also recommend incorporating patient representatives into FMEA teams, which has led some studies to include patients or their family members in these groups.

In this study, FMEA was used to analyze medical safety adverse events through a structured, step-by-step approach. A diverse project management team was formed, and data was collected via questionnaires and three rounds of Delphi surveys to integrate multi-perspective insights. Brainstorming and consensus-building quantified failure mode risks using severity, occurrence, and detectability scores, with RPN values prioritizing risks. The Theory of Planned Behavior (TPB) guided the development of targeted corrective measures by addressing attitudes, norms, and behavioral control, reducing the likelihood of adverse events through systematic, behavior-focused interventions.

Although previous studies have evaluated various training programs aimed at improving patient safety, the relationship between such training and the occurrence of adverse events remains insufficiently explored. The existing literature underscores the significant influence of patient safety culture on the frequency and severity of medical safety events. However, the need for a clear and effective method to assess this relationship remains critical.

The aim of the current study is to clarify the role of patient safety culture in preventing adverse medical events by using FMEA to explore the correlation between the two. Specifically, the study seeks to assess whether FMEA can provide new insights into how specific elements of patient safety culture are linked to the occurrence of medical safety events and, ultimately, improve safety outcomes.

# Survey Objects and Methods

## Object of Investigation

A total of 80 patients from a hospital were selected as the study subjects for this mixed-method study. However, 10 patients were excluded due to transfer to another hospital, 5 patients were excluded due to incomplete data, and 5 patients were excluded because their families requested discontinuation of treatment during the study period. Ultimately, 60 patients were included as the study subjects. A total of 440 on-duty medical staff (including clinical, medical skills, and management personnel) were also included s participants.

Inclusion criteria: All hospital employees who provided informed consent.

Exclusion criteria: Those who were absent for various reasons and non-employees (such as external interns).

# Investigation Method

## FMEA Method

The Failure Mode and Effect Analysis (FMEA) method was used to analyze medical safety adverse events. The aim was to assess whether FMEA could provide insights into how specific dimensions of safety culture influence the occurrence of adverse medical events, such as medication errors, pressure ulcers (PU), and falls. This approach classifies and quantifies adverse events based on their incidence, severity, and existing detection and control measures.[10,11] The FMEA process includes the following four steps:

- **Step 1: Establish a project management team**. A multidisciplinary team was formed, consisting of 20 members, including doctors, head nurses, nurses, and key staff from various departments (clinical, medical technology, and management). Among them, the head nurses and doctors serve as team leaders, responsible for drafting the management plan. Four nursing key personnel act as quality control officers, primarily overseeing the work of nursing staff. Nurses, as the specific executors of the project, are tasked with coordinating relevant treatments and completing various nursing operations. Department key personnel and administrative staff are mainly responsible for data collection, data organization, organizing regular training sessions for team members to learn FMEA-related theoretical knowledge, and determining the theme of "medical safety adverse events." The team analyzed medical safety adverse events that occurred over the past three years and discussed each stage of these adverse events.
- **Step 2: Develop a flow chart**. The project management team created a process flowchart for "medical safety adverse events" and described the sub-processes. In this step, each team member completed a questionnaire designed to identify and describe processes and sub-processes based on literature reviews and scenario-based simulations. Through three rounds of a Delphi survey, a structured, iterative process where a group of experts anonymously responds to questionnaires in multiple rounds, team members were asked to agree or disagree with each process identified in the initial questionnaire until consensus was reached. Processes that met a predefined threshold of agreement were integrated, and similar sub-processes were appropriately modified. The final flowchart detailing the process and sub-processes of medical safety adverse events was then created.
- **Step 3: Perform failure mode and effect analysis scoring**. The team analyzed the links between medical safety adverse events, assessing severity (S), occurrence (O), and detectability (D). The risk priority number (RPN) was calculated using the formula: RPN = occurrence × detectability × severity, with each factor rated on a scale of 1 to 10. "Unlikely to occur" was scored as 1, while "very likely to occur" was scored as 10. The product of these three values represents the RPN for that failure mode. The RPN value was used to determine the priority of failure modes, with higher scores indicating higher risk. By calculating and prioritizing the RPN, corrective actions were formulated for failure modes with RPN $\geq$ 124.
- **Step 4: Implement rectification measures**. Based on the theory of planned behavior, corrective actions were formulated and strictly enforced. Failure modes with RPN $\geq$ 124 were identified, and appropriate corrective measures were implemented. The corrective measures for emergency resuscitation are shown in Supplementary Table 1.

## Questionnaire Survey

With the hospital's permission, a survey was conducted to gather information on the general demographic characteristics of medical staff, patient safety culture, and medical safety adverse events. A total of 440 questionnaires were distributed, and 420 were returned, yielding a response rate of 95.45%.

# Survey Tools and Indicators

## General Demographic Characteristics of Medical Staff

Demographic data collected included gender (male or female), age brackets (≤30, 31–40, 41–50, ≥51), education level (junior college, undergraduate, master's, doctorate), professional title (senior, associate senior, intermediate, junior, none), and job category.

### Patient Safety Culture Questionnaire

The Hospital Survey on Patient Safety Culture (HSOPSC),[12] developed by healthcare research and quality institutions, was used to assess patient safety culture. This survey comprises 12 dimensions and 42 items. Each dimension was scored using a five-point Likert scale, with responses ranging from "never" to "always" or "very different" to "very agree." A higher score indicates a better safety culture, while a lower score suggests the opposite. The Cronbach's alpha coefficient for the questionnaire ranged from 0.57 to 0.80.

### Medical Safety Adverse Events

This study focused on four common hospital safety adverse events: medication errors, pressure ulcers, falls, and adverse reactions. The frequency of adverse events reported by nurses over the past year was assessed using a seven-point Likert scale,[13] ranging from "not at all" to "every day." The internal consistency of the questionnaire was estimated with a Cronbach's alpha of 0.789.

#### Selection Criteria for Medical Safety Adverse Events

(1) Frequency of Occurrence: Over the past three years, records show that medication errors, pressure ulcers, falls, and adverse drug reactions have occurred relatively frequently in our hospital. These events have a high probability of occurrence, providing sufficient data samples for the study. (2) Severity: These events can cause varying degrees of harm to patients' health. For example, medication errors may worsen patients' conditions, adverse drug reactions may lead to organ damage, and pressure ulcers and falls can cause physical trauma, affecting patients' recovery progress. (3) Controllability: These events can, to some extent, be effectively prevented and controlled through interventions such as optimizing management processes and enhancing medical staff training, aligning with the research goal of improving medical safety.

#### Reasons for Selecting Medical Safety Adverse Events

(1) Medication Errors: Medication is involved throughout the entire treatment process for patients. Incorrect medication not only directly affects treatment outcomes but may also lead to a series of complications, seriously threatening patients' safety. Analyzing such events helps standardize medication processes and reduce error rates. (2) Pressure Ulcers: These often occur in patients who are bedridden or have limited mobility. Pressure ulcers not only increase patients' suffering and prolong hospital stays but also easily lead to severe consequences such as infections. Researching them can promote improvements in nursing quality and prevent their occurrence. (3) Falls: Falls are relatively common accidents in hospitals, particularly among elderly and frail patients. Injuries such as fractures caused by falls can worsen patients' conditions and increase medical costs. Focusing on analyzing falls helps improve environmental facilities and reduce the risk of falls. (4) Adverse Drug Reactions: These are primarily related to medication. Understanding their mechanisms and influencing factors can assist doctors in selecting appropriate treatment plans, improving treatment safety, and reducing unnecessary medical risks.

### Comparison of RPN Values Before and After FMEA Intervention

Based on the method outlined in FMEA Method, the RPN values of the 60 patients included in the study were compared before and after the FMEA intervention.

### Confidentiality Measures

During data collection, identifiable information such as patient names was replaced with numerical codes. Additionally, encryption technology was employed, and strict access controls were implemented to ensure that only authorized researchers could access patient data, thereby safeguarding patient identity information from being disclosed.

## Statistical Methods

Data analysis was performed using SPSS 26.0 software (SPSS, Inc., Chicago, Illinois). Descriptive statistics were used to analyze the demographic characteristics of participants. Continuous variables were expressed as mean and standard deviation (SD), while qualitative variables were expressed as proportions (%). Responses to medical safety adverse

events were categorized as "never happened" (coded as 0) and "had happened" (coded as 1), and a multiple logistic regression model was applied to assess the relationship between medical safety adverse events and patient safety culture. Demographic variables for all nurses were controlled, and a significance level of $P<0.05$ was considered statistically significant.

# Results

## General Demographic Characteristics of Medical Staff

Among the 420 respondents, 60.00% were women. The age group most represented was 31–40 years old, accounting for 55.95% of the respondents. In terms of education, the majority held undergraduate degrees, representing 46.43%. Most of the participants had intermediate professional titles, comprising 47.38% of the group. The majority of job roles were doctors, making up 39.29%. (See Table 1)

## Analysis of the Survey Results on Hospital Patient Safety Culture

The average overall score for patient safety culture was 3.08±0.49, with individual dimensions ranging from 2.53±0.79 for "staffing" to 3.55±0.69 for "shift transitions and interdepartmental handoffs." (See Table 2)

## Incidence Rate of Medical Safety Adverse Events

A majority of nurses reported that medication errors (39.00%), pressure ulcers (47.40%), falls (59.90%), and adverse reactions (41.30%) occurred "several times a year." Some nurses indicated that these adverse events occurred with varying frequency, ranging from daily to several times a week, or occasionally once a week. Only 1.8% of nurses reported experiencing adverse reactions daily, with no reports of daily medication errors, pressure ulcers, or falls. (See Table 3)

**Table 1** General Demographic Characteristics of Medical Staff (n=420)

| Basic Information | Number of People (n) | Composition (%) |
|---|---|---|
| **Gender** | | |
| Man | 168 | 40.00 |
| Woman | 252 | 60.00 |
| **Age (years)** | | |
| ≤30 | 57 | 13.57 |
| 31–40 | 235 | 55.95 |
| 41–50 | 102 | 24.29 |
| ≥51 | 26 | 6.19 |
| **Academic Degree** | | |
| College for Professional Training | 36 | 8.57 |
| Undergraduate Degree | 195 | 46.43 |
| Master's Degree | 144 | 34.29 |
| Doctoral Student | 45 | 10.71 |
| **Professional Title** | | |
| Senior | 46 | 10.95 |
| Deputy Senior | 89 | 21.19 |
| Intermediate | 199 | 47.38 |
| Primary | 55 | 13.10 |
| None | 31 | 7.38 |
| **Job Category** | | |
| Doctor | 165 | 39.29 |
| Nurse | 127 | 30.24 |
| Administration | 98 | 23.33 |
| Other | 30 | 7.14 |


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**Table 2** Analysis of the Survey Results on Hospital Patient Safety Culture

| Dimension | Average Score |
|---|---|
| Event Reporting Frequency | 3.41±0.86 |
| Overall Cognition of Patient Safety | 3.36±0.70 |
| Expectations and Actions of Managers to Promote Patient Safety | 3.11±0.74 |
| Organizational Learning-Continuous Improvement | 3.23±0.83 |
| Teamwork within the Department | 3.47±0.80 |
| Openness of Communication | 2.97±0.75 |
| Feedback and Communication about Mistakes | 3.13±0.82 |
| Non-Punitive Response to Mistakes | 2.57±0.87 |
| Staffing | 2.52±0.78 |
| Management Support for Patient Safety | 2.93±0.75 |
| Cooperation between Departments | 3.04±0.68 |
| Shift transitions and interdepartmental handoffs | 3.54±0.68 |
| **Average Total Score** | **3.07±0.48** |

**Table 3** Incidence Rate of Medical Safety Adverse Events (n=338)

| Adverse Event | Never Happened | Several Times a Year | Once a Month or Less | Several Times a Month | Once a Week | Several Times a Week | Every Day |
|---|---|---|---|---|---|---|---|
| Medication Error | 153 (46.60%) | 128 (39.00%) | 28 (8.50%) | 16 (4.90%) | 1 (0.30%) | 2 (0.60%) | 0 (0.00%) |
| Pressure Ulcer | 128 (39.10%) | 155 (47.40%) | 25 (7.60%) | 13 (4.00%) | 4 (1.20%) | 2 (0.60%) | 0 (0.00%) |
| Fall | 105 (32.10%) | 196 (59.90%) | 24 (7.30%) | 2 (0.60%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |
| Adverse Effect | 120 (36.70%) | 135 (41.30%) | 32 (9.80%) | 20 (6.10%) | 2 (0.60%) | 12 (3.70%) | 6 (1.80%) |

## Comparison of RPN Values Before and After FMEA Intervention

After implementing FMEA interventions, the RPN values for various failure modes decreased significantly. (See Table 4)

## Multivariate Logistic Regression Results of the Relationship Between Patient Safety Culture and Medical Safety Adverse Events

The multivariate logistic regression model showed significant associations between medication errors and factors such as "event reporting frequency" (OR=0.706), "managers' expectations and actions to promote patient safety" (OR=0.733), and "management support for patient safety" (OR=0.755).

Pressure ulcers were significantly associated with "managers' expectations and actions to promote patient safety" (OR=0.729) and "shift transitions and interdepartmental handoffs" (OR=0.707).

Falls were significantly associated with "cooperation between departments" (OR=0.735), "feedback and communication about mistakes" (OR=0.756), and "shift transitions and interdepartmental handoffs" (OR=0.660).

Adverse reactions were significantly associated with "management support for patient safety" (OR=0.701). (See Table 5)

**Table 4** Comparison of RPN Values Before and After FMEA Intervention

| Potential Failure Mode | Before Intervention | After Intervention | Change in RPN |
|---|---|---|---|
| Medication Error | 216.80 | 101.95 | 114.84 |
| Pressure Ulcer | 226.27 | 90.87 | 135.39 |
| Fall | 280.71 | 93.49 | 187.21 |
| Adverse Effect | 331.74 | 80.08 | 251.65 |

**Table 5** Multiple Logistic Regression Results of the Relationship Between Patient Safety Culture and Medical Safety Adverse Events

| Variable | OR (95% CI) | P Value |
|---|---|---|
| **Medication Error** | | |
| Event Reporting Frequency | 0.706 (0.539, 0.935) | 0.012* |
| Expectations and Actions of Managers to Promote Patient Safety | 0.733 (0.539, 0.997) | 0.048* |
| Management Support for Patient Safety | 0.755 (0.560, 1.019) | 0.012* |
| **Pressure Ulcer** | | |
| Expectations and Actions of Managers to Promote Patient Safety | 0.729 (0.540, 0.984) | 0.039* |
| Shift transitions and interdepartmental handoffs | 0.707 (0.514, 0.974) | 0.034* |
| **Fall** | | |
| Cooperation between Departments | 0.735 (0.556, 0.972) | 0.031* |
| Feedback and Communication about Mistakes | 0.756 (0.575, 0.994) | 0.046* |
| Shift transitions and interdepartmental handoffs | 0.660 (0.477, 0.913) | 0.012* |
| **Adverse Effect** | | |
| Management Support for Patient Safety | 0.701 (0.519, 0.947) | 0.021* |

**Table 6** Effect Analysis of the Patient Safety Culture Assessment Scale on Medical Safety Adverse Events

| Effect Analysis | Direct Effect | Indirect Effect | Total Effect |
|---|---|---|---|
| Evaluation of Patient Safety Culture | −0.335 | −0.478 | −0.57 |

## Analysis of the Effect of the Patient Safety Culture Assessment Scale on Medical Safety Adverse Events

The assessment of patient safety culture demonstrated a direct negative effect on the occurrence of medical safety adverse events, with a standardized coefficient of $\beta = -0.335$ (see Table 6).

# Discussion

Failure Mode and Effects Analysis (FMEA) is a highly effective prospective analysis method that can be applied across various healthcare processes. Previous literature and studies[14] have demonstrated that FMEA effectively evaluates the relationship between medical safety adverse events and patient safety culture. Medical incident reporting systems, for instance, play a crucial role in improving healthcare quality by offering customized feedback for safety improvement, although challenges like decentralization, bias, and limited interoperability across regions hinder their effectiveness.[3] Furthermore, frameworks such as RCA and HIT systems provide critical insights into systemic problems and human-technology interfaces that may lead to adverse events, emphasizing the need for integrated, multi-layered approaches to safety management.

In this study, we used FMEA to explore the correlation between medical safety adverse events and patient safety culture. The results showed a significant reduction in the RPN after FMEA intervention, as compared to pre-intervention levels. A large proportion of nurses reported that medication errors (39.00%), pressure sores (47.40%), falls (59.90%), and adverse reactions (41.30%) occurred "several times a year." Only 1.8% of nurses indicated experiencing adverse reactions daily, with no reports of daily occurrences of medication errors, pressure sores, or falls. Carl et al[15] reported a medical safety adverse event occurrence rate ranging between 35–60%, with medication errors and falls comprising 60.5% and 33.3% of these events, respectively. Similarly, Liu et al[16] observed that 35.7% of medication errors and 34.5% of falls were reported, indicating a notable incidence of medical safety adverse events among hospitalized patients.

Logistic regression analysis in our study identified several predictors of medication errors in patient safety training, including "incident reporting frequency" "managers' expectations and actions to promote patient safety" and "management support for patient safety." While these factors have been previously recognized in the literature, [17] our study makes

a significant contribution by quantifying and prioritizing these factors using the FMEA framework. By employing FMEA, we not only confirmed the importance of these predictors but also highlighted their specific impact on different types of adverse events, such as pressure sores and falls. For example, "managers' expectations and actions" were found to significantly predict both pressure sores (OR=0.729) and adverse reactions, while "shift transitions and interdepartmental handoffs" was identified as a key factor influencing falls and pressure sores. These findings underscore the importance of management involvement and communication in improving patient safety outcomes. Shift transitions and interdepartmental handoff shift transitions and interdepartmental handoffsMoreover, "management support for patient safety" was a predictor of adverse reactions. These findings underscore the importance of reporting and analyzing adverse events to mitigate medication errors. In line with this, Tu et al also emphasized that error reporting plays a crucial role in reducing medication errors.[17] They noted that adverse event reporting by healthcare professionals enables management to enhance service delivery and decrease the frequency of such incidents.

Our results also indicated a significant relationship between higher average scores in "managers expectations and actions to promote patient safety" and reductions in medication errors and pressure sores. Furthermore, the leadership and management style within medical institutions, particularly managers' expectations and actions in promoting patient safety, can substantially influence the occurrence of medication errors and adverse reactions, which, in turn, impacts the overall frequency of medical safety adverse events. Wang et al[18] highlighted that nursing managers should encourage and empower healthcare providers to innovate in service delivery, which can help prevent adverse medical events and improve patient safety. Our study found that managers' expectations and actions to enhance patient safety can predict the occurrence of pressure sores. Frequent feedback from nursing managers not only improves nurses' skills and problem-solving abilities but also aids in preventing adverse reactions.

The study also identified a significant relationship between "feedback and communication about mistakes" and falls. Nursing managers can prevent medical safety adverse events by providing regular feedback on errors and fostering problem-solving skills among nurses. When healthcare providers receive feedback on error reporting, they may feel more inclined to report errors voluntarily, irrespective of the severity. The primary purpose of error reporting is to help healthcare system managers identify error causes, develop corrective measures, prevent error recurrence, and ultimately improve patient safety.

Additionally, the study revealed that a high average score in "shift transitions and interdepartmental handoffs" was significantly associated with a lower incidence of pressure sores and falls. Effective patient handover relies on healthcare providers accurately conveying patient information to the incoming nursing staff. Li et al [19] emphasized that structured handover communication procedures can reduce preventable medical safety adverse events by up to 30%. Pera [20] further underlined the importance of standardized and structured handovers in enhancing patient safety by ensuring clear transitions of information, responsibility, and accountability.

In our study, we conducted a systematic hazard analysis by identifying failure modes and their effects, followed by assigning severity, occurrence, and detection scores for each mode. We then calculated the initial RPNs and used a priority matrix to classify failure modes into four categories—emergency, urgent, programming, and monitoring—with emergency requiring the highest priority. After implementing FMEA interventions, we recalculated the RPNs and observed a significant reduction, indicating that the corrective actions effectively mitigated risks. This quantitative reduction in RPNs not only confirmed the effectiveness of the interventions but also highlighted FMEA's role as a powerful tool for monitoring safety culture improvements. By tracking RPN changes, we demonstrated how FMEA provides a clear, actionable metric for healthcare organizations to evaluate and enhance patient safety strategies.[21]

Similarly, Chiozza and colleagues[22] found that implementing suggestions from FMEA discussions significantly reduced medical safety errors and improved the detectability of errors.[22] Some studies report that FMEA's simplicity and its quantitative characteristics are notable advantages.[23] However, Roseen et al[9] argued that while FMEA includes a numerical component (RPN), it should primarily be viewed as a qualitative method.

The strength of this study lies in its use of Failure Mode and Effect Analysis (FMEA) to systematically identify and prioritize risk factors associated with medical safety adverse events, leading to actionable safety improvements. The incorporation of multivariate logistic regression further strengthened the analysis by identifying key predictors of adverse events linked to patient safety culture.

This study also acknowledge certain limitations. The first limitation of this study is the reliance on self-reported data, which may introduce bias, particularly in the reporting of adverse events and safety culture perceptions. Additionally, the pre- and post-intervention RPN calculations were performed by the same team, potentially influencing the objectivity of the results.

In conclusion, this study demonstrates that FMEA is an effective tool for exploring the relationship between medical safety adverse events and patient safety culture. The significant associations identified between factors such as incident reporting frequency, management support for safety, and handover practices with adverse events like medication errors, pressure ulcers, and falls highlight key areas for improvement. The use of FMEA enabled the identification of high-risk failure modes and led to a substantial reduction in RPN values post-intervention, indicating the effectiveness of targeted safety interventions. These findings underscore the critical role of a positive safety culture in reducing adverse events and improving patient safety outcomes. This study provides valuable evidence that FMEA can be used not only to assess but also to actively mitigate risks in healthcare settings.

## Data Sharing Statement

Data is provided with in the manuscript files.

## Ethics Approval and Consent to Participate

The study was approved by the Ethics Committee of Harbin Medical University. All Patients and their families participated voluntarily and signed informed consent forms, and the study was performed in accordance with the Helsinki II declaration. Informed consent was obtained from all the study subjects before enrollment.

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## Disclosure

The authors declare that they have no competing interests in this work.

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