

LEGAL REALISM AND HEALTH CRIMINAL LAW REFORM IN THE ERA OF MEDICAL AND TECHNOLOGICAL ADVANCES

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Abstract

Health criminal law faces evolving challenges driven by rapid technological advancements and shifting social dynamics. Issues such as medical malpractice, drug counterfeiting, patient data privacy, and equitable access to healthcare require legal frameworks that are both adaptive and rights-based. However, Indonesia's current legal regulations often fall short in addressing these complex realities, revealing a gap between normative provisions and practical implementation. This research analyses the challenges of enforcing health criminal law in the modern era through the lens of legal realism and proposes adaptive legal solutions. Utilising normative legal research, including statutory and conceptual approaches, the study examines primary, secondary, and tertiary legal materials to assess the responsiveness of existing regulations. The findings highlight legal uncertainty, weak enforcement mechanisms, and insufficient alignment with technological and ethical developments. The novelty of this study lies in offering an integrated framework based on legal realism that emphasises pragmatic and contextually informed legal reform. Proposed solutions include comprehensive regulatory reform, restorative justice approaches, professional capacity-building, transparent oversight mechanisms, clear standards of criminal liability, and stronger protections against drug counterfeiting and patient data breaches. The study emphasises the need to strike a balance between law enforcement and human rights protection in the context of technological innovation in healthcare.

Keywords: *health criminal law, technology, realism, malpractice.*

Abstrak

Hukum pidana kesehatan menghadapi tantangan baru akibat kemajuan teknologi dan perubahan sosial yang pesat. Isu seperti malpraktik medis, pemalsuan obat, privasi data pasien, dan akses layanan kesehatan yang adil menuntut pendekatan hukum yang adaptif dan berkeadilan. Namun, regulasi yang berlaku di Indonesia belum mampu mengakomodasi kompleksitas tersebut secara efektif, sehingga menimbulkan kesenjangan antara norma hukum dan realitas praktik. Penelitian ini bertujuan untuk menganalisis tantangan penerapan hukum pidana kesehatan dari perspektif realisme hukum dan merumuskan solusi adaptif terhadap persoalan kontemporer. Metode yang digunakan adalah penelitian hukum normatif dengan pendekatan perundang-undangan dan konseptual melalui analisis bahan hukum primer, sekunder, dan tersier. Hasil penelitian menunjukkan bahwa pendekatan realisme hukum dapat memberikan dasar yang lebih kontekstual dan pragmatis dalam merespons dinamika sektor kesehatan. Kebaruan penelitian ini terletak pada tawaran

solusi berupa penguatan regulasi komprehensif, penerapan keadilan restoratif, peningkatan kompetensi tenaga medis, pengawasan transparan, standar pertanggungjawaban pidana yang jelas, serta perlindungan terhadap data pasien dan pemalsuan obat. Penelitian ini menekankan pentingnya keseimbangan antara penegakan hukum dan perlindungan hak asasi manusia dalam menghadapi perkembangan teknologi kesehatan.

Kata Kunci: *hukum pidana kesehatan, malpraktik, teknologi, realisme.*

Introduction

Criminal law serves the primary function of enforcing social order, protecting public interests, and safeguarding individual rights from detrimental actions. In the realm of healthcare, criminal law plays a crucial role in maintaining the integrity of healthcare services, protecting patient rights, and regulating actions that conflict with medical ethics and the law.¹ Along with the development of science, technology, and social change in the modern era, Health Criminal Law faces increasingly complex challenges.²

The development of health technology, particularly over the last two decades, has led to numerous significant advances. These include innovations in disease diagnosis and the development of medical devices, as well as advances in treatment techniques such as gene therapy and assisted reproductive technology.³ On the one hand, these innovations hold great promise for enhancing the quality of life in the community; on the other hand, they also present new legal challenges. For example, the use of artificial intelligence in diagnosing diseases can raise dilemmas regarding criminal liability in the event of errors or malpractice.⁴ Likewise, assisted reproductive technology has sparked debates about the rights and obligations of parents, children, and healthcare providers.

The increasingly complex relationship between criminal law and health issues, especially in the context of human rights. In criminal law studies, human rights discussions have traditionally centred on the protections afforded to suspects, defendants, and convicted individuals. However, given that criminal law is deeply rooted in principles of retribution and offender accountability, this emphasis on victims' rights, while significant, risks narrowing the broader human rights discourse within the field of criminal law. To strengthen the analytical foundation, it would be beneficial to situate the protection of victims within a

¹ Jonathan Montgomery, "Medicalizing Crime—Criminalizing Health? The Role of Law," in *The Criminal Justice System and Health Care* (Oxford University Press, 2007), 257–72, <https://doi.org/10.1093/acprof:oso/9780199228294.003.0015>.

² Zainab Ompu Jainah, *Kapita Selektta Hukum Pidana* (Tangerang: Tira Smart, 2018).

³ Aswin Thacharodi et al., "Revolutionizing Healthcare and Medicine: The Impact of Modern Technologies for a Healthier Future—A Comprehensive Review," *Health Care Science* 3, no. 5 (October 9, 2024): 329–49, <https://doi.org/10.1002/hcs2.115>.

⁴ Mohammad Hussein Al-Ahmad and Istabraq Saad Al-Khazraji, "Criminal Liability for Artificial Intelligence Crimes," in *Studies in Computational Intelligence*, 2025, 575–87, https://doi.org/10.1007/978-3-031-74220-0_45.

more holistic framework—one that ensures a balanced consideration of the rights of all parties involved. Integrating the rights of victims alongside the foundational legal principles of due process, a fair trial, and proportionate sentencing would deepen the discussion and reflect a more comprehensive approach to justice.⁵

The development of medical technology, social dynamics, and global challenges, such as the COVID-19 pandemic, has demonstrated that the health aspect is not only a medical matter but also closely related to the law, particularly in criminal law enforcement.⁶ In this context, Health Criminal Law plays an essential role in regulating actions that can endanger public health, whether carried out individually or institutionally. However, in practice, the application of criminal law in the health sector often faces a humanitarian dilemma. On the one hand, criminal law aims to maintain social order and provide sanctions for violations. However, on the other hand, there is a humanitarian dimension that must be considered, particularly regarding patient rights, the professional responsibilities of medical personnel, and the community's right to receive adequate health services.⁷ For example, cases of medical malpractice, drug abuse, or the spread of misleading health information all require a balanced approach that balances the enforcement of rules with the protection of fundamental human rights.

In Indonesia, several high-profile incidents have demonstrated the need for robust legal intervention to protect patients' rights, ensure ethical medical practice, and maintain public trust. A relevant case that exemplifies this issue is the Siloam Hospital case in 2021, where a patient's family assaulted a nurse after a perceived error in intravenous treatment. Although the nurse was the victim, the incident sparked widespread debate on medical professionalism, patient rights, and the legal obligations of hospitals to ensure both safety and ethical conduct in healthcare settings. This case highlighted the need for clearer legal standards and protections regarding alleged malpractice, as well as the proper channels for dispute resolution.

Legal realism, as a jurisprudential approach that considers law not merely as a set of abstract norms but as a product of social, institutional, and practical realities, offers a relevant and pragmatic lens for analysing the development and enforcement of Health Criminal Law in contemporary society. Legal realism not only focuses on written legal norms but also highlights how the law is applied

⁵ Victorian Law Reform Commission, *The Role of Victims of Crime in the Criminal Trial Process : Report*, 2016.

⁶ Junia Putri et al., “Prespektif Hukum Kesehatan Dalam Penyelenggaraan Layanan Kesehatan Berbasis Digital Kedokteran Jarak Jauh (Telemedicine),” *Jurnal Rectum: Tinjauan Yuridis Penanganan Tindak Pidana* 6, no. 2 (2024), <https://doi.org/http://dx.doi.org/10.46930/jurnalrectum.v6i2.4127>.

⁷ Muhammad Ali Ausath, “Upaya Penerapan Ekosida Sebagai Kejahatan Luar Biasa Di Indonesia,” *Litra: Jurnal Hukum Lingkungan, Tata Ruang, Dan Agraria* 2, no. 1 (October 31, 2022): 115–28, <https://doi.org/10.23920/litra.v2i1.1091>.

and understood in practice. The importance of this issue lies in the fact that Health Criminal Law encompasses not only written legal provisions but also the complex interactions among patients, medical professionals, the pharmaceutical industry, and society as a whole.⁸ In many cases, the difference between legal theory and practice in the field is often a source of injustice or abuse of power.

One of the significant challenges facing Health Criminal Law in the modern era is the issue of criminal liability in the context of medical malpractice. Medical malpractice refers to errors or omissions in the provision of medical care that result in harm or danger to patients. In Indonesia, cases of medical malpractice often spark controversy because it is challenging to determine the boundaries between errors that are subject to criminal sanctions and those that are merely violations of professional ethics.⁹ In this context, legal realism emphasises the importance of considering practical aspects, such as the condition of health facilities, the workload of medical personnel, and the level of patient understanding of the risks of treatment. Additionally, the issue of counterfeiting drugs and medical devices is a crucial concern in criminal healthcare law. Counterfeiting drugs not only endangers public health but also threatens trust in the health system as a whole. The circulation of counterfeit medicines often involves organised crime networks, so handling it requires cooperation between law enforcement, health institutions, and regulators at the national and international levels. The perspective of legal realism in this context emphasises the importance of a pragmatic approach in enforcing the law, namely by combining strict criminal law enforcement with strict supervision of the distribution chain of drugs and medical devices.¹⁰

While criminal sanctions were widely applied during the COVID-19 pandemic in Indonesia, public resistance highlighted a disconnect between legal enforcement and societal acceptance. Existing studies have primarily focused on the normative aspects of public health law, with limited attention given to how legal realism can inform more socially grounded approaches to enforcement.¹¹ This study addresses that gap by exploring the application of legal realism to bridge the divide between legal authority and public legitimacy in times of health crises.

Additionally, the modern era is also characterised by an increasing number of cases involving violations of patient privacy rights. The primary causes of these breaches were hacking and IT incidents, accounting for 81.2% of significant

⁸ Yoserwan, *Doktrin Ultimium Remedium Dalam Hukum Pidana Indonesia (Implementasinya Dalam Hukum Pidana Ekonomi)* (Padang: Andalas University Press, 2019).

⁹ Sutarno, *Hukum Kesehatan Kontemporer: Prinsip, Perkembangan Kajian Dan Permasalahan* (Surabaya: Fakultas Hukum UHT Surabaya, 2019).

¹⁰ Reda Mantovani, "Perlindungan Konsumen Terhadap Tindak Pidana Pemalsuan Obat," *Jurnal Magister Ilmu Hukum* 6, no. 2 (August 30, 2023): 78, <https://doi.org/10.36722/jmih.v6i2.2315>.

¹¹ Aras Firdaus and Rudy Hendra Pakpahan, "Kebijakan Hukum Pidana Sebagai Upaya Penanggulangan Kedaruratan Covid-19," *Majalah Hukum Nasional* 50, no. 2 (December 15, 2020): 201–19, <https://doi.org/10.33331/mhn.v50i2.61>.

healthcare data breaches in 2024. With the increasing digitalisation of health data, including electronic medical records, the risk of data leakage is also on the rise. Health data is very sensitive information, and patient privacy must be strictly protected. In many countries, including Indonesia, violations of patient privacy can be subject to criminal sanctions. In Indonesia, several laws specifically regulate the protection of patient data and impose penalties for breaches of this regulation. Law Number 29 of 2004 concerning Medical Practice stipulates that any physician or dentist who intentionally discloses medical confidentiality, except for law enforcement purposes, may be subject to imprisonment for up to one year and/or a fine of up to IDR 50,000,000. Additionally, Law Number 36 of 2009 concerning Health guarantees every individual's right to the confidentiality of their health information, while Article 322 of the Indonesian Criminal Code (KUHP) provides criminal penalties for anyone who unlawfully discloses secrets obtained through their professional position. However, the complexity of digital data management often makes it difficult to determine who should be held responsible when a data leak occurs.¹²

In this case, legal realism requires that criminal law not only focus on normative violations but also consider technical and operational factors that affect data management. The legal realism approach is also relevant in addressing ethical issues in modern medical practice. For example, the practice of euthanasia, which has been legally recognised in several countries, is still controversial in many jurisdictions, including Indonesia. Although euthanasia is generally prohibited by Indonesian criminal law, there is a growing debate about the patient's right to choose to end their life in a terminally ill condition. In cases like this, criminal law must strike a balance between protecting human rights and upholding the moral and ethical values of society. Legal realism, with its focus on social context and pragmatism, can guide the formulation of solutions that align with the realities on the ground.¹³

In this modern era, the challenges in Health Criminal Law are increasingly strengthened by globalisation, which expands the reach of health problems across countries. In addition, the development of health technology and the digitalisation of the healthcare system also present new challenges, including patient data privacy, misuse of medical technology, and fraud in digital-based healthcare services.¹⁴ In this case, the legal realism approach offers a relevant view, namely, how the law

¹² Riska Pradita, Retno Kusumo, and Rahmawati, "Pentingnya Aspek Keamanan Informasi Data Pasien Pada Penerapan Rme Di Puskesmas," *Journal Of Sustainable Community Service* 2, no. 2 (March 30, 2022): 52–62, <https://doi.org/10.55047/jscs.v2i2.437>.

¹³ Lintang Ardiansyah et al., "Analisis Tindakan Eutanasia Dalam Perspektif Hukum Islam Dan Kode Etik Kedokteran Indonesia," *Hukum Inovatif: Jurnal Ilmu Hukum Sosial Dan Humaniora* 1, no. 3 (2024), <https://doi.org/https://doi.org/10.62383/humif.v1i3.318>.

¹⁴ Hassan Mumtaz et al., "Current Challenges and Potential Solutions to the Use of Digital Health Technologies in Evidence Generation: A Narrative Review," *Frontiers in Digital Health* 5 (September 2023), <https://doi.org/10.3389/fdgh.2023.1203945>.

can be applied realistically by taking into account dynamic social conditions and the need for substantive justice, especially in issues that intersect with health and humanity.

Another challenge facing Health Criminal Law in the modern era is the problem of accessibility to adequate health services. Although health services are a universally recognised fundamental right, in reality, many people still do not receive adequate health services. Such conditions are often driven by the unequal distribution of medical resources, the high cost of treatment, or even discriminatory practices in healthcare services. In some instances, these forms of injustice in accessing health services may lead to violations of criminal law, including patient neglect or discriminatory treatment in medical care. The legal realism approach, in this case, encourages the application of criminal law that is more sensitive to the social and economic context by considering the conditions that affect access to health services.¹⁵

In addition, advances in biotechnology, such as gene editing and cloning, also pose new challenges for health and criminal law. These technologies have great potential to cure diseases previously considered incurable, but they also pose significant risks of misuse. For example, gene editing carried out without permission or outside the boundaries of what is ethically and legally permissible can raise major problems, both in terms of health and morality.¹⁶ In this case, criminal law must be able to anticipate technological developments and provide a clear legal framework to protect society from potential dangers.

This study adopts a legal realist approach to contemporary issues in health criminal law, with a particular emphasis on the rights and protection of victims. By centring its analysis on victims' perspectives, the study aims to offer fresh insights and practical solutions to current legal challenges. This clear focus enhances the study's relevance and impact within legal scholarship, ensuring that its arguments and recommendations are both coherent and aligned with its stated objectives.

Methods

This study employs a normative legal research method, focusing on analysing written legal norms, their interpretation, and implementation in Indonesia's criminal healthcare law, particularly regarding medical malpractice, patient privacy, and drug counterfeiting. The research employs a statutory approach to examine relevant national and international regulations, including Law No. 36 of 2009 on Health and Law No. 29 of 2004 on Medical Practice, to identify their practical application and implementation challenges.

¹⁵ Rinna Dwi Lestari, *Rekonstruksi Regulasi Perlindungan Hukum Bagi Dokter Dan Pasien Dalam Pelayanan Kesehatan Melalui Telemedicine Berbasis Nilai Keadilan* (Semarang: Universitas Islam Sultan Agung, 2023).

¹⁶ Evy Yulianti et al., *Rekayasa Genetika* (Purbalingga: Eureka Media Aksara, 2024).

Complementing this, a conceptual approach is employed to explore legal theories, particularly legal realism, to understand how social context influences the application of health criminal law. This approach facilitates the analysis of key concepts, including criminal liability, medical malpractice, patient privacy, and health technology, in contemporary legal practice. The data sources comprise primary legal materials (laws, court decisions, and international instruments), secondary materials (books and academic articles on health, criminal law, and legal realism), and tertiary materials (legal encyclopedias and dictionaries). Data collection relies on document and library research, including a review of court decisions to assess judicial application of health criminal law.

The analysis combines descriptive methods to clarify the substance and formulation of legal rules and evaluative methods to assess the effectiveness of these laws in addressing modern challenges, such as technological advancements and data privacy. Finally, the study evaluates how the legal realism framework can enhance the responsiveness and adequacy of health criminal law in practice.

Result and Discussion

Challenges of Implementing Health Criminal Law in the Modern Era Reviewed from the Perspective of Legal Realism

Health Criminal Law is a subset of criminal law that regulates and controls the behaviour of individuals and organisations in the context of health.¹⁷ In the modern era, the application of Health Criminal Law faces complex challenges alongside the rapid development of medical technology, social change, and globalisation.¹⁸ In this context, the legal realism approach provides a relevant framework for understanding and addressing these challenges, as it emphasises that law must reflect social reality and be applied realistically rather than merely as a normative text.

In Health Criminal Law, various new challenges arise due to significant changes in modern society, especially those caused by the development of medical technology and biotechnology.¹⁹ Technologies such as telemedicine, the use of artificial intelligence (AI) in medical diagnosis, and biotechnological innovations, including genetic engineering and gene therapy, all provide significant benefits to the healthcare industry. Despite the significant benefits, the use of health technology also presents various risks that may result in legal complications, particularly

¹⁷ Vid Jakulin, "Criminal Offences against Public Health under the Criminal Code of the Republic of Slovenia," *Medicine, Law & Society* 13, no. 1 (2020), <https://doi.org/10.18690/mls.13.1.45-66>.2020.

¹⁸ Nataliya Gutorova, Oleksandr Zhytnyi, and Oleksii Soloviov, "Falsification of Medical Products: Criminal Law Mechanism Combating Threats to Public Health," *Wiadomosci Lekarskie (Warsaw, Poland : 1960)* 72, no. 5 cz 1 (2019): 856–61.

¹⁹ Yeung Lap Fu, "A Study on Medical Biotechnology System from Legal Perspective," *Journal of Commercial Biotechnology* 23, no. 4 (February 1, 2018), <https://doi.org/10.5912/jcb822>.

when errors occur or the technology is misused.²⁰ In addressing these challenges, legal realism offers a relevant analytical framework, as it emphasises the importance of considering social context, empirical conditions, and practical consequences in legal interpretation and enforcement.²¹

According to the legal realism view, law cannot be separated from the social practices that surround it. One of the leading figures in this school, Oliver Wendell Holmes Jr., stated that law is not just written regulations but must be seen from the perspective of how the law is applied in real life.²² In the context of Health Criminal Law, this approach is crucial for understanding how criminal law regulations governing the healthcare sector operate in the evolving realities of the medical world. New challenges, such as criminal liability for malpractice involving technology, cannot be addressed by simply referring to the text of the regulations; instead, they must consider the practices that develop in the field and the social impact of applying the technology.²³

The challenge of implementing criminal law in the context of health and humanity in the modern era, viewed from the perspective of legal realism, lies in how the law can adapt to the complexity of rapidly developing health problems while maintaining balance with humanitarian principles. The perspective of legal realism emphasises the importance of understanding the law in its social context, where the law cannot be applied rigidly without considering the conditions and social dynamics that influence it.²⁴ In the case of Health Criminal Law, legal realism demands a pragmatic approach, which not only focuses on formal rules but also considers the real effects of law application on human life.

One of the primary challenges in applying Health Criminal Law in the modern era is the increasing number of cases related to medical malpractice, patient rights violations, and the misuse of medical technology. In situations like this, criminal law faces a dilemma between maintaining social order and protecting individual rights.²⁵ For example, in cases of malpractice, the law must enforce the

²⁰ E. Coiera, J. Ash, and M. Berg, "The Unintended Consequences of Health Information Technology Revisited," *Yearbook of Medical Informatics* 25, no. 01 (August 6, 2016): 163–69, <https://doi.org/10.15265/IY-2016-014>.

²¹ Novita Ardiyanti et al., "Legal Responsibility For The Use Of Artificial Intelligence In Medical Practice," *De'rechtsstaat* 10, no. 1 (March 31, 2024): 121–32, <https://doi.org/10.30997/jhd.v10i1.11323>.

²² Horacio J. J. Piombo, "The Legal Pragmatism of Oliver Wendell Holmes, Jr. And the Predictive Theory of Law," *Doxa. Cuadernos de Filosofía Del Derecho*, no. 43 (June 1, 2020): 189, <https://doi.org/10.14198/DOXA2020.43.08>.

²³ Indra Rahmatullah, "Filsafat Realisme Hukum; Konsep Dan Aktualisasinya Dalam Hukum Bisnis Di Indonesia," *Adalah* 5, no. 3 (June 27, 2021), <https://doi.org/10.15408/adalah.v5i3.21395>.

²⁴ Setyo Utomo, "Tantangan Hukum Modern Di Era Digital," *Jurnal Hukum Media Bhakti* 1, no. 1 (February 2020), <https://doi.org/10.32501/jhmb.v1i1.5>.

²⁵ Gede Gilang Adi Wiraditya and I Dewa Made Suartha, "Pertanggungjawaban Pidana Dalam Malapraktik Kedokteran Dalam Perspektif Hukum Kesehatan Indonesia," *Jurnal Kertha Desa* 1, no. 2023 (9AD).

legal responsibility of medical personnel while also acknowledging that the medical profession is inherently full of risks and uncertainties. The perspective of legal realism encourages flexibility in the application of rules, allowing for the realisation of substantive justice, taking into account the context in which medical personnel work and the limitations they may face.

Additionally, another challenge is how criminal law can respond to developments in health technology, such as the use of big data, artificial intelligence (AI), and telemedicine, which can introduce new risks to public health. For example, violations of patients' medical records and their misuse. In this context, legal realism requires dynamic rules that can adapt quickly to technological changes and global challenges without compromising the fundamental goal of protecting human rights, including the right to health.²⁶ For example, in the case of the use of artificial intelligence (AI) in medical diagnosis, criminal law faces the question of who should be held responsible if an error occurs in the diagnosis made by the AI system. Does the responsibility lie with the doctor who uses AI, the software developer, or even the hospital that facilitates the use of the technology? In the modern era, global challenges such as the pandemic also underscore the importance of striking a balance between the application of criminal law and humanitarian considerations. When health policies such as social restrictions, vaccinations, or mandatory isolation are implemented, criminal law is often used as an instrument to enforce compliance. However, the perspective of legal realism requires us to consider how these policies affect the lives of individuals, especially those who are most socially and economically vulnerable. The application of criminal law that is too harsh without considering societal conditions can lead to injustice and even exacerbate inequality in access to healthcare services.²⁷

The lack of clarity in Indonesia's regulations regarding criminal liability for the use of advanced medical technologies, such as AI, can largely be attributed to the fact that the relevant laws, namely Law No. 29 of 2004 on Medical Practice and Law No. 36 of 2009 on Health, were enacted before the emergence of artificial intelligence in healthcare. As a result, these laws do not address the unique legal challenges posed by modern technologies. Such a condition reflects a significant legal loophole, particularly in light of the growing use of artificial intelligence and other medical technologies in contemporary healthcare systems.²⁸ This situation underscores the need for a comprehensive revision of Indonesia's health legislation to ensure it remains relevant and effective in regulating the use of advanced medical

²⁶ Sibro Mulisi, *Argumentasi Hukum Kedudukan Kecerdasan Buatan Di Indoneisa* (Surabaya: Universitas 17 Agustus, 2018).

²⁷ Siska Elvandari, "Penerapan Sanksi Terhadap Tempat Usaha Yang Tidak Gunakan Aplikasi Peduli Lindungi Dalam Perspektif Hukum Kesehatan Di Indonesia," *UNES Journal of Suara Justisia* 7, no. 1 (April 2023): 220, <https://doi.org/10.31933/ujsj.v7i1.317>.

²⁸ Muhamad Azhar and Utik Handayani, "Perlindungan Hukum Terhadap Korban Malpraktik Layanan Kesehatan Berbasis Telemedicine," *Law, Development and Justice Review* 6, no. 1 (April 2023): 51–65, <https://doi.org/10.14710/ldjr.6.2023.51-65>.

technologies, including AI. Without such updates, legal uncertainty will persist, potentially hindering innovation and the safe integration of new technologies into medical practice.

From the perspective of legal realism, Health Criminal Law must consider these changes in the medical field and adjust its regulations to reflect the realities of the field. This approach emphasises that the law must be pragmatic and adapt to technological developments. Otherwise, a legal vacuum will result in difficulties in enforcing criminal responsibility.²⁹ Thus, the legal realism approach proposes that Health Criminal Law integrates the practical aspects of medical technology use, including aspects of shared responsibility among doctors, technology developers, and health institutions.

In addition to AI, the development of biotechnology, including genetic engineering and gene therapy, also presents new challenges in Health Criminal Law. Gene therapy aimed at treating genetic diseases has excellent potential in the medical world, but on the other hand, its uncontrolled use can pose a significant risk to public health. In this context, legal realism encourages regulations that not only focus on the technical and scientific aspects but also on the social impacts of applying this technology. Legal realism acknowledges that criminal law must be capable of protecting the public from the potential misuse of medical technology, including in matters related to gene therapy or human genetic manipulation.³⁰

One of the most frequent health criminal law issues of concern in many countries, including Indonesia, is the case of medical malpractice. In the modern era, malpractice is not only limited to medical errors in care provision but also encompasses failures in the use of new medical technologies, such as surgical robots or diagnostic devices that utilise artificial intelligence.³¹ Such factors contribute to the increasing complexity of determining criminal liability in cases of medical malpractice. In the Indonesian context, Article 359 of the Criminal Code regulates criminal penalties for negligence causing death or serious injury, which is often the legal basis for medical malpractice cases. However, with the advancement of technology, this law is usually considered inadequate to handle cases involving sophisticated technology. For example, in the case of an error caused by an AI device that misdiagnoses a disease, it is difficult to determine whether the doctor can be entirely blamed if they used the device correctly.³²

²⁹ Rahmatullah, "Filsafat Realisme Hukum; Konsep Dan Aktualisasinya Dalam Hukum Bisnis Di Indonesia."

³⁰ Dyah Ayu Widyastuti, "Terapi Gen: Dari Bioteknologi Untuk Kesehatan," *Al-Kauniah: Jurnal Biologi* 10, no. 1 (April 30, 2017), <https://doi.org/10.15408/kauniah.v10i1.4864>.

³¹ Setyo Trisnadi, "Perlindungan Hukum Profesi Dokter Dalam Penyelesaian Sengketa Medis," *Masalah-Masalah Hukum* 45, no. 2 (April 19, 2016): 150, <https://doi.org/10.14710/mmh.45.2.2016.150-156>.

³² Aria Chandra Gunawan, Dika Yudanto, and Amir Junaidi, "Tinjauan Hukum Pidana Terhadap Tindakan Malpraktek Dalam Bidang Kesehatan Atau Medis," *Unes Law Review* 6,

In the context of Indonesian law, Article 359 of the Criminal Code (KUHP) establishes criminal liability for negligence resulting in death or serious injury. The main elements of this article include (1) the existence of a negligent act, (2) the occurrence of death or serious injury as a consequence, and (3) a causal relationship between the negligent act and the resulting harm. When this provision is applied to cases involving artificial intelligence (AI) in medical practice, the assessment of negligence becomes increasingly complex. If a doctor follows established procedures but an AI device misdiagnoses a disease, it raises questions regarding the fulfilment of the negligence element. Specifically, it becomes challenging to determine whether a doctor's actions can be classified as negligent if they have relied on AI in accordance with prevailing standards and protocols. Consequently, the application of Article 359 KUHP to cases involving AI requires a careful analysis of whether the human operator's conduct deviated from the standard of care or whether the error was primarily attributable to the limitations or malfunction of the AI technology itself. This complexity underscores the need for updated legal frameworks that clearly define the boundaries of liability in the era of advanced medical technology.

The legal realism approach, which emphasises the importance of viewing law in its social context, provides a solution by suggesting that criminal responsibility should be viewed more holistically. In this case, not only should doctors be held responsible, but also the software development companies and medical institutions that provide the technology.³³ With a more realistic and pragmatic approach, Health Criminal Law can be more effective in handling malpractice cases involving modern technology. In addition, legal realism also emphasises the importance of considering contextual factors, such as the workload of medical personnel, the condition of health facilities, and the level of patient understanding of the risks of treatment. These factors often affect the outcome of medical actions taken. They must be taken into account in determining whether an action can be categorised as malpractice that is worthy of criminal sanctions.³⁴

In the modern era, privacy and security of health data are also serious challenges in health criminal law. With the increasing use of electronic medical records (EMRs) and the digitalisation of health data, the risk of data leakage is also on the rise. Health data is very sensitive and personal information, so violations of patient data privacy can have serious legal consequences.³⁵ In Indonesia, Law No.

no. 2 (2023), <https://doi.org/https://doi.org/10.31933/unesrev>.

³³ Rahmatullah, "Filsafat Realisme Hukum; Konsep Dan Aktualisasinya Dalam Hukum Bisnis Di Indonesia."

³⁴ Dudzai Mureyi, Nyaradzai Arster Katena, and Tsitsi Monera-Penduka, "Perceptions of Diabetes Patients and Their Caregivers Regarding Access to Medicine in a Severely Constrained Health System: A Qualitative Study in Harare, Zimbabwe," ed. Rajat Das Gupta, *PLOS Global Public Health* 2, no. 3 (March 2022): e0000255, <https://doi.org/10.1371/journal.pgph.0000255>.

³⁵ Rospita Adelina Siregar, "Penerapan Permenkes Nomor 24 Tahun 2022 Tentang Rekam Medis Terhadap Efektivitas Pelayanan Kesehatan," *Jurnal Ilmu Hukum Kyadiren* 5, no. 2 (2024),

27 of 2022 concerning the Protection of Personal Data protects personal data, including health data. The articles in this law regulate criminal sanctions for parties who collect, store, or process data without valid permission. Specifically, violations may result in imprisonment for up to four years and/or a fine of up to IDR 4,000,000,000 (four billion rupiah). However, in practice, law enforcement related to health data privacy violations still faces challenges, especially in determining responsibility when data leaks occur in complex digital health systems.

Legal realism emphasises that the application of criminal law in the context of health data privacy violations must take into account the technical aspects of digital data management. In many cases, data leaks can occur due to negligence of the security system, not solely the fault of individuals.³⁶ Therefore, the legal realism approach suggests that criminal law in these cases should not only target the individuals directly responsible but also the companies or service providers who failed to protect patient data. For example, in cases where an electronic medical record system is hacked and patient data is leaked, criminal responsibility may extend not only to the party that carried out the hack but also to the healthcare institution or technology vendor that failed to implement adequate security systems. This approach is more realistic in dealing with the complexity of digital technology and can provide more effective protection for patient privacy.³⁷

Counterfeiting of drugs and medical devices is a serious problem that is also a significant challenge in Health Criminal Law. In Indonesia, Law No. 36 of 2009 concerning Health, specifically Articles 196 and 197, regulates criminal sanctions for anyone who produces or distributes counterfeit drugs and medical devices. This violation not only harms society economically but also endangers public health in general.³⁸ Legal realism in this context emphasises the importance of strict law enforcement against drug counterfeiters, but also highlights that a repressive approach alone is not enough. Legal realism advocates for a more comprehensive approach, including tighter supervision of the drug distribution chain, public education about the dangers of counterfeit drugs, and collaboration between the government and the pharmaceutical industry to ensure that products circulating in the market are safe and meet standards.³⁹

<https://doi.org/https://doi.org/10.46924/jihk.v5i2.182>.

³⁶ Mateus De Oliveira Fornasier, "Freedom of Expression and the Metaverse: On the Importance of Content Creation for the Emergence of a Complex Environment," *Revista de Investigações Constitucionais* 10, no. 1 (December 2023): 236, <https://doi.org/10.5380/rinc.v10i1.87584>.

³⁷ Siti Ashira Salvina Day and Rahayu Subekti, "Pertanggungjawaban Penyedia Sistem Rekam Medis Elektronik Dari Partner System Terhadap Kebocoran Data," *Demokrasi: Jurnal Riset Ilmu Hukum, Sosial Dan Politik* 1, no. 3 (May 2024): 92–101, <https://doi.org/10.62383/demokrasi.v1i3.253>.

³⁸ Rusdiyanto, "Pertanggungjawaban Tindak Pidana Terhadap Pelaku Pemalsuan Obat," *Inkeracht* 2, no. 2 (2018).

³⁹ Rahmatullah, "Filsafat Realisme Hukum; Konsep Dan Aktualisasinya Dalam Hukum Bisnis

In law enforcement related to drug counterfeiting, legal realism also emphasises the importance of the role of the community and non-governmental institutions. The community needs to be encouraged to report cases of counterfeiting more actively, and health institutions must have transparent mechanisms in place to track and prevent the circulation of counterfeit drugs.⁴⁰ This approach is more realistic in dealing with problems that often involve complex and hidden criminal networks. Overall, the challenges of implementing Health Criminal Law in the modern era are diverse and complex, particularly due to the advancement of medical technology and digitalisation in the healthcare sector. From the perspective of legal realism, Health Criminal Law must be able to adapt to the changing realities on the ground. This approach emphasises the importance of considering the social and technological context in the application of the law, as well as the need for more flexible and pragmatic laws to respond to modern challenges.

Adopting a legal realist approach enables Health Criminal Law to respond more effectively to the real-world risks arising from technological advancements, such as medical malpractice involving artificial intelligence (AI), digital health data breaches, and the proliferation of counterfeit drugs.⁴¹ Legal realism emphasises that law should not be confined to normative texts alone but must also reflect how legal rules function in practice. This perspective encourages the development of legal frameworks that provide practical and meaningful protection for society.

The central challenge, then, is finding a fair balance: how to enforce legal norms that protect public health while also respecting individual rights in a landscape shaped by constant shifts in technology, social expectations, and ethical standards. Legal realism reminds us that the law must remain grounded in reality—adaptable to changing circumstances, sensitive to context, and always committed to achieving substantive justice.

Reform Strategies for Health Criminal Law Grounded in Legal Realism

Health Criminal Law, particularly in the modern era, faces various new challenges arising from technological developments, social changes, and growing public awareness of their rights in the health sector.⁴² The legal realism approach, which focuses on applying law in accordance with social conditions and realities, offers a relevant perspective for addressing these challenges.⁴³ Legal realism

Di Indonesia.”

⁴⁰ Yoserwan, *Doktrin Ultimum Remedium Dalam Hukum Pidana Indonesia (Implementasinya Dalam Hukum Pidana Ekonomi)*.

⁴¹ Elena V. Provodina, Oksana Yu. Krasovskaya, and Natalya A. Greshnova, “Fundamentals of Developing Legal Mechanisms for the Protection of Society in the Context of Scientific and Technological Progress,” 2023, 359–67, https://doi.org/10.1007/978-3-030-78083-8_34.

⁴² David Vandervort, “Medical Device Data Goes to Court,” in *Proceedings of the 6th International Conference on Digital Health Conference* (New York, NY, USA: ACM, 2016), 23–27, <https://doi.org/10.1145/2896338.2896341>.

⁴³ Patricia Mindus, “Realism Today: On Dagan’s Quest Beyond Cynicism and Romanticism in Law,” *International Journal for the Semiotics of Law - Revue Internationale de Sémiotique Juridique* 28, no. 2 (June 28, 2015): 401–22, <https://doi.org/10.1007/s11196-014-9397-2>.

emphasises that law is not only viewed from a normative perspective but must also consider the social, economic, and cultural dynamics that influence its application. Thus, this approach can be a pragmatic guide in responding to changes and problems that arise in the field of Health Criminal Law.⁴⁴ The solution to current challenges must, therefore, prioritise not just formal enforcement but law that is alive, responsive to context and respectful of human dignity.

From a legal realism standpoint, one key challenge lies in the application of Article 359 of the Indonesian Criminal Code (KUHP), which governs criminal liability for negligence resulting in death. In cases involving AI-based medical tools, assessing negligence becomes complicated.⁴⁵ When a physician follows standard procedures but an AI tool delivers a flawed diagnosis, it becomes necessary to distinguish between human error and systemic technological failure. Legal realism requires judges to assess the broader institutional and technological context rather than rigidly applying the text of the law. This nuanced view allows for a more just determination of responsibility.

Another pressing issue is the handling of digital health data. The enactment of Law No. 27 of 2022 on Personal Data Protection (UU PDP) is a pivotal step forward. However, enforcement must go beyond the statutory text. Many health institutions lack the infrastructure or training to ensure data security. Legal realism advocates for a shift toward institutional accountability, necessitating the implementation of active compliance mechanisms, encryption technologies, and clear protocols for internal access to patient data. Law enforcement must focus on systemic vulnerabilities rather than merely assigning individual blame.

Drug counterfeiting is also a persistent problem. Despite criminal provisions under Law No. 36 of 2009 on Health and Law No. 8 of 1999 on Consumer Protection, enforcement often fails to disrupt the wider distribution chain. A realistic solution is to combine criminal sanctions with technological surveillance tools, such as blockchain or QR tracking systems, to monitor the distribution of drugs from factory to consumer. Law enforcement should be coordinated with the BPOM and include community reporting channels to detect counterfeit circulation in real-time.

Legal realism also emphasises the importance of evolving jurisprudence. Courts should not interpret laws in isolation but rather build upon established patterns from prior cases involving medical malpractice, privacy breaches, and drug crimes. Law No. 29 of 2004 on Medical Practice and Law No. 36 of 2009 on Health should be interpreted in light of current healthcare realities, such as overburdened systems, rural health disparities, and rapidly evolving technologies.

⁴⁴ Carla I. Mercado et al., "A Shift in Approach to Addressing Public Health Inequities and the Effect of Societal Structural and Systemic Drivers on Social Determinants of Health," *Public Health Reports*®, October 11, 2024, <https://doi.org/10.1177/00333549241283586>.

⁴⁵ Andrew D Selbst, "Negligence and AI's Human Users," *Boston University Law Review* 100, no. 4 (2020): 1315 – 1376, <https://www.scopus.com/inward/record.uri?eid=2-s2.0-85093508249&partnerID=40&md5=9609e2d59aa8e829190e53f2269ceb89>.

In response to inequitable access to healthcare, realism advocates for reform in the allocation of resources and legal support for marginalised communities. Although Article 28H of the 1945 Constitution guarantees the right to health, disparities persist. Realist-driven lawmaking would advocate for specific budgetary allocations, robust legal safeguards against discrimination, and policies that reflect the lived experiences of rural and vulnerable communities.

Legal challenges arising from AI and biotechnology must also be addressed proactively. Since Indonesia currently lacks a regulatory framework for medical AI, a new legal instrument is needed that defines clear standards of liability, consent, and oversight. This framework should be developed through interdisciplinary collaboration among legal, medical, ethical, and technological experts.

Ultimately, the legal realism approach offers not only a critical lens but a transformative method. It advocates for laws that function effectively not only in theory but in practice. Proposed measures include the incorporation of restorative justice mechanisms in health law enforcement, ongoing legal education for medical professionals, and increased public participation in legal reform processes. Legal realism teaches us that Health Criminal Law must be flexible, context-sensitive, and committed to substantive justice, ensuring protection for both individual rights and public health in a rapidly changing world.

Conclusion

The implementation of criminal law in the healthcare sector is facing increasing complexity due to rapid advancements in medical technology and dynamic social change. A purely normative legal approach is no longer sufficient to address pressing issues such as technology-driven medical malpractice, digital health data breaches, and the misuse of biotechnology. Through the lens of legal realism, which emphasises the alignment between legal norms and social realities, health criminal law must be re-examined to ensure greater adaptability and contextual relevance. This study reveals a persistent tension between law enforcement and the protection of human rights, underscoring the need for a balance between legal certainty and substantive justice. Accordingly, several reforms are necessary: strengthening comprehensive regulations on criminal liability in health-related cases, applying restorative justice mechanisms focused on victim recovery, improving legal literacy among medical professionals, enhancing community-based oversight and accountability systems, developing objective standards for criminal liability in malpractice cases, employing digital technologies to combat drug counterfeiting, and reinforcing patient data protection through preventive legal frameworks and robust cybersecurity measures. These recommendations aim to ensure that health criminal law remains just, responsive, and effective in the face of contemporary healthcare challenges.

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