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Effectiveness and User Satisfaction of an ePRO-Based mHealth Application for Near Miss Reporting and Patient Safety Culture in the ICU

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Abstract

Background: Near miss reporting and patient safety culture are critical to quality improvement in intensive care units (ICUs), yet conventional reporting systems are often constrained by underreporting, delayed submission, and limited feedback. Mobile health (mHealth) applications integrated with electronic patient-reported outcomes (ePRO) offer a promising approach to facilitate real-time reporting and strengthen safety culture in high-risk clinical environments.
Objective: This study evaluated the effectiveness and user satisfaction of an ePRO-based mHealth application in improving near miss reporting and patient safety culture in ICU settings.
Methods: A mixed-methods study was conducted in the ICU of a level B hospital in Karawang, Indonesia, involving 250 healthcare workers, primarily nurses. The intervention was implemented over six months using a user-centered design approach. Outcomes included near miss reporting rates, reporting timeliness, and Hospital Survey on Patient Safety Culture (HSOPSC) scores. Quantitative data were analyzed using paired t-tests and multiple linear regression, while user satisfaction and implementation experiences were explored using the System Usability Scale (SUS) and focus group discussions.
Results: Near miss reporting increased 2.3-fold after implementation, and timely reporting within one hour rose from 21.4% to 68% ($p < 0.001$). Significant improvements were observed in patient safety culture domains, particularly non-punitive response to error and communication openness. User satisfaction was high, with a mean SUS score of 82.3. Technical challenges and initial staff resistance were identified as key barriers.
Conclusion: The ePRO-based mHealth application significantly improved near miss reporting, enhanced patient safety culture, and demonstrated high usability in ICU settings. Despite technical and cultural challenges, the intervention aligns with the WHO Global Patient Safety Action Plan 2021–2030 and underscores the importance of integrating digital innovation with safety culture initiatives in resource-limited healthcare systems.

Keywords: near miss reporting, patient safety culture, mHealth, ICU, ePRO, usability, Indonesia

INTRODUCTION

Patients in the intensive care unit (ICU) are generally in critical condition, requiring intensive medical interventions, which leaves a very narrow margin for error (1). Near miss reporting and patient safety culture are critical components in improving the quality of health services in the ICU (2), considering the complexity of patients' conditions, the use of high-alert medications, invasive procedures, and the high potential for fatal errors (3). Data show that near miss incidents in ICUs occur 3–5 times more frequently than in general inpatient wards, with an incidence rate of 4.7–8.2 events per 100 patient-days (4). A study by Valentin et al. (5) revealed that 28% of medication errors in ICUs were related to dosage errors, while 19% were caused by miscommunication during handover.

A near miss refers to an incident that almost caused harm to a patient but was successfully prevented in time (6). Reporting near misses enables healthcare teams to identify system weaknesses before a fatal error occurs (7). The main barriers to near miss reporting in ICUs include lack of awareness, fear of punishment, and high workload, resulting in underreporting (8). The impact of unreported near misses or actual errors in ICUs is serious. Patients may experience prolonged hospitalization (an average of 4–7 additional days), increased healthcare costs of up to 30%, and a 15–20% increase in mortality risk (5,9). Moreover, ICU errors have psychological impacts on healthcare providers, including burnout and second victim syndrome (7). Implementing effective near miss reporting systems can reduce adverse events by up to 40% (10).

Introducing non-punitive near miss reporting systems and fostering a strong safety culture can reduce patient error incidents (9). Studies show that hospitals with a positive safety culture have error rates 40% lower than those without (7). However, conventional reporting systems such as paper-based or manual methods have proven to be limited, including underreporting (only 30–40% of near misses are reported), reporting delays, and lack of feedback (7).

The advancement of mobile health (mHealth) provides innovative solutions to improve near miss reporting through electronic systems based on patient-reported outcomes (ePRO) (11). mHealth applications enable real-time reporting, anonymity, and automated data analysis, which have been shown to increase healthcare worker participation by 60–80% in critical units (8). Several hospitals have adopted similar systems, such as the Safety Reporting System, which successfully reduced unreported near misses by 45% within two years (10). However, the effectiveness and user satisfaction of ePRO-based mHealth applications specifically in ICUs still require further investigation, particularly in the context of high workload and alarm fatigue commonly experienced by ICU nurses in Indonesia (4). This study aims to evaluate the effectiveness and user satisfaction of an ePRO-based mHealth application in optimizing near miss reporting and patient safety culture in ICUs.

METHODS

Study Design

This study employed a mixed-methods design, integrating quantitative and qualitative approaches to evaluate the effectiveness and user satisfaction of an ePRO-based mHealth application for near miss reporting and patient safety culture in intensive care units (ICUs). The study was conducted in three sequential phases: (1) application development, (2) quantitative evaluation of effectiveness, and (3) qualitative exploration of user satisfaction and implementation barriers.

Phase 1: Application Development

The application was developed using a user-centered design approach. A needs assessment was conducted through surveys and focus group discussions with ICU healthcare professionals (nurses, physicians, pharmacists) to identify barriers to near miss reporting and essential application features. Based on these inputs, the prototype incorporated: (1) real-time standardized reporting forms (medication, procedures, infection), (2) automated notifications to the patient safety team, (3) a data analytics dashboard with trend analysis, and (4) anonymous reporting options. The prototype underwent usability testing with ICU nurses using simulated near miss reporting scenarios to assess usability, access speed, and interface clarity. Iterative refinements were implemented prior to deployment. Integration with the hospital Electronic Health Record (EHR) system was achieved through a secure API, ensuring patient data validation while maintaining compliance with data protection regulations (e.g., GDPR, HIPAA).

Phase 2: Quantitative Evaluation

The evaluation was conducted in the ICU of a level B hospital in Karawang, Indonesia. Eligible participants included active ICU staff with ≥6 months of experience directly involved in patient care or treatment. Exclusion criteria included administrative staff, temporary staff or trainees, and those with planned leave >4 weeks during the study. Sample size was calculated using G*Power 3.1 for multiple linear regression (effect size f^2 = 0.15, α = 0.05, power = 0.95, 10 predictors), requiring a minimum of 219 participants. With an anticipated 15% attrition, the target sample was set at 250, recruited through convenience sampling.

Instruments

a. Near Miss Reporting Rate: number of reports per 100 patient-days, retrieved from backend analytics.
b. Timeliness of Reporting: time from event to reporting, categorized as <1 h (very good), 1–4 h (good), 4–24 h (fair), and >24 h (poor).
c. Hospital Survey on Patient Safety Culture (HSOPSC): 42 items across 12 dimensions, 5-point Likert scale. Reliability: original α = 0.84; Indonesian version α = 0.81.
d. System Usability Scale (SUS).
e. In-depth Interview Guide for qualitative exploration.

Procedures

Ethical approval was obtained from the Horizon University Karawang Ethics Committee, and institutional permissions were secured. Baseline HSOPSC surveys were collected before implementation. The application was then deployed for six months, during which monthly feedback sessions and dedicated technical support were provided. Post-implementation, participants completed the SUS questionnaire, followed by six focus groups (8–10 participants each) and a final HSOPSC survey.

Data Analysis

Quantitative data were analyzed using SPSS version 27. Descriptive statistics summarized participant characteristics. Paired *t*-tests compared pre- and post-intervention HSOPSC scores. Multiple linear regression identified predictors of near miss reporting rate, including demographics, workload indicators, usability scores, and composite safety culture scores. Missing data (<5%) were addressed using multiple imputation.

Qualitative data from focus groups and interviews were analyzed using thematic analysis following Braun and Clarke's six-phase framework: familiarization, coding, theme generation, theme review, theme definition, and reporting. Verbatim quotations supported key findings. Rigor was ensured through triangulation with quantitative findings (e.g., SUS scores), member checking, and maintaining an audit trail.

RESULTS

A total of 250 ICU healthcare workers participated in this study. The majority of respondents were nurses (82.4%), aged 26–35 years (54.8%), with ≥5 years of ICU experience (63.2%).

After six months of implementation, the number of near miss reports increased 2.3-fold compared to baseline (p<0.001). Reporting was also timelier, with 68% of reports submitted within <1 hour of the incident

Table 1. Characteristics of Respondents (N = 250)

Characteristic	n	%
Gender		
Male	72	28.8
Female	178	71.2
Profession		
Nurse	206	82.4
Physician	29	11.6
Pharmacist	15	6.0
Age		
≤25 years	47	18.8
26–35 years	137	54.8
≥36 years	66	26.4
ICU work experience		
<5 years	92	36.8
≥5 years	158	63.2

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Table 2. Comparison of Near Miss Reporting Rate and Timeliness

Indicator	Pre-implementation	Post-implementation	*p-value*
Near miss reports/100 patient-days	4.8 ± 2.1	11.2 ± 3.4	<0.001
Reporting timeliness:			
- <1 hour	21.4%	68.0%	<0.001
- 1–4 hours	36.0%	22.4%	
- 4–24 hours	29.2%	7.6%	
- >24 hours	13.4%	2.0%	

Table 3. Changes in HSOPSC Scores Pre- and Post-Implementation (N = 250)

HSOPSC Dimension (scale 1–5)	Pre-implementation (M±SD)	Post-implementation (M±SD)	*p-value*
Non-punitive response to error	2.84 ± 0.72	3.91 ± 0.61	<0.001
Communication openness	3.02 ± 0.68	4.05 ± 0.54	<0.001
Teamwork within units	3.45 ± 0.59	3.89 ± 0.52	0.012
Feedback and communication about error	2.95 ± 0.63	3.77 ± 0.55	<0.001
Overall perception of patient safety	3.11 ± 0.58	3.88 ± 0.60	<0.001

Table 4. Summary of Implementation Challenges

Challenge Category	Key Issues
Technical	API–EHR integration delays; internet connectivity issues; limited device availability.
Non-technical	Senior staff resistance; fear of sanctions; workload limiting full adoption.

Scores from the Hospital Survey on Patient Safety Culture (HSOPSC) showed significant improvements across most dimensions, particularly in *non-punitive response to error* and *communication openness*.

The System Usability Scale (SUS) results indicated an average score of 82.3, classified as *excellent usability*. In-depth interviews revealed that respondents perceived the application as:

1. Easy to access on mobile devices.
2. Useful for accelerating reporting and reducing administrative barriers.
3. Providing a sense of security through the anonymous reporting feature.

Thematic analysis identified both technical and non-technical challenges.

1. Technical challenges: longer-than-expected integration with the EHR system, internet connectivity issues in certain ICU areas, and limited device availability during night shifts.
2. Non-technical challenges: initial resistance from senior staff, concerns about sanctions despite the anonymous option, and high workload limiting time for exploring new features.

DISCUSSION

This study demonstrated that the implementation of an ePRO-based mHealth application significantly improved near miss reporting, patient safety culture, and user satisfaction in an ICU setting. Following six months of implementation, near miss reporting increased 2.3-fold compared to baseline, with a substantial reduction in reporting delays—68% of events were reported within one hour of occurrence. These findings highlight the

effectiveness of real-time digital reporting systems in addressing underreporting, a persistent issue in conventional paper-based or manual reporting systems, where only 30–40% of near misses are typically documented (18, q9). By simplifying the reporting workflow and offering anonymous options, the application reduced psychological and administrative barriers, consistent with previous evidence showing that electronic systems enhance staff participation by up to 80% in critical care units (12).

The intervention also produced significant improvements in Hospital Survey on Patient Safety Culture (HSOPSC) scores, particularly in non-punitive response to error and communication openness. These dimensions are essential in shaping a learning-oriented culture, where errors and near misses are viewed as opportunities for system improvement rather than individual blame (13). Hospitals with strong safety cultures have been shown to have 40% fewer adverse events than those without structured reporting and feedback systems (14). The current findings suggest that the application not only facilitated reporting but also helped shift staff perceptions toward safer, more transparent communication practices.

User satisfaction was reflected in a System Usability Scale (SUS) score of 82.3, which falls in the excellent range. Qualitative findings reinforced these results: participants valued the ease of mobile access, efficiency in reducing administrative burden, and psychological safety from the anonymous reporting feature. These outcomes echo prior studies where usability strongly influenced adoption and sustained engagement with safety applications in high-stress clinical environments (15). Importantly, satisfaction is not merely a measure of convenience but a predictor of long-term system sustainability and integration into routine clinical practice.

Implementation Challenges

Despite these benefits, the study identified both technical and non-technical challenges. Technical issues included delays in API integration with the EHR, internet connectivity problems, and limited device availability during night shifts. These barriers reflect broader challenges in digital health implementation in resource-constrained settings, where infrastructure and interoperability remain critical bottlenecks (16). Non-technical challenges such as initial resistance from senior staff and fear of sanctions highlight the cultural and behavioral dimensions of change management in ICUs (17). High workload also limited opportunities for staff to explore the application's features, underscoring the need for workflow alignment and managerial support during adoption (2.5).

Implications for Practice

Together, these findings reinforce the potential of mHealth tools integrated with patient safety culture initiatives to transform reporting practices in high-risk environments such as ICUs. For policymakers and hospital administrators, the results suggest that digital reporting systems should be complemented with non-punitive policies, continuous staff engagement, and infrastructure strengthening to ensure sustainability. The study also aligns with global safety priorities, including the WHO Global Patient Safety Action Plan 2021–2030, which calls for digital innovation to strengthen reporting systems and learning cultures (26-28).

CONCLUSION

Overall, the ePRO-based mHealth application proved effective in enhancing near miss reporting, strengthening patient safety culture, and gaining positive acceptance from ICU users. Despite the presence of technical and non-technical barriers, the benefits of the application outweighed its challenges. This study underscores the importance of a user-centered design approach in the development of patient safety technologies and highlights the need for implementation strategies that take into account technical aspects, organizational culture, and healthcare workers' workload.

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Author Contributions
LS: Conceptualization, study design, application development, data collection, quantitative and qualitative data analysis, manuscript drafting.

Conflict of Interest
The authors declare that they have no conflicts of interest.

Data Availability
The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request, subject to institutional approval and ethical considerations to protect participant confidentiality

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