

Risk Management, Patient Safety Culture, and Medication Safety Knowledge Associated with Medication Errors

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Abstract

Background: Medication errors are preventable patient-safety problems. Hospital pharmacy services require coordinated risk management, a supportive safety culture, and adequate medication-safety knowledge. **Objective:** To examine associations of risk management, patient safety culture, and medication-safety knowledge with medication errors among pharmacy personnel at Bumi Waras Hospital. **Method:** An analytical cross-sectional study in November-December 2025 included all 31 pharmacists and pharmacy technicians. Structured questionnaires assessed the three predictors, and a researcher-developed register captured medication errors. Descriptive analysis and multiple regression were performed. **Result:** Risk management was low (42.01), patient safety culture high (75.30), and medication-safety knowledge moderate (69.58). Risk management was not associated with medication errors ($\beta=0.078$; $p=0.664$), whereas patient safety culture ($\beta=-0.447$; $p=0.041$) and knowledge ($\beta=-0.488$; $p=0.024$) showed significant inverse associations. The model was significant ($F(3,27)=20.308$; $p<0.001$; $R^2=0.693$). Of 25 incidents, 80% were dispensing errors and 84% caused no harm. **Conclusion:** Stronger safety culture and knowledge were associated with fewer errors; risk management was not independently associated. Cross-sectional findings do not establish causality. **Recommendation:** Strengthen non-punitive reporting, staffing and workflow review, risk documentation, and recurrent education; conduct larger multicenter longitudinal studies with standardized incident denominators.

Keywords: medication errors; patient safety culture; risk management; medication safety; pharmacy service

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INTRODUCTION

Medication safety is a core component of patient safety because preventable harm may arise at prescribing, transcribing, dispensing, administration, and monitoring stages. The World Health Organization (WHO) has positioned medication-related harm as a global safety priority and calls for integrated organizational strategies that reduce avoidable harm across health systems (1). A systematic review of medical care settings estimated that approximately 6% of patients experience preventable harm, with drug-related incidents representing one of the largest categories (2). A separate meta-analysis showed that preventable medication harm occurs across care settings and that a meaningful proportion is severe or potentially life-threatening (3). Contemporary hospital data further demonstrate that adverse events and preventable events remain common despite decades of safety improvement efforts (4).

Medication errors are preventable events that may cause or lead to inappropriate medication use or patient harm while medicines are under the control of a healthcare professional, patient, or consumer (5,6). Safe medication systems therefore require more than individual vigilance. Current hospital-pharmacy guidance emphasizes system design, risk assessment, error-reporting mechanisms, interdisciplinary learning, high-alert medication safeguards, and continuing staff competency development (7). Dispensing errors are particularly relevant to pharmacy services; a recent systematic review found wide variation in reported dispensing-error rates and highlighted that estimates depend strongly on the denominator, detection method, and error definition used (8).

The local context that motivated this study was a persistent gap between medication errors detected by the research team and those entering the hospital's formal reporting pathway. During a preliminary review from January to March 2025, 28 medication-error incidents were identified, whereas only two were documented in the hospital reporting system. This discrepancy suggested under-reporting and limited organizational learning from medication-related incidents. Under-reporting is not unique to one institution. Recent Indonesian evidence identifies barriers

related to reporting infrastructure, fear of blame, organizational culture, and knowledge gaps (9), while patient safety culture has also been linked to reporting behaviors among healthcare professionals in Indonesian hospitals (10).

Medication errors arise from interacting human, task, organizational, and system factors. Systematic evidence identifies workload, communication problems, supply and storage issues, interruptions, inadequate knowledge, and failures in checking processes as recurrent contributors (11-13). Patient safety culture shapes whether staff communicate openly, respond constructively to mistakes, and report events for learning rather than concealment. Studies among nurses have associated stronger safety culture with more appropriate medication-error reporting and better safety-related outcomes (14-16). In Indonesia, the Hospital Survey on Patient Safety Culture 2.0 has been cross-culturally adapted and psychometrically evaluated, supporting the feasibility of structured assessment of safety-culture dimensions in hospital settings (17).

Medication-safety knowledge is another important layer of defense because pharmacists and pharmacy technicians must recognize high-risk medicines, verify prescriptions, identify inappropriate doses or routes, communicate clearly, involve patients, and understand reporting procedures. Studies of pharmacists in different health systems demonstrate persistent variation in medication-safety knowledge and reporting readiness (19-21). Nevertheless, knowledge alone may not prevent errors when risk-management processes are fragmented or when organizational culture discourages reporting.

Although risk management, safety culture, and medication-safety knowledge are conceptually interrelated, limited evidence has examined all three simultaneously within a hospital-pharmacy workforce in Indonesia while also describing the observed pattern of medication errors and under-reporting.

OBJECTIVE

This study aimed to examine the associations of risk management, patient safety culture, and medication-safety knowledge with

medication errors among pharmacy personnel at Bumi Waras Hospital. Because the study was cross-sectional, the analysis estimated statistical associations rather than causal effects.

METHODS

Design

This study used an analytical cross-sectional design and was conducted in the Pharmacy Installation of Bumi Waras Hospital, Bandar Lampung, Indonesia, from November to December 2025. The design was selected to examine concurrent associations between organizational and individual factors and the medication-error outcome within the pharmacy workforce.

Sample size and sampling technique

The target population comprised all pharmacists and pharmacy technicians working in the Pharmacy Installation during the study period. Total sampling was applied because the eligible workforce was small and fully accessible. Thirty-one staff members participated. Participation was voluntary and followed an explanation of the study and informed consent.

Variables and instruments

The independent variables were risk management, patient safety culture, and medication-safety knowledge. Risk management was assessed across seven process domains: risk identification, risk analysis, risk evaluation, risk control, risk communication, risk review, and risk documentation. Patient safety culture comprised ten domains broadly consistent with the AHRQ SOPS Hospital Survey 2.0 framework, including staffing, teamwork, management support, communication openness, response to error, organizational learning, supervisor or clinical-leader support, event reporting, handoffs, and information exchange (18). The availability of a validated Indonesian HSOPSC 2.0 provides relevant contextual support for structured safety-culture assessment in Indonesian hospitals (17). Medication-safety knowledge covered the use of generic names, assessment of medication appropriateness, medication-history collection, high-alert medicines, patient memory aids, correct medication and patient identification, clear written communication,

prescription and medication verification, patient involvement, and incident reporting. The three questionnaires used five-point Likert response options. Descriptive index scores were transformed to a 20-100 scale and classified as low (20.00-46.67), moderate (46.68-73.33), or high (73.34-100.00).

Instrument quality assessment

The source study assessed questionnaire item validity using Pearson item-total correlations and internal consistency using Cronbach's alpha. Because the census sample contained only 31 participants, confirmatory factor analysis was not interpreted in the present report; stable factor-analytic estimates would require a substantially larger validation sample. The researcher-developed medication-error register was subjected to expert content review using item- and scale-level content validity indices.

Medication error surveillance and outcome

Medication errors were recorded using a researcher-developed incident register that captured the number of incidents, stage of the medication-use process, and harm category. Medication-use stages reported in the source data were dispensing, administration, and transcribing. Harm was categorized as no harm or mild harm in accordance with the classification used in the source study. Because the original report did not provide a defensible denominator for the stated incident rate, this revised manuscript reports event counts and percentages rather than an incident-rate estimate. This avoids comparison of rates that may use non-equivalent denominators, an issue emphasized in medication-error research (8,24,25).

Data collection process

After informed consent, structured questionnaires were administered to eligible pharmacy staff. Medication-error events identified during the same study period were entered into the research incident register. Formal hospital reporting records were also reviewed to describe the extent to which detected events were represented in the institutional reporting system.

Data analysis

Data were analyzed using IBM SPSS Statistics version 30. Descriptive analysis summarized participant characteristics and the transformed index scores. Regression diagnostics included assessment of normality, multicollinearity, and heteroscedasticity. A multiple regression model examined the simultaneous associations of risk management, patient safety culture, and medication-safety knowledge with the medication-error outcome. Standardized regression coefficients (β), *t* statistics, *p* values, the model *F* statistic, and coefficient of determination (*R*²) were reported. Statistical significance was set at *p*<0.05. *R*² was interpreted as the proportion of outcome variance explained by the combined model, not as a percentage reduction in medication errors.

Ethical consideration

Ethical approval was obtained from the IRB Universitas Esa Unggul. All participants provided informed consent.

RESULT

Participant Characteristics

All 31 eligible pharmacy staff participated. The sample was predominantly female (93.5%), and 87.1% were 30 years of age or younger. Most participants were pharmacy technicians (74.2%), had a Diploma 3 in Pharmacy (54.8%), and had worked for 1-5 years (71.0%). Most staff had previously attended in-house training on patient safety culture, risk management, and medication safety (Table 1).

Table 1. Participant characteristics (n=31).

Characteristic	n	%
Sex: Female	29	93.5
Sex: Male	2	6.5
Age <25 years	13	41.9
Age 26-30 years	14	45.2
Age 31-35 years	1	3.2
Age 36-40 years	1	3.2
Age 41-45 years	1	3.2
Age 46-50 years	0	0.0
Age >51 years	1	3.2
Education: Diploma 3 Pharmacy	17	54.8

Characteristic	n	%
Education: Bachelor of Pharmacy	6	19.4
Education: Pharmacist profession	8	25.8
Role: Pharmacy technician	23	74.2
Role: Pharmacist	8	25.8
Tenure <1 year	5	16.1
Tenure 1-5 years	22	71.0
Tenure 6-10 years	2	6.5
Tenure >11 years	2	6.4
Training: Patient safety culture	29	93.5
Training: Risk management	28	90.3
Training: Medication safety	27	87.1

Descriptive Index Scores

The transformed index for risk management was 42.01 and was classified as low. Patient safety culture had an index of 75.30 and was classified as high. Medication-safety knowledge had an index of 69.58 and was classified as moderate (Table 2).

Table 2. Descriptive index scores of the main study variables.

Variable	Index score	Category
Risk management	42.01	Low
Patient safety culture	75.30	High
Medication-safety knowledge	69.58	Moderate

Multivariable Associations with Medication Errors

Risk management was not associated with the medication-error outcome (β =0.078, *t*=0.439, *p*=0.664). Patient safety culture (β =-0.447, *t*=-2.150, *p*=0.041) and medication-safety knowledge (β =-0.488, *t*=-2.399, *p*=0.024) showed significant inverse associations. The overall model was significant, *F*(3,27)=20.308, *p*<0.001, and explained 69.3% of outcome variance (*R*²=0.693) (Table 3).

Table 3. Multiple regression results. Model: *F*(3,27)=20.308, *p*<0.001; *R*²=0.693.

Predictor	beta (t; p)
Risk management	0.078 (0.439; 0.664)
Patient safety culture	-0.447 (-2.150; 0.041)
Medication-safety knowledge	-0.488 (-2.399; 0.024)

Medication Error Profile

Twenty-five medication-error incidents were captured in the research incident register during November-December 2025, averaging approximately 12-13 events per month. Dispensing errors accounted for 20 events (80%), administration errors for 4 (16%), and transcribing errors for 1 (4%). Twenty-one events (84%) were classified as no harm and four (16%) as mild harm. The source manuscript reported that none of these 25 events appeared in the hospital's formal incident-reporting system during the same period, indicating substantial under-reporting (Table 4).

Table 4. Medication-error incidents identified during the study period (n=25 incidents).

Medication-error characteristic	n	%
Dispensing error	20	80.0
Administration error	4	16.0
Transcribing error	1	4.0
No harm	21	84.0
Mild harm	4	16.0

DISCUSSION

This study produced four principal findings. First, risk-management implementation was classified as low, whereas patient safety culture was high and medication-safety knowledge was moderate. Second, risk management was not independently associated with the medication-error outcome after the other predictors were included. Third, stronger patient safety culture and greater medication-safety knowledge were inversely associated with medication errors. Fourth, research surveillance identified 25 medication-error incidents during the two-month study period, with dispensing errors accounting for 80% and no-harm events for 84%. The combined regression model explained 69.3% of the observed variance; this value should not be interpreted as a 69.3% reduction in incidents.

The non-significant risk-management coefficient should not be interpreted as evidence that risk management is unimportant. Hospital medication safety depends on proactive risk identification, standardized processes, reporting and learning, high-alert

medication controls, and multidisciplinary review (7). Systematic evidence likewise shows that medication errors are frequently rooted in interacting system conditions, such as workload, workflow design, communication, storage, documentation, and checking failures (11-13). In the present study, the low risk-management index may indicate that the formal risk-management cycle had not yet matured sufficiently or varied enough across the small workforce to show an independent statistical association. Limited power, measurement error, and residual confounding are alternative explanations. The finding therefore warrants organizational strengthening rather than dismissal of risk-management activity.

Patient safety culture showed a significant inverse association with medication errors. This is consistent with the principle that a strong safety culture supports open communication, teamwork, learning from error, and psychologically safer reporting. Jang et al. found that perceptions of patient safety culture were related to appropriate medication-error reporting among nurses (14), while Hessels et al. linked safety-culture dimensions with missed care and adverse-event indicators (15). Indonesian hospital evidence similarly supports relationships between safety culture and adverse-event or reporting outcomes (10,16). The high overall culture index in the present study should therefore be viewed as an asset, but it does not imply that all culture domains are strong. The source analysis identified operational concerns around staffing, response to error, and event reporting, which are precisely the domains most relevant to converting a generally positive safety climate into reliable daily practice.

Medication-safety knowledge also demonstrated a significant inverse association with the medication-error outcome. Medication knowledge functions as a frontline defense by helping staff recognize high-risk medicines, detect dose or route problems, conduct independent verification, communicate clearly, and escalate unsafe conditions. Pharmacist surveys have repeatedly identified gaps between positive attitudes toward medication safety and incomplete technical or reporting

knowledge (19-21). The present sample is notable because most participants had previously attended medication-safety training, yet the overall knowledge index remained only moderate. This pattern suggests that one-off training may be insufficient. Competency-based refreshers, case-based learning from local incidents, and periodic verification of high-alert medication practices may be more useful than attendance-focused training alone.

The dominance of dispensing errors is operationally important because dispensing is a core pharmacy responsibility and is directly influenced by workflow, staffing, labeling, storage, look-alike/sound-alike medicines, interruptions, and verification procedures. A recent meta-analysis demonstrated substantial heterogeneity in dispensing-error estimates across settings and methods (8), and human-factors research in hospital pharmacies has highlighted workload, communication, standardization, and staffing as contributors (12). Therefore, the present finding should prompt process mapping of the dispensing pathway rather than attribution to individual staff performance. Recommended actions include independent verification for selected high-risk processes, clearer storage and labeling, workload review, interruption management, and use of local incident data to prioritize failure-mode analysis.

Under-reporting is a second major service issue. During the study period, 25 incidents were captured in the research register, while no corresponding events were documented in the formal hospital reporting system. This pattern is consistent with evidence that clinicians may withhold medication-error reports because of fear of blame, inadequate reporting infrastructure, uncertainty about what should be reported, lack of feedback, and time pressure (9,22,23). A non-punitive reporting culture should not mean absence of accountability; rather, organizations should distinguish human error, system vulnerability, and reckless behavior while ensuring that reports lead to feedback and improvement. Simplified electronic reporting, confidential reporting options, leadership feedback, and routine

multidisciplinary review can help convert incident data into organizational learning.

The study has several limitations. The cross-sectional design precludes conclusions about temporal sequence or causality. The sample was a census of one pharmacy installation but remained small (n=31), limiting statistical power, precision, and generalizability. Self-reported questionnaire data are susceptible to social-desirability and common-method bias. The small sample also precluded reliable confirmatory factor analysis within this study. Medication-error surveillance depended on a researcher-developed register, and the absence of a clearly documented common denominator prevented valid calculation of a comparable incident rate; for this reason, only counts and proportions are emphasized in the revised report. Finally, the discrepancy between research-detected and formally reported incidents indicates that routine reporting data alone may underestimate the true burden of medication errors.

Despite these limitations, the study offers practical value for health-service management because it integrates an organizational risk perspective, safety culture, staff knowledge, and observed incident patterns in a single hospital pharmacy context. The findings support a layered safety strategy: strengthen formal risk-management processes, protect and deepen a just reporting culture, and maintain medication-safety competency through recurrent, practice-based education. The Indonesian pharmacy workforce is increasingly expected to deliver medication-management services that depend on clinical knowledge and patient-centered safety practices (26); these competencies should be embedded in hospital quality and safety systems rather than treated as isolated educational activities.

CONCLUSION

Patient safety culture and medication-safety knowledge were significantly and inversely associated with the medication-error outcome among pharmacy staff at Bumi Waras Hospital, while risk management did not show an independent association in the multivariable

model. The combined model explained 69.3% of the observed variance in the medication-error outcome. During November-December 2025, 25 medication-error incidents were identified, most of which were dispensing errors and caused no harm. These findings indicate a need to strengthen risk-management implementation and formal incident reporting while preserving a supportive safety culture and improving medication-safety competency. Because the study was cross-sectional and single-center with a small sample, the findings should be interpreted as associations and not as evidence of causation.

RECOMMENDATION

For clinical and management practice, the hospital should prioritize a non-punitive and easy-to-use medication-error reporting pathway, systematic review of pharmacy staffing and dispensing workflow, prospective risk assessment for high-risk medication processes, and recurring competency-based medication-safety education. For research, multicenter longitudinal studies should use standardized medication-error definitions, explicit event-detection methods, and denominators such as dispensed items, medication orders, or opportunities for error. Larger samples are also needed to validate the measurement model and to examine potential confounders and mediating mechanisms.

AUTHOR CONTRIBUTIONS STATEMENT

S.K.: Conceptualization, methodology, investigation, data curation, writing-original draft; A.B.S.: supervision, methodology, validation, writing-review and editing; Y.R.: supervision, formal analysis, validation, writing-review and editing.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

DECLARATION OF GENERATIVE AI AND AI-ASSISTED TECHNOLOGIES

During preparation of this revised manuscript, the authors used OpenAI ChatGPT to assist with English-language translation, academic language editing, manuscript restructuring, and Vancouver-style reference formatting. All

AI-assisted content was critically reviewed and edited by the authors, who take full responsibility for the accuracy, integrity, and final content of the manuscript.

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