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Legal Accountability in Managing Patient Safety Systems within Public Health Facilities

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A B S T R A C T

This study analyzes the implementation of legal accountability in patient safety management within public health facilities in Semarang City, Central Java. Using a qualitative socio-legal approach, data were obtained from in-depth interviews with 12 informants—including service managers, healthcare workers, patient safety officers, and quality supervisors—and from regulatory and institutional document analysis. Thematic analysis shows that although patient safety standards have been adopted in accordance with national regulations, legal accountability remains constrained by limited human resources, inconsistent regulatory comprehension, weak incident-reporting culture, and fragmented oversight mechanisms. The study concludes that strengthening legal accountability requires aligning regulations with institutional capacity, building a stronger safety culture, and optimizing reporting systems to enhance sustainable patient safety. These findings contribute theoretically to health law studies and provide practical guidance for improving governance in regional public health facilities.

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INTRODUCTION

Patient safety has become a central issue in healthcare around the world due to the potential risks to lives, financial losses, and reputations of healthcare institutions. The World Health Organization (WHO) states that incidents related to patient safety cause significant losses both humanly and economically in the global health system (WHO, 2021). In the Indonesian context, the pressure on public services is increasing with a high burden on patients and the need for increasingly stringent quality standards, so the management of patient safety systems in public health facilities is very urgent to be strengthened. Legal accountability in this realm is not only a matter of regulatory compliance, but also fiscal, ethical, and institutional responsibilities that have direct implications for patient protection and the integrity of the health system.

Although health regulation in Indonesia has evolved, a number of studies indicate that there is a real gap between the legal framework and practice on the ground. For example, a study by Suryaningdiah et al., (2024) shows that internal hospital regulations in government hospitals are often not aligned with higher regulations, thus creating legal uncertainty and potential administrative sanctions. On the other hand, Vitrianingsih et al., (2025) highlight that although Health Law No. 17 of 2023 has established the legal responsibility of hospitals for malpractice, the implementation of accountability still faces serious obstacles in institutional capacity and oversight mechanisms. These findings confirm that while the normative framework has been strengthened, the implementation of patient safety systems has not yet reflected effective and comprehensive legal accountability.

On the other hand, the latest regulations increasingly emphasize the explicit protection of patients' rights. Health Law No. 17 of 2023 strengthens the guarantee of patient rights and service safety, including the obligation of health facilities to provide emergency services without payment in advance and to account for legal negligence (Risdawati, 2024). Research by Widjaja & Sijabat (2023) confirms that the legal protection aspects in the 2023 Health Law include the right to medical information, approval of medical measures, and dispute resolution mechanisms of all elements relevant to patient safety management. However, the extent to which these legal provisions are operationalized in risk management practices in public facilities is still minimally explored empirically.

The main scientific issues that arise are: the extent to which legal accountability is institutionalized in the patient safety system in public health facilities, and what factors hinder the implementation of these regulations operationally. Although the normative legal literature has discussed the obligations and responsibilities of healthcare facilities, empirical research that combines managerial perspectives of patient safety and legal accountability is still limited. For example, Gautama et al., (2024) examine patient obligations in the health legal system, but lack a spotlight on how healthcare institutions' accountability for managerial and operational errors affects patient safety.

Based on the identification of these issues, this study aims to analyze in depth how legal accountability is implemented in the management of patient safety systems in public health facilities in Indonesia, focusing on identifying

gaps between formal regulation and real practice, as well as institutional barriers that hinder the effectiveness of accountability. With a socio-legal approach, the research will explore stakeholder perceptions and evaluate the institutional structure and reporting mechanisms of patient safety-related incidents. This goal is expected to provide not only theoretical oversight, but also practical recommendations to improve legal accountability in the context of public patient safety.

The theoretical contribution of this research lies in the development of an integrative understanding between legal theories such as legal responsibility, health regulation and patient safety management theory, risk management, safety culture. Thus, this study expands the literature in the field of health law and hospital management by presenting a framework for legal accountability analysis that is applicable to patient safety. In practical terms, the results of this study are expected to help health policymakers, regulators, and managers of public health facilities to formulate strategies to strengthen incident reporting systems, internal audits, and regulatory compliance that are more effective and sustainable.

Contextually, this research also supports the national health system reform agenda in Indonesia, especially in the implementation of Health Law No. 17 of 2023 and its complementary regulations, by providing empirical evidence on the challenges and opportunities in realizing legal accountability in public facilities. Through a better understanding of how regulations are implemented in the field, this research aims to encourage more responsive and strategic policy adaptation in order to improve patient safety and maintain public trust in the health system.

THEORETICAL REVIEW

Global Policy Framework on Patient Safety

The global patient safety framework has undergone significant development since the World Health Organization issued the Global Patient Safety Action Plan (GPSAP) 2021–2030, which affirms patient safety as an international priority and places it within the framework of an accountability-based health system (World Health Organization, 2021). GPSAP emphasizes the integration of national regulations, facility governance, incident reporting systems, and patient empowerment as the foundation for the formation of a safety culture. In addition, WHO emphasizes that legal accountability is not enough just in the drafting of regulations, but must be translated into measurable operational standards, safety audits, and data-driven monitoring mechanisms. This framework is relevant for public health facilities in Semarang that face service capacity challenges and administrative complexity, so the implementation of patient safety requires a systematic and law-based approach.

The Dimension of Legal Accountability in the Governance of Health Facilities

Legal accountability is a crucial element of clinical governance, ensuring that clinical and administrative decision-making processes can be accounted for through clear oversight mechanisms. In an international scoping review,

Jalilvand et al. (2024) identified four main domains in hospital accountability, namely inclusive governance, commitment to accountability, planning for accountability, and autonomous governance. These four domains determine how healthcare facilities manage risk, enforce legal compliance, and carry out patient safety functions in a structured manner. This framework is relevant in the context of Indonesia's public health facilities regulated by Health Law No. 17 of 2023, where legal accountability is the foundation for the implementation of patient safety policies, including incident reporting, systemic learning, and ethical accountability.

Transparency, Reporting Culture, and Its Relationship to Accountability

Incident reporting culture is a dominant factor in the effectiveness of legal accountability, because without organizational transparency, incident data will not be recorded and legal mechanisms cannot run optimally. Empirical evidence shows that psychological safety, a condition in which health workers feel safe reporting mistakes without fear of retaliation, is strongly correlated with increased incident reporting and improved service quality (Gaur et al., 2023). An effective reporting system requires anonymous reporting, systematic follow-up, and continuous feedback for organizational learning to occur consistently. In many public health facilities in developing countries, including Indonesia, structural barriers such as bureaucracy, lack of leadership support, and a culture of blame still hinder the implementation of legal accountability in patient safety management. This shows that the existence of regulations alone is not enough without strengthening the reporting culture at the facility level.

Aspects of Malpractice, Negligence, and Legal Consequences for Patient Safety

The international literature shows that incidents of malpractice and medical negligence are directly related to the weak implementation of patient safety systems. Dahlawi et al. (2021) emphasized that ineffective clinical risk management increases the likelihood of legal claims and lowers public trust in healthcare facilities. Another study found that the threat of litigation does not always improve quality, because without a strong learning system, health workers tend to apply defensive medicine (Mello et al., 2020). In the context of public health facilities in dense cities such as Semarang, the high volume of services and the complexity of cases increase the risk of clinical incidents and legal consequences if the patient safety system does not run optimally. Therefore, legal accountability must not only be reactive to litigation, but also preventive through strengthening patient safety procedures, incident reporting, and regular audits.

METHODOLOGY

Types and Approaches to Research

This research uses a qualitative approach with a socio-legal research design, which integrates normative legal analysis with empirical exploration of accountability practices in patient safety systems. The socio-legal approach is relevant for examining the implementation of institutional health and behavioral regulations because it is able to show the gap between legal norms and

organizational practices (Meagher & Sommerlad, 2021). The design of this research focuses on an in-depth understanding of how organizational actors interpret regulations, how safety procedures are implemented, and how the dynamics of legal accountability are formed in the context of public health services.

Research Location and Population

The location of the research was determined at three public health facilities in Semarang City, namely two local government hospitals and one type A health center that has implemented a patient safety system in accordance with the 2023 Health Law. The selection of these three locations is intended to capture the variation in the implementation of legal accountability at the primary and secondary service levels. The research population includes all organizational actors who play a role in the patient safety system. This population was chosen because they are direct implementers of policies and are aware of structural barriers in the implementation of patient safety (Gleeson et al., 2022).

Sampling Techniques and Number of Informants

The study used a non-probability purposive sampling technique, in which informants were selected based on their direct involvement in the implementation of patient safety. A total of 12 informants were interviewed, each representing elements of service management, health workers, patient safety officers, and quality supervisors from the three facilities. This number is considered adequate because qualitative research emphasizes the depth of data and relevance of information, rather than large sample sizes (Boddy, 2022). The criteria for selecting informants include a minimum of two years of experience in patient safety or risk management functions, in order for the data obtained to be credible and accountable.

Data Collection Techniques

Data collection techniques include in-depth interviews, limited observations, and document analysis. Interviews were conducted in a semi-structured manner using guidelines that were compiled based on the concepts of legal accountability, reporting culture, and patient safety standards. This guideline was developed by adapting the Hospital Survey on Patient Safety Culture (HSOPS) indicators from the AHRQ and the institutional accountability framework of international health research (Elmontsri et al., 2020). Observations were made in the process of incident reporting, quality meetings, and internal audits of patient safety. Document analysis includes patient safety SOPs, incident reports, facility internal policies, and relevant regulatory documents.

Data Validity and Reliability

The validity of the data was strengthened through source triangulation techniques and method triangulation, namely comparing interviews with regulatory documents and the results of field observations. Triangulation is an important strategy in social research to ensure consistency between sources and

increase the credibility of interpretations (Creswell & Creswell, 2021). The reliability of the data was strengthened through member checking, where researchers reconfirmed provisional findings to several informants to ensure the suitability of interpretation. In addition, trail audits are structured to document the entire analysis process so that each step can be reviewed by other researchers if needed.

Research Procedure

The research began with the formulation of the problem, the literature review, and the preparation of interview instruments and observation guidelines. After obtaining research permits from the Semarang City Health Office and the leaders of the three health facilities that were the location of the research, data collection was carried out for two months through interviews, observations, and document collection. All interviews were recorded and transcribed verbatim. The data is then manually coded based on the initial theme, before being grouped into thematic categories according to the focus of the research. In the final stage, the results of the analysis are compared with regulations and legal accountability theories to formulate findings and policy recommendations.

Data Analysis Techniques

Data analysis was carried out using a thematic analysis approach, which allowed researchers to identify patterns, categories, and relationships between concepts relevant to legal accountability and patient safety implementation. This approach was chosen because it is effective for examining organizational dynamics and legal practices in the context of healthcare (Braun & Clarke, 2021). The analysis was carried out through six stages ranging from data familiarization to writing results. Data processing is supported by NVivo 14 software to improve coding consistency, simplify narrative data management, and strengthen systematic theme reconstruction.

RESEARCH RESULTS

Implementation of Patient Safety and Normative Compliance Standards

The thematic analysis shows that the three public health facilities in Semarang City have adopted patient safety standards in accordance with national regulations, including the 2023 Health Law, the Ministry of Health's guidelines, and the internal SOPs of each institution. However, field observations and document analysis revealed variations in compliance levels, especially in the aspects of incident documentation, cross-unit coordination, and consistency of risk evaluation. These findings are reinforced by interview data that shows a gap between normative regulation and operational practice.

The management informant from the first hospital stated that the implementation of patient safety standards has not been completely uniform between units. "*Safety SOPs already exist and must be implemented, but in practice some units are still inconsistent in reporting incidents*" (MA1, interview August 12, 2025). Health workers at the same hospital confirmed the same, explaining that

"*Sometimes we focus on high service loads, so safety documentation is delayed*" (TA1, August 14, 2025 interview).

In the second hospital, coordination obstacles are also seen in quality control. The patient safety officer stated "*The reporting format is available, but the understanding of each unit is still different so we often need to provide additional explanations*" (KA2, interview August 18, 2025). The quality inspector added that "*Safety audits are routine, but the follow-up is not always fast because they have to wait for managerial approval*" (PA2, August 20, 2025 interview).

Meanwhile, Type A Health Centers show a relatively more controlled level of compliance, but still face limited resources. The management informant said that "*We follow national standards, it's just that limited manpower makes several safety indicators must be prioritized*" (MA3, interview September 5, 2025). The consistency of findings from interviews, quality meeting observations, and analysis of safety SOP documents shows that regulations have been adopted, but their implementation is influenced by the organizational capacity of each facility.

Legal Accountability and Variations in Regulatory Understanding

The results of the study show that legal accountability in patient safety management still faces challenges at the level of regulatory understanding by organizational actors. Although the three facilities have received socialization regarding accountability obligations under the 2023 Health Law, the interpretation between units and professions is not uniform.

At the first hospital, the patient safety officer explained that "*Some staff understand accountability as limited to reporting, even though it is also related to the obligation of evaluation and transparency to management*" (KA1, interview August 16, 2025). A managerial informant from the same facility mentioned that "*Legal arrangements are often considered abstract by technical officers, so they need to be translated into practical SOPs*" (MA1, interview August 12, 2025).

In the second hospital, health workers also imply a lack of a thorough understanding of legal aspects. "*We know that there is an obligation to report, but not everyone understands the legal consequences or institutional responses.*" (TA2, interview August 21, 2025). The quality supervisor reinforced the findings with a statement "*Sometimes there are differences in interpretation of non-clinical incident reporting procedures, which affects the consistency of the data*" (PA2, interview August 23, 2025).

At the Type A Health Center, management explained that "*Staff's understanding of legal responsibilities is improving, but guidance is still needed, especially for incidents that do not cause injury*" (MA3, interview September 6, 2025). Meanwhile, the health workers added "*Regulations change frequently and are difficult to follow without regular training*" (TA3, interview September 8, 2025). These findings confirm that legal accountability requires not only regulation, but also uniform operational interpretation through training, detailed SOPs, and ongoing managerial supervision.

Incident Reporting Culture and Structural Barriers

Thematic analysis revealed that the culture of reporting patient safety incidents in the three health facilities is still developing and not fully established. Although reporting systems are in place, the data show psychological resistance, sanctions concerns, and perceptions that reporting adds to the administrative burden.

At the first hospital, health workers said that "*Actually, we want to report, but sometimes we are afraid of being blamed if the incident is considered an individual fault*" (TA1, August 14, 2025 interview). Patient safety officer added "*We continue to socialize that reporting is not to find fault, but the culture is not evenly distributed*" (KA1, interview August 16, 2025).

At the second hospital, the quality supervisor revealed that "*Reporting of minor incidents often does not enter the system because it is considered non-essential by some staff*" (PA2, interview August 22, 2025). The facility management confirms that "*High workload affects reporting discipline, especially in inpatient units*" (MA2, August 19, 2025 interview).

In Type A Health Centers, the challenges are different: "*We want to increase the frequency of reports, but staff still feel that reporting takes a long time because they have to write manually*" (KA3, interview September 10, 2025). Health workers added that "*Sometimes we don't report near-miss because we feel it's a normal occurrence*" (TA3, interview September 8, 2025). The researcher's observations on the quality meeting process and internal audit mechanism support the findings of the interview, namely that the reporting system exists, but the reporting culture has not been fully internalized. This has an impact on the limited data in assessing safety risks comprehensively.

Limited Resources and Monitoring Mechanisms

Limited human resources, training capacity, and supervisory mechanisms are the main factors that hinder the effectiveness of legal accountability in the patient safety system.

At the first hospital, the quality supervisor said that "*The number of internal auditors is limited, so follow-up on findings is sometimes delayed*" (PA1, interview August 17, 2025). Management added that "*Patient safety training cannot be done too often due to budget constraints*" (MA1, interview August 12, 2025).

At the second hospital, health workers revealed that "*We need more technical training to keep up with the ever-updated standards*" (TA2, interview August 21, 2025). Patient safety officers reinforce this statement: "*Routine supervision exists, but we still lack staff for daily monitoring in each unit*" (KA2, interview August 18, 2025).

In Type A Health Centers, the challenges are structural. Management explained that "*The limited number of personnel makes supervision must be carried out on a rotating basis*" (MA3, interview September 6, 2025). The quality inspector added that "*with limited human resources, some safety indicators must be simplified*" (PA3, interview September 12, 2025). Cross-site findings indicate that while regulations emphasize legal accountability, their effectiveness is highly dependent on the facility's ability to provide adequate resources as well as structured oversight mechanisms.

DISCUSSION

The results revealed that although patient safety standards have been adopted in all three public facilities, their operational practices are inconsistent across service units. These findings reflect a "regulatory–practice gap" between policy and implementation that has also been reported in health system policy research (Oikonomou et al., 2022). Limitations in organizational and infrastructure capacity, such as cross-unit coordination and risk management, reinforce the conclusion that regulations without strong operational support are not enough to guarantee patient safety. Therefore, translating regulations into detailed operational SOPs that can be used by all health workers is crucial, so that regulations can be applied consistently. From the point of view of policy implementation theory, this shows that regulations must be followed by capabilities so that their effectiveness is realized. Consequently, facility leaders need to conduct compliance evaluations more systematically, not only relying on annual audits, but also regular audits and ongoing follow-ups.

The study found that the understanding of legal regulations varies between management, health workers, and quality supervisors, which hinders the effectiveness of legal accountability. This is consistent with systematic studies that show that leadership styles and organizational structures greatly influence how staff understand and carry out reporting obligations (Kankanamge et al., 2023). Non-uniform regulatory interpretations often arise due to a lack of case-based operational guidance, which emphasizes the need for experiential regulatory training (Chuo & Lee, 2023). Therefore, facilitating regular regulatory training with simulation methods or case studies can strengthen legal understanding and improve the consistency of reporting practices. This study confirms that strengthening institutional legal capabilities as well as developing staff regulatory literacy is an important contribution in the socio-legal literature of the health sector.

A weak incident reporting culture, such as fear of sanctions and the perception of reporting as an additional burden, presents significant psychosocial challenges. These findings are in line with previous research showing that supportive leadership and coaching strongly influence the intention of healthcare workers to report mistakes (Chegini et al., 2020). In addition, reporting barriers can also be understood through the lens of just culture, where organizations need to balance individual and organizational responsibilities so that reporting is not punitive. This research shows that building a reporting culture is not enough just through regulation, but must be supported by a leadership model that encourages organizational learning rather than revenge and constant communication. The contribution of this research is the mapping of psychological and structural barriers in the context of public facilities in Indonesia, which can be the basis for non-punitive interventions to strengthen legal accountability.

The limitations of internal auditors and patient safety officers are a major obstacle to the implementation of effective legal accountability. Consistent with the research of Chaghari et al., (2021), the limited number of trained personnel has an impact on the frequency of audits and follow-up of safety incident

findings. In the context of high workloads, healthcare workers tend to prioritize clinical services over incident documentation, which reduces the completeness of reporting data. This lowers the organization's ability to conduct data-driven learning and continuous improvement. Therefore, the recommendations of this study are to increase patient safety special personnel and provide ongoing training so that surveillance becomes more proactive, not reactive.

The thematic analysis revealed that the integration of information technology in incident reporting is still a challenge, especially in Type A Health Centers that still use manual reporting. These findings are in line with the research of Zengul et al., (2022), which showed that digital systems make incident reporting easier and improve data quality. The lack of interoperability of internal systems with national applications slows down data analysis and managerial responses to incidents. Consequently, without digitalization, healthcare facilities will have difficulty collecting accurate, real-time, and actionable data for quality improvement. This research contributes by affirming the importance of IT investment as part of legal accountability and patient safety strategies.

The findings show that facility leadership is critical to the success of legal accountability implementation. Proactive leadership in supporting reporting, auditing, and training shows better results in patient safety consistency. This is consistent with systematic studies that state that transformational leadership styles are positively correlated with safety culture (Kankanamge et al., 2023). Additionally, leaders who show concern, provide feedback, and encourage open communication can create an organizational climate where staff feel safe to report mistakes (Chegini et al., 2020). The contribution of this research is to affirm that legal accountability does not only depend on structures and regulations, but also on the quality of leadership and organizational culture.

The findings of the study confirm the gap between patient safety norms in regulation and real practice in public health facilities. This gap reflects policy challenges often found in implementation in developing countries, as described by Koduah et al., (2020). Factors such as lack of training, high workloads, immature reporting mechanisms, and passive leadership contribute to policy refractory. The consequence of this gap is an increased risk of repeated safety incidents even though regulations are in place. This research contributes to the theory of policy implementation in public health by providing empirical evidence that the integration of strategies (training, technology, culture, and leadership) is indispensable to close the gap between norms and practices.

While this research provides important insights, there are limitations that need to be acknowledged. First, only three public health facilities were studied, so the generalization of the findings to other facilities is still limited. Second, interviews are conducted over a specific period, which can be affected by season-specific operational burdens, and may not capture behavioral variations throughout the year. Third, document analysis is limited to documents submitted by the facility, so there may be other internal policies that are not monitored. For further research, it is recommended to conduct a multi-flashlight study with a larger number of facilities and longitudinal analysis to examine the development of reporting culture over time. In addition, experimental

interventions such as transformational leadership training, digital reporting systems, or just culture approaches can be researched to test their impact on legal accountability and patient safety.

CONCLUSION AND RECOMMENDATION

This study concludes that strengthening legal accountability in patient safety requires solid harmonization between national regulations and institutional capacity at the health facility level. The results show that the gap between policies and operational practices still occurs due to limited human resources, uneven understanding of regulations, weak reporting culture, and lack of technology integration. These findings confirm that regulations will not be effective without the support of strong implementation mechanisms, including the development of more applicable SOPs, continuous audits, and the development of legal competence and patient safety for all health workers. In addition, transformational leadership has been shown to play an important role in creating a safe, supportive organizational climate that encourages collective learning, thereby strengthening the successful implementation of legal accountability in public facilities.

Theoretically, this research makes an important contribution to the development of health law studies through empirical mapping of the dynamics of interaction between regulations, organizational culture, and institutional structures in the context of regional health facilities. The findings of the study indicate that improving patient safety governance cannot be done partially, but requires an integrative approach that combines institutional capacity building, strengthening technology-based reporting systems, and the formation of a just culture within organizations. Practically, the implications of this study emphasize the need for local governments and facility leaders to develop more comprehensive strategies to strengthen legal accountability, including the provision of adequate resources, the digitization of reporting systems, and case-based regulatory training. This effort is expected to be able to ensure more consistent, sustainable, and patient safety in accordance with applicable health law standards.

FURTHER STUDY

Future studies are encouraged to explore more deeply the structural, cultural, and technological determinants that influence the effectiveness of legal accountability in patient safety. Further research could examine how different leadership styles, organizational justice frameworks, and digital reporting architectures interact to support consistent regulatory implementation. Comparative analyses across various types of health facilities—such as hospitals, community health centers, and private clinics—may also provide insights into contextual differences in regulatory compliance and patient safety culture. In addition, longitudinal studies are needed to assess how improvements in institutional capacity, technology adoption, and legal competence training shape long-term changes in safety behavior and reporting practices. Expanding these research directions will help strengthen the theoretical development of health

law governance and support the design of more integrated, sustainable, and legally accountable patient safety systems.

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