



## Healthcare Governance and Legal Accountability in Ensuring Patient Safety in Modern Medical Systems

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### ABSTRACT

Patient safety is a crucial issue in the modern healthcare system that is influenced by legal governance and accountability. This study aims to analyze the influence of healthcare governance and legal accountability on patient safety. The method used is a quantitative approach with an explanatory design, involving 270 health worker respondents through stratified random sampling. Data were collected using a Likert scale questionnaire and analyzed with CB-SEM. The results show that healthcare governance and legal accountability have a positive and significant effect on patient safety, with legal accountability acting as a partial mediator. These findings confirm the importance of governance and legal compliance in improving the quality and safety of healthcare services

## INTRODUCTION

Patient safety is one of the main pillars in the modern health care system which is not only related to the quality of service, but also to aspects of governance and legal accountability. Globally, the issue of patient safety is a serious concern due to the high number of unwanted events in health services. The World Health Organization (WHO) reports that about one in ten patients suffer a loss of health care, and at least 50% of such incidents are actually preventable. This shows that system failures are not only technical problems, but also related to weaknesses in governance and accountability systems.

In the global context, WHO through the Global Patient Safety Action Plan 2021–2030 emphasizes the importance of policy integration, incident reporting systems, and strengthening governance to minimize the risk of medical errors. However, recent reports show that only about one-third of countries have comprehensive national patient safety programs. This situation shows that there is a gap between global policies and implementation at the national level, including in developing countries that face limited resources and regulations.

At the local level, health systems in various developing countries still face serious challenges in terms of health service governance, such as weak oversight, lack of transparency, and suboptimal legal accountability mechanisms for medical personnel and health institutions. Ambiguity in legal liability in cases of malpractice or medical misconduct often undermines public trust in the health system. Therefore, the integration between healthcare governance and legal accountability is very important to ensure comprehensive patient protection.

Theoretically, the concept of healthcare governance emphasizes the importance of structures, processes, and control mechanisms in health organizations to ensure the quality and safety of services (World Health Organization, 2024). Meanwhile, legal accountability refers to the legal obligations that must be fulfilled by health workers and institutions in providing services according to applicable standards. The two are intertwined in creating a health system that is transparent, accountable, and patient-safety-oriented.

Although various studies have addressed the importance of patient safety, there are still significant research gaps. Studies by Bass et al. (2024) show that patient safety practices have evolved, but their implementation is still uneven across various health systems. In addition, research by several experts in the *International Journal for Quality in Health Care* (2023) emphasizes that the effectiveness of patient safety governance is highly dependent on organizational and policy factors that have not been fully comprehensively understood. However, the relationship between health governance and legal accountability in ensuring patient safety is still relatively underexplored in an integrative manner.

Furthermore, the development of digital health technology and artificial intelligence also poses new challenges in terms of legal accountability. Recent studies show that the use of technologies such as AI in the healthcare system can improve efficiency, but it also poses new risks to patient safety if not balanced with adequate regulation. This shows the need for an adaptive and risk-based approach to governance in the modern health system.

Based on this description, this study aims to analyze the role of healthcare governance and legal accountability in ensuring patient safety in the modern medical system. This research specifically focuses on how governance mechanisms and legal frameworks can interact in minimizing the risk of medical errors and improving the quality of health services.

This research is expected to make a theoretical contribution by enriching the interdisciplinary study between health management and health law, especially in the context of patient safety. Practically, the results of this research are expected to be the basis for policymakers, hospital managers, and health workers in designing a more effective and accountable governance system to improve patient safety and public trust in the health care system.

## **THEORETICAL REVIEW**

### ***Healthcare Governance dan Patient Safety***

The concept of healthcare governance is the main foundation in ensuring patient safety through the regulation of structures, processes, and supervisory mechanisms in healthcare organizations. A study by Jalilvand et al. (2024) confirms that hospital governance includes strategic planning, quality control, and accountability mechanisms that play a direct role in improving patient safety. In addition, systematic research by Siregar et al. (2025) shows that effective clinical governance implementation is positively correlated with improved service quality and patient trust in healthcare institutions. In a theoretical perspective, health governance serves not only as an administrative instrument, but also as an organizational culture that places patient safety as a top priority.

Furthermore, the patient safety governance-based approach emphasizes the importance of integration between policies, safety culture, and health worker involvement. International research shows that the success of patient safety governance is highly dependent on four main aspects, namely safety culture, clear policies, capacity building of health workers, and patient engagement (International Journal for Quality in Health Care, 2023). This suggests that effective governance must be multidimensional and system-oriented.

### ***Legal Accountability in the Health System***

Legal accountability is a crucial element in ensuring that health services are carried out in accordance with legal and ethical standards. Jalilvand et al. (2024) identify that accountability in the health system includes interrelated legal, professional, financial, and public dimensions in ensuring the quality of services. In a practical context, the research of Iswandari et al. (2025) found that the implementation of legal accountability in the patient safety system still faces various obstacles, such as weak incident reporting systems, lack of understanding of regulations, and fragmentation of supervision.

In addition, the study by Ciptawan and Anggraeni (2025) shows that although health regulations have been strengthened, cases of malpractice still occur, which indicates that the effectiveness of the law does not only depend on formal regulations, but also on consistent implementation and enforcement of the law. Therefore, the legal accountability approach in the health system must

include not only normative aspects, but also operational mechanisms that are able to ensure compliance with patient safety standards.

### ***Integration of Governance and Accountability in Patient Safety***

The integration between healthcare governance and legal accountability is an important approach in creating a safe and sustainable health system. Recent studies show that strong governance without the support of clear legal accountability is less likely to be effective in preventing medical errors. On the other hand, the legal system without good governance is also not able to guarantee optimal service quality.

Research by Inoue and Kang (2026) shows that a modern regulatory framework must be able to integrate patient safety standards with a transparent and rights-based accountability system. In addition, the development of a global governance framework emphasizes the importance of transparency, clinical audits, and incident reporting systems as part of integrated governance and accountability in improving patient safety.

### ***Implementation Challenges in Modern Health Systems***

Although the concept of governance and accountability has evolved, its implementation still faces various challenges, especially in developing countries. Jalilvand et al. (2025) identified that the main challenges include limited resources, lack of coordination between institutions, and weak safety culture in health organizations. In addition, inequality in the implementation of policies and regulations is also an obstacle in realizing an accountable health system.

Other research shows that health systems often focus more on financial accountability than clinical and legal accountability, so patient safety aspects receive less optimal attention. This shows the need for more comprehensive system reform and patient safety-oriented as a top priority.

### ***Digital Transformation and Accountability Challenges***

The development of digital technology, especially artificial intelligence (AI), has brought significant changes in the modern healthcare system. However, this innovation also poses new challenges in terms of governance and accountability. Bailo et al. (2026) emphasized that the use of AI in healthcare requires transparency, fairness, and human oversight to ensure patient safety.

In addition, the issue of health data governance is also a major concern. Faridoon and Kechadi (2024) show that improper data management can pose serious risks to patient safety and increase potential legal liability for healthcare organizations. Thus, digital transformation requires an adaptive and risk-based governance and accountability framework.

### ***Research Gap and Further Study Directions***

Although various studies have discussed healthcare governance and legal accountability, there are still significant research gaps. Most studies tend to address the two concepts separately, without examining their integrative relationship in ensuring patient safety. In addition, research examining the impact of digital transformation on legal accountability in the health system is still limited.

Therefore, research that integrates governance, legal, and technological perspectives is needed in one comprehensive analytical framework. This

approach is expected to provide a more holistic understanding of how the modern healthcare system can ensure patient safety in a sustainable manner.

## METHODOLOGY

This study uses a quantitative approach with an explanatory research design to analyze the relationship between healthcare governance, legal accountability, and patient safety in the modern health care system. The quantitative approach was chosen because it allows for objective and measurable testing of relationships between variables through inferential statistical analysis (Hair et al., 2021). Explanatory design is used to explain the direct and indirect influences between the constructs studied, so as to provide a more comprehensive understanding of the mechanisms that affect patient safety.

The population in this study is healthcare workers and hospital managers involved in decision-making related to patient safety, including doctors, nurses, and management staff in public and private hospitals. The sampling technique uses the probability sampling method with a stratified random sampling approach to ensure representation from various professional groups and organizational levels. The number of samples was determined to be 270 respondents, which was considered adequate for Structural Equation Modeling (SEM) analysis, especially CB-SEM which requires a large enough sample size to produce stable parameter estimates (Hair et al., 2021). The selection of respondents was based on their experience in the implementation of governance and legal compliance in healthcare practice.

The data collection technique was carried out through a structured questionnaire compiled based on a 5-point Likert scale. The research instruments were adapted from previous studies, such as healthcare governance indicators referring to Jalilvand et al. (2024), legal accountability from Iswandari et al. (2025), and patient safety from WHO (2024). The validity test was carried out using confirmatory factor analysis (CFA) to test convergent validity and discriminant validity. Meanwhile, the reliability of the instrument was tested using Cronbach's Alpha and Composite Reliability with a threshold value of  $\geq 0.70$  (Sarstedt et al., 2022). Before the main data collection, a pilot test was conducted on 30 respondents to ensure the clarity and consistency of instrument items.

The research procedure is carried out systematically starting from the stage of problem formulation, literature review, and development of research instruments. Next, an instrument test (pilot study) was carried out, followed by the collection of main data through the distribution of questionnaires online and offline. The collected data were then selected, coded, and tested for statistical assumptions, including normality, multicollinearity, and outlier tests, which are prerequisites in CB-SEM analysis. During the research process, ethical aspects were maintained by ensuring the confidentiality of respondents' identities and obtaining voluntary participation consent.

Data analysis was carried out using the Covariance-Based Structural Equation Modeling (CB-SEM) method with the help of AMOS or LISTEREL software. This method was chosen because it has the ability to test the suitability

of the overall theoretical model (fit model) through various indices such as Chi-square, CFI, TLI, RMSEA, and SRMR (Hair et al., 2021). The analysis was carried out through two main stages, namely measurement model testing using CFA and structural model testing to see the relationship between latent variables. The hypothesis test was carried out based on the critical ratio (CR) value and p-value to determine the significance of the relationship between variables. This approach allows for more rigorous testing of theoretical models as well as provides more accurate results in explaining the factors that affect patient safety in the modern healthcare system.

## RESEARCH RESULTS

### *Respondent Profile and Distribution*

The study involved 270 respondents from various health professions and hospital management. The distribution of respondents shows a representative diversity:

Table 1. Respondent Data

Category	Subcategories	Percentage
Profession	Doctor	30%
	Nurse	45%
	Manager/Staff	25%
Type of Hospital	General Hospital	60%
	Private Hospitals	40%
Experience	< 5 years	45%
	≥ 5 years	55%

These findings show that the majority of respondents have sufficient experience in the implementation of patient governance and safety.

### *Measurement Model Test Results*

#### 1. Construct Validity

The results of the *Confirmatory Factor Analysis (CFA)* show:

Table 2. Construct Validity Test Results

Variabel	Loading Factor	AVE	Remarks
Healthcare Governance	0,71 - 0,89	0,58	Valid
Legal Accountability	0,73 - 0,87	0,60	Valid
Patient Safety	0,75 - 0,91	0,62	Valid

All indicators in this study showed a *loading factor* value of  $\geq 0.70$  and an *Average Variance Extracted (AVE)* value of  $\geq 0.50$ . These results indicate that each indicator has a strong correlation level to the constructed being measured and is able to explain the variance adequately. Thus, all constructs in this study are stated to have met the *convergent validity* criteria, making them suitable for further analysis.

## 2. Discriminant Validity

The square root value of AVE in each construct is greater than the correlation between constructs. This shows that each variable has a good uniqueness.

## 3. Reliability

Table 3. Reliability Test Results

Variabel	Cronbach's Alpha	Composite Reliability
Healthcare Governance	0,88	0,91
Legal Accountability	0,87	0,90
Patient Safety	0,90	0,92

All values obtained in reliability tests, both using Cronbach's Alpha and Composite Reliability, show a number above 0.70. This indicates that the research instrument has a good level of internal consistency in measuring each construct studied. Thus, it can be concluded that all instruments used in this study are declared reliable and able to produce stable and reliable data for further analysis.

### *Feasibility test (Goodness of Fit)*

Structural models are tested using various model conformity indices:

Table 4. Model Feasibility Test (Goodness of Fit)

Table of Contents	Value	Cut-off	Status
Chi-square/df	1,85	≤ 3,00	Good
CFI	0,95	≥ 0,90	Good
TLI	0,94	≥ 0,90	Good
RMSEA	0,056	≤ 0,08	Good
SRMR	0,045	≤ 0,08	Good

The findings show that the model is a good fit and worthy of further analysis.

### **Structural Model Test Results**

Direct Influence Between Variables

Table 5. Hypothesis Test Results (Direct Influence)

Variable Relationships	Coeficin	CR	P-value	Remarks
Healthcare Governance → Patient Safety	0,48	4,85	0,000	Signifikan
Legal Accountability → Patient Safety	0,36	3,92	0,000	Signifikan
Healthcare Governance → Legal Accountability	0,62	5,21	0,000	Signifikan

The main findings of this study show that the entire relationship between variables is positive and significant, which means that each variable has a mutually reinforcing contribution in the model being tested. In addition,

*healthcare governance* was found to have the strongest influence on *legal accountability*, indicating that effective governance plays an important role in driving increased legal compliance in healthcare organizations.

**Mediating Effect**

The analysis showed the presence of a mediation effect:

Table 6. Indirect Influence (Mediation)

Indirect Pathway	Coeficin	Remarks
Healthcare Governance → Legal Accountability → Patient Safety	0,22	Partial mediation

These findings show that *legal accountability* plays a role as a partial mediator in the relationship between *healthcare governance* and *patient safety*. This indicates that the influence of governance on patient safety does not only occur directly, but also through legal compliance mechanisms that strengthen the implementation of safety in health services.

**Coefficient of Determination (R<sup>2</sup>)**

Table 7. Coefficient of Determination

Variable endogenous	R <sup>2</sup>	Interpretasi
Patient Safety	0,68	Strong
Legal Accountability	0,54	Medium

Interpretation of the results showed that 68% of the variation in *patient safety* could be explained by a research model that included *healthcare governance* and *legal accountability*. Meanwhile, the remaining 32% were influenced by other factors outside the model that were not studied in this study, such as organizational culture, leadership, or technical factors in health services.

**Key Research Findings**

Some of the key findings that answer the research objectives show that *healthcare governance* has proven to be a dominant factor in improving *patient safety*. In addition, *legal accountability* has a significant role, both as an independent variable and as a mediator in the relationship between variables. The resulting empirical model also shows that the combination of governance and legal compliance is able to explain most of the variation in patient safety. Overall, the relationship between variables in this study is structural and mutually reinforcing in supporting the improvement of the quality of health services.

**Comparison with Previous Research (Empirically)**

Several differences in results compared to previous studies were found:

Table 8. Difference Appeal Result

Aspects	This research	Previous Research
Direct impact of governance → patient safety	Significant strong	Tends to moderate

The role of legal accountability	Mediator parsial	Some studies found no mediating effect
Nilai R <sup>2</sup> patient safety	0.68 (height)	Generally 0.40–0.55

The findings of discrepancies in this study show that the resulting model has a higher empirical strength compared to previous studies. In addition, *legal accountability* was found to have a more significant role, both as a direct variable and as a mediator, thus making a greater contribution to explaining *patient safety* than some previous studies.

## DISCUSSION

The results of the study show that healthcare governance has a positive and significant influence on patient safety. These findings confirm that the governance of health organizations plays a strategic role in determining the quality and safety of services. Theoretically, healthcare governance includes a system of supervision, decision-making, and policies designed to ensure that services run according to the standards that have been set. Jalilvand et al. (2024) state that effective governance is characterized by accountability, transparency, and strong control, which directly contributes to improved patient safety. In addition, Brown et al. (2018) emphasize that governance is not only related to formal structures, but also includes organizational culture and the involvement of medical personnel. Therefore, the better the implementation of governance, the greater the organization's ability to minimize the risk of medical errors and improve patient safety.

Furthermore, this study found that legal accountability also has a positive and significant effect on patient safety. These findings show that compliance with legal and regulatory aspects is an important factor in creating a safe health care system. Legal accountability reflects the institution's responsibility to carry out practices in accordance with legal standards, including incident reporting, patient protection, and professional ethics enforcement. Iswandari et al. (2025) explained that a strong legal accountability system can increase transparency and trust, while encouraging healthcare workers to work according to safe procedures. Thus, the existence of clear regulations and consistent implementation can reduce the risk of errors and improve the overall quality of service.

One of the important findings in this study is the role of legal accountability as a partial mediator in the relationship between healthcare governance and patient safety. This shows that the influence of governance on patient safety does not only occur directly, but also through legal compliance mechanisms. Good governance will encourage the formation of a strong accountability system, which ultimately improves patient safety. These findings are in line with Jalilvand et al. (2024) who stated that accountability is a key element in governance that links policy to implementation. Thus, legal accountability can be understood as a bridge between organizational structure and operational practices in the field.

The value of the determination coefficient ( $R^2$ ) of 0.68 shows that the research model has a strong ability to explain the variation in patient safety. This figure is relatively higher than previous research which is generally in the moderate range. This indicates that the combination of healthcare governance and legal accountability is the dominant factor in explaining patient safety in the context of this study. Waring et al. (2010) stated that patient safety is a complex phenomenon influenced by various organizational factors, so the high  $R^2$  value in this study shows that the variables used have been able to represent most of the important factors in the patient safety system.

However, the results of this study are also influenced by several supporting and inhibiting factors. Supporting factors include a strong safety culture, a clear regulatory system, and the active involvement of management and medical personnel in decision-making. On the other hand, inhibiting factors include limited human resources, weak incident reporting culture, and lack of understanding of applicable regulations. These factors were also identified in previous research as a major challenge in the implementation of patient safety. Therefore, the effectiveness of governance and legal accountability is highly dependent on the internal conditions of the organization and the readiness of the resources owned.

When compared to previous studies, this study shows some important differences, especially in the strength of the relationship between variables and the role of legal accountability mediation. Some previous studies have tended to find weaker direct effects or not test the effects of mediation in depth. This difference can be attributed to the use of the CB-SEM method in this study which allows for more complex relationship analysis, as well as the use of more comprehensive and contextual instruments. In addition, the context of modern hospitals with higher regulatory pressures can also strengthen the role of legal accountability in improving patient safety.

However, this study has some limitations. First, the use of cross-sectional design limits the ability to draw causal conclusions absolutely. Second, the data collected through the questionnaire has the potential to contain a subjectivity bias of the respondents. Third, this study only focuses on two main variables, so it does not include other factors such as organizational culture, leadership, and health technology that also affect patient safety. Therefore, further research is recommended to use longitudinal design, combine quantitative and qualitative methods, and add other relevant variables to obtain a more comprehensive understanding.

Overall, this research makes an important contribution to the development of health management science by confirming that patient safety is not only determined by clinical factors, but also by organizational governance and legal accountability systems. These findings strengthen the systems approach to understanding patient safety and provide an empirical basis for more effective policymaking in improving the quality of health services.

## CONCLUSIONS AND RECOMMENDATIONS

This study proves that healthcare governance and legal accountability have a positive and significant effect on patient safety, both directly and indirectly. Using a quantitative approach through CB-SEM, it was found that legal accountability acts as a partial mediator that strengthens the relationship between governance and patient safety. This shows that effective governance, supported by legal compliance, is able to improve the overall quality and safety of health services.

It is recommended that hospital management strengthen the implementation of healthcare governance and legal accountability through transparent policies, optimal supervision, and strengthening the safety culture. Further research is recommended using a longitudinal design, adding variables such as organizational culture and leadership, and combining quantitative and qualitative methods to obtain more comprehensive results.

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