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Original Article

Research on the causes and management strategies of medical safety adverse events

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Abstract

Objective: This study aims to explore the causes of medical safety adverse events in depth and propose corresponding management strategies to reduce the occurrence of similar incidents, improve the quality of healthcare services, and enhance patient safety.

Methods: A retrospective analysis was conducted to examine details of adverse events, including the department where the event occurred, the main causes, event severity levels, and the time of occurrence.

Results: Inpatient wards were found to be the primary departments where adverse events occurred, accounting for over 35% of cases, with a growing trend. The main causes of adverse events included poor doctor-patient communication, improper use of medication, unequal allocation of medical resources, surgical errors, and others. Among these, poor doctor-patient communication accounted for over 20% of cases, making it the most significant cause of adverse events. Furthermore, the majority of events were classified as level III and level IV, each accounting for over 30%, though level I and II events should not be overlooked. In terms of timing, adverse events primarily occurred between 1:00-4:30 AM and 7:00-10:30 PM.

Conclusion: Hospitals should strengthen the reporting mechanism for medical safety adverse events, streamline and optimize the reporting process, and establish an early warning system for such events. Additionally, a cross-departmental collaborative control structure should be implemented, with high-level leadership driving improvements. By introducing management tools and enhancing patient safety culture, these measures will help prevent the recurrence of similar incidents and improve the quality of healthcare services and patient safety.

Keywords: Medical safety; adverse events; cause analysis; strategy recommendations

1 Introduction

Medical adverse events refer to any factors or incidents that may undermine a patient's treatment, increase their suffering or burden, potentially lead to medical disputes or accidents, disrupt medical order, or endanger healthcare personnel's safety during clinical treatment and hospital operations [1]. With the continuous advancement of society, the transformation of medical models, and the evolution of disease patterns, patient demand for medical services has become more diversified, with increasingly strict requirements for service quality. In the daily operation of hospitals, identifying and promptly reporting medical hazards, as well as effectively managing and reducing medical safety adverse events, is crucial for improving medical quality and ensuring patient safety. Healthcare authorities should actively and promptly collect relevant information on medical safety adverse events, conduct in-depth analyses, issue risk alerts, propose improvements, and take effective measures to continuously enhance medical quality [2]. This management model has been accepted by many healthcare institutions worldwide and holds significant importance in the accreditation standards of tertiary hospitals in China. The Ministry of Health's Medical Administration and Hospital Management Department commissioned the Chinese Hospital Association to establish a medical safety adverse event reporting system, encouraging healthcare professionals and institutions to proactively report medical safety information for unified collection and analysis. This system regularly provides internal shared data to participating healthcare institutions, aiming to enhance their ability to identify,

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respond to safety hazards, and prevent adverse events, ultimately promoting improved medical quality and ensuring patient safety [3]. This study reviews and analyzes the causes of medical safety adverse events at a comprehensive hospital and proposes targeted management strategies to prevent similar events in the future.

2 Materials and Methods

2.1 General Information

The data for this study were sourced from the medical safety adverse event reporting system of a comprehensive hospital in 2022 and 2023. After excluding duplicate reports and non-adverse events, a total of 314 events were included (208 events reported in 2022, 216 in 2023).

2.2 Methods

The analysis was based on the "China Hospital Quality and Safety Management Group Standards" and the "2019 National Medical Service and Quality Safety Report," using retrospective analysis to examine the departments where medical safety adverse events occurred, their primary causes, event severity levels, and the time of occurrence. Corresponding countermeasures and recommendations were also proposed.

2.3 Classification of Medical Safety Adverse Events

Medical safety adverse events are classified into four levels based on severity:

• Level I (Warning Events): These involve faults that have caused adverse consequences for the patient, potentially leading to medical accidents or errors, including bodily harm, functional impairment, or even death. Immediate attention and proper handling are required.

• Level II (Adverse Consequence Events): These events occur without fault but result in consequences, mainly due to non-human factors such as medications or medical devices. These events may lead to medical accidents, complications, or the natural progression of a disease. Although the consequences can be severe, they do not constitute a medical accident or error. In-depth analysis and preventive measures are needed.

• Level III (No Consequence Events): These events involve fault or error but have not resulted in harm or have only minor consequences. These should be addressed by correcting the errors, reinforcing training, and preventing recurrence.

• Level IV (Hazard Events): These events involve no fault and no consequences, as the error was detected and corrected in time, preventing further harm. While no adverse outcomes occurred, healthcare institutions should continue to monitor and ensure the safety and effectiveness of the medical process.

3 Results

3.1 Overall Situation of Adverse Events

In 2022 and 2023, a total of 424 medical safety adverse events were reported at the hospital. In 2022, 208 events were reported (49.06% of the total), while in 2023, 216 events were reported (50.94%). The number of adverse events remained relatively stable between the two years but showed a slight increase.

3.2 Departmental Analysis of Adverse Events

The primary departments where adverse events occurred were inpatient wards, emergency departments, operating rooms, and outpatient departments. The detailed distribution is shown in Table 1.

From Table 1, it is evident that inpatient wards accounted for more than 35% of adverse events, with a growing trend. The emergency department, operating rooms, and outpatient departments were also high-risk areas, each contributing around 10% of the total events. The number of adverse events in the obstetrics and gynecology department increased in 2023, likely due to the specific nature of the patient population in this department.

3.3 Analysis of the Main Causes of Medical Adverse Events

The main causes of adverse events included poor doctor-patient communication, improper use of medication, unequal allocation of medical resources, surgical errors, medical equipment malfunctions, patient factors, healthcare worker fatigue, and medical errors (see Table 2).

Table 1. Distribution of Medical Adverse Events by Department

Department	2022		2023	
	Number of Adverse Events	Percentage (%)	Number of Adverse Events	Percentage (%)
Inpatient Ward	80	38.46	88	40.74
Emergency Department	40	19.23	36	16.67
Operating Room	28	13.46	32	14.81
Outpatient Department	24	11.54	21	9.72
Intensive Care Unit	16	7.69	15	6.95
Pediatrics	12	5.77	14	6.48
Obstetrics & Gynecology	8	3.85	10	4.63
Total	208	100	216	100

Table 2. Analysis of Causes of Medical Safety Adverse Events

Cause	2022		2020	
	Number of Adverse Events	Percentage (%)	Number of Adverse Events	Percentage (%)
Poor doctor-patient communication	48	23.08	52	24.07
Improper use of medications	38	18.27	37	17.13
Unequal allocation of medical resources	31	14.90	35	16.20
Surgical errors	24	11.54	27	12.50
Equipment failure	27	12.98	23	10.65
Patient-related factors	13	6.25	19	8.80
Healthcare worker fatigue	19	9.13	16	7.41
Medical errors	8	3.85	7	3.24
Total	208	100	216	100

Table 2 shows that poor doctor-patient communication was the leading cause of adverse events, accounting for over 20%. Other significant contributing factors included improper medication use, unequal distribution of medical resources, and surgical errors. Compared to 2022, there was an increase in events caused by poor doctor-patient communication and patient factors in 2023, while incidents due to healthcare worker fatigue and medical equipment failures decreased.

3.4 Analysis of Medical Adverse Event Levels

Adverse events were categorized into four levels: Level I (warning), Level II (adverse consequence), Level III (no consequence), and Level IV (hazard). Table 3 presents the distribution of adverse events across these levels.

Table 3 reveals that Level III and Level IV events were the most common, each accounting for more than 30% of cases. Level I and Level II events were less frequent but still significant. Compared to 2022, the number of Level I and Level II events decreased in 2023, suggesting that the hospital has made some progress in preventing serious adverse events, although further efforts are still needed.

3.5 Analysis of the Time Periods of Medical Adverse Events

Medical adverse events mainly occurred between 1:00–4:30 AM and 7:00–10:30 PM, as shown in Table 4, which outlines the occurrence of adverse events during these periods.

Table 3. Analysis of the Levels of Medical Safety Adverse Events

Level	2022		2023	
	Number of Adverse Events	Percentage (%)	Number of Adverse Events	Percentage (%)
Level I	12	5.77	10	4.63
Level II	36	17.31	32	14.81
Level III	96	46.15	90	41.67
Level IV	64	30.77	84	38.89
Total	208	100	216	100

Table 4. Analysis of Medical Safety Adverse Events by Time Period

Time Period	2022		2023	
	Number of Adverse Events	Percentage (%)	Number of Adverse Events	Percentage (%)
1:00–4:30 AM	96	46.16	99	45.83
7:00–10:30 PM	64	30.77	68	31.48
9:00–11:30 AM	28	13.46	25	11.58
2:00–5:30 PM	12	5.77	15	6.94
5:00–8:30 AM	4	1.92	6	2.78
Others	4	1.92	3	1.39
Total	208	100	216	100

Table 4 indicates that the periods between 1:00–4:30 AM and 7:00–10:30 PM were the main times for adverse events, with each period accounting for over 30% of total incidents. This may be related to the fewer medical staff on duty during these late-night hours. While the number of adverse events during other times of day was relatively lower, they still warrant attention. The number of adverse events during each time period remained fairly consistent over the two years, suggesting that the hospital's safety management during different times of day still requires strengthening.

4. Discussion

With the advancement of medical technology and the increasing frequency of medical disputes, medical safety has become an important issue in the healthcare field [4]. As public expectations for health and healthcare quality grow in China, the number of medical disputes has steadily increased in recent years. This has had a significant impact on doctor-patient relationships and the overall healthcare environment. In this context, hospital management faces the urgent task of strengthening safety management and reducing the risks associated with medical safety adverse events. This is a critical and pressing challenge [5].

4.1 Strengthening the Reporting Mechanism, Simplifying and Optimizing the Reporting Process

Timely reporting of medical safety adverse events is crucial for identifying potential risks, analyzing factors affecting medical safety and quality, assessing the impact on patients, and formulating effective preventive strategies [6]. In light of this, the comprehensive hospital in the case study has established and strengthened its "Medical Safety Adverse Event Reporting System," clearly defining the criteria, classification standards, types, reporting steps, and timeframes for adverse events. Based on this, the hospital has further simplified and optimized the reporting process, clarified the reporting guidelines and detailed content, and set specific reporting deadlines for events of different severity levels. For example, Level I and Level II adverse events are required to be reported immediately, while for Level III and IV events, the hospital has adopted an encouraging

and non-punitive reporting policy. The hospital encourages all staff to report adverse events as soon as they are discovered and provides an anonymous reporting option to alleviate the psychological burden on the reporter. To ensure the effectiveness of the reporting mechanism, the hospital regularly conducts training for all staff on the medical safety adverse event reporting process and enforces the principle of non-punitive, proactive reporting. This is designed to encourage healthcare personnel to report incidents actively. Additionally, the hospital has introduced incentive measures, ensuring the confidentiality of reporters, and shares typical adverse event case studies to prevent recurrence of similar events at the source.

4.2 Establishing a Medical Safety Adverse Event Early Warning System and Appointing Dedicated Medical Safety Managers

In modern management systems, proactively anticipating and assessing all factors that may impact quality is essential, particularly in high-risk sectors like healthcare. Given the high uncertainty of the risks faced in healthcare, appointing dedicated medical safety adverse event managers is a key component for the successful implementation of medical risk management programs [7]. To ensure patient safety and learn from past experiences, the hospital in the case study has implemented the "Hospital Medical Safety Adverse Event Reporting System" since August 2012. This system encourages all clinical and medical departments to immediately report adverse events via the internal network system to the relevant departments based on the type of event—for instance, surgical events are reported to the medical department, and medication events are reported to the pharmacy department. Each functional department is assigned dedicated personnel responsible for receiving and swiftly assessing reported medical adverse event risks. Based on the assessment results, these personnel develop specific risk prevention measures and establish strategies and early warning systems for medical risk management. The hospital also applies the PDCA (Plan-Do-Check-Act) cycle principle for continuous, comprehensive management of medical safety to ensure steady improvements in medical quality.

4.3 Deepening Quality Monitoring of Key Processes to Effectively Curb Adverse Events

The hospital in the case study has established a dual-layer management system, consisting of the hospital-level and departmental-level management teams. At the hospital level, the central supervision team includes key departments such as quality control, medical management, nursing management, infection control, medical supplies, logistics, and information technology [8], which collectively form a special task force coordinated by the quality control office. At the departmental level, each clinical and medical department has its own safety administrator responsible for daily monitoring of medical safety adverse events within their department, with the goal of promoting deep involvement in patient safety management across all staff members. Safety administrators are tasked with analyzing the department's adverse event data, accurately identifying risk points in the clinical processes, and using advanced management tools to thoroughly analyze issues, develop, and implement targeted improvement strategies. The hospital's special task force focuses on high-risk areas such as inpatient wards, emergency departments, operating rooms, outpatient clinics, medical technology departments, and intensive care units. They use cross-departmental joint inspections and special corrective actions to effectively reduce the occurrence of adverse events. Analyzing the hospital's data from 2022 to 2023, inpatient wards were found to be the most frequent location for adverse events, likely due to the complexity of patient conditions in these areas, as well as the heavy workload and mental stress of medical staff. In response, the management has implemented measures such as flexible reallocation of human resources and strengthening the self-discipline and emergency response capabilities of medical staff to further reduce the occurrence of adverse events.

4.4 Advancing the Hospital's Information Technology Upgrades and Improving the Medical Safety Adverse Event Management System

The use of an online management system for medical safety adverse events enables real-time tracking and dynamic management of adverse events, quickly revealing shortcomings in work processes and promptly transmitting safety information to medical staff, thus effectively preventing the recurrence of similar events [9]. Since 2015, the hospital in this study has implemented a direct, non-punitive reporting system for medical safety adverse events across the entire hospital. The traditional paper-based "Adverse Event Report Form" was upgraded to an electronic version, streamlining the reporting process by eliminating the requirement for signatures from department heads or chief nurses. This both facili-

tates the reporting process and enhances confidentiality. Dedicated personnel from relevant functional departments can directly intervene in investigations, verify situations, and take appropriate measures to protect the privacy of reporters. Through the continuous monitoring of the direct reporting system for medical safety adverse events, the hospital can regularly or as needed collect, categorize, summarize, and analyze these events. For incidents that show an unusual increase in reports, such as medication-related events, the hospital conducts in-depth analysis and takes effective preventive measures to avoid recurrence. Additionally, the hospital includes the execution of adverse event reporting as part of the evaluation criteria in the "Comprehensive Assessment System for Clinical and Medical Departments" using a series of management measures to continually improve and optimize the medical safety adverse event management system.

4.5 Establishing a Cross-Departmental Collaborative Control Framework Led by Senior Management for Medical Safety Adverse Events

Medical and nursing services are closely interconnected, forming a patient-centered service system that relies on close collaboration among multiple departments [10]. The occurrence of medical safety adverse events is not the responsibility of any single healthcare worker or department, but highlights systemic gaps in the medical service process that involve multiple departments and steps. Therefore, in managing these adverse events, it is necessary to build consensus and create a control framework led by senior management, with collaboration from multiple departments [11]. Under this framework, the lead department convenes relevant departments to hold joint meetings to carefully screen Level I and Level II adverse events and potential risks. These meetings aim to investigate the essence of the issues, thoroughly examine the causes of the events, and develop corrective measures. After the meeting, the lead department prepares two copies of the forms—one for archive and the other to be sent to the responsible department for implementation of corrective measures as per the functional department's recommendations. After a three-month correction period, the lead department tracks and checks the implementation of the corrective actions. By leveraging the MDT (Multidisciplinary Team) collaboration mechanism from functional departments, the hospital can effectively address challenges in the adverse event handling process, prevent similar incidents from recurring, and ensure that adverse events are closed-looped in management, ultimately contributing to steady improvements in medical service quality [12].

4.6 Introducing Management Tools to Deepen Medical Safety Adverse Event Management and Enhance Management Efficiency

The comprehensive hospital in this study is shifting its focus from merely tracking the number of reported adverse events to emphasizing substantial quality improvements in event management. This process requires the support of management tools. The occurrence of medical safety adverse events often reflects deficiencies in the quality management processes of healthcare services [13]. When investigating the causes of these events, it is essential to use management tools such as fishbone diagrams, cause-and-effect diagrams, and root cause analysis to thoroughly examine various factors, including personnel, equipment, materials, methods, and the environment, in a layered approach. This allows for accurate identification and analysis of the root causes, followed by the proposal and implementation of targeted corrective actions. For issues that cannot be solved independently, they should be reported to the Medical Quality Management Committee, where the PDCA cycle can be used to systematically optimize relevant work systems, improve workflows, reduce risks, and decrease the likelihood of similar events occurring again [14].

4.7 Strengthening the Patient Safety Culture in Healthcare Institutions

Creating a positive patient safety culture is fundamentally about recognizing the inherent risks in healthcare and establishing a non-punitive feedback system, while encouraging cross-departmental collaboration to address patient safety issues. Studies have shown that a positive patient safety culture can effectively reduce the frequency of adverse events [15]. Therefore, the first step is to acknowledge the potential for errors in medical activities and subsequently optimize existing systems and operational procedures in detail. Based on this, all healthcare workers should internalize the essence of patient safety culture, shifting from blaming errors to learning from mistakes and adopting a continuous improvement mindset. This will better safeguard patient safety and promote the ongoing enhancement of medical quality [16].

4.8 Enhancing Medical Knowledge and Strengthening Healthcare Workers' Professional Competency

The overall competence of healthcare workers is directly linked to patient well-being. Research has shown that some healthcare workers still have room for improvement in terms of professional knowledge and competence, which may lead to delayed responses, improper interventions, or even misdiagnosis. Therefore, strengthening healthcare workers' professional abilities is crucial [17]. Since implementing the proactive reporting system for medical safety adverse events, the comprehensive hospital in the case study has prioritized employee training and education, integrating the culture of proactive reporting into daily hospital operations and encouraging staff participation while alleviating concerns. The hospital regularly organizes seminars, such as those focused on medical safety risk education, where industry experts analyze typical cases and provide in-depth professional training for healthcare workers. Training topics are broad, covering not only the cultivation of medical humanities, communication skills with patients, but also the interpretation of healthcare laws and regulations, with the aim of improving the overall competence of all healthcare workers in the hospital.

4.9 Improving the Reward and Punishment System to Enhance Medical Service Quality

The hospital in the case study actively encourages all employees to report medical safety adverse events voluntarily and has established a comprehensive reward and punishment system to ensure the smooth operation of the medical safety adverse event management system. For each adverse event report that is confirmed, the hospital provides a reward of 50 RMB. If the reported event contributes significantly to improving service processes or enhancing safety standards, the reward is increased to 200 RMB. Conversely, for individuals who deliberately conceal, omit, or falsely report adverse events, the hospital imposes fines ranging from 50 to 2000 RMB, depending on the severity of the situation. In cases where adverse consequences occur, the hospital doubles the penalty according to its regulations. The hospital also implements a dual-reporting system for high-risk events, such as adverse drug reactions, suspicious medical device failures, hospital infections, improper surgical site or method selection, patient falls or bed exits, etc. These events must be reported not only internally within the hospital but also to the national regulatory platform for higher-level oversight. Furthermore, for departments where the number of reported adverse drug reactions exceeds 1% of the department's annual discharges, the hospital provides an additional 10 RMB reward for each additional case reported, with rewards distributed at the end of the year.

5 Conclusion

Through a detailed review and analysis of medical safety adverse events at a comprehensive hospital in 2022 and 2023, this study identified the main causes of adverse events, the distribution of events by department, event severity levels, and time period characteristics. The study found that poor doctor-patient communication, improper medication use, and uneven distribution of medical resources were major causes of adverse events, with inpatient wards being the most frequent department for such events. Furthermore, adverse events were mainly concentrated during the early morning and late evening hours, suggesting safety risks during these times. Based on these results, the study proposed a series of targeted management strategies, including strengthening the reporting mechanism for medical safety adverse events, simplifying and optimizing reporting processes, building early warning systems, appointing dedicated personnel, improving management systems using online systems, creating a cross-departmental control framework led by senior management, utilizing management tools to deepen management practices, and strengthening the reward and punishment system. Implementing these strategies will help improve the hospital's risk warning and response capabilities, reduce the occurrence of adverse events, and enhance medical service quality and patient safety.

In conclusion, managing medical safety adverse events is a systematic process that requires collaboration from all hospital departments to prevent and control adverse events from the source, ultimately providing safer and more efficient medical services to patients.

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Conflicts of Interest

The authors declare no conflicts of interest.

Author Contributions

The author contributed solely to the article.

Ethics Approval and Consent to Participate

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Availability of Data and Materials

The data presented in this study are available on request from the corresponding author.

Supplementary Materials

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