

Juridical Analysis of Patient Safety Policies in Hospitals in Indonesia

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Abstract

Patient safety is a core element of the healthcare system, aimed at preventing adverse events and improving service quality. In Indonesia, it is governed by Law Number 17 of 2023 on Health and Minister of Health Regulation Number 11 of 2017 on Patient Safety, yet implementation remains uneven. Many hospitals show low compliance, government monitoring is limited, and significant gaps persist between urban and rural facilities. This study examines the legal framework and effectiveness of patient safety policies using a normative juridical method with statutory and conceptual approaches. Primary legal sources, including laws and regulations, along with secondary academic references, were analyzed qualitatively through a deductive process. The results indicate that although the regulatory framework provides comprehensive guidance, its execution in practice is still inadequate. Persistent obstacles include insufficient transparency in incident reporting, weak legal oversight, limited training for healthcare workers, and restricted access for patients to essential medical information. The study concludes that improving patient safety requires stronger hospital accountability, more transparent reporting mechanisms, and enhanced protection of patient rights within the legal system. Strengthening these aspects is expected to support safer and higher-quality healthcare services while providing greater legal certainty for patients in Indonesia.

Keywords: Health Policy; Health Regulation; Hospital; Legal Responsibility; Patient Safety

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1. Introduction

Patient safety is a fundamental element in providing quality and sustainable healthcare services. Patient safety in healthcare refers to efforts to ensure that patients do not experience unexpected injuries while receiving medical treatment. According to Delpita and Kosasih, patient safety involves the identification and management of risks, as well as the reporting and analysis of incidents to prevent the occurrence of injuries.¹ Patient safety is a top priority in healthcare services, particularly in hospitals, as it plays a crucial role in measuring and evaluating the quality of care.² Patient safety also defined as being

¹ Y. D. Primasa and K. Kosasih, "Pengaruh Penerapan Standar Akreditasi Terhadap Mutu dan Keselamatan Pasien," *Action Research Literate* 8, no. 10 (2024): 2898.

² Liza Salawati. "Penerapan keselamatan pasien rumah sakit." *Averrous: Jurnal Kedokteran Dan Kesehatan Malikussaleh* 6, no. 1 (2020): 99.

free from preventable harm, encompassing all aspects of potential physical, social, or psychological injury.³ Furthermore, patient safety serves as an indicator of the quality of nursing services, and nurses' knowledge of patient safety significantly influences the quality of care provided.⁴

According to the World Health Organization (WHO), patient safety is a fundamental right that must be respected in all healthcare services. WHO expresses concern that one in ten patients experiences preventable incidents in healthcare facilities, emphasizing the need for a robust system to minimize such risks.⁵ Patient safety not only affects the quality of care but also contributes to patient satisfaction, which serves as a key indicator of hospital service performance.⁶ In Indonesia, patient safety has been recognized as a basic right that must be protected within the healthcare system, as mandated by Law of the Republic of Indonesia Number 17 of 2023 on Health and Regulation of the Minister of Health (*Peraturan Menteri Kesehatan*) of the Republic of Indonesia Number 11 of 2017 on Patient Safety. The policy of enforcing patient safety has become an integral part of hospital accreditation, which is increasingly critical in ensuring high service standards that meet the needs of society.⁷

The implementation of patient safety policies in Indonesian hospitals currently faces several challenges. Among these, the lack of knowledge and positive attitudes among healthcare workers toward patient safety represents a significant obstacle. Research has shown a strong correlation between nurses' attitudes and the implementation of patient safety policies, which can directly influence the quality of healthcare services.⁸ Secondly, weak organizational

³ Kinanthi Cahyaning Utami, Yanuar Jak, dan Dicky Yulius Pangkey, "Pengaruh Budaya Keselamatan Pasien Terhadap Sikap Melaporkan Insiden Keselamatan Pasien di Rumah Sakit Mandaya Karawang," *Jurnal Manajemen dan Administrasi Rumah Sakit Indonesia (MARSII)* 7, no. 2 (2023): 126.

⁴ Yoke Arfebi, Fatima Nuraini Sasmita, Devi Listiana, and Dian Dwiana, "Hubungan Pengetahuan Perawat dengan Keselamatan Pasien pada Mutu Pelayanan Keperawatan," *Jurnal Ilmu Kedokteran dan Kesehatan* 9, no. 2 (2022): 831.

⁵ Kevin Jodjana, Simon Sia Niha, and Henny A. Manafe, "Penerapan Sasaran Keselamatan Pasien di Rumah Sakit: Literatur Review," *Jurnal Ilmiah Universitas Batanghari Jambi* 23, no. 2 (2023): 2027.

⁶ Andi Nurul Azizah, Andi Surahman Batara, and Nurul Ulfah Mutthalib, "Hubungan *Patient Safety* dengan Kepuasan Pasien Rawat Inap di Rumah Sakit Tenriawaru Kabupaten Bone," *Window of Public Health Journal* 4, no. 4 (2023): 605

⁷ Mira Asmirajanti et al., "Penerapan Standar Akreditasi Terhadap Mutu dan Keselamatan Pasien Sebelum dan Selama Pandemi Covid-19," *The Journal of Hospital Accreditation* 3, no. 2 (2021): 65. See too, Esraida Simanjuntak dan Mustamil Alwi Dasopang, "Tinjauan Pelaksanaan Review Berkas Rekam Medis Sesuai Standar Manajemen Informasi Dan Rekam Medik (MIRM 13.4) Di Rumah Sakit Imelda Pekerja Indonesia Tahun 2020," *Jurnal Ilmiah Perekam dan Informasi Kesehatan Imelda (JIPIKI)* 6, no. 1 (2021): 8.

⁸ Annisa Rahmi Galleryzki et al., "Hubungan Sikap Keselamatan dengan Implementasi Sasaran Keselamatan Pasien oleh Perawat di Rumah Sakit," *Jurnal Kepemimpinan dan Manajemen Keperawatan* 4, no. 1 (2021): 12. See too, Ernawaty Siagian, "Penerapan Budaya Keselamatan Pasien oleh Tenaga Kesehatan," *Klabat Journal of Nursing* 2, no. 2 (2020): 45.

culture and insufficient encouragement to report safety incidents create uncertainty in policy implementation. Without adequate management support to respond wisely to incident reports, healthcare personnel tend to be reluctant to report such events.⁹ Furthermore, limited resources and inadequate infrastructure exacerbate implementation difficulties. Hospitals often lack proper facilities, leading to suboptimal compliance with safety standard.¹⁰ Lastly, the continually evolving accreditation requirements demand rapid and efficient adaptation from hospitals to maintain compliance, posing an additional challenge amid the ongoing pressure to enhance the quality of care in the post-pandemic era.¹¹

As healthcare institutions, hospitals hold the responsibility to ensure the safety and security of patients throughout the course of medical treatment. The Regulation of the Minister of Health of the Republic of Indonesia Number 11 of 2017 on Patient Safety establishes the patient safety standards that must be implemented by all healthcare facilities, including strategies for preventing adverse events (*Kejadian Tidak Diinginkan* or KTD) and systems for reporting patient safety incidents. However, data from the Ministry of Health indicate that patient safety incidents, such as medical errors, nosocomial infections, and failures in patient management continue to occur frequently in hospitals across Indonesia. Contributing factors to these issues include low compliance with Standard Operating Procedures (SOPs), a shortage of competent medical personnel, and weak supervision and evaluation of the implementation of patient safety policies.

From a legal perspective, regulations concerning patient safety in hospitals have not yet established an effective enforcement mechanism. The Law of the Republic of Indonesia Number 17 of 2023 on Health stipulates the obligation of hospitals to provide legal protection for patients; however, in practice, many cases still

⁹ Dian Widya Christiany Jacobus, Yuliani Setyaningsih, and Septo P. Arso, “Analisis Pengaruh Budaya Keselamatan Pasien, Budaya Organisasi, dan Lingkungan yang Mendukung terhadap Motivasi Melaporkan Insiden Keselamatan Pasien—Systematic Review,” *An-Nadaa: Jurnal Kesehatan Masyarakat (e-Journal)* 9, no. 2 (2022): 158. See too, Sri Wahyuningsih Nugraheni, Novita Yuliani, and Alin Dhyana Veliana, “Studi Literatur: Budaya Keselamatan Pasien dan Insiden Keselamatan Pasien di Rumah Sakit,” in *Prosiding Seminar Informasi Kesehatan Nasional*, 2021, 291.

¹⁰ Bayu Kisworo, Rizki Fitriyanti, Aria Aulia Nastiti, and Dimas Hadi Prayoga, “Peningkatan Pelaksanaan Sasaran Keselamatan Pasien oleh Pengembangan Budaya Keselamatan Pasien berbasis Knowledge Management,” *Jurnal Manajemen Kesehatan Yayasan RS. Dr. Soetomo* 10, no. 1 (2024): 105. See too, Eleonora Maryeta Toyo, Karol Giovanni Battista Leki, Ferika Indarsari, and Suwito Woro, “Evaluasi Sistem Pelaporan Insiden Keselamatan Pasien dengan Metode HMN di Rumah Sakit,” *Majalah Farmasetika* 8, no. 1 (2022): 58.

¹¹ Mira Asmirajanti et al., “Penerapan Standar Akreditasi Terhadap Mutu dan Keselamatan Pasien Sebelum dan Selama Pandemi Covid-19,” *The Journal of Hospital Accreditation* 3, no. 2 (2021): 66.

reveal that patients or their families face difficulties in obtaining justice due to medical negligence or systemic failures in ensuring patient safety. Moreover, legal rulings on medical disputes in Indonesia continue to reflect disparities in the protection of patients' legal rights. Patients often encounter challenges in proving allegations of medical negligence because of limited access to medical records and the lack of an optimal legal advocacy mechanism.

In the context of health policy, a more comprehensive approach is needed to ensure that patient safety policies in hospitals are not merely regulatory frameworks on paper but can be effectively implemented in practice. Evaluating the implementation of patient safety policies is essential to identify gaps within existing regulations and to develop solutions that strengthen the legal protection system for patients in Indonesia. As of the present, the total number of hospitals in Indonesia, both public and private, amounts to 3,217. Based on this data, the researcher finds it important to conduct a more in-depth analysis. The current classification of hospitals shows that 78 hospitals are categorized as Class A, 447 as Class B, 1,737 as Class C, and 949 as Class D.¹²

The main legal issue driving this research stems from the persistent misalignment between the legal framework governing patient safety and its implementation in hospitals, resulting in uncertainty regarding the legal protection afforded to patients. In light of this problem, the study focuses on several research questions. First, how the legal framework for patient safety in Indonesia is structured and to what extent hospital patient safety policies comply with the provisions of Law Number 17 of 2023 on Health and its implementing regulations. Second, what forms of legal responsibility hospitals and healthcare professionals bear in ensuring patient safety as part of their obligation to provide safe healthcare services. Third, how patient safety policies are implemented in hospitals, including the legal and regulatory barriers encountered, as well as the juridical solutions needed to strengthen legal protection for patients.

The significance of this research lies in its contribution to both the theoretical and practical development of law concerning patient safety in Indonesia. This study provides a comprehensive juridical analysis of patient safety policies, linking legal frameworks, such as Law Number 17 of 2023 on Health and Permenkes Number 11 of 2017 to the practical realities of hospital operations,

¹² Raka Maheswara. "Jumlah Rumah Sakit di Indonesia Berdasarkan Kelas." *Dataloka.id*. November 29, 2024. Retrieved in August 23, 2025 from. <https://dataloka.id/humaniora/1903/jumlah-rumah-sakit-di-indonesia-berdasarkan-kelas-november-202>

highlighting gaps between regulatory standards and actual implementation. This study offers actionable insights for strengthening legal enforcement, improving hospital compliance, enhancing accountability mechanisms, and promoting patient rights, thereby supporting the creation of a more robust, transparent, and effective patient safety system. By addressing the challenges faced by hospitals, healthcare personnel, and patients, the research not only advances academic understanding of health law but also informs policymakers, hospital administrators, and legal practitioners on how to better protect patients and ensure that patient safety regulations translate into tangible improvements in healthcare services. The objective of this research is to examine the legal framework of patient safety in Indonesian hospitals, evaluate compliance with Law Number 17 of 2023 and related regulations, analyze the legal responsibilities of hospitals and healthcare professionals, and identify obstacles in policy implementation to propose effective juridical solutions.

2. Research Method

This research utilizes a normative legal methodology, incorporating both statutory and conceptual approaches. The normative legal method is used because the core issues in this study concern the adequacy, coherence, and enforceability of patient-safety regulations, which require systematic analysis of statutory provisions and underlying legal concepts. This approach is directly relevant for evaluating whether existing laws align with hospital policies and for assessing the legal responsibilities and protections embedded within the regulatory framework. The statutory approach focuses on examining regulations pertaining to patient safety, including the Republic of Indonesia Law Number 17 of 2023 on Health, which is further detailed in the Minister of Health Regulation (*Peraturan Menteri Kesehatan*) Number 11 of 2017 concerning Patient Safety. Meanwhile, the conceptual approach explores the foundational legal principles behind patient safety policies, such as the rights and duties of patients and the legal obligations of hospitals. Conceptually, this study argues that patient safety policies, as the independent variable, affect legal protection for patients, the dependent variable, mediated by their implementation in hospitals. The research data comprise both primary and secondary legal sources. Primary materials consist of laws and regulations relevant to patient safety, while secondary sources include academic journals and policy reports. Data were collected through library research and analyzed qualitatively using juridical and deductive reasoning, enabling the interpretation and assessment of the effectiveness of patient safety policy implementation within hospitals.

In this study, several theoretical frameworks guide the analysis of patient safety and its legal implications in hospitals. At the grand theory level, John Rawls' Justice Theory provides the foundational perspective, framing patient safety as an aspect of distributive justice within healthcare.¹³ This theory emphasizes that access to safe and quality medical services is a fundamental right and a core component of legal protection for individuals. At the middle theory level, Rechtsstaat Theory, as developed by Immanuel Kant and Hans Kelsen, highlights the supremacy of law, the protection of human rights, and the limitation of power as pillars of a constitutional state.¹⁴ Within this framework, the state, through hospitals as public service institutions, holds the obligation to protect patients' rights, including their right to safety in medical care, implying that patient safety policies must have a clear and enforceable legal basis.

At the small theory level, Satjipto Rahardjo's Legal Protection Theory views law as a mechanism for safeguarding society, particularly vulnerable groups such as patients, and is applied to assess how effectively patient safety policies provide legal protection in cases of negligence, errors, or medical incidents.¹⁵ Finally, at the applied theory level, the Legal Responsibility Theory derived from the Law of the Republic of Indonesia Number 17 of 2023 on Health elucidates the forms of legal accountability: civil, criminal, and administrative, within the hospital-patient relationship, offering a framework to evaluate responsibility when patient safety standards are not met.¹⁶ Together, these theories provide a comprehensive lens to examine the legal dimensions of patient safety policy implementation in Indonesian hospitals.

3. Research Results and Discussion

3.1 The Legal Framework of Patient Safety in Indonesia

Patient safety is a core component of healthcare, focused on minimizing adverse events and enhancing service quality. Within hospitals, ensuring patient safety has emerged as a worldwide priority, with healthcare institutions expected to deliver care that is safe, effective, and adheres to established standards.¹⁷ Within the legal framework of healthcare, patient

¹³ John Rawls, *A Theory of Justice* (Cambridge, MA: Harvard University Press, 1971), 56.

¹⁴ Hans Kelsen, *Teori Hukum Murni (Reine Rechtslehre)* (Bandung: Nusamedia, 2005), 76.

¹⁵ Satjipto Rahardjo, "Hukum Progresif: Hukum yang Membebaskan," *Jurnal Hukum Progresif* 1, no. 1 (2005): 4.

¹⁶ Undang-Undang Republik Indonesia Nomor 17 Tahun 2023 Tentang Kesehatan

¹⁷ Usman Sasyari, "Gaya Kepemimpinan yang Efektif dalam Meningkatkan Keselamatan Pasien," *Healthcare Nursing Journal* 3, no. 1 (2021): 60. See too, Sri Wahyuningsih Nugraheni, Novita Yuliani, and Alin Dhyhan Veliana, "Studi Literatur: Budaya Keselamatan Pasien dan Insiden Keselamatan Pasien di Rumah Sakit," in *Prosiding Seminar Informasi Kesehatan Nasional*, 2021, 293.

safety represents a shared responsibility encompassing the roles of the government, hospitals, healthcare professionals, and patients themselves.¹⁸ The government plays a crucial role by establishing regulations and policies to ensure patient safety in healthcare facilities. Hospitals, on their part, are expected to implement accreditation standards that enhance service quality and patient safety.¹⁹ Moreover, healthcare professionals, particularly nurses, play a vital role in carrying out safety procedures and providing education to patients.²⁰ On the other hand, patients also have an important role by actively participating in their care and reporting any adverse events to healthcare workers.²¹ Thus, the success of patient safety depends on the collaboration among all involved parties.²² Therefore, regulations governing patient safety possess a multidisciplinary dimension, encompassing aspects of law, health policy, medical ethics, and human rights.

In Indonesia, patient safety is regulated through various legal instruments, including Law of the Republic of Indonesia Number 17 of 2023 on Health and Regulation of the Minister of Health of the Republic of Indonesia Number 11 of 2017 on Patient Safety. The Law Number 17 of 2023 on Health outlines the fundamental principles underpinning the organization of the national health system, including patient safety. Several provisions in this law emphasize both the patient's right to safety and the obligations of the government and healthcare facilities in maintaining safety standards. Article 4 paragraph (1) establishes that every individual has the right to receive healthcare services that are safe, high-quality, and affordable to achieve optimal health. Additionally, Article 4 paragraph (1) letter (k) affirms that patients are entitled to protection from health risks, including those arising from unsafe

¹⁸ Artha Ferninda Oktavian and Budhi Setianto, "Analisis Faktor yang Memengaruhi Pelaksanaan Keselamatan Pasien," *Jurnal Sosial dan Sains* 2, no. 8 (2022): 835. See too, Made Indra Wijaya et al., "Budaya Keselamatan Pasien terhadap Kompetensi Keselamatan Pasien pada Perawat di Rumah Sakit Umum Daerah Payangan," *Jurnal Ilmu Kesehatan Masyarakat* 13, no. 1 (2024): 10.

¹⁹ Mira Asmirajanti et al., "Penerapan Standar Akreditasi Terhadap Mutu dan Keselamatan Pasien Sebelum dan Selama Pandemi Covid-19," *The Journal of Hospital Accreditation* 3, no. 2 (2021): 68. See too, Y. D. Primasa and K. Kosasih, "Pengaruh Penerapan Standar Akreditasi Terhadap Mutu dan Keselamatan Pasien," *Action Research Literate* 8, no. 10 (2024): 2899

²⁰ Indrayadi Indrayadi, Nor Afni Oktavia, and Meti Agustini, "Perawat dan Keselamatan Pasien: Studi Tinjauan Literatur," *Jurnal Kepemimpinan dan Manajemen Keperawatan* 5, no. 1 (2022): 65.

²¹ Andi Nurul Azizah, Andi Surahman Batara, and Nurul Ulfah Mutthalib, "Hubungan Patient Safety dengan Kepuasan Pasien Rawat Inap di Rumah Sakit Tenriawaru Kabupaten Bone," *Window of Public Health Journal* 4, no. 4 (2023): 606. See too, Ananda Ainun Djariah and Ella Andyanie, "Hubungan Pengetahuan, Sikap, dan Motivasi Kerja Perawat dengan Pelaksanaan Keselamatan Pasien di Ruang Rawat Inap RSUD Kota Makassar Tahun 2020," *Window of Public Health Journal* (2020): 320.

²² Hilda Hijrianti, Ida Faridah, and A. Y. G. Wibisno, "Pengaruh Tingkat Pengetahuan, Sikap dan Penerapan Perawat tentang Keselamatan Pasien (Patient Safety) dengan Kejadian Risiko Jatuh," *Jurnal Ilmiah Kedokteran dan Kesehatan* 2, no. 1 (2023): 48.

healthcare practices. Article 23 paragraph (1) further reinforces that health services must be implemented responsibly, safely, with quality, equity, non-discrimination, and fairness.

The law also outlines the government's responsibility in ensuring patient safety. Article 6 paragraph (1) stipulates that both the central and regional governments are tasked with regulating, organizing, fostering, and supervising health efforts to ensure they are safe and of high quality. Article 7 paragraph (1) further emphasizes that the government must enhance and develop health services to improve access and quality, including patient safety aspects. Additionally, Article 9 mandates the government to maintain a healthy environment for the public, which encompasses monitoring hospital service quality to ensure ongoing compliance with patient safety standards.

The law also defines the responsibilities of hospitals and medical personnel in ensuring patient safety. Article 10 paragraph (1) stipulates that hospitals, as healthcare service providers, are obligated to deliver services that guarantee the safety of patients. Article 12 emphasizes the government's role in regulating, developing, supervising, and improving the quality and competence of medical and health personnel to ensure adherence to patient safety standards. Furthermore, Article 19 paragraph (1) assigns both the central and regional governments the responsibility to organize individual and community health efforts, which include establishing and maintaining patient safety systems within hospitals. Based on these provisions, patient safety is not solely the obligation of medical personnel or hospitals but also a responsibility of the government to ensure the availability of a safe and high-quality healthcare system for the public.

Beyond its regulation under the Law of the Republic of Indonesia Number 17 of 2023, patient safety is detailed in a more technical and operational framework through the Regulation of the Minister of Health (Permenkes) Number 11 of 2017 on Patient Safety. This regulation sets forth national standards for patient safety that are required to be applied in all healthcare facilities, with particular emphasis on hospitals. The Regulation of the Minister of Health (Permenkes) of the Republic of Indonesia Number 11 of 2017 concerning Patient Safety outlines key provisions aimed at ensuring safer healthcare delivery in hospitals. It defines patient safety as a systematic approach within hospital services that seeks to minimize risks and prevent avoidable injuries, emphasizing principles such as a systems approach, a

culture of safety, incident reporting, and continuous improvement. The regulation establishes six primary patient safety goals, based on World Health Organization (WHO) and Joint Commission International (JCI) guidelines: correctly identifying patients to ensure services are provided to the right individual, improving effective communication to prevent errors, enhancing medication safety, ensuring correct procedures and sites during medical or surgical actions, reducing healthcare-associated infections through hygiene and preventive measures, and minimizing patient falls by maintaining a safe environment, particularly for the elderly and those with mobility challenges.

To support these objectives, hospitals are mandated to implement a non-punitive patient safety incident reporting system (*Insiden Keselamatan Pasien/IKP*), allowing medical personnel to report incidents without fear of sanction, and to utilize these reports to evaluate and prevent future errors. Additionally, each hospital must establish a Hospital Patient Safety Team (*Tim Keselamatan Pasien Rumah Sakit/TKPRS*) responsible for incident analysis, strategy development, and the socialization and training of patient safety practices among healthcare staff. Despite these regulations, violations of patient safety standards continue to occur, sometimes resulting in medical malpractice or adverse events (*Kejadian Tidak Diinginkan/KTD*). Law Number 17 of 2023 provides a legal foundation for accountability, stipulating in Article 4 paragraph (1) letter (j) that patients have the right to access information regarding their health data and medical actions received, enabling them to file claims if information is withheld. Article 12 further underscores the government's responsibility to protect patients, indicating that negligence in implementing patient safety measures may entail legal consequences for both hospitals and the medical personnel involved.

3.2 Legal Responsibility of Hospitals in Ensuring Patient Safety

Hospitals, as healthcare service facilities, bear a significant legal responsibility in ensuring patient safety. This obligation includes risk management and the implementation of accreditation standards in accordance with existing regulations, ensuring that every medical action performed adheres to safety principles.²³ Although many hospitals have attempted to foster a culture of

²³ Mira Asmirajanti et al., "Penerapan Standar Akreditasi Terhadap Mutu dan Keselamatan Pasien Sebelum dan Selama Pandemi Covid-19," *The Journal of Hospital Accreditation* 3, no. 2 (2021): 68. See too, Y. D. Primasa and K. Kosasih, "Pengaruh Penerapan Standar Akreditasi Terhadap Mutu dan Keselamatan Pasien," *Action Research Literate* 8, no. 10 (2024): 2903

safety, challenges still persist in consistently meeting all these criteria.²⁴ According to the Law of the Republic of Indonesia Number 17 of 2023 concerning Health, hospitals are required to provide healthcare services that are safe, of high quality, and affordable for every patient. Article 10 states that hospitals must ensure the availability of sufficient health resources, including competent medical personnel, adequate medical equipment, and healthcare systems that guarantee patient safety. Furthermore, Article 12 emphasizes that the government is responsible for regulating, guiding, supervising, and improving the quality and competence of medical and health personnel. This means that hospitals are not only required to provide safe facilities for patients but also must ensure that every healthcare worker has sufficient capacity to apply patient safety standards.

The Regulation of the Minister of Health (Permenkes) Number 11 of 2017 concerning Patient Safety also underscores the legal obligations of hospitals to protect patients. According to this regulation, hospitals are mandated to achieve six key patient safety objectives: accurate patient identification, effective communication among healthcare personnel, safe medication practices, assurance of correct medical procedures, prevention of healthcare-associated infections, and prevention of patient falls. Non-compliance with these standards can render a hospital legally liable for negligence that may compromise patient safety. In the Indonesian legal system, hospital responsibility for patient safety carries clear legal consequences. If a medical error or patient safety incident occurs due to hospital or medical personnel negligence, the patient or the patient's family may file a lawsuit based on Article 1365 of the Indonesian Civil Code (*Kitab Undang-Undang Hukum Perdata*/KUHPerdata), which stipulates that any act causing harm to another person must be compensated appropriately. Moreover, in more serious cases, such as medical malpractice resulting in injury or death, the hospital and the medical personnel involved may face administrative, civil, or even criminal sanctions.

However, in practice, many patients still encounter difficulties in obtaining justice and legal accountability from hospitals. One of the main obstacles is the limited patient access to medical records, which often serve as key evidence in medical dispute resolution. Although Article 4 paragraph (1) point (j) of Law Number 17 of 2023 concerning Health states that every patient

²⁴ Yennike Tri Herawati, "Budaya Keselamatan Pasien di Ruang Rawat Inap Rumah Sakit X Kabupaten Jember," *Jurnal Ilmu Kesehatan Masyarakat* 11, no. 1 (2015), 35.

has the right to obtain information about their health data, including the treatment and medical procedures received or to be received, in reality, many hospitals are reluctant to disclose patients' medical records openly.

The legal process for resolving patient safety cases in Indonesia often does not favor patients, as many medical disputes are prolonged and difficult to prove. This situation is caused by a legal system that tends to provide greater protection to medical professionals than to patients as victims of medical negligence.²⁵ Existing regulations and legal practices often prioritize the interests of the medical profession, making it difficult for patients to seek justice.²⁶ The culture of secrecy within hospital systems further exacerbates this issue; patient safety incidents are often not reported transparently and are instead handled internally without the involvement of independent parties.²⁷ Studies indicate that the lack of effective reporting systems and transparency in incident management can result in further harm to patients. Therefore, to create a safer environment for patients, legal system reforms and cultural changes in hospitals are necessary to promote openness and accountability in patient safety incident reporting.

To ensure that hospitals truly fulfill their legal responsibilities in guaranteeing patient safety, stricter legal mechanisms and stronger oversight systems are required. The government needs to tighten regulations related to patient safety audits, enhance transparent patient safety incident reporting mechanisms, and provide broader access for patients to obtain their medical information. In addition, an independent institution is needed to handle medical disputes more fairly so that patients who suffer losses due to hospital negligence can obtain their legal rights without facing complex bureaucratic barriers.

3.3. Implementation of Patient Safety Policies in Hospitals: Legal Barriers, Regulatory Challenges, and Juridical Solutions

Regulations concerning patient safety in hospitals have been comprehensively established through the Law of the Republic of Indonesia

²⁵ Essy Mandriani, Hardisman Hardisman, and Husna Yetti, "Analisis Dimensi Budaya Keselamatan Pasien oleh Petugas Kesehatan di RSUD dr Rasidin Padang Tahun 2018," *Jurnal Kesehatan Andalas* 8, no. 1 (2019): 132.

²⁶ Ekorini Listiowati, Dirwan Suryo Soularito, and Merita Arini, "E-Note System: Pencatatan, Pelaporan dan Analisis Insiden Keselamatan Pasien," in *Prosiding Seminar Nasional Program Pengabdian Masyarakat* (2020), 35.

²⁷ Frima Ulfa Agustina, Tuti Afriani, and Hanny Handiyani, "Analisis Fungsi Supervisi Kepala Ruang dalam Pengurangan Risiko Jatuh di Rumah Sakit X Jakarta: A Pilot Project," *Dunia Keperawatan: Jurnal Keperawatan dan Kesehatan* 8, no. 3 (2020): 470.

Number 17 of 2023 on Health and the Regulation of the Minister of Health of the Republic of Indonesia Number 11 of 2017 on Patient Safety. However, the implementation of these regulations across hospitals in Indonesia still faces numerous challenges. Some hospitals have successfully implemented patient safety standards, yet many healthcare facilities continue to struggle in effectively applying these policies. Organizational factors, including weak leadership and an underdeveloped culture of safety within hospitals, often become major obstacles to improving patient safety.^{28,29} In addition, the lack of awareness and understanding among healthcare workers regarding risks and safety procedures also contributes to the occurrence of safety incidents.³⁰

In the context of policy implementation, there are two main aspects that need to be analyzed: (1) the extent to which patient safety policies have been implemented in hospitals, and (2) the key challenges that hinder the successful implementation of patient safety policies in Indonesia. Patient safety is a top priority within the healthcare system. The Regulation of the Minister of Health (Permenkes) of the Republic of Indonesia Number 11 of 2017 on Patient Safety establishes six main patient safety goals, which include patient identification, effective communication, medication safety, accuracy of medical procedures, prevention of nosocomial infections, and prevention of patient falls. Based on reviews of patient safety implementation across various hospitals, it can be concluded that the application of these policies remains uneven and is influenced by several key factors, including the level of hospital compliance with regulations, the extent of patient involvement in safeguarding their own care, and the awareness and commitment of healthcare workers to maintaining patient safety standards.

The effectiveness of patient safety policy implementation in hospitals largely depends on adherence to existing regulations. In accordance with Permenkes Number 11 of 2017 on Patient Safety, most hospitals have established Hospital Patient Safety Teams (*Tim Keselamatan Pasien Rumah Sakit*/TKPRS),

²⁸ Indrayadi Indrayadi, Nor Afni Oktavia, and Meti Agustini, "Perawat dan Keselamatan Pasien: Studi Tinjauan Literatur," *Jurnal Kepemimpinan dan Manajemen Keperawatan* 5, no. 1 (2022): 67. See too, Meki Pranata, Zulfa Maria Qibtiyah, and Chilmia Nurul Fatiha, "Hubungan Demografi Tenaga Kefarmasian terhadap *Patient Safety* di Rumah Sakit Islam Sultan Agung Kota Semarang," *Jurnal Ilmu Kefarmasian Indonesia* 20, no. 1 (2022): 138.

²⁹ Meki Pranata, Zulfa Maria Qibtiyah, and Chilmia Nurul Fatiha, "Hubungan Demografi Tenaga Kefarmasian terhadap *Patient Safety* di Rumah Sakit Islam Sultan Agung Kota Semarang," *Jurnal Ilmu Kefarmasian Indonesia* 20, no. 1 (2022): 138.

³⁰ Annisa Rahmi Galleryzki et al., "Hubungan Sikap Keselamatan dengan Implementasi Sasaran Keselamatan Pasien oleh Perawat di Rumah Sakit," *Jurnal Kepemimpinan dan Manajemen Keperawatan* 4, no. 1 (2021): 15

tasked with overseeing and assessing the execution of patient safety measures. Despite this, compliance with patient safety standards is not uniform across all hospitals. While some facilities have implemented Patient Safety Incident Reporting (IKP) systems, challenges persist in accurately documenting and reporting Adverse Events (*Kejadian Tidak Diinginkan/KTD*). A significant barrier is the hesitancy of healthcare personnel to report incidents due to concerns over potential legal repercussions or institutional sanctions.

A crucial component of effective patient safety implementation is the active participation of patients in their own medical care. According to Article 4 paragraph (1) of the Law of the Republic of Indonesia Number 17 of 2023 on Health, patients have the right to receive clear information about their health condition and the risks associated with any medical procedure to be performed. However, in practice, many patients still do not receive sufficient information regarding their rights and responsibilities within the healthcare system. Many patients fail to understand the importance of proper patient identification, effective communication with medical staff, and oversight of medications administered to them. As a result, patients become more vulnerable to preventable medical errors that could be avoided if they were more actively involved in ensuring their own safety.

Awareness and commitment among healthcare workers remain central to the effective implementation of patient safety, as emphasized in the Indonesian Ministry of Health Regulation Number 11 of 2017, which states that patient safety must be embedded as a core culture within hospitals and understood by all healthcare personnel across every aspect of service delivery. Despite this mandate, cultivating a strong patient-safety culture continues to face several challenges, including limited training opportunities, as many hospitals do not yet require patient-safety training as part of mandatory onboarding for new healthcare staff; heavy workloads that hinder healthcare professionals' ability to consistently apply patient-safety standards; and the persistence of a blame-oriented work culture that focuses on individual fault rather than identifying systemic causes of safety failures.

However, several challenges persist in fostering this culture among healthcare personnel. These include a lack of mandatory patient safety training for medical and other healthcare staff, as many hospitals have not yet incorporated such training into orientation programs for new employees; high workloads that reduce healthcare workers' ability to consistently focus

on patient safety standards; and an organizational culture that tends to place blame on individuals rather than addressing the systemic root causes of patient safety issues. Addressing these challenges is essential to ensure that patient safety becomes a core value within hospital operations.

To ensure that patient safety truly becomes a priority in healthcare services, it is essential to enhance continuous education and training on patient safety for all medical and healthcare personnel. Although patient safety policies have been clearly regulated in existing legislation, their implementation in hospitals across Indonesia continues to face significant challenges. Some of the main obstacles in implementing patient safety in hospitals include lack of supervision and evaluation by the government, disparities in the implementation of patient safety between urban and regional hospitals, and Low transparency in patient safety incident reporting.

Article 6 of the Law of the Republic of Indonesia Number 17 of 2023 on Health mandates that both central and regional governments are responsible for fostering and supervising the implementation of quality and safe healthcare services. In practice, however, government oversight of hospital compliance with patient safety standards remains suboptimal. Key issues contributing to this deficiency include the absence of a systematic patient safety audit in hospitals, which leads to a lack of accurate data on compliance levels; poor coordination between central and regional authorities in monitoring and evaluating patient safety policies; and the lack of strict sanctions for hospitals that fail to properly implement patient safety standards. As a result, many hospitals perceive these regulations as formalities without real consequences for noncompliance, undermining the effectiveness of patient safety policies.

Disparities in the implementation of patient safety between urban and regional hospitals. One of the major challenges in enforcing patient safety policies is the uneven implementation between hospitals in urban areas and those in remote regions. Hospitals in large cities tend to have better systems for implementing patient safety due to more adequate infrastructure, a greater number of healthcare professionals, and better access to modern medical technology. Conversely, hospitals in remote areas often face obstacles in implementing patient safety policies because of limited medical personnel, inadequate facilities, and minimal access to training and patient safety education. This disparity leads to differences in the quality of care between urban and regional hospitals, ultimately contributing to a higher risk of patient safety incidents in regional hospitals.

Low transparency in patient safety incident reporting remains a significant challenge in Indonesian hospitals. Although the Regulation of the Minister of Health (Permenkes) of the Republic of Indonesia Number 11 of 2017 on Patient Safety mandates the establishment of a non-punitive patient safety incident reporting system to ensure that medical personnel feel safe reporting adverse events (*Kejadian Tidak Diinginkan/KTD*), several obstacles persist in practice. Many healthcare workers remain reluctant to report incidents due to fear of legal consequences and administrative sanctions. In addition, hospitals often lack a clear and structured reporting system, and there is insufficient legal protection for personnel who do report incidents, resulting in numerous adverse events going unreported officially.

To enhance the effectiveness of patient safety policies in hospitals in Indonesia, a series of more comprehensive and integrated strategies are needed. Although Law Number 17 of 2023 concerning Health and the Regulation of the Minister of Health (Permenkes) of the Republic of Indonesia Number 11 of 2017 concerning Patient Safety have provided a clear legal basis, their implementation still faces various obstacles, such as lack of supervision, low transparency in patient safety incident reporting, and disparities in implementation between urban and regional hospitals. Therefore, to strengthen patient safety policies in Indonesia, it is necessary to enhance hospital supervision and accountability systems, improve transparency and reporting of patient safety incidents, mandate patient safety training for all healthcare personnel, and implement legal reforms to reinforce the protection of patient rights.

Therefore, the government needs to strengthen the patient safety audit system by implementing stricter and data-driven supervision mechanisms. This can be achieved by mandating regular patient safety audits in every hospital, accompanied by strict administrative sanctions for those failing to meet established standards. Additionally, the implementation of a patient safety score-based assessment system is essential, where hospitals demonstrating high compliance receive incentives, while those with low compliance are subject to sanctions or targeted improvement programs. Furthermore, the involvement of independent institutions in the audit process is crucial to ensure that evaluations are conducted objectively and do not solely rely on the hospital's internal reporting mechanisms. Enhancing transparency and reporting of patient safety incidents

Low transparency in reporting patient safety incidents is a major challenge in implementing patient safety policies in Indonesia. Many medical personnel are reluctant to report incidents due to fear of legal consequences or administrative sanctions.³¹ This fear hinders the collection of accurate data on safety incidents, which is crucial for analyzing the causes of errors and preventing similar events in the future.³² Effective IKP reporting allows hospitals to better detect and understand incidents, enabling the implementation of appropriate preventive measures.³³

Research shows that an organizational culture supporting incident reporting is crucial to increase the participation of healthcare personnel in reporting such events.³⁴ In this context, a system that protects reporters from negative consequences is needed to encourage more open and honest reporting. Thus, improving transparency in the IKP reporting process can contribute to creating a stronger patient safety culture in Indonesian hospitals.³⁵ To increase transparency in patient safety incident reporting, the government needs to implement several key measures. First, hospitals should be required to adopt an electronic patient safety incident reporting system that is easily accessible to all medical personnel and healthcare workers, ensuring that reporting becomes more efficient and traceable. Second, the application of a non-punitive principle in incident reporting is crucial so that healthcare personnel do not fear repercussions when reporting errors or safety issues; instead, the system should emphasize learning and systemic improvement rather than individual punishment. Finally, the government should establish an external reporting mechanism that enables patients or their families to

³¹ Inge Dhamanti, Sandra Leggat, and Simon Barraclough, "Practical and Cultural Barriers to Reporting Incidents among Health Workers in Indonesian Public Hospitals," *Journal of Multidisciplinary Healthcare* (2020): 353. See too, Putu May Indrayani, Pande Putu Januraga, and Surya Negara, "The Impact of Hospital Accreditation on Patient Safety Culture in the Health Services Implementation at Sanglah General Hospital, Bali," *Public Health and Preventive Medicine Archive* 9, no. 2 (2021), 45.

³² Savitri Citra Budi, Sunartini Hapsara, Fatwa Sari Tetra, and Lutfan Lazuardi, "Incident Report: Between the Shadows of Obligation and Formality," *Open Access Macedonian Journal of Medical Sciences* 9, no. E (2021): 110. See too, Rie Koyoshi, Shin-ichiro Miura, Satoshi Imaizumi, Misako Nagao, Takeshi Imamura, Asami Oshikawa, Takeshi Shiraishi, Hideichi Wada, and Akinori Iwasaki, "The COVID-19 Pandemic and Its Impact on Patient Safety Incidents at a University Hospital: A Retrospective Study," *Clinical Infection and Immunity* 9 (2024): 5.

³³ Elaine M. Griffith et al., "Multifaceted Intervention to Improve Patient Safety Incident Reporting in Intensive Care Units," *Journal of Patient Safety* 19, no. 7 (2023): 423.

³⁴ Joice Merny Laoh. "Health Workers' Perspective on Patient Safety Incident Disclosure in Indonesian Hospitals." *Journal of Multidisciplinary Healthcare* (2023): 1423–1424.

³⁵ Cerrone et al., "How Patient Safety Culture Influences Adverse Event Reporting and Use of the Incident Reporting Tool: A Systematic Review," *PrePrints Organization* 2, no. 1 (2023): 5. See too, Kai Wehkamp, Eva Kuhn, Rainer Petzina, Alena Buyx, and Annette Rogge, "Enhancing Patient Safety by Integrating Ethical Dimensions to Critical Incident Reporting Systems," *BMC Medical Ethics* 22, no. 1 (2021): 26–35.

directly report patient safety incidents to health authorities or independent institutions, thereby ensuring stronger external oversight and accountability in the enforcement of patient safety policies.

Patient safety depends not only on policy and regulations but also on the understanding and skills of medical personnel in applying patient safety standards. Therefore, patient safety training must become a mandatory part of the education and training system for healthcare personnel in Indonesia. Research indicates that education focusing on patient safety is crucial to equip healthcare workers with the necessary knowledge and skills.³⁶

Training programs should include effective communication and teamwork aspects, which have been proven to significantly prevent adverse patient events.³⁷ Furthermore, simulation-based approaches in healthcare education can enhance medical personnel's readiness to handle real-life situations and improve overall patient safety outcomes.³⁸ Integrated simulation-based education not only improves clinical skills but also fosters a strong safety culture within healthcare services.³⁹ Thus, establishing a solid foundation through patient safety training at the education level will greatly contribute to improving the quality of medical services and protecting patients in the future.⁴⁰ To achieve this, several measures can be implemented. Hospitals should require patient safety training for all new healthcare personnel, including doctors, nurses, and other medical staff before they begin their duties. Additionally, patient safety training should be made a mandatory component of the hospital accreditation process, guaranteeing that every healthcare worker has adequate knowledge and skills in this area. Furthermore, hospitals are encouraged to conduct regular patient safety

³⁶ Daniel Lungu and John Harvey, "Patient Safety: A Systematic Review of the Literature with Evidence-Based Measures to Improve Patient Safety in Healthcare Settings," *Texila International Journal of Academic Research* 10, no. 2 (2023): 30. See too, Ilaria Tocco Tussardi, Roberto Benoni, Francesca Moretti, Stefano Tardivo, Albino Poli, Albert W. Wu, Michela Rimondini, and Isolde Martina Busch, "Patient Safety in the Eyes of Aspiring Healthcare Professionals: A Systematic Review of Their Attitudes," *International Journal of Environmental Research and Public Health* 18, no. 14 (2021): 7524.

³⁷ Ying Wang, Yi-Wen Chen, Xin-Ping Hu, and Hua Mei, "Bibliometric Analysis of Research Hotspots and Global Trends in Patient Safety Education for Nursing Students," *Medicine* 103, no. 42 (2024): e40163.

³⁸ Tatjana Baldovin et al., "Shaping the Future of Healthcare: Improving Quality and Safety through Integrating Simulation into Public Health Education," *Frontiers in Public Health* 12 (2024): 1446.

³⁹ Cristina Alves Bernardes et al., "Factors that Influence the Patient Safety Climate: Perception of the Multidisciplinary Team," *Contribuciones a las Ciencias Sociales* 17, no. 4 (2024): 20.

⁴⁰ Sehrish Aijaz et al., "Exploring the Depth of Patient Safety and Care: An Investigation into the Knowledge and Attitudes of Healthcare Students Across Undergraduate, Graduate, and Postgraduate Levels," *Journal of Health and Rehabilitation Research* 4, no. 1 (2024): 1314. See too, Ni Nyoman Gunahariati et al., "Development of Patient Safety Learning Module Based on Problem Based Learning for Nursing Students at the College of Health Sciences," *Bali Medical Journal* 11, no. 1 (2022): 175.

incident simulations, providing medical personnel with practical experience in managing potential safety incidents within a safe and controlled environment.

Patients who suffer injuries due to medical negligence or failures in the patient safety system often encounter difficulties in obtaining justice. High legal barriers, such as lengthy litigation processes and significant costs, make patients feel trapped in an unsupportive system.⁴¹ Often, patients face a legal system that tends to protect medical personnel rather than prioritize their rights as victims. In addition, the lack of transparency in incident reporting worsens the situation, with many cases not reported openly and transparently.⁴² Therefore, legal reforms that uphold justice and strengthen transparent reporting mechanisms are vital to ensuring fair treatment for patients who experience medical negligence. These reforms should begin with strengthening regulations on patients' rights to medical information, as many hospitals remain reluctant to provide transparent access to medical records despite Article 4 paragraph (1) point (j) of Law Number 17 of 2023 guaranteeing such rights. Clearer legal provisions are needed to regulate this access and define mechanisms patients can pursue if access is denied. Furthermore, establishing a fairer and more objective medical dispute resolution mechanism is essential, given that many disputes are often prolonged and difficult to prove due to limited patient access to medical data and systemic bias toward medical personnel. Creating an independent institution to manage such disputes transparently would help patients obtain justice more effectively. Lastly, hospitals should be required to provide fair and timely compensation to patients who suffer harm as a result of medical negligence or failures in patient safety systems, ensuring that patients are not burdened by bureaucratic delays in receiving their rightful protection and redress.

4. Closing

Patient safety policies in Indonesia are firmly established within the legal framework, particularly under Law Number 17 of 2023 concerning Health and the Regulation of the Minister of Health (Permenkes) Number 11 of 2017, which

⁴¹ Owen M. Bradfield et al., "Vocational and Psychosocial Predictors of Medical Negligence Claims among Australian Doctors: A Prospective Cohort Analysis of the MABEL Survey," *BMJ Open* 12, no. 6 (2022): e055432.

⁴² Roxana Mihaela Claponea and Magdalena Iorga, "Burnout, Organizational Justice, Workload, and Emotional Regulation among Medical and Non-Medical Personnel Working in Romanian Healthcare Units," *Behavioral Sciences* 13, no. 3 (2023): 225.

mandate that hospitals implement patient safety principles to safeguard patients' rights and well-being. Legally, patient safety forms an essential part of the right to safe and quality healthcare and constitutes a critical aspect of patients' legal protection, obligating the state, through hospitals, to provide accountable safety systems and procedures. However, the practical implementation of these policies faces significant challenges, including uneven understanding of patient safety culture among healthcare personnel, weak reporting of safety incidents, limited periodic supervision by authorities, and low compliance with established standards. These difficulties are further compounded by disparities between urban and regional hospitals, restricted patient access to medical information, limited transparency in incident reporting, and inadequate mechanisms for resolving medical disputes, all of which hinder patients' ability to obtain justice when affected by medical negligence.

Based on the research findings, several recommendations are proposed to strengthen patient safety in Indonesian hospitals: the government should enhance patient safety regulations and legal oversight, while hospitals must ensure the full implementation of patient safety SOPs and maintain active patient safety committees. Furthermore, the Ministry of Health should implement structured legal education and training programs to instill a strong patient safety culture among medical personnel and healthcare workers. Additionally, hospital supervision and accountability systems need to be reinforced through stricter juridical audits and improved transparency in incident reporting. Legal reforms are also necessary to provide clearer protection for patients, including guaranteed access to medical information and more equitable mechanisms for resolving medical disputes.

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