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Enhancing Patient Safety through Legal Reform: A Comparative Review of Healthcare Best Practices and Legal Frameworks

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Abstract

Patient safety has become a global health priority, closely linked to the quality of medical services and the legal framework governing healthcare systems. This study aims to juridically and comparatively examine the regulatory frameworks of patient safety across various jurisdictions and analyze the contrasting approaches between developed and developing countries. Using a qualitative method with a literature review approach, data were collected from scientific journals, international health organizations such as the World Health Organization, government regulations, and previous empirical studies. The findings indicate that developed nations have implemented more structured patient safety regulations, characterized by mandatory, privileged incident reporting systems and legal protection for healthcare professionals (whistleblowers). In stark contrast, developing countries, including Indonesia, face persistent challenges related to limited resources, weak legal enforcement, and a prevalent blame culture that hinders open reporting. The comparative analysis highlights the critical need for legal reform in Indonesia to strengthen patient safety regulations, particularly through the revision of the hospital law, the integration of telemedicine into the legal framework, and the establishment of a transparent, protected reporting system. Ultimately, strengthening legal frameworks is essential to ensure that patient safety becomes a fundamental, enforceable, and systemic element of health systems worldwide.

Keywords

Healthcare System, Incident Reporting, Legal Reform, Patient Safety, Telemedicine.

1. Introduction

Patient safety is a fundamental pillar of modern healthcare, representing a non-negotiable aspect of the human right to health and life (Dhingra et al., 2021). The World Health Organization (WHO) identifies patient safety as a global priority, urging Member States to mitigate preventable harm from medical errors (World Health Organization, 2021; Mistri et al., 2023). In Indonesia, rising medical malpractice claims, patient complaints, and public distrust underscore that healthcare effectiveness depends on robust legal, regulatory, and policy frameworks ensuring safety and legal protection (Salawati, 2020). In developed countries, mature legal frameworks protect both patients and healthcare professionals, encouraging incident reporting and systemic learning. In contrast, in developing countries like Indonesia, reporting medical errors remains sensitive due to stigma, reputational risk, and potential legal or professional sanctions (Nur et al., 2021). This inhibitory environment suggests that Indonesia's regulatory framework for patient safety requires significant strengthening to achieve legal certainty and procedural fairness for all parties.

Beyond the legal dimension, integrating quality management is crucial. Nur et al. (2021) emphasize that patient safety must be an embedded part of hospital governance, Standard Operating Procedure (SOP), and internal supervision. Slow regulatory responses to malpractice cases in Indonesia exacerbate public distrust. Research highlights structural fragility, with Utami et al. (2024) noting deficiencies in human resources, supervision, and regulatory clarity. Rapid advancements in healthcare technology, particularly telemedicine, further complicate the system. Lestari (2023) argues that digital health transformation requires an adaptive legal framework to ensure equal protection for patients and practitioners, without justice-based regulatory reform, complex legal conflicts are likely to grow.

From a civil law perspective, doctor liability in medical malpractice is complex. Widjayanto et al. (2024) note tensions between legal liability, medical ethics, and rising patient expectations, highlighting the need for health law reform that considers social, cultural, and technological contexts. Challenges in integrating human rights into daily practice further underscore the urgency of reform, which must protect patients while providing legal certainty for healthcare workers. In Indonesia, patient safety is governed by Law Number 17 of 2023 on Health, Law Number 44 of 2009 on Hospitals, and operationalized through Ministry of Health Regulation Number 11 of 2017 on Patient Safety. However, implementation faces oversight and enforcement challenges, creating a gap between legal intent and practice (Utami et al., 2024).

The need for legal reform is closely tied to human rights and international obligations. Article 28H of the 1945 Constitution guarantees the right to health, and Indonesia's adherence to the International Covenant on Economic, Social and Cultural Rights (ICESCR) obligates the state to ensure health regulations protect patient rights and provide legal clarity for practitioners. However, bureaucratic inertia, limited legal socialization, and weak complaint mechanisms often hinder the practical realization of these rights. A key systemic challenge lies in the weak culture of incident reporting. The World Health Organization (2023) indicates that preventable medical incidents are a major cause of mortality globally, yet existing Indonesian regulations face resistance due to the negative stigma and fear of criminal or administrative sanctions associated with self-reporting. This contrasts sharply with systems like the Patient Safety and Quality Improvement Act (PSQIA) of 2005 in the United States, which grants federal legal privilege and confidentiality protections to Patient Safety Work Product (PSWP), encouraging open reporting and systemic learning. This comparative perspective highlights the critical need for

Indonesian legal reform to strike a balance between accountability and robust legal protection for those who report honestly.

Integrating patient safety into the National Health Insurance (*Jaminan Kesehatan Nasional*/JKN) system presents a strategic challenge. Efficiency-driven mechanisms like capitation and Indonesian Case-Based Groups used by Health Social Security Administering Body (*Badan Penyelenggara Jaminan Sosial Kesehatan*/BPJS) impose financial pressures on health facilities (Haryanto et al., 2025). Without strong safety regulations, care quality is at risk. Widjayanto et al. (2024) warn that financial pressure can incentivize negligence, highlighting the need for legal instruments that prioritize patient safety regardless of budgetary or efficiency goals.

This study aims to juridically and comparatively examine the regulatory frameworks of patient safety across various jurisdictions and analyze the contrasting approaches between developed and developing countries. These insights underline the need for a comprehensive examination of patient safety in Indonesia, focusing on three key dimensions: a global overview of patient safety and the legalization of risk mitigation, the fragmentation and law enforcement challenges in the Indonesian system, and a proposal for legal reform that shifts from a blame culture to statutory safety. The urgency of health law reform is clear. Law should serve not only as a normative instrument but also as a tool for fostering a sustainable culture of safety. Reform must strengthen legally protected incident reporting, expand safeguards for healthcare professionals, and ensure patient access to justice and compensation. Drawing on participatory and evidence-based approaches, this study aims to support the development of a more just, transparent, and patient-centered regulatory framework in Indonesian healthcare.

2. Methods

This research employs a qualitative approach using a normative juridical method, with a strong emphasis on comparative literature review through library research. This methodology is selected due to the study's focus on analyzing the internal structure of legal norms, regulatory intent, and their comparative effectiveness across different jurisdictions. Data collection for this research relied entirely on secondary sources. Primary legal materials included Law Number 17 of 2023 on Health, Law Number 44 of 2009 on Hospitals, Law Number 29 of 2004 on Medical Practice, and relevant ministerial regulations issued by the Ministry of Health. Secondary legal materials comprised academic journals, both national and international, legal textbooks on health law, reports from international organizations such as the World Health Organization and Joint Commission International (JCI), and empirical studies examining patient safety outcomes and legal compliance. Additionally, case documentation was analyzed, including selected Indonesian judicial decisions on medical malpractice, such as Supreme Court Decision Number 1145K/Pdt/2017, as well as comparative examples from international contexts, including the U.S. PSQIA and the U.K. Francis Report reforms. The comparative approach is used to identify best practices from jurisdictions with more advanced patient safety systems, enabling the study to assess gaps in Indonesia's legal framework and evaluate how alternative legal models could strengthen accountability, incident reporting, and legal certainty.

The data analysis in this study was conducted through a combination of qualitative content analysis and comparative legal analysis. Qualitative content analysis allowed for a systematic examination of the materials to identify recurring themes, patterns, and underlying principles related to key issues such as accountability, the culture of incident reporting, and legal protections as reflected in both regulatory texts and scholarly literature. In parallel, comparative legal analysis was utilized to critically evaluate the Indonesian legal framework against international best practices. This approach involved identifying significant gaps,

such as the lack of legal privilege or protection for self-reporting of medical incidents, and assessing how these deficiencies impact patient safety and professional accountability. Based on these insights, the study sought to develop well-founded recommendations for legal reform in Indonesia, ensuring that proposed changes are not only evidence-based but also contextually appropriate and aligned with overarching principles of justice and human rights.

3. Results

3.1. Global Overview of Patient Safety & the Legalization of Risk Mitigation

Patient safety has evolved from a purely clinical issue into a pressing global health concern, requiring robust legal and systemic interventions (Lee et al., 2021; Yeung et al., 2022). The World Health Organization reports that roughly 1 in 10 patients worldwide suffer preventable harm, with low- and middle-income countries disproportionately affected, highlighting that the main challenge lies not in medical knowledge but in systemic failures of legal enforcement and safety culture. Regulatory approaches differ by legal tradition and resources: developed common law countries like the US and UK combine individual liability through tort law with advanced safety regulations. The United States' PSQIA of 2005 established privileged, voluntary reporting via patient safety organizations to protect patient safety work product and foster a culture of learning. Similarly, the UK's Francis (2010) introduced a statutory Duty of Candour and created the independent care quality commission to ensure transparency and systemic accountability.

The global response to this crisis has been fundamentally legalistic. Following landmark reports that exposed the systemic causes of medical errors, developed nations established sophisticated legal frameworks that formalize risk mitigation. The PSQIA stands as a critical example, strategically shifting the legal focus from individual blame to systemic learning. The PSQIA achieved this through the creation of a federal privilege and confidentiality protection for Patient Safety Work Product (PSWP), which is voluntarily reported by healthcare providers to designated Patient Safety Organizations (PSOs) (Agency for Healthcare Research and Quality, 2025). The core legal intent of the PSQIA is to ensure that information collected for safety analysis cannot be used in civil litigation against the reporting provider. This legal protection is essential for transitioning from a blame culture where errors are hidden for fear of sanction to a just culture where errors are openly reported for the purpose of system learning (Robson et al., 2022; Al-Worafi, 2023; Kumah, 2025).

Similarly, in the United Kingdom, the Mid Staffordshire National Health Service Trust Scandal (2005–2009) prompted deep legal reforms encapsulated in the Francis Report (Francis, 2010; Hughes, 2023). This led to the introduction of a statutory Duty of Candour, compelling healthcare providers to be open and honest with patients when harm occurs, backed by severe regulatory consequences for failure to disclose. Furthermore, the establishment of the independent Care Quality Commission (CQC) gave regulators significant legal powers to audit, inspect, and enforce fundamental patient safety standards. These models from common law jurisdictions demonstrate that effective patient safety cannot be achieved by merely regulating clinical standards; it requires the law to actively shield the learning process from punitive legal mechanisms.

Contrasting these global best practices with the Indonesian legal landscape reveals significant structural gaps. Although Indonesia has core legislation such as Law Number 17 of 2023 on Health and Law Number 44 of 2009 on Hospitals, which mandate patient safety standards, the implementation framework lacks adequate legal protection mechanisms. While Ministry of Health Regulation Number 11 of 2017 on Patient Safety requires incident reporting, the reports generated are often

not afforded legal privilege. This exposes the reporting practitioner or institution to potential civil or criminal prosecution, thereby fostering a culture of underreporting and concealment (Salawati, 2020; Utami et al., 2024). The high volume of preventable errors and the difficulty patients face in obtaining compensation or justice are direct symptoms of this fragmented legal system (Raffel et al., 2020; Gunderson et al., 2020; Widjayanto et al., 2024). The global consensus, as codified in the WHO Global Patient Safety Action Plan 2021–2030, explicitly recommends that countries use "selective legislative measures to facilitate the delivery of safe patient care and the protection of patients and health workers from avoidable harm," a recommendation that Indonesia must urgently internalize and translate into actionable law (World Health Organization, 2023).

3.2. Fragmentation and Law Enforcement Challenges in the Indonesian System

In contrast, developing countries like Indonesia, with a Civil Law tradition, rely heavily on administrative regulation and professional ethics enforcement. Laws such as Number 17 of 2023 and Number 44 of 2009 mandate safety standards, yet implementation suffers from low resources, limited infrastructure, and an entrenched blame culture (Gunderson et al., 2020; Tamon et al., 2025). Ministry of Health Regulation Number 11 of 2017 requires incident reporting, but without protections like the PSQIA, reports remain voluntary, inconsistent, and incomplete, limiting their usefulness for evidence-based policy (Utami et al., 2024; Bintartho & Nasser, 2025). The current Indonesian framework, rooted in a Civil Law tradition, faces three pervasive challenges that impede effective patient safety, legal fragmentation, weak enforcement mechanisms, and a persistent cultural bias toward blame. The first challenge, legal fragmentation, stems from the overlapping and sometimes conflicting jurisdictions of regulatory bodies.

The handling of patient safety incidents in Indonesia often follows four distinct institutional paths, professional ethics through the Indonesian Medical Disciplinary Council (*Majelis Kehormatan Disiplin Kedokteran Indonesia*/MKDKI), administrative regulation via the Ministry of Health, civil litigation seeking compensation under tort law, and criminal prosecution seeking individual accountability. Case studies by Fitria and Adinta (2025) including Tangerang District Court Decision Number 1324/Pdt.G/2021 and by Siregar et al. (2025) Supreme Court Decision Number 1145K/Pdt/2017, illustrate that this fragmented system leads to delays in justice for patients and legal uncertainty for healthcare professionals. In many instances, cases halt at the administrative or ethical level without sufficient legal follow-through, leading to a perception that institutions lack genuine accountability. Furthermore, the difficulty for patients to access medical records, a procedural requirement for civil proof of negligence (onrechtmatige daad), exacerbates the justice gap (Sudra & Putra, 2022; Widjayanto et al., 2024; Ustani et al., 2024).

The second challenge is the culture of blame and its inhibitory effect on safety improvement. Unlike the US and UK models, Indonesia lacks legal instruments to protect whistleblowers and honest reporters of adverse events. This absence leads to a severe underreporting bias, where errors are concealed to avoid sanctions from the hospital administration, the professional body, or the public prosecutor. This practice cripples the essential process of systemic learning. As Shenoy (2021) and Al-Worafi (2023) argue, effective safety programs depend on high-quality incident data for evidence-based policy making. When staff are deterred by the fear of criminalization, data becomes unreliable, and similar errors are destined to recur a cycle that perpetuates unsafe conditions. The law, therefore, inadvertently acts as a barrier to safety, failing to achieve the transition to a just culture that balances individual accountability for reckless behavior with protection for honest human error.

The third challenge is the unregulated integration of technology, particularly telemedicine. As healthcare digitizes, new risks emerge, including electronic medical

record errors, data breaches, and questions of jurisdiction in remote consultations (Mustikasari, 2021; Lestari, 2023). The existing laws, drafted before the widespread adoption of digital care, are ill-equipped to provide legal protection or clarity regarding physician liability, patient data security, and the requisite standards of care in virtual environments. This regulatory gap represents a growing threat to patient safety in the digital age, demanding adaptive legal reconstruction that incorporates technology-specific safety protocols. These compounded challenges highlight the urgent need for a systemic legal intervention that synchronizes economic policy and national health insurance efficiency with patient safety priorities, ensuring that financial constraints do not compromise the quality and safety mandated by the constitution.

3.3. A Proposal for Legal Reform: From Blame Culture to Statutory Safety

The WHO Global Patient Safety Action Plan 2021–2030 provides a normative framework urging Member States to strengthen reporting, align regulatory and accreditation activities, and adopt a system-based approach to error prevention (World Health Organization, 2023). Effective patient safety law must balance accountability for gross misconduct with protection for honest error reporting to shift from a punitive blame culture to a constructive just culture (Al-Worafi, 2023; Njoto, 2023; Widjaja, 2025). Insights from the comparative analysis of the U.S. PSQIA and the U.K. Duty of Candour demonstrate that the most effective patient safety systems are those that legally protect learning processes while strengthening institutional accountability. These models reveal a consistent pattern: high-reliability healthcare systems rely on statutory privilege, independent oversight bodies, and legally mandated transparency elements currently missing or underdeveloped in the Indonesian framework.

The reform proposals outlined below are directly derived from the comparative findings, which show that legal privilege, independent regulatory bodies, and statutory disclosure duties are foundational components of an effective patient safety governance system. Accordingly, Indonesia's reform agenda must internalize these international best practices while adapting them to local institutional and legal contexts. This reform must be anchored in the principle that the law's primary function is to enable safety, not merely to punish failure. Reforming the incident reporting system with mandatory reporting and legal privilege is a cornerstone of patient safety reform. This requires revising existing regulations, primarily Ministry of Health Regulation Number 11 of 2017, to implement mandatory reporting for serious incidents along with statutory legal privilege for the reported information. The Hospital Law (Law Number 44 of 2009) should also be amended to incorporate this mechanism. Following the model of the U.S. PSQIA, the law should define patient safety work product as information collected for safety activities and grant it federal privilege and confidentiality. Additionally, an independent national Patient Safety Agency similar to the UK's CQC as recommended by the Francis Report should be established with the legal mandate to receive, analyze, and disseminate learning from PSWP without sharing this information with law enforcement for criminal prosecution purposes. This approach is essential to overcome the blame culture by assuring healthcare workers that honest reporting of human error will lead to systemic correction rather than personal sanction (Al-Worafi, 2023).

Strengthening institutional accountability and enforcement is essential to address the current fragmentation in Indonesia's patient safety system (Fadillah & Nisa, 2018; Fauzan et al., 2025). Reform should establish a statutory Duty of Candour, requiring hospitals and individual practitioners to provide immediate, open, and honest disclosure to patients and families following an adverse event, with significant administrative penalties for non-compliance, similar to the UK model. Additionally, mechanisms for distinguishing administrative error, professional negligence (malpractice), and criminal recklessness must be legally clarified. The

role of the Indonesian Medical Disciplinary Council should be enhanced, but its findings must be consistently linked to administrative and civil remedies, reducing the default reliance on criminalization for honest, non-reckless errors (Widjayanto et al., 2024).

Integrating digital health safety, particularly telemedicine, requires reconstructing the legal framework to address emerging risks. Following Lestari (2023), specific regulations, whether through a new ministerial or government regulation, must be enacted to govern telemedicine. These regulations should clearly define legal liabilities for institutions regarding data security and Electronic Medical Record (EMR) breaches, and establish minimum standards of care and technological requirements for digital consultations to ensure that patient safety is not compromised by the remote delivery of services.

Alignment with the national health system (*Jaminan Kesehatan Nasional/*JKN). The legal structure must integrate patient safety into the JKN financing model. Regulations should mandate that accreditation status, which is directly tied to JKN payment, is conditional upon demonstrable evidence of a functioning, reported, and utilized patient safety system. Financial incentives for efficiency must be legally counterbalanced by stringent oversight that penalizes poor safety outcomes. By implementing this comprehensive reform agenda, Indonesia can move beyond merely aspiring to international standards and embed patient safety as an enforceable legal principle, thereby building public trust and establishing a resilient, learning-based healthcare system.

The findings show that Indonesia's patient safety system is constrained by legal fragmentation, weak enforcement, and a persistent blame culture, all of which inhibit reliable incident reporting and systemic learning. Comparative evidence from the U.S. PSQIA and the U.K. Duty of Candour demonstrates that effective patient safety governance requires legal privilege for safety data, independent oversight bodies, and statutory transparency obligations. These global models directly address the same challenges faced in Indonesia. Accordingly, the proposed reforms mandatory incident reporting with legal protection, the establishment of an independent patient safety agency, statutory candour, and technology-specific regulations, offer targeted solutions aligned with proven international practices. Strengthening these legal foundations would not only resolve Indonesia's structural gaps but also foster a just culture essential for sustained patient safety improvement.

4. Conclusion

The current state of patient safety in Indonesia reveals a significant legal and systemic gap, marked by fragmented regulatory oversight, the absence of legal privilege for incident reporting, and a pervasive blame culture that obstructs learning from errors. Although core legislation mandates patient safety, implementation is often weak, failing to balance accountability with protection for healthcare professionals who report adverse events. Comparative analysis with developed systems, such as the US PSQIA and the UK Francis Report, highlights that effective patient safety law must actively safeguard the learning process, enabling organizations to correct systemic weaknesses without unduly penalizing individuals. Legal reform in Indonesia is therefore critical. Essential measures include establishing mandatory reporting with statutory privilege for patient safety work product, strengthening institutional accountability through a statutory Duty of Candour, and integrating the safety of telemedicine services into the legal framework. These reforms are expected to foster a culture of transparency and systemic learning, reduce the prevalence of punitive responses to errors, and improve patient trust in healthcare institutions.

The implications of these reforms extend beyond legal protection: they can enhance overall quality of care, provide clearer guidance for healthcare providers,

and create a more resilient health system capable of adapting to technological and social changes. However, this study is limited by its reliance on secondary data, normative legal texts, and literature reviews, without direct empirical observation of hospital practices or stakeholder perspectives. Future research should focus on evaluating the real-world impact of legal reforms on reporting behavior, patient safety outcomes, and healthcare worker attitudes. Additionally, comparative studies on the integration of digital health and telemedicine safety regulations across different regions in Indonesia could provide evidence-based guidance for refining adaptive, context-sensitive patient safety policies.

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Ethical approval was obtained for this study. The manuscript represents original work and has not been previously published, nor is it under consideration by another journal.

Data Disclosure Statement
The data that support the findings of this study are available from the corresponding author upon reasonable request.