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Medical Governance and Legal Responsibility in Promoting Patient Safety in Modern Healthcare Systems

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A B S T R A C T

The growing complexity of contemporary healthcare systems highlights the need to strengthen medical governance and legal accountability as essential components for enhancing patient safety. This study investigates the role of medical governance and legal responsibility in influencing patient safety outcomes within modern healthcare services. A quantitative research approach was employed using a survey method involving 120 healthcare professionals. Data were collected through structured questionnaires and analyzed using multiple linear regression supported by IBM SPSS Statistics version 27. The findings indicate that effective medical governance practices, adherence to legal standards, and strong institutional supervision significantly contribute to improved patient safety. Furthermore, the consistent implementation of legal accountability mechanisms helps reduce the likelihood of medical errors and enhances the overall quality of healthcare delivery. This study provides implications for the development of healthcare policies that emphasize governance improvement and legal accountability as strategic foundations for achieving patient-centered safety outcomes

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INTRODUCTION

The increasing complexity of modern healthcare systems has made patient safety a major concern in global health service delivery. Patient safety is no longer viewed only as an issue related to clinical practice, but also as a reflection of how healthcare organizations are governed, monitored, and held accountable. The World Health Organization (WHO), through the Global Patient Safety Report 2024, reported that many patients worldwide continue to experience preventable harm due to weaknesses in safety systems, limited institutional oversight, and inadequate healthcare governance. These challenges indicate that improving patient safety requires more than improving clinical quality; it also depends on strengthening medical governance and ensuring the effective implementation of legal responsibilities within healthcare institutions. In many developing countries, including Indonesia, issues such as medical errors, malpractice, poor compliance with service standards, and limited transparency in reporting healthcare incidents remain important challenges in building safe and accountable healthcare systems.

In Indonesia, healthcare regulatory reform through Law Number 17 of 2023 concerning Health represents an effort to strengthen patient protection and increase accountability among healthcare providers. However, the implementation of these regulations still faces several challenges, including differences in hospital capacity, limited internal supervision, and organizational cultures that do not always encourage open reporting of medical incidents. Sijabat (2023) highlighted that effective patient protection requires clear, transparent, and institutionally supported accountability mechanisms within the healthcare system. Therefore, strengthening medical governance is essential not only to improve service efficiency but also to ensure that healthcare institutions consistently prioritize patient safety and legal protection.

Conceptually, medical governance refers to the way healthcare institutions manage quality, responsibility, and risk through mechanisms such as clinical supervision, compliance with healthcare standards, transparency, risk management, and continuous quality improvement. Hibbert et al. (2023) explained that effective patient safety governance supports the development of healthcare systems that rely on evidence-based decision-making and proactive approaches to preventing medical risks. Similarly, the OECD (2023) emphasized that legal accountability is a key element in maintaining public trust in healthcare systems by ensuring responsibility, regulatory compliance, and protection of patient rights. Thus, medical governance and legal responsibility are closely connected elements in creating healthcare services that are safe, transparent, and focused on patient outcomes.

Previous studies have widely discussed patient safety from various perspectives, particularly service quality, patient safety culture, and hospital management practices. Hibbert et al. (2023), for example, examined patient safety governance models from a health policy perspective, while Ahmed et al. (2025) explored the relationship between governance and patient safety through teamwork and continuous improvement approaches in private hospitals. Meanwhile, Vitrianingsih et al. (2025) focused on hospital legal responsibility in

malpractice cases following the implementation of the 2023 Health Law. Although these studies provide important insights, research that simultaneously examines medical governance and legal responsibility as factors influencing patient safety remains limited, particularly in Indonesian hospital contexts.

This limitation represents an important research gap. Many previous studies have examined governance mainly from an administrative perspective or discussed legal responsibility as a normative issue without empirically assessing its relationship with patient safety outcomes. In addition, the rapid development of digital healthcare services, electronic medical records, and other healthcare technologies has created new challenges related to accountability, data management, and patient safety. These changes highlight the need for empirical studies that examine how governance mechanisms and legal responsibility work together in supporting safer healthcare systems.

Based on this background, this study aims to analyze the influence of medical governance and legal responsibility on patient safety in modern healthcare systems. Specifically, this research examines how governance practices, regulatory compliance, institutional supervision, and legal accountability contribute to improving patient safety and reducing the risk of medical errors in hospital settings. A quantitative approach is applied to provide measurable evidence regarding the relationship between these factors.

This study is expected to contribute theoretically by expanding discussions on healthcare governance and legal accountability in relation to patient safety. By examining the connection between institutional governance, legal compliance, and healthcare quality, this research provides a broader understanding of the factors that support safer healthcare delivery. Practically, the findings may serve as input for hospitals, government institutions, and policymakers in developing stronger medical governance systems, improving regulatory implementation, and promoting a sustainable patient safety culture. Ultimately, this research supports the development of healthcare services that are more transparent, accountable, professional, and patient-oriented in the era of healthcare modernization.

THEORETICAL REVIEW

Medical Governance in the Modern Health Care System

Medical governance is a medical governance concept that emphasizes the importance of clinical supervision, compliance with service standards, risk management, procedural transparency, and continuous quality evaluation. In the modern health system, medical governance is not only understood as an administrative mechanism, but also as an institutional framework to ensure that the entire service process runs safely, ethically, and is oriented towards patient safety. WHO (2024) emphasizes that patient safety needs to be placed as a strategic priority in the health system because injuries due to unsafe services are still a significant global problem.

Hibbert et al. (2023) explain that effective patient safety governance must be built through organizational learning, the use of safety data, strengthening organizational culture, and patient involvement in service evaluation. Good

medical governance allows healthcare institutions to identify service risks, strengthen clinical surveillance, and improve the quality of medical decision-making. Thus, medical governance is seen as closely related to improving patient safety in the modern health care system. Based on this description, the first hypothesis is formulated as follows:

H1: Medical governance has a positive and significant effect on patient safety in the modern health care system.

Legal Responsibility and Legal Accountability of Hospitals

Legal responsibility refers to the legal obligations of health workers and hospital institutions in carrying out services in accordance with professional standards, health regulations, and the protection of patient rights. In the context of modern healthcare, legal responsibilities are not only related to the resolution of medical disputes, but also include risk prevention efforts, documentation of medical measures, informed consent, and the protection of patient rights as a whole. Vitrianingsih et al. (2025) explained that the legal responsibility of hospitals is closely related to patient protection and the quality of health services after the enactment of the latest health regulations.

Sijabat (2023) also emphasized that legal protection for patients is an important part of a safe and professional health service system. Legal certainty is able to encourage health workers to work more carefully, transparently, and in accordance with medical service standards. Therefore, legal responsibility is expected to contribute to improving patient safety through strengthening institutional accountability and compliance with health regulations. Based on this explanation, the second hypothesis is formulated as follows:

H2: Legal responsibility has a positive and significant effect on patient safety in the modern health care system.

Patient Safety as an Indicator of Health Service Quality

Patient safety is the main indicator in assessing the quality of health services because it is directly related to the prevention of patient injury, the reduction of medical errors, and the protection of patients from avoidable risks. WHO through the Global Patient Safety Action Plan 2021–2030 places patient safety as a global agenda that must be realized through strengthening health service systems, safety culture, and effective institutional governance.

Alabdullah et al. (2024) stated that patient safety is influenced by various organizational factors, such as communication, teamwork, incident reporting culture, and hospital management support. This condition shows that patient safety is not only influenced by the competence of individual health workers, but also by the effectiveness of the governance system and legal accountability in health care institutions. Therefore, the integration of medical governance and legal responsibility is seen as important in creating a health service system that is safe and oriented towards patient protection.

The Relationship between Medical Governance and Legal Responsibility to Patient Safety

Patient safety cannot be achieved through medical governance or legal responsibility alone, but requires the integration of both in the modern healthcare system. Medical governance provides a mechanism for supervision, quality control, and risk management of health services, while legal responsibility

ensures that all medical actions are carried out in accordance with regulations and patient protection principles. The OECD (2023) explains that patient safety requires a combination of effective governance and strong legal accountability so that the health service system can run safely, transparently, and sustainably.

Previous research has mostly focused on patient safety culture, quality of service, or normative studies of hospital legal responsibilities. Empirical studies that integrate medical governance and legal responsibility in explaining patient safety are still relatively limited. Therefore, this study tries to fill the research gap through a quantitative approach to test the relationship between variables simultaneously. Based on this description, the third hypothesis is formulated as follows:

H3: Medical governance and legal responsibility simultaneously have a positive and significant effect on patient safety in the modern health care system.

Conceptual Framework

The following figure shows a conceptual framework of research that illustrates the relationship between *medical governance* and *legal responsibility* for *patient safety* in the modern healthcare system. This framework is based on the theories of health governance, legal accountability, and patient safety which explains that the effectiveness of medical supervision and compliance with health regulations have an important role in improving the safety and quality of patient services.

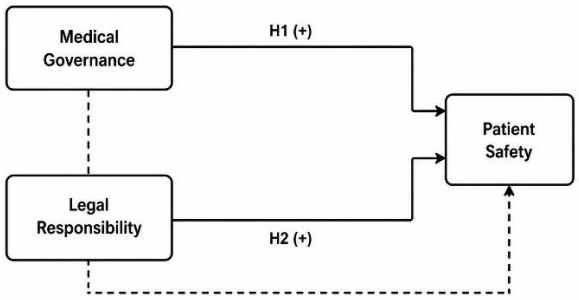

Figure 1. Research Framework of the Influence of Medical Governance and Legal Responsibility on Patient Safety

METHODOLOGY

Types of Research

This study uses a quantitative approach with an explanatory research design to analyze the influence of medical governance and legal responsibility on patient safety in the modern health care system. This approach is used to objectively test the relationships between variables through statistical analysis. Medical governance variables are measured through indicators of clinical supervision, SOP compliance, service transparency, and risk management, while legal responsibility is measured through legal compliance, medical documentation, protection of patient rights, and institutional accountability. Patient safety variables are measured through service safety indicators, reduction of medical errors, and quality of patient protection. Creswell and Creswell (2023) explain that quantitative explanatory research is effectively used to test the

relationship between variables in the context of organizations and public services.

Population and Sample

The population of this study comprised healthcare professionals, including physicians, nurses, medical administrative personnel, and hospital management staff. Respondents were selected using a purposive sampling technique, resulting in a total of 120 participants who met the inclusion criteria based on their direct involvement in patient care activities and their understanding of medical governance practices and healthcare regulations.

Data were collected using a structured closed-ended questionnaire measured on a five-point Likert scale. The instrument was developed by adapting indicators from the WHO Patient Safety Framework and previous studies related to healthcare governance and patient safety (Hibbert et al., 2023). Before conducting the main analysis, the instrument was evaluated through validity and reliability testing. The validity assessment was performed using the Pearson Product Moment correlation test with a significance threshold of <0.05, while reliability was examined using Cronbach's Alpha, with a minimum acceptable value of 0.70.

Research Instruments, Data Collection Procedures, and Data Analysis Techniques

Data collection was conducted by distributing both direct and online questionnaires to respondents who fulfilled the established research criteria. Prior to the main data collection process, a pilot test was conducted involving 30 respondents to evaluate the quality and suitability of the questionnaire items. This preliminary assessment was carried out to ensure that the research instrument was capable of measuring the intended variables appropriately.

The collected data were analyzed using descriptive analysis and multiple linear regression to examine the partial and simultaneous effects of medical governance and legal responsibility on patient safety. The statistical analysis involved several stages, including normality testing, multicollinearity assessment, heteroscedasticity testing, partial hypothesis testing using the t-test, simultaneous testing using the F-test, and evaluation of the coefficient of determination (R^2). Data processing and statistical calculations were performed using IBM SPSS Statistics version 27 as the primary analytical software (Hair et al., 2022).

RESEARCH RESULTS

Respondent Characteristics

This study involved 120 respondents consisting of health workers and hospital administration personnel. Based on the results of data processing using IBM SPSS Statistics version 27, the majority of respondents were female and dominated by the nursing profession. Most of the respondents have 3-7 years of work experience so they are considered to have an adequate understanding of the implementation of medical governance, legal responsibility, and patient safety.

Table 1. Respondent Characteristics

Features	Category	Frequency	Percentage
Gender	Male	52	43.3%
	Female	68	56.7%
Profession	Doctor	32	26.7%
	Nurse	45	37.5%
	Medical Administration	25	20.8%
	Hospital Management	18	15.0%
Long Time Working	< 3 Years	28	23.3%
	3–7 Years	54	45.0%
	> 7 Years	38	31.7%

Validity and Reliability Test Results

The results of the validity test showed that all statement items in the variables of medical governance, legal responsibility, and patient safety had a corrected item-total correlation value greater than 0.30 with a significance level of < 0.05. Thus, all items are declared valid and suitable for use in the research. Furthermore, the results of the reliability test showed that all variables had a Cronbach's Alpha value above 0.70, so that the research instrument was declared reliable and consistent.

Table 2. Validity Test Results

Variabel	Number of Items	Corrected Item-Total Correlation	Remarks
Medical Governance	8	> 0.30	Valid
Legal Responsibility	7	> 0.30	Valid
Patient Safety	8	> 0.30	Valid

Table 3. Reliability Test Results

Variabel	Cronbach's Alpha	Remarks
Medical Governance	0.892	Reliabel
Legal Responsibility	0.874	Reliabel
Patient Safety	0.901	Reliabel

Results of Descriptive Analysis of Research Variables

Based on the results of the descriptive analysis, the medical governance variable obtained a mean value of 4.18 which shows that the implementation of medical governance is in the good category. The legal responsibility variable obtained a mean value of 4.09, while patient safety obtained a mean value of 4.22 which indicates that the level of patient safety is relatively high.

Table 4. Results of Descriptive Analysis of Variables

Variabel	Minimum	Maximum	Mean	Hours of deviation
Medical Governance	3.12	4.88	4.18	0.421
Legal Responsibility	3.05	4.79	4.09	0.438
Patient Safety	3.24	4.91	4.22	0.397

Table 5. Mean Value of Each Indicator

Variabel	Indicator	Mean
Medical Governance	SOP Compliance	4.31
	Clinical Supervision	4.28
	Service Transparency	3.94
Legal Responsibility	Protection of Patients' Rights	4.26
	Medical Documentation	3.88
Patient Safety	Service Security	4.35
	Medical Error Reporting	3.97

Classical Assumption Test Results

Normality Test

The results of the Kolmogorov-Smirnov test showed a significance value of 0.087 or greater than 0.05, so that the research data was declared to be normally distributed.

Table 6. Normality Test Results

Method	Significance Value	Remarks
Kolmogorov-Smirnov	0.087	Normal

Multicollinearity Test

The results of the multicollinearity test showed that all independent variables had a tolerance value of > 0.10 and a VIF value of < 10, so that the regression model was declared free of multicollinearity.

Table 7. Multicollinearity Test Results

Variabel	Tolerance	LIVE	Remarks
Medical Governance	0.642	1.557	Multicollinearity does not occur
Legal Responsibility	0.642	1.557	Multicollinearity does not occur

Heteroscedasticity Test

The results of the Glejser test showed that all independent variables had a significance value greater than 0.05, so that the regression model was declared not to experience heteroscedasticity.

Table 8. Heteroscedasticity Test Results

Variabel	Say.	Remarks
Medical Governance	0.214	Heteroscedasticity does not occur
Legal Responsibility	0.187	Heteroscedasticity does not occur

Multiple Linear Regression Analysis Results

The results of multiple linear regression analysis showed that medical governance and legal responsibility have a positive and significant influence on patient safety.

Table 9. Multiple Linear Regression Test Results

Variabel	B	t	Say.
Constant	8.214	2.987	0.004
Medical Governance	0.486	5.921	0.000
Legal Responsibility	0.391	4.884	0.000

Based on the results of multiple linear regression analysis, the regression equation is obtained as follows:

$$Y = 8.214 + 0.486X_1 + 0.391X_2 + e$$

The results of the study showed that medical governance had a positive and significant influence on patient safety with a significance value of 0.000 (< 0.05). Thus, H1 is accepted. Legal responsibility also showed a positive and significant influence on patient safety with a significance value of 0.000 (< 0.05), so that H2 was accepted.

Simultaneous Test Results (F Test)

The results of the simultaneous test showed that medical governance and legal responsibility together had a significant effect on patient safety.

Table 10. F Test Results

Model	F	Say.	Remarks
Regression	56.738	0.000	Signifikan

Result of Coefficient of Determination (R^2)

The results of the determination coefficient showed that the variables of medical governance and legal responsibility were able to explain the variation in patient safety by 58.5%, while the rest were influenced by other variables outside the research model.

Table 11. Determination Coefficient Results

Models	R Square	Adjusted R Square
Regression Model	0.592	0.585

Research Findings

This study found that medical governance is the variable that has the most dominant influence on patient safety compared to legal responsibility. These findings can be seen from the higher value of the regression coefficient and the higher value of t-value in the medical governance variable. In addition, indicators of clinical surveillance and compliance with SOPs are the factors that contribute the most to improving patient safety.

On the other hand, legal responsibility also plays an important role in strengthening the culture of patient safety through increasing legal compliance, protection of patient rights, and accountability of health care institutions.

Table 12. Summary of Research Findings

Hipotesis	Results	Remarks
H1	Accepted	Medical governance has a positive and significant effect on patient safety
H2	Accepted	Legal responsibility has a positive and significant effect on patient safety
H3	Accepted	Medical governance and legal responsibility simultaneously have a significant effect on patient safety

DISCUSSION

The findings of this study demonstrate that medical governance and legal responsibility significantly contribute to patient safety improvement. The partial regression analysis shows that medical governance has a regression coefficient of 0.486 with a t-value of 5.921 and a significance level of p = 0.000. Meanwhile, legal responsibility also shows a significant contribution, with a regression coefficient of 0.391, a t-value of 4.884, and p = 0.000. When examined simultaneously, both variables have a significant effect on patient safety, as indicated by the F-value of 56.738 with p = 0.000. Furthermore, the Adjusted R Square value of 0.585 indicates that medical governance and legal responsibility explain 58.5% of the variation in patient safety, while the remaining variation is influenced by other factors outside the research model. These results suggest that patient safety is not solely dependent on the clinical competence of healthcare professionals but is also strongly influenced by organizational governance, regulatory compliance, institutional accountability, and the effectiveness of healthcare monitoring systems.

From a theoretical perspective, these findings support the concept of clinical governance, which emphasizes the responsibility of healthcare organizations to continuously improve service quality, maintain clinical standards, and establish a safe environment for patients. According to NHS England, clinical governance involves systematic processes of monitoring, evaluation, and quality assurance to ensure continuous improvement in healthcare performance and patient safety. In this study, high mean scores were observed in indicators related to SOP compliance and clinical supervision. This finding suggests that effective medical governance encourages healthcare workers to consistently follow established procedures, reduce variations in clinical practices that may create risks, and strengthen organizational mechanisms for preventing medical errors.

The dominant influence of medical governance on patient safety indicates that internal healthcare management systems play a crucial role in controlling clinical processes. This finding is reasonable because medical governance is directly associated with various patient safety mechanisms, including adherence to clinical guidelines, implementation of clinical audits, supervision of healthcare workers, incident reporting systems, and continuous quality improvement practices. Hibbert et al. (2023) emphasized that effective patient safety

governance requires data-driven systems, strong organizational oversight, transparency, and learning processes derived from patient safety incidents. Therefore, stronger governance structures provide healthcare organizations with greater capacity to identify, prevent, and address potential risks before they negatively affect patients.

In addition to medical governance, legal responsibility was also found to have a significant relationship with patient safety. This finding indicates that legal accountability functions not only as a corrective mechanism after medical errors occur but also as a preventive approach that encourages professional responsibility, compliance with regulations, and protection of patient rights. The OECD highlights that accountability is an essential component of patient safety governance because reporting systems and improvement efforts cannot function effectively without clear responsibility structures, transparency, and institutional consequences. In this study, patient rights protection achieved a relatively high mean score, whereas medical documentation obtained a lower score compared with other indicators. This finding implies that healthcare workers demonstrate strong awareness regarding patient rights; however, documentation practices still require improvement because medical records serve both as legal evidence and as an important component of continuous healthcare delivery.

The results of this study are also consistent with the direction of global patient safety policies, particularly the Global Patient Safety Action Plan 2021–2030, which positions patient safety as a fundamental priority within healthcare systems. WHO emphasizes that reducing preventable harm requires integrated efforts involving healthcare policies, safe clinical practices, organizational commitment, and implementation of safety strategies at the point of care. Therefore, this study reinforces the perspective that patient safety should be understood as the outcome of interaction between clinical governance and legal accountability rather than merely an individual responsibility of healthcare providers.

Although legal responsibility showed a significant effect, its contribution was lower compared with medical governance. Several factors may explain this finding. First, legal responsibility is often perceived as a reactive mechanism because it commonly becomes prominent after complaints, disputes, or medical incidents occur. Ciptawan (2025) explained that although healthcare regulations in Indonesia provide a strong normative foundation, their effectiveness remains influenced by the quality of governance implementation, institutional supervision, and the development of legal culture among healthcare professionals. Second, the relatively lower score of medical documentation indicators suggests that administrative compliance remains an area requiring improvement, considering that documentation is a key element of legal accountability in healthcare services. Third, incident reporting practices may not yet be fully optimized due to concerns related to sanctions, professional stigma, or potential legal consequences.

The implications of these findings indicate that improving patient safety requires strengthening two interconnected approaches. The first approach focuses on enhancing medical governance through improved SOP

implementation, regular clinical audits, healthcare worker supervision, non-punitive incident reporting systems, and data utilization for continuous quality improvement. The second approach involves strengthening legal responsibility through improved patient rights protection, completeness of informed consent procedures, proper medical documentation, complaint management mechanisms, and clear institutional accountability when healthcare incidents occur. The integration of these approaches can support the development of a patient safety system that is preventive, transparent, and accountable.

This research contributes to the broader understanding that patient safety is shaped by the interaction between managerial, clinical, and legal dimensions within healthcare organizations. Beyond demonstrating the statistical relationship between medical governance, legal responsibility, and patient safety, this study highlights that medical governance represents the most influential factor in improving patient safety outcomes. From a practical perspective, these findings suggest that hospitals should position patient safety as a key indicator of organizational performance rather than merely as an administrative requirement.

Despite these contributions, this study has several limitations. First, the sample size was limited to 120 healthcare workers and hospital administrative personnel, which requires caution when generalizing the findings to broader healthcare populations. Second, the quantitative questionnaire-based design limits the ability to explore deeper experiences of healthcare workers regarding legal challenges, professional pressures, and barriers to incident reporting. Third, the research model only included medical governance and legal responsibility as explanatory variables, while patient safety may also be influenced by other factors, such as organizational culture, workload, clinical leadership, health information technology, interprofessional communication, and reporting culture.

Future studies are therefore encouraged to adopt mixed-method approaches to provide deeper insights by combining quantitative findings with qualitative perspectives from physicians, nurses, hospital managers, and patients. Further research may also incorporate additional variables, including patient safety culture, clinical leadership, digital health governance, workload, and incident reporting systems, to examine potential mediating or moderating effects between governance, legal responsibility, and patient safety. Comparative studies involving public and private hospitals are also recommended to identify differences in governance practices, accountability mechanisms, and patient safety implementation across various healthcare institutions.

CONCLUSIONS AND RECOMMENDATIONS

Based on the results of the research, it can be concluded that medical governance and legal responsibility have a positive and significant influence on patient safety in the modern health service system. Medical governance was the most dominant variable with a regression coefficient value of 0.486 and a t-value of 5.921, while legal responsibility had a regression coefficient of 0.391 with a t-value of 4.884. Simultaneously, the two variables were also shown to have a

significant effect on patient safety with an F value of 56.738 and an Adjusted R Square of 0.585, indicating that 58.5% of patient safety variations can be explained by medical governance and legal responsibility. These findings show that improving patient safety is greatly influenced by the effectiveness of medical governance, compliance with SOPs, clinical supervision, protection of patient rights, and legal accountability of healthcare institutions. Thus, patient safety does not only depend on the individual competence of health workers, but also on the quality of the governance system and legal certainty that are applied consistently in health service organizations.

Based on these findings, hospitals and health care institutions are advised to strengthen the implementation of medical governance through increased clinical supervision, service quality audits, compliance with SOPs, and the development of a culture of incident reporting without a culture of blame. In addition, strengthening legal responsibility also needs to be carried out through optimizing medical documentation, protecting patient rights, increasing compliance with health regulations, and strengthening institutional accountability mechanisms. This study still has limitations in the number of respondents and the use of a questionnaire-based quantitative approach, so the next study is recommended to use a mixed methods approach by adding other variables such as patient safety culture, clinical leadership, workload, and digital health governance in order to provide a more comprehensive understanding of the factors that affect patient safety in the modern health care system.

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