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**Research article**

# Risk-Based Regulatory Model for Healthcare Workers with Communicable Diseases in Ensuring Patient Safety in Indonesia

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**ABSTRACT**

**Background:** Patient safety is a fundamental principle in healthcare systems aimed at ensuring safe and high-quality healthcare services. However, Indonesian regulations concerning healthcare workers with communicable diseases remain inadequate, particularly regarding periodic health screening and risk-based practice restrictions. This study aimed to analyze the Indonesian legal framework from a patient safety perspective and to formulate a risk-based regulatory model.

**Methods:** This study employed normative legal research using statutory, conceptual, and comparative approaches. The statutory approach examined Indonesian laws and regulations related to patient safety, healthcare workers, infection prevention and control, and labor law. The conceptual approach analyzed principles of health law and bioethics, including patient safety, non-maleficence, beneficence, and the precautionary principle. The comparative approach compared Indonesian regulations with international standards issued by the Centers for Disease Control and Prevention (CDC) and the National Health Service (NHS). Data were collected through documentary and library research using primary, secondary, and tertiary legal materials. Data analysis was conducted qualitatively through grammatical interpretation, systematic interpretation, and legal harmonization analysis.

**Results:** The study found that Indonesian regulations have not comprehensively regulated periodic health screening, risk-based practice restrictions, and monitoring systems for healthcare workers with communicable diseases. Significant normative gaps and legal uncertainty remain regarding the balance between healthcare workers' rights and patient safety. Compared with CDC and NHS standards, Indonesia has not yet optimally implemented a risk-based regulatory approach.

**Conclusion:** Indonesia requires a comprehensive risk-based health regulatory framework integrating patient safety, healthcare workers' rights, and proportional supervisory mechanisms. The proposed "Risk-Based Integrated Health Regulation" model may serve as a foundation for future health law reform and patient safety protection in Indonesia.

## INTRODUCTION

Patient safety is one of the core principles in modern healthcare systems aimed at ensuring that every patient receives safe, high-quality care and is protected from preventable harm. The World Health Organization defines patient safety as the absence of preventable harm or risk of injury during the process of healthcare deliver (Auraaen, 2020; Rahman et al., 2023; World Health Organization, 2021).

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In the context of health law in Indonesia, patient safety is not only regarded as an ethical obligation of healthcare professionals but also as a legal obligation that must be fulfilled by medical personnel, healthcare workers, and healthcare facilities (Herisasono et al., 2023). This provision is reflected in Article 4 letter a of Law No. 17 of 2023 on Health, which affirms every individual's right to safe and quality healthcare services. In addition, Article 29 paragraph (1) letter a of Law No. 44 of 2009 on Hospitals also regulates the obligation of hospitals to prioritize patient safety in service delivery.

Although patient safety regulations have developed, they have largely focused on healthcare service systems, medical errors, and infection prevention and control procedures in healthcare facilities. The issue of potential transmission of infectious diseases from medical personnel and healthcare workers to patients has not received adequate attention, particularly in health law studies (Güerri-Fernández et al., 2024; Hartuti et al., 2021; Suryani et al., 2021). Medical personnel and healthcare workers have a professional responsibility to ensure that the care they provide does not pose risks to patients, including the risk of transmitting infectious diseases (Bowdle & Munoz-Price, 2020).

Medical personnel and healthcare workers are required to meet competency and health standards as regulated in Law No. 17 of 2023 on Health. The principle of non-maleficence in healthcare ethics also requires every healthcare provider to maintain their health condition to avoid becoming a source of disease transmission to patients. This is particularly important because the health status of healthcare workers is directly related to patient safety, especially when they suffer from infectious diseases such as Tuberculosis (TB), Hepatitis B, Hepatitis C, and Human Immunodeficiency Virus (HIV) (Sacuk et al., 2021). In certain medical procedures, particularly invasive procedures involving blood and bodily fluids, there is a potential risk of disease transmission that may endanger patients (Beers, 2021).

This issue not only raises medical risks but also legal questions concerning professional responsibility, the protection of patients' rights, and the protection of healthcare workers' rights. On one hand, patients have the right to receive safe healthcare services free from the risk of infection (Millar, 2011; World Health Organization, 2021). On the other hand, healthcare workers also have the right to employment protection, confidentiality of medical conditions, and non-discriminatory treatment as guaranteed under labor and human rights regulations (Nardodkar et al., 2016). This situation creates a legal dilemma between protecting healthcare workers' rights and ensuring patient safety obligations. Regulations on patient safety in Minister of Health Regulation No. 11 of 2017 on Patient Safety and Minister of Health Regulation No. 27 of 2017 on Infection Prevention and Control still place greater emphasis on service systems and infection control procedures. These regulations do not specifically regulate periodic health examinations, screening for infectious diseases, or practice restrictions for healthcare workers with certain infectious conditions. This indicates a normative gap in Indonesia's health law framework.

In high-risk healthcare services, such as hemodialysis units, viral infection control is a critical aspect. The Indonesian Nephrology Association (Perhimpunan Nefrologi Indonesia/Pernefri), through its National Hemodialysis Consensus, states that both patients and healthcare workers in dialysis units are at high risk of transmission of Hepatitis B, Hepatitis C, and HIV. Therefore, Pernefri recommends preventive measures such as routine screening of patients and healthcare workers, patient isolation based on infection status, the use of dedicated dialysis machines, strict infection prevention standards, and Hepatitis B vaccination for healthcare workers. However, these recommendations remain professional standards and do not yet have explicit binding force in statutory regulations.

This condition shows a gap between professional norms and legal norms in ensuring patient safety. Current regulations in Indonesia do not explicitly regulate supervisory mechanisms, periodic health screening, or risk-based practice restrictions for healthcare workers with infectious diseases. In contrast to Indonesia, several countries such as the United States, through the Centers for Disease Control and Prevention (CDC), and the United Kingdom, through the National Health Service (NHS), have implemented a risk-based regulatory approach, which emphasizes the level of risk of medical procedures rather than solely focusing on the disease status of healthcare workers.

Based on these issues, a more comprehensive legal study is needed regarding the health obligations of medical personnel and healthcare workers as part of patient safety protection. This research contains novelty as it not only discusses legal arrangements and professional liability of healthcare workers with infectious diseases but also proposes a risk-based regulatory model that integrates patient safety, protection of healthcare workers' rights, and a comprehensive health law approach. In this way, it is expected that a balance can be achieved between protecting healthcare workers' rights and patients' rights to receive safe and high-quality healthcare services.

## METHODS

### *Design and Study Approach*

This study employed a normative legal research design focusing on the analysis of legal norms and regulations related to healthcare workers with communicable diseases in relation to patient safety in Indonesia. The research utilized statutory, conceptual, and comparative approaches. The statutory approach involved examining relevant laws and regulations governing patient safety, healthcare professionals, infection prevention and control, and labor law. The conceptual approach was used to analyze legal principles in health law and bioethics, including patient safety, non-maleficence, beneficence, and the precautionary principle (Walshe & Boaden, 2005). The comparative approach was applied by comparing Indonesian regulatory frameworks with international guidelines such as those issued by the Centers for Disease Control and Prevention (CDC), United States, and the National Health Service (NHS), United Kingdom. This study did not involve human participants; therefore, no sampling, place of data collection, or time-bound fieldwork was required, as the research relied exclusively on legal documents and literature.

### *Research Instruments and Data Collection*

The primary research instrument was the researcher, who acted as the key tool for collecting, identifying, and interpreting legal materials. Data collection was conducted through documentary review of legal sources.

The legal materials consisted of:

1. Primary legal materials, including statutes, government regulations, ministerial regulations, and other relevant legal instruments in Indonesia.
2. Secondary legal materials, including scientific journal articles, books, research reports, and international organizational guidelines.
3. Tertiary legal materials, including legal dictionaries and supporting reference literature.

Data were collected through systematic library research by identifying, selecting, and categorizing relevant legal documents from national and international sources.

### *Data Analysis*

The data were analyzed using qualitative legal analysis. The analytical process included grammatical interpretation to understand the literal meaning of legal texts, systematic interpretation to examine the relationship between legal norms, and legal harmonization analysis to assess consistency across regulations. The analysis also evaluated the alignment of Indonesian regulatory frameworks with international patient safety principles and standards.

### *Research Process*

The research was conducted through several structured stages. First, relevant legal issues concerning healthcare workers with communicable diseases and patient safety were identified. Second, relevant legal materials were collected and categorized based on primary, secondary, and tertiary sources. Third, the selected legal materials were analyzed using statutory, conceptual, and comparative approaches. Finally, the findings were synthesized to evaluate the adequacy of Indonesian regulations in ensuring patient safety and to identify gaps in the regulatory framework in comparison with international standards.

### *Ethical Considerations*

This study is a normative legal research that relies exclusively on the analysis of written legal materials and publicly available documents. Therefore, it does not involve human participants, clinical data, or animal subjects. As such, formal ethical approval from an institutional review board was not required. Nevertheless, the study adhered to ethical standards of academic integrity by ensuring proper citation

and acknowledgment of all primary, secondary, and tertiary legal sources used. All materials were analyzed objectively and transparently to avoid misinterpretation or misrepresentation of legal texts. The research also maintained intellectual honesty by respecting copyright regulations and academic conventions in legal scholarship

## RESULTS

**Table 1.** Indonesian Legal and Regulatory Framework Related to Patient Safety, Healthcare Workers, and Communicable Diseases

| No | Legal Instrument | Year | Issuing Authority | Subject Matter |
|---|---|---|---|---|
| 1 | Constitution of the Republic of Indonesia (UUD 1945) | 1945 | Government of Indonesia | Fundamental legal basis for the right to health and state responsibility in healthcare provision |
| 2 | Law No. 44 of 2009 on Hospitals | 2009 | Government of Indonesia | Regulation on hospital obligations, including prioritization of patient safety |
| 3 | Law No. 17 of 2023 on Health | 2023 | Government of Indonesia | Comprehensive health law regulating healthcare services, standards, and rights of patients and healthcare workers |
| 4 | Law No. 11 of 2020 on Job Creation (Cipta Kerja) | 2020 | Government of Indonesia | Regulatory framework affecting labor and healthcare-related employment policies |
| 5 | Law No. 1 of 2023 on the Criminal Code (KUHP) | 2023 | Government of Indonesia | Criminal law provisions relevant to negligence and professional liability in healthcare practice |
| 6 | Government Regulation No. 88 of 2019 on Occupational Health | 2019 | Government of Indonesia | Regulation on occupational health standards, including healthcare workplace safety |
| 7 | Minister of Manpower and Transmigration Decree No. KEP.68/MEN/IV/2004 on HIV/AIDS Prevention in the Workplace | 2004 | Ministry of Manpower and Transmigration | Workplace HIV/AIDS prevention and non-discriminatory employment practices |
| 8 | Minister of Health Regulation No. 269/Menkes/Per/III/2008 on Medical Records | 2008 | Ministry of Health | Regulation on medical record management and confidentiality |
| 9 | Minister of Health Regulation No. 53 of 2015 on Viral Hepatitis Control in Indonesia | 2015 | Ministry of Health | National strategy for prevention and control of viral hepatitis |
| 10 | Minister of Health Regulation No. 66 of 2016 on Occupational Health and Safety in Hospitals | 2016 | Ministry of Health | Hospital occupational health and safety standards for healthcare workers |
| 11 | Minister of Health Regulation No. 11 of 2017 on Patient Safety | 2017 | Ministry of Health | Standards and systems for patient safety implementation in healthcare facilities |
| 12 | Minister of Health Regulation No. 27 of 2017 on Infection Prevention and Control | 2017 | Ministry of Health | Guidelines for infection prevention and control in healthcare settings |

## DISCUSSION

### *Legal Regulation of Healthcare Workers in the Perspective of Patient Safety*

Patient safety is a fundamental component of modern health law systems and is not merely an ethical obligation but also a legal duty imposed on medical personnel, healthcare workers, and healthcare facilities. From the perspective of occupational health and safety, healthcare providers are expected to undergo periodic medical examinations to ensure that they do not pose a risk of disease transmission to patients, particularly during invasive procedures involving blood and bodily fluids. Empirical evidence indicates that healthcare workers infected with Hepatitis B or Hepatitis C who perform invasive procedures may potentially transmit infections to patients, although the risk is relatively low when strict infection prevention standards are applied (Hebo et al., 2019; Henriot et al., 2022; Tavoschi et al., 2019). Nevertheless, such risks remain legally significant under the principles of due care and professional responsibility. In Indonesia, patient safety is constitutionally grounded in Article 28H paragraph (1) of the 1945 Constitution, which guarantees the right to healthcare services. This principle is further reinforced by Law No. 17 of 2023 on Health and Law No. 44 of 2009 on Hospitals, which require healthcare services to be safe, of high quality, and patient-centered. Ministerial regulations such as Minister of Health Regulation No. 11 of 2017 on Patient Safety and Regulation No. 27 of 2017 on Infection Prevention and Control provide operational frameworks for risk management and infection control. However, these regulations primarily focus on procedural and systemic aspects rather than the health status of individual healthcare workers. As a result, there remains a normative gap concerning mandatory health screening and risk-based practice restrictions for healthcare workers with communicable diseases.

### *Normative Conflict Between Healthcare Workers' Rights and Patient Safety*

A key issue in the regulation of healthcare workers with infectious diseases lies in the normative conflict between the protection of workers' rights and the obligation to ensure patient safety. Healthcare workers are entitled to employment rights, non-discrimination, and medical confidentiality under labor and human rights regulations, including Minister of Manpower and Transmigration Decree No. 68/MEN/IV/2004, which prohibits discrimination against workers with HIV/AIDS. On the other hand, patients are entitled to safe healthcare services free from preventable infection risks (Domer et al., 2022; Haque et al., 2020). This creates a legal tension between the right to work and the right to health. Such conflict cannot be resolved through discriminatory approaches but requires a proportional and risk-based regulatory framework. The principle of proportionality in health law suggests that restrictions on rights are justified only when necessary, evidence-based, and proportionate to the level of risk involved. In this regard, a risk-based regulatory approach becomes essential to reconcile both competing interests.

### *Legal Liability for Disease Transmission by Healthcare Workers*

Legal liability arising from the transmission of infectious diseases from healthcare workers to patients may be classified into civil, criminal, and administrative responsibility. Under civil law, Article 1365 of the Indonesian Civil Code establishes liability for unlawful acts causing harm, while Article 1366 extends liability to negligence. Hospitals may also be held vicariously liable under Article 1367 for the actions of healthcare personnel under their supervision. From a criminal law perspective, Articles 359 and 360 of the Criminal Code provide sanctions for negligence resulting in death or injury. If a healthcare worker knowingly performs high-risk procedures while carrying a communicable disease without adequate precautions, such conduct may constitute gross negligence. In administrative terms, healthcare workers may face sanctions ranging from warnings to license revocation for violations of professional and service standards, as regulated under Law No. 17 of 2023 on Health. These legal frameworks reflect the principle of duty of care, which obligates healthcare professionals to act prudently and avoid harm to patients (Walshe & Boaden, 2005).

### *Regulatory Gaps and Weaknesses in the Indonesian Health System*

Despite the existence of various legal instruments governing patient safety and infection control, significant regulatory weaknesses remain. First, there is no explicit obligation for periodic health screening of healthcare workers for communicable diseases such as tuberculosis, hepatitis, and HIV. Second, there is no clear legal framework regulating practice restrictions based on health conditions, creating legal uncertainty in clinical decision-making. Third, monitoring and enforcement mechanisms remain weak, particularly in the implementation of infection prevention and control (IPC) and occupational health and safety programs in hospitals. Fourth, there is no national standard governing fitness-to-practice assessments based on health status. These gaps demonstrate a legal vacuum that may

compromise patient safety and weaken regulatory certainty. The absence of explicit norms also indicates that current regulations are still insufficient to operationalize the principle of non-maleficence in concrete legal terms.

***International Comparison of Risk-Based Regulatory Approaches***

In contrast to Indonesia, countries such as the United States and the United Kingdom have implemented risk-based regulatory frameworks for healthcare workers with infectious diseases. The Centers for Disease Control and Prevention (CDC) in the United States allows healthcare workers with HIV or hepatitis to continue practicing under certain conditions, including restrictions on exposure-prone procedures, mandatory expert review panels, and viral load monitoring (Henderson et al., 2022). Similarly, the National Health Service (NHS) in the United Kingdom, through the UK Advisory Panel, applies strict guidelines requiring viral load monitoring and restricting exposure-prone procedures for infected healthcare workers. Both systems emphasize risk management rather than categorical exclusion. Compared to these jurisdictions, Indonesia remains limited in adopting risk-based classification, mandatory monitoring systems, and clear procedural restrictions, thereby highlighting its regulatory lag in addressing patient safety risks.

***Case Illustration: Hepatitis B Transmission in Hemodialysis Settings***

A relevant illustrative case involves a nurse working in a hemodialysis unit diagnosed with Hepatitis B who continued performing high-risk procedures such as vascular access and wound care. Subsequently, a patient undergoing dialysis was diagnosed with Hepatitis B, with epidemiological investigation suggesting possible nosocomial transmission. The case highlights systemic failures, including the absence of periodic screening, lack of practice restrictions, and weak infection control implementation. Legally, the case may give rise to civil liability for medical negligence, criminal liability under negligence provisions, and administrative sanctions against the hospital. More importantly, it demonstrates that patient safety is not solely dependent on procedural compliance but also on the health status of healthcare providers.

***Discussion and Analytical Findings***

The findings indicate that current Indonesian health regulations are insufficiently responsive to the practical risks encountered in healthcare settings. There is a significant gap between general legal norms and specific clinical risks, resulting in legal uncertainty and insufficient patient protection. The absence of mandatory health screening and risk-based practice restrictions reflects a substantial legal vacuum. Furthermore, there is an imbalance between protecting healthcare workers' rights and ensuring patient safety, necessitating comprehensive regulatory reform. Strengthening regulation, standardizing fitness-to-practice criteria, enhancing hospital monitoring systems, and ensuring balanced protection of rights are essential policy directions. Without such reforms, Indonesia's health law system will continue to lag behind international standards.

***Proposed Risk-Based Integrated Health Regulation Model***

This study proposes a "Risk-Based Integrated Health Regulation" model based on three fundamental principles: patient safety priority, non-discrimination, and risk-based regulation. The model introduces mandatory periodic health screening for healthcare workers, classification of medical procedures based on risk levels, and adaptive practice restrictions rather than outright prohibition. Procedures are categorized into high, medium, and low risk, with restrictions applied proportionally based on clinical risk. The model also strengthens the role of hospital occupational health and patient safety committees through expert panel mechanisms similar to those implemented by the CDC and NHS. This approach ensures that healthcare workers with infectious diseases may continue working under appropriate restrictions while maintaining patient safety.

The model offers several advantages, including resolving the normative conflict between patient rights and worker rights, aligning Indonesian regulations with international standards, and providing a concrete and implementable legal framework. If adopted, the model is expected to reduce infection risks in healthcare settings, provide legal certainty for healthcare institutions, and ensure a balanced protection of rights. Ultimately, this framework contributes to the development of a more integrated and risk-sensitive health law system in Indonesia

## CONCLUSION

Regulations in Indonesia concerning healthcare workers with communicable diseases remain insufficiently comprehensive in governing periodic health screening obligations, risk-based practice restrictions, and patient safety–oriented supervisory mechanisms, resulting in normative gaps and legal uncertainty in the protection of patient safety. Compared to international standards such as those of the CDC and NHS, Indonesia has not yet fully implemented an optimal risk-based regulatory approach. Therefore, a reformulation of risk-based health regulation is needed to integrate patient safety protection, healthcare workers' rights, and a proportional national supervisory system. The proposed "Risk-Based Integrated Health Regulation" model in this study is expected to serve as a foundation for developing a more comprehensive regulatory framework within Indonesia's health law system. The Indonesian government should develop national regulations on periodic health screening for medical and healthcare personnel, the Ministry of Health should formulate national guidelines on risk-based practice restrictions, hospitals should strengthen monitoring systems for healthcare workers' health status, harmonization between health law and labor law should be conducted to balance healthcare worker protection and patient safety, and further research should be undertaken to assess the implementation of a risk-based regulatory model within Indonesia's healthcare system.

## CONFLICTS OF INTEREST

No conflict of interest of this study.

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