

Implementation and Evaluation of the Patient Reported Incident Management System (PRIM): A Pilot Implementation for Patient Empowerment

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ABSTRACT

This study aims to identify the nature and prevalence of patient safety incidents and the design, development, and implementation of a patient-reported incident management system. The system's effectiveness in capturing patient-reported incidents and promoting patient empowerment was also evaluated. Findings reveal that nearly 33.8% of patients reported experiencing a patient safety incident, with 81.6% of these incidents identified by the patients themselves. After the implementation of the system, 47% of reported incidents were addressed by staff, indicating a significant improvement in patient empowerment. Furthermore, there was a 71% increase in overall incident reporting. Following the introduction of the patient-reported incident management system, 67% of patients reported feeling more empowered, and 53% provided positive feedback regarding the system's user-friendliness.

KEYWORDS

Patient-Reported Incident Management System, Patient Empowerment, Patient-Reporting, Patient Safety

INTRODUCTION

Individuals seeking healthcare often experience significant harm due to deficiencies in the quality of care (Brabcová et al., 2023; Liukka et al., 2020). Approximately 10% of patients in low- and middle-income countries experience harm, placing patient harm 14th on the global burden of disease list (Singh & Mahomed, 2023). Additionally, the financial impact of patient harm is severe,

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accounting for approximately 15% of total healthcare costs due to limited resources and patient safety systems (Mgobozi & Mahomed, 2021; Poku et al., 2023; Singh & Mahomed, 2023).

The World Health Organization (WHO, 2020) supports this observation, noting that the burden of patient safety incidents (PSIs)—unforeseen events that can result in patient harm—is disproportionately higher in developing countries (Dhingra-Kumar et al., 2021). Findings from Middle Eastern and African countries report that patient harm is the leading cause of 14% permanent disability and 16% moderate disability, resulting in economic repercussions (WHO, 2020). This has attracted the attention of health policymakers and researchers, who work on developing and implementing interventions aimed at mitigating patient harm at both individual and institutional levels (Ahsani-Estahbanati et al., 2022; Li et al., 2024; Rodziewicz et al., 2018; Ward et al., 2011; Zegers et al., 2016).

BACKGROUND

PSIs include a range of events, from near misses to severe harm or fatalities (Shemsu et al., 2024). Such events pose a significant global threat, with prevalence more pronounced in low- and middle-income countries, where an estimated 134 million adverse events are reported annually. These incidents are intricately linked to adverse treatment outcomes, contributing to increased morbidity, mortality, healthcare expenditure, prolonged hospital stays, decreased quality of life, and poor patient satisfaction with healthcare delivery (Al-Wafi, 2023; Shemsu et al., 2024; WHO, 2020). Consequently, researchers have explored various strategies aimed at minimizing patient harm across healthcare settings (Ahsani-Estahbanati et al., 2022; Li et al., 2024; Rodziewicz et al., 2018; Zegers et al., 2016).

Existing literature has classified interventions to contain patient harm or PSIs into the following categories: (1) electronic system-based approaches; (2) process interventions like critical incident reporting; (3) audit and feedback; (4) inter-professional education; (5) patient-centered strategies; (6) leadership and managerial strategies; (7) patient care programs; (8) workplace culture enhancements; and (9) direct observation (Ahsani-Estahbanati et al., 2022; Gleeson et al., 2020; Rodziewicz et al., 2018; Zegers et al., 2016). While most interventions focus on healthcare workers (Ahsani-Estahbanati et al., 2022; Gleeson et al., 2020; Rodziewicz et al., 2018; Zegers et al., 2016), a few studies highlight patient- and family-centered interventions that promote patient safety (Ahsani-Estahbanati et al., 2022; Li et al., 2024).

Likewise, the importance of voluntary incident reporting to monitor patient safety risks is observed in healthcare settings globally (Ahsani-Estahbanati et al., 2022; Cavell & Mandaliya, 2021; Cottell et al., 2020; Gleeson et al., 2020). The validity and seriousness of incidents reported voluntarily by healthcare professionals have been scrutinized within the scientific community, as healthcare personnel often show reluctance to report adverse patient events (Macrae, 2016; Yusuf & Irwan, 2021).

Additionally, studies underscore the substantial impact of inadequate organizational support (Archer et al., 2017; Hamed & Konstantinidis, 2022; Shemsu et al., 2024), fear of negative professional and legal repercussions (Hamed & Konstantinidis, 2022; Naom et al., 2020), and insufficient training in incident reporting systems (Hamed & Konstantinidis, 2022; Lee et al., 2018; Naom et al., 2020) as key barriers to staff participation in incident reporting. This has led to investigations into patient-engaged interventions to reduce PSIs (Abdi et al., 2024; Avanecean et al., 2017; Berger et al., 2014; Rossiter et al., 2020).

Studies on patient engagement interventions have reported marginal reductions in PSIs, including falls, bed sores, and medication errors (Abdi et al., 2024; Avanecean et al., 2017; Berger et al., 2014; Rossiter et al., 2020; Sahlstrom et al., 2018). Sahlstrom et al. (2018) examined the impact of patient-reported PSIs in Finnish hospitals, highlighting the types of PSIs and the action plans and organizational changes adopted to prevent recurring patient harm.

Additionally, Madden et al. (2022) and WHO (n.d.) validated the ability of patients to identify a range of adverse events in healthcare that might otherwise remain hidden. While previous research on patient engagement interventions has yielded encouraging findings, there remains a need for rigorous

scientific validation to substantiate these claims (Abdi et al., 2024; Avanecean et al., 2017; Rossiter et al., 2020). Accordingly, building on this foundation, the current study aims to implement and evaluate the patient-reported incident management system (PRIM) to address the following research questions:

- How does PRIM affect the reporting of PSIs?
- What is PRIM's contribution to patient empowerment in a healthcare setting?

This study contributes to the existing literature by demonstrating that patients play a critical role in identifying and reporting safety events. Their involvement is directly correlated with increased reporting rates and improved incident management outcomes. The study highlights the importance of integrating patient perspectives into incident reporting as an essential step toward fostering a more inclusive, patient-centered healthcare environment. In the context of prior research, these findings validate the existing literature on patient engagement in safety reporting. Unlike traditional systems that rely solely on staff-reported incidents, PRIM introduces a dual reporting mechanism that brings previously underreported incidents to light. This approach aligns with global movements toward patient empowerment and positions PRIM as a valuable model for healthcare institutions seeking to improve patient safety measures.

THEORIES ON PATIENT REPORTING INCIDENTS

The implementation of PRIM aligns with several key theoretical frameworks that underscore its value in enhancing patient safety and empowerment. The patient empowerment theory emphasizes the critical role of involving patients in their care decisions, fostering a sense of agency and active participation that has been shown to improve both patient outcomes and satisfaction (Aujoulat et al., 2007). This empowerment is further contextualized within the safety culture theory, which suggests that a robust organizational commitment to safety—including transparency, dual-reporting mechanisms, and patient engagement—can prevent incidents by encouraging open communication and accountability (Nieva & Sorra, 2003).

The Swiss cheese model illustrates how patient reporting helps address latent system vulnerabilities by identifying and mitigating gaps in safety that healthcare staff alone may not detect (Reason, 2000). The structure-process-outcome framework reinforces PRIM's impact on healthcare quality by highlighting how the structured integration of patient-reported incidents improves processes that support favorable safety outcomes (Donabedian, 1988). The health belief model and human factors theory further clarify how patients' perceptions of risk, benefits of reporting, and system usability influence patients' willingness to report incidents, with PRIM's design accommodating ease of use to facilitate engagement (Carayon, 2006; Rosenstock, 1974).

Finally, the systems theory and communication theory position PRIM as an essential component within the hospital's safety ecosystem, enhancing information flow and fostering interconnectivity between patients and providers, ultimately supporting a resilient and patient-centered safety culture (Bertalanffy, 1969; Glanz et al., 2015). Together, these theoretical perspectives validate the importance of PRIM in elevating patient voices, bolstering incident reporting, and fostering a collaborative approach to healthcare safety within healthcare.

METHODS

Study Approach

The present study adopted the prospective observational research approach to develop, implement, and evaluate PRIM. It aimed to empower patients to report incidents during their hospital stay.

The study demonstrated successful pilot implementation involving the design, development, and implementation of PRIM. The implementation applied agile methodology.

Research Setting

A post-implementation evaluation was performed in the medical and surgical wards of a 2032 bed quaternary teaching hospital to measure the frequency of PSIs. This assessment enabled the researcher to understand error trends within the wards and evaluate the effectiveness of PRIM.

This article focuses on dissemination ideation and preliminary results from large-scale quality improvement efforts. Questionnaire scoring involved assigning the highest numerical values to positive responses and the lowest to negative responses. Data analysis was conducted to explore the frequency and percentage of PSIs, as well as their management by healthcare workers. The agile methodology was followed in the following sequential manner.

Step 1: Definition and Analysis of Concepts

The researchers' primary objective was to establish a system enabling patients to report incidents encountered during their hospital stay. To achieve this goal, a survey was administered to 145 patients discharged over a four-week period from an inpatient, multi-specialty ward to investigate the nature and prevalence of PSIs experienced during their hospital stay. An Organization for Economic Co-Operation and Development (OECD) questionnaire was used for data collection to ensure it was grounded in internationally recognized standards. The questionnaire incorporated diverse components, including assessments of communication dynamics between staff and patients, confidence levels in the treatment and care procedures, and an open-ended question inviting patients to describe their experiences with PSIs. The form also inquired about how staff managed incidents within the healthcare setting.

Step 2: Planning Details

The second step involved the detailed planning of the OECD questionnaire and the identification of key elements for analysis. Specifically, the survey was designed to assess how effectively healthcare providers communicate with patients, how comfortable patients feel raising concerns, providers' confidence in safety and care processes, and how PSIs are identified, reported, and managed. The survey findings were intended to identify strengths and areas for improvement in patient care, particularly in communication, the handling of safety incidents, and the overall support provided to patients during critical moments.

Based on prevalence data and historical hospital incident records, a meticulous selection process was conducted to identify and shortlist approximately 10 significant incidents. These incidents were included in the nominal group technique procedure, where participants from various departments—such as operations, nursing, and quality assurance—were involved. Each participant selected the top 5 critical incidents from the identified list of 10. This collaborative process resulted in the selection of five critical incidents deemed essential for inclusion in PRIM. The incidents—falls, phlebitis, medication reactions, pressure ulcers, and delays in medication administration—were integrated into PRIM to enhance the accuracy and effectiveness of patient-reported incident management and safety improvement initiatives.

Step 3: Design Development

PRIM was co-designed by patients, caregivers, safety committee members, and nursing staff. A QR-coded bookmark was created and placed beside patients' beds, enabling them to report incidents. Patients could also report incidents via links sent to their registered mobile numbers.

The system incorporated five specific incidents selected through the nominal group process. When a patient encountered any of the listed incidents, they could report it by scanning the QR code or using the mobile link. A unique ticket identification was generated when a report was received. Subsequently, a resolution team member was notified to provide a resolution with input from a

multidisciplinary team. Following the resolution, a verification officer thoroughly reviewed the case before officially closing the ticket (see Figure 1).

Figure 1. Patient-reported incident management system quick response code bookmark



KASTURBA HOSPITAL
MANIPAL
(Teaching hospital of KMC Manipal, a unit of MAHE)

**PLEASE REPORT ANY OF THE BELOW MENTIONED INCIDENT
IF YOU HAVE EXPERIENCED DURING YOUR HOSPITAL STAY**

FALL
ರೋಗಿಯ ಪತನ

Graft



IV LINE SWELLING / INFLAMMATION
ರಕ್ತನಾಳದ ಉದುವಿಕೆ



MEDICATION REACTION OR CONCERNS
ಔಷಧಿಯಿಂದ ಅಲರ್ಜಿ ಪ್ರತಿಕ್ರಿಯೆ ಅಥವಾ ಆತಂಕಗಳು



MEDICATION NOT ADMINISTERED ON TIME
ನನ್ನ ಔಷಧಿಗಳನ್ನು ಸಮಯಕ್ಕೆ ಸರಿಯಾಗಿ ನೀಡಲಾಗಿಲ್ಲ



**BEDSORE / ULCERS ON MY BODY AFTER
BEING ADMITTED TO THE HOSPITAL**
ಆಸ್ಪತ್ರೆಗೆ ದಾಖಲಾದ ನಂತರ ನನ್ನ ದೇಹದಲ್ಲಿ ಹುಣ್ಣು
ಕಾಣಿಸಿಕೊಂಡಿತು



**SCAN AND REPORT YOUR INCIDENT
INFORM THE NURSING COUNTER FOR IMMEDIATE CARE**



Step 4: Deployment of PRIM

A bookmark with the QR code was placed beside patients' beds to enable smooth incident reporting and was piloted in an inpatient multi-speciality ward for a four-month period. Additionally, patient feedback was collected during discharge regarding the benefit and ease-of-use of the system.

During discussions, it became apparent that a step needed to be integrated into the process, allowing for the acceptance or rejection of raised tickets based on their nature and relevance to the reported incidents. This modification was prompted by the observation that several irrelevant incidents were raised, and users previously lacked the option to such incidents deemed irrelevant.

Step 5: Review and Monitor

Continuous review and monitoring play a pivotal role in evaluating the effectiveness of PRIM. Data generated through PRIM underwent systematic comparison in pre- and post-implementation. Additionally, patient perspectives were reviewed pertaining to the empowerment and efficiency of the system's design. The evolution of the system is anticipated to be responsive to changing safety requirements for patients and hospitals.

RESULTS

Patient Response to OECD Survey

Table 1 highlights survey results related to patient communication, safety, and incident management in the healthcare setting. Most respondents (87.6%) reported always experiencing good communication with doctors and staff, while 75.9% of respondents indicated they had a designated contact for concerns. Most patients (89%) felt comfortable speaking about their concerns; 89.7% of patients felt that healthcare staff welcomed input. Confidence in the safety and care processes was high, with 93.8% of respondents expressing definite confidence. However, 33.8% of patients reported experiencing a PSI. Most of these incidents (81.6%) were identified by the patients themselves. While 68.8% of respondents felt their incidents were managed in a desired manner, reasons for dissatisfaction included the patient's inability to tell their story (46.7%) and lack of explanations from staff (26.7%). These findings underscore the importance of effective communication and support in incident management to ensure patient satisfaction and safety.

Table 1. Response of patients to organization for economic co-operation and development questionnaire

Variable			Frequency	Percentage
Communication	Good communication with doctors and staff	Always	127	87.6
		Usually	10	6.9
		Sometimes	8	5.5
	Point of contact for concerns	Yes	110	75.9
		No	35	24.1
	Comfort in speaking out	Yes, definitely	129	89
		Yes, to some extent	14	9.7
		No not really	2	1.4
	Welcoming of speaking out	Yes, definitely	130	89.7
		Yes, to some extent	14	9.7
		No not really	1	0.7
	Confidence in safety and care process	Yes, definitely	136	93.8
		Yes, to some extent	8	5.5
		No not really	1	0.7
Patient Safety Incident	Experience of safety incident	Yes	49	33.8
		No	96	66.2
	Identification of safety incident	By patient	40	81.6
		By staff	7	14.3
		By family members	2	4.1
	Reporting of safety incident	Yes	33	78.6
		No	9	21.4
Incident Management	Incidents managed in a desired manner	Yes	33	68.8
		No	15	31.3
	Reason for desired management	Staff provided explanation	7	21.2
		Staff apologized	3	9.1
		Staff offered support	22	66.7
		Do not remember	1	3
	Reason for undesired management	Staff did not provide explanation	4	26.7
		Staff did not apologize	1	6.7
		Staff did not offer support	3	20.6
		Was not able to tell their story	7	46.7

Effect of PRIM on PSI During Hospital Stay

This section explores the PSIs experienced by patients and the influence of PRIM on these incidents. Figure 2 illustrates the PSIs reported by patients.

Figure 2. Patients experiencing patient safety incidents during hospital stays

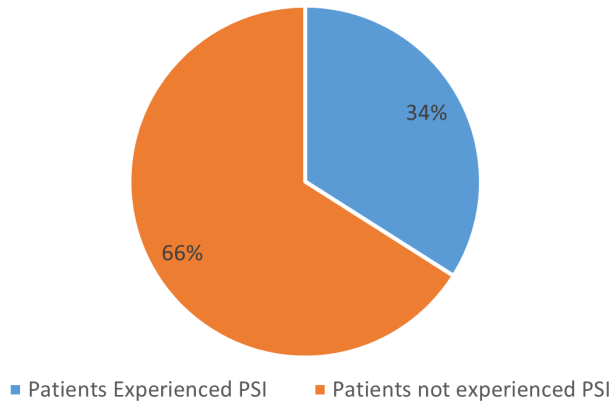


Figure 2 shows that nearly 34% of patients ($n = 49$) encountered safety incidents, while the majority, 66% ($n = 96$), did not encounter such occurrences. Most incidents were noticed by patients, followed by staff and family.

The comparison between staff-reported (through hospital incident management software) and patient-reported incidents provides insights into the perception of incidents and reporting behaviors post-PRIM implementation. Figure 3 summarizes the number of incidents reported, while Figure 4 outlines the percentage distribution of each incident type.

Figure 3. Number of incidents reported by patient and staff post-patient-reported incident management system implementation

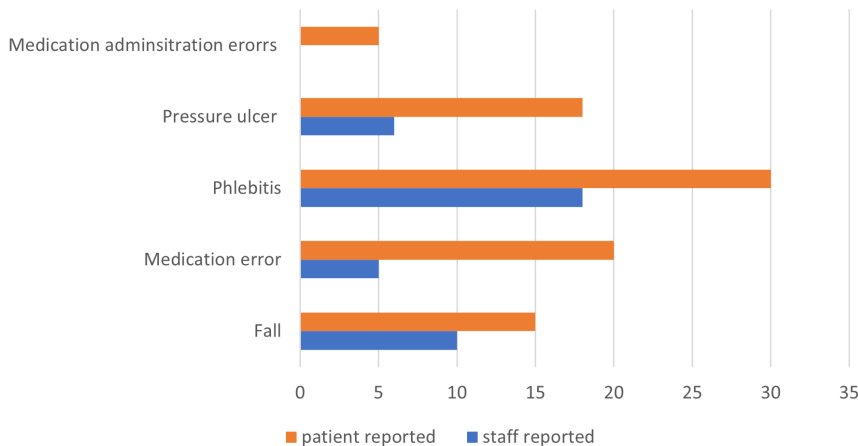
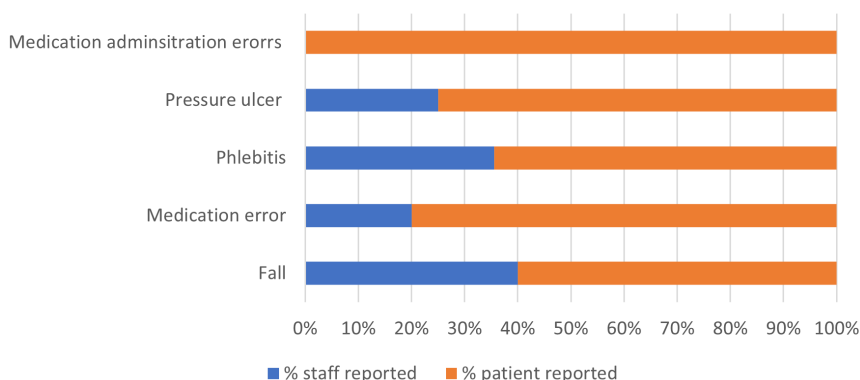


Figure 4. Percentage of patient- and staff-reported incidents



The distribution of reports shows that patients reported higher numbers of incidents across all categories. For instance, while staff reported 10 fall-related incidents, patients reported 15. Similarly, medication errors were reported 20 times by patients as compared to only 5 reports by staff. This trend continues across the categories of phlebitis (18 versus 30), pressure ulcers (6 versus 18), and medication administration errors, where no incidents were reported by staff, but patients reported 5 incidents.

Figure 4 presents the percentage distribution of each type of incident reported by both groups. It becomes clear that patients are more likely to report certain types of incidents, especially medication errors (80%). In contrast, the reporting of phlebitis was more evenly distributed (staff at 21% and patients at 38%). A notable finding was in medication administration errors, where 100% of reports were from patients, indicating a gap in staff awareness or reporting of these incidents.

PRIM's Contribution to Patient Empowerment

This section presents the influence of PRIM on empowering patient safety reports. Figure 5 presents patients' responses after the implementation of PRIM.

Figure 5. Pie chart on patient empowerment

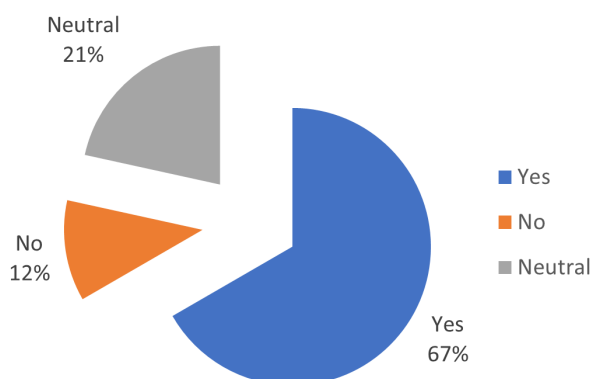
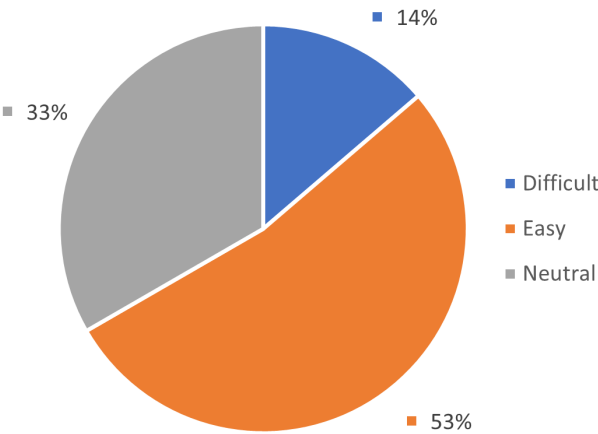


Figure 4 shows that 67% of patients reported feeling empowered by PRIM, reflecting a high level of satisfaction and engagement. A smaller portion (12%) indicated they did not feel empowered, while 21% of patients provided neutral feedback. This distribution indicates that the implementation of PRIM had a positive impact on most patients' sense of control and participation in their care.

According to Figure 6, 53% (27) of respondents rated PRIM as accessible and user-friendly. However, 33% (17) of respondents provided a neutral response, and 14% (7) faced difficulties in using the system. While a significant portion of users found the system easy to navigate, neutral and negative responses suggest there is room for improvement in making the system universally accessible. The percentage of respondents who found the system difficult to use may highlight issues with the system's interface, complexity, or lack of user training. Future iterations of PRIM should focus on improving the user experience, including simplifying navigation and providing more robust user support. These efforts can ensure that a broader range of users can comfortably interact with the system.

Figure 6. User friendliness and ease of use of patient-reported incident management system



DISCUSSION

This study demonstrates PRIM's significant impact on enhancing patient empowerment and its potential for scalability in managing PSIs. The findings underscore the importance of integrating patient perspectives into safety management systems, highlighting broader implications for patient-centered care and safety. Numerous studies emphasize the role of patient involvement in care processes, asserting that patients can identify and report safety incidents (Agoritsas et al., 2005; Guijarro et al., 2010; Madden et al., 2022; Panagioti et al., 2017). The current study supports these assertions, with nearly 81% of patients reporting safety incidents themselves, addressing a knowledge gap where patients have often been perceived as unable to spontaneously report such incidents (Kinnunen & Sarantob, 2013; Ward & Armitage, 2012; Yan et al., 2012).

The comparison between incidents reported by patients and those reported by staff highlights the complementary nature of the two reporting channels (Davis et al., 2013; Hernan et al., 2021; Kinnunen et al., 2013). Patients reported a significantly higher number of incidents than the hospital's internal system, suggesting that self-reporting through PRIM unveils a broader spectrum of safety incidents that may otherwise go unnoticed by staff. Consistent with existing literature, the study reveals that a considerable number of incidents were inadequately documented or omitted from medical records and hospital reporting systems (Davis et al., 2013; Armitage et al., 2018; Bjerkan et al., 2021).

Alarmingly, nearly 65% of the incidents were underreported by staff, underscoring the need for a more inclusive and comprehensive reporting approach. PRIM facilitated the reporting of incidents that were either infrequently reported or absent in the hospital reporting system. Nearly half of the incidents reported by patients through PRIM were subsequently addressed by staff, emphasizing the system's role as a valuable quality improvement tool.

The study's data reveal a notable difference in reporting patterns between the pre- and post-implementation phases of PRIM. Prior to the system's use, incident reports were comparatively low. However, once the system was integrated, incident reporting surged by 71%. This is attributed to the dual reporting mechanism, including PRIM and traditional staff reporting. PRIM has a transformative impact in amplifying the scope and depth of incident reporting within the hospital, enhancing quality of care.

Although there is a large body of literature on structural empowerment among staff (Kim & Kim, 2019; Rathert et al., 2012; Russ et al., 2020), evidence on patient empowerment remains limited (Busch et al., 2021; Hilda et al., 2022; Russ et al., 2020). This study contributes to the existing body of knowledge by showing that patient empowerment is a crucial aspect, with patients reporting a sense of control and involvement in their care. This empowerment positively influences patient engagement, adherence to treatment plans, and satisfaction with healthcare experiences.

Furthermore, this study highlights the user-friendly nature of the PRIM system, with most patients expressing a sense of empowerment following its implementation. These findings align with existing literature, which emphasizes the importance of patient feedback and active involvement in improving patient safety (Busch et al., 2021; Hilda et al., 2022). The study's findings advocate for the integration of patient perspectives into incident reporting, adding to existing knowledge and promoting a more inclusive, patient-centric approach to healthcare safety.

The efficacy of an intervention ranges from low impact (e.g., educational initiatives, labeling, and policy modifications) to moderate influence (e.g., checklists and improved communication), and high impact (e.g., changes to the physical environment; Gosbee, 2002; Gosbee & Gosbee, 2010). PRIM clearly adds value, not only by enhancing patient safety but also by fostering a more collaborative and transparent healthcare environment. By amplifying the patient's role in incident reporting, PRIM presents a sustainable model for improving overall healthcare quality and safety.

CONCLUSION

This study underscores the effectiveness of PRIM in enhancing patient safety reporting and empowerment within healthcare settings. Based on the findings, several practical recommendations are proposed to maximize the system's impact and applicability.

- Comprehensive training for healthcare staff can address underreporting and improve engagement with patient-reported incidents.
- Dedicated feedback channels within PRIM will empower patients, reinforcing the positive effects observed in this study.
- Regular monitoring and auditing of PRIM's usage will ensure continuous improvement, while policies emphasizing patient engagement can solidify their involvement in safety reporting.
- Enhanced cross-departmental collaboration and customizable reporting interfaces tailored to diverse patient needs will address user experience concerns and improve system usability.
- Transparent reporting of outcomes will foster patient trust, while advanced data analytics can identify trends.
- Education aimed at patients will encourage the proactive use of PRIM.
- Aligning the system with existing policies will ensure its long-term integration and effectiveness.

Together, these recommendations provide a comprehensive approach for healthcare leaders, policymakers, and administrators to adopt PRIM as a transformative tool in advancing patient safety, fostering a culture of transparency and collaboration in healthcare.

COMPETING INTERESTS

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