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Legal Responsibility for Medical Risks, Medical Errors, and Malpractice in Health Services

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Abstract. Disputes in medical care are often difficult to resolve due to the legal, ethical, and complex aspects of proving the case. It is not uncommon for medical procedures that do not meet patients' expectations to be attributed to medical error, when in fact they may be caused by unavoidable medical risks. This study aims to assess and differentiate between medical risks, medical errors, and malpractice, and to understand their legal liability. The method used is a normative-juridical approach with descriptive-analytical specifications. Data were collected through literature review and analyzed qualitatively and normatively. The results indicate that medical risks are part of healthcare services that may be unavoidable, unlike medical negligence, which involves an element of error. While medical errors and malpractice have fundamental differences, in legal practice, they are often difficult to distinguish. Medical errors are unintentional mistakes, while malpractice involves negligence or disregard for professional standards. A clear understanding of these three concepts is crucial to prevent the criminalization of medical personnel who work according to procedures and to provide balanced legal protection for patients and healthcare providers.

Keywords: Medical Risk, Medical Error, Malpractice, Legal Liability, Health Services.

Abstrak. *Sengketa dalam perawatan medis seringkali sulit diselesaikan karena aspek hukum, etika, dan rumitnya pembuktian kasus. Tidak jarang prosedur medis yang tidak memenuhi harapan pasien dikaitkan dengan kesalahan medis, padahal sebenarnya mungkin disebabkan oleh risiko medis yang tidak dapat dihindari. Penelitian ini bertujuan untuk menilai dan membedakan antara risiko medis, kesalahan medis, dan malpraktik, dan untuk memahami tanggung jawab hukum mereka. Metode yang digunakan adalah pendekatan yuridis normatif dengan spesifikasi deskriptif-analitis. Data dikumpulkan melalui tinjauan pustaka dan dianalisis secara kualitatif dan normatif. Hasil penelitian menunjukkan bahwa risiko medis merupakan bagian dari layanan kesehatan yang mungkin tidak dapat dihindari, tidak seperti kelalaian medis, yang melibatkan unsur kesalahan. Meskipun kesalahan medis dan malpraktik memiliki perbedaan mendasar, dalam praktik hukum, keduanya seringkali sulit dibedakan. Kesalahan medis merupakan kesalahan yang tidak disengaja, sementara malpraktik melibatkan kelalaian atau pengabaian terhadap standar profesional. Pemahaman yang jelas tentang ketiga konsep ini sangat penting untuk mencegah kriminalisasi terhadap tenaga medis yang bekerja sesuai prosedur dan untuk memberikan perlindungan hukum yang seimbang bagi pasien dan penyedia layanan kesehatan.*

Kata kunci: *Risiko Medis, Kesalahan Medis, Malpraktik, Tanggung Jawab Hukum, Layanan Kesehatan.*

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1. Introduction

The complexity of healthcare services often gives rise to legal disputes, particularly when unexpected outcomes such as disability or death occur.[1] In the Indonesian legal context, health is recognized as a human right guaranteed by the constitution and laws and regulations, as stipulated in Law Number 17 of 2023 concerning Health. As public demand for quality medical services increases, legal challenges arise in distinguishing between medical risks, medical errors, and malpractice. Medical risks are unavoidable consequences of medical procedures, even if performed in accordance with professional standards and operational procedures. In contrast, medical errors are unintentional errors that can occur due to human or systemic factors, although they do not always result in harm. Malpractice, on the other hand, occurs when medical personnel are negligent or ignore professional standards, resulting in losses for which they are legally accountable.[2] In this context, the role of informed consent is crucial as the legal and ethical basis for the doctor-patient relationship.[3] When patients are not fully informed about the risks of medical procedures and losses occur, lawsuits can arise. A clear understanding and a fair legal system are essential to distinguish between medical risks that cannot be punished, medical errors that must be corrected, and malpractice that can be subject to criminal or civil sanctions in order to protect patient rights and maintain the professionalism of medical personnel.[4]

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[1] Joko Sriwidodo et al., "Toward Equitable Healthcare: A Medical Dispute Resolution Framework to Address Medical Supply Delays in Health Law," *Journal of Legal Affairs and Dispute Resolution in Engineering and Construction* 17, no. 3 (2025): 452. See also, Zaid Ibrahim Yousef Gharaibeh, "The Impacts of Applications of Criminal Law on Medical Practice," *Medical Archives* 76, no. 5 (2022): 377.

[2] Agatha Parks-Savage et al., "Prevention of Medical Errors and Malpractice: Is Creating Resilience in Physicians Part of the Answer?," *International Journal of Law and Psychiatry* 60, no. 4 (2018): 35. See also, Brian Ferguson et al., "Malpractice in Emergency Medicine A Review of Risk and Mitigation Practices for the Emergency Medicine Provider," *Journal of Emergency Medicine* 55, no. 5 (2018): 661; Lucian L. Leape, "The Preventability of Medical Injury," In *Human error in medicine* (Florida: CRC Press, 2018), 18.

[3] Margherita Pallocci et al., "Informed Consent: Legal Obligation or Cornerstone of the Care Relationship?," *International Journal of Environmental Research and Public Health* 20, no. 3 (2023): 7. See also, Sophie Ludewigs et al., "Ethics of the Fiduciary Relationship between Patient and Physician: The Case of Informed Consent," *Journal of Medical Ethics* 51, no. 1 (2025): 61.

[4] Veronica Grembi and Nuno Garoupa, "Delays in Medical Malpractice Litigation in Civil Law Jurisdictions: Some Evidence from the Italian Court of Cassation," *Health Economics, Policy and Law* 8, no. 4 (2013): 425. See also, Kuan-Han Wu et al., "An Analysis of Causative Factors in Closed Criminal Medical Malpractice Cases of the Taiwan Supreme Court: 2000–2014," *Legal Medicine* 23, no. 9 (2016): 71.

Medical professionals, as the primary providers of healthcare, play an indispensable role in ensuring public health. Nonetheless, effective healthcare delivery requires cooperation between medical practitioners and patients or their families. Transparency between patients and physicians is crucial in determining appropriate medical actions.[5] Yet, societal perceptions often hinder this transparency, as some individuals may view sharing their health information as a source of shame for themselves or their families. Patients are required to provide complete and honest information regarding their health condition, which doctors, in turn, have the right to receive, enabling them to determine the most appropriate course of action.[6] This obligation is expressly stated in Article 276 of Law Number 17 of 2023 concerning Health, which states that patients must provide complete and honest information regarding their health problems. This provision reflects a legal norm that emphasizes the importance of transparency as both a right and an obligation in the relationship between patients and medical personnel. This transparency serves as the foundation for doctors to determine appropriate and responsible medical procedures and serves as a form of protection for patients' rights to standardized healthcare services. In practice, implementing this norm still faces significant challenges. Many patients or their families are reluctant to provide open and comprehensive information about their health condition, either due to ignorance, fear of social stigma, or a lack of understanding of the importance of open medical information.[7] This communication barrier leads to misunderstandings and even accusations of malpractice against medical personnel when outcomes do not meet expectations. Gaps in legal implementation in healthcare practice. Although regulations explicitly stipulate patient obligations, they have not been accompanied by adequate education, monitoring systems, or enforcement mechanisms to ensure these norms are effectively implemented.[8]

The rise in medical disputes often leads to accusations of malpractice without distinguishing between medical risks and negligence[9]. Amidst growing awareness

[5] Lynne Robins et al., "Identifying Transparency in Physician Communication," *Patient Education and Counseling* 83, no. 1 (2011): 74.

[6] Nancy E. Kass and Ruth R. Faden, "Ethics and Learning Health Care: The Essential Roles of Engagement, Transparency, and Accountability," *Learning Health Systems* 2, no. 4 (2018): 2. See also, Allen Kachalia, "Improving Patient Safety through Transparency," *New England Journal of Medicine* 369, no. 18 (2013): 1677.

[7] Kathryn R. Tringale and Jona A. Hattangadi-Gluth, "Truth, Trust, and Transparency the Highly Complex Nature of Patients' Perceptions of Conflicts of Interest in Medicine," *JAMA Network Open* 2, no. 4 (2019): 2.

[8] Jennifer J. Robertson and Brit Long, "Suffering in Silence: Medical Error and Its Impact on Health Care Providers," *Journal of Emergency Medicine* 54, no. 4 (2018): 403.

[9] R. Madan et al., "Consequences of Medical Negligence and Litigations on Health Care Providers a Narrative Review," *Indian Journal of Psychiatry* 66, no. 4 (2024): 317. See also, Muhammad

of patient rights, legal protection for medical personnel must also be enforced fairly. Patients who feel aggrieved by healthcare services often blame medical personnel, accusing them of violating their physical integrity or life by causing injury or death due to alleged negligence. Many adverse outcomes in healthcare arise from uncontrollable factors, including medical risks falsely attributed to medical error.[10] Given that health is a fundamental human right protected by law, and the right to life is equally important, the existence of a legal framework governing medical practice is not only necessary but also crucial. Legislation governs the conduct of healthcare personnel, particularly actions that lead to health deterioration or death that could have been prevented with proper care.[11]

Several studies[12] have shown that there are times when patient and doctor expectations differ from expected outcomes. Moreover, Finkelstein et al.[13] explain that unexpected complications or unexplained adverse events can arise. Some also argue that doctors cannot guarantee successful treatment or that it is completely risk-free[14] Healthcare, as an inherently uncertain field, is susceptible to various possibilities, including medical risks that arise during the delivery of care. Therefore, the doctor's role is to provide the best possible effort, not to guarantee results.[15]

Thus, a paradigm shifts from an individual-blaming approach to a systemic approach in addressing medical errors is needed. According to Rodziewicz and Hipskind,[16] medical errors are generally caused by system failures, not solely

Fakih et al., "Resolving Medical Disputes: Lessons from US Arbitration for Indonesia's Legal Framework," *Hasanuddin Law Review* 11, no. 1 (2025): 151.

[10] Maité Garrouste-Orgeas et al., "Overview of Medical Errors and Adverse Events," *Annals of Intensive Care* 2, no. 1 (2012): 5. See also, Femi Oyebode, "Clinical Errors and Medical Negligence," *Medical Principles and Practice* 22, no. 4 (2013): 326.

[11] Miha Šepec, "Medical Error Should It Be a Criminal Offence?," *Medicine, Law & Society* 11, no. 1 (2018): 49.

[12] Mohamad Rizky Pontoh, "Penegakan Hukum Pidana Terhadap Risiko Medik dan Malpraktek dalam Pelaksanaan Tugas Dokter," *Lex Crimen* 2, no. 7 (2013): 6. See also, Ismail Koto and Erwin Asmadi, "Pertanggungjawaban Hukum Terhadap Tindakan Malpraktik Tenaga Medis di Rumah Sakit," *Volksgeist: Jurnal Ilmu Hukum dan Konstitusi* 12, no. 4 (2021): 182.

[13] Daniel Finkelstein et al., "When a Physician Harms a Patient by a Medical Error: Ethical, Legal, and Risk-Management Considerations," *Journal of Clinical Ethics* 8, no. 4 (1997): 331.

[14] Megan Prictor, "Where Does Responsibility Lie? Analysing Legal and Regulatory Responses to Flawed Clinical Decision Support Systems When Patients Suffer Harm," *Medical Law Review* 31, no. 1 (2023): 7. See also, Henny Saida Flora, "7 Tanggung Jawab Dokter Dalam Pemberian Pelayanan Kesehatan," *Fiat Iustitia: Jurnal Hukum* 2, no. 3 (2023): 3.

[15] Asep Hendradiana and Gunarto Gunarto, "The Legal Renewal of Malpractices by Medical Personnel Based on Restorative Justice," *Jurnal Hukum* 40, no. 1 (2024): 76. See also, Yulia Audina Sukmawan and Akhmad Khisni, "Legal Protection of Health Worker in the Medical Malpractice Lawsuit in Banjarmasin," *Jurnal Daulat Hukum* 2, no. 2 (2019): 263.

[16] Thomas L. Rodziewicz and John E. Hipskind, "Medical Error Prevention," in *StatPearls* (Treasure Island, FL: StatPearls Publishing, 2020), 16.

individual negligence. Therefore, a non-punitive incident reporting system is needed to encourage transparency and continuous improvement. Lee Theng Lim[17] and Sepec[18] also emphasized the importance of distinguishing between medical errors and malpractice in a legal context, as not all errors are punishable. On the other hand, Guillod[19] stated that transparency with patients about risks and errors is part of an effective patient safety culture. This safety-based approach focuses on learning from incidents, not simply imposing sanctions. Furthermore, Birkeland[20] highlighted the role of shared decision-making as a mechanism to strengthen informed consent and reduce legal risk. Thus, current theory and research emphasize the importance of integrating risk communication, professional accountability, and system improvement to ensure patient safety and legal protection for healthcare professionals. In this context, medical risks, errors, and malpractice share a common potential to negatively impact outcomes, necessitating a structured and integrated approach to their analysis.[21] Therefore, this study aims to explore and clarify the interplay between medical risk assessment, medical errors, malpractice, and their associated legal responsibilities. The purpose of this study is to examine in depth the differences between medical risks, errors, and malpractice and the implications of their legal liability in healthcare.

2. Research Method

The research method used in this study is a normative juridical approach, namely an approach that examines law as a norm or rule that applies in society. This research focuses on library research that relies on primary and secondary legal materials. The primary legal materials used include laws and regulations such as Law Number 17 of 2023 concerning Health, Law Number 1 of 2023 concerning the Criminal Code, and the Civil Code, which are relevant in examining aspects of legal responsibility for medical risks, medical errors, and malpractice. Meanwhile, secondary legal materials are obtained from scientific literature, legal journals, and the views of health law experts who support the analytical framework. The specifications of this research are descriptive-analytical, namely describing

[17] Lee Theng Lim et al., "Medico-Legal Dispute Resolution: Experience of a Tertiary-Care Hospital in Singapore," *Plos One* 17, no. 10 (2022): 6.

[18] Šepec, "Medical Error Should It Be a Criminal Offence?" 52.

[19] Olivier Guillod, "Medical Error Disclosure and Patient Safety: Legal Aspects," *Journal of Public Health Research* 2, no. 3 (2013): 184.

[20] Søren Fryd Birkeland, "Informed Consent Obtainment, Malpractice Litigation, and the Potential Role of Shared Decision-Making Approaches," *European Journal of Health Law* 24, no. 3 (2017): 264.

[21] Brenda Langkai, "Malpraktik Medis Dalam Perkara Pidana," *Lex Administratum* 11, no. 5 (2023): 3.

applicable legal regulations and theories and analyzing them in depth within the context of the problem under study. This research does not involve direct field studies, but rather all data is obtained through document studies and analyzed using normative qualitative methods, with an emphasis on understanding the substance of the law and its relationship to the reality of health services. The analysis is conducted systematically and logically, avoiding overlap between the legal concepts discussed. The presentation of the results is carried out through a focused sentence structure and based on strong legal arguments. The conclusion-drawing process is carried out inductively, namely drawing general conclusions from a review of relevant regulations, principles, and legal theories.

3. Results and Discussion

3.1. Medical Risk in Doctor-Patient Legal Relationships

Medical risks would not arise if no treatment or medical actions were undertaken during healthcare or nursing services provided through therapeutic transactions.[22] Although the occurrence of medical risks in healthcare services is minimal, nearly every medical procedure inherently involves some degree of risk.[23] This poses a significant challenge for medical professionals (doctors/dentists), particularly in understanding the potential risks associated with their medical practices, estimating the likelihood of these risks, and overcoming communication barriers to ensure patients fully understand the associated risks.[24] Discussing these risks with patients is a fundamental responsibility of doctors. It enables them to fulfill their role as trusted advisors and upholds the ethical principle of autonomy, as enshrined in the doctrine of informed consent.[25]

[22] Mia Amiati et al., "Navigating Ambiguity: Critiques of Indonesia's Health Law and Its Impact on Legal Redress for Medical Malpractice Victims," *Hasanuddin Law Review* 10, no. 1 (2024): 94.

[23] Timothy Hoff and Grace E. Collinson, "How Do We Talk about the Physician–Patient Relationship? What the Nonempirical Literature Tells Us," *Medical Care Research and Review* 74, no. 3 (2017): 251.

[24] John Jolly et al., "Evaluation of a Simulation-Based Risk Management and Communication Masterclass to Reduce the Risk of Complaints, Medicolegal and Dentolegal Claims," *BMJ Simulation & Technology Enhanced Learning* 6, no. 2 (2020): 71. See also, Sidney T. Bogardus Jr et al., "Perils, Pitfalls, and Possibilities in Talking about Medical Risk," *JAMA* 281, no. 11 (1999): 1037.

[25] Brian Shipman, "The Role of Communication in the Patient–Physician Relationship," *Journal of Legal Medicine* 31, no. 4 (2010): 434. See also, Wendy Levinson et al., "Developing Physician Communication Skills for Patient-Centered Care," *Health Affairs* 29, no. 7 (2010): 1313; Mehrnaz Mostafapour et al., "Beyond Medical Errors: Exploring the Interpersonal Dynamics in Physician-Patient Relationships Linked to Medico-Legal Complaints," *BMC Health Services Research* 24, no. 1 (2024): 7.

The relationship between doctors and patients is legally characterized as an equal relationship.[26] This relationship involves two legal subjects: the doctor (from the perspective of morality and law) and the patient. First, from the doctor's moral perspective, it begins with the oath to perform their duties with dignity as a doctor and to establish a doctor-patient relationship based on humanity.[27] From a legal perspective, Article 1 of Law Number 17 of 2023 on Health states that medical personnel are individuals dedicated to the healthcare sector, possessing professionalism, knowledge, and skills acquired through medical or dental professional education, and authorized to perform healthcare efforts.[28] Based on this, doctors or dentists are obligated to provide healthcare services in accordance with professional standards, professional service standards, standard operating procedures, and professional ethics, beginning with the patient's consent tailored to their health needs. Second, from the patient's perspective, when they express their willingness to be assisted by the doctor, this is conveyed through informed consent, whether in written form, verbally, or through body language (e.g., a nod). Clear information from both parties is essential in therapeutic transactions, requiring patients to provide adequate explanations about their health condition and doctors to deliver comprehensive, understandable information about the proposed medical actions.[29]

Healthcare services are complex activities involving various components, including healthcare professionals, patients, and medical technology. In this process, medical risks cannot be entirely avoided. Medical risks arise from therapeutic transactions, where patients seek solutions for their health needs, and healthcare professionals are expected to assist in addressing those issues. The relationship between these two legal subjects is of equal standing, forming a horizontal contract characterized by *inspanning verbintenis*.[30] This legal relationship grants both the patient and the doctor rights and obligations. *Inspannings verbintenis*

[26] Paola Delbon, "The Protection of Health in the Care and Trust Relationship between Doctor and Patient: Competence, Professional Autonomy and Responsibility of the Doctor and Decision-Making Autonomy of the Patient," *Journal of Public Health Research* 7, no. 3 (2018): 98.

[27] Herbert M. Adler, "The Sociophysiology of Caring in the Doctor-Patient Relationship," *Journal of General Internal Medicine* 17, no. 11 (2002): 883.

[28] Egun Nofianto, "The Legal Protection of Patients as a Victim of Medical Malpractice by Physicians on Telemedicine Services," *International Journal of Law and Society* 1, no. 3 (2024): 61.

[29] Sunny Ummul Firdaus and M. Alief Hidayat, "The Role of Informed Consent in Therapeutic Transactions," in *Youth International Conference for Global Health* (Paris: Atlantis Press, 2023), 34. See also, Rob Heywood et al., "Informed Consent in Hospital Practice: Health Professionals' Perspectives and Legal Reflections," *Medical Law Review* 18, no. 2 (2010): 155.

[30] Sulistini et al., "Medical Disputes on the Concept of Inspanningsverbintenis vs Resultaatsverbintenis: A Critical Review," *European Journal of Humanities and Social Sciences* 3, no. 2 (2023): 106. See also, Fayuthika Alifia Kirana Sumeru and Hanafi Tanawijaya, "Inspanning Verbintenis dalam Tindakan Medis yang Dikategorikan sebagai Tindakan Malpraktek," *Jurnal Hukum Adigama* 5, no. 2 (2022): 494.

does not guarantee a cure but represents a maximum effort to improve the patient's health with utmost care, based on the doctor's knowledge, skills, and competence.[31]

According to Article 1233 of the Indonesian Civil Code, obligations arise either from an agreement or by virtue of the law. In relation to this, healthcare services in the doctor-patient relationship can take the form of legal mandates or agreements.[32] First, the doctor-patient relationship based on legal mandates involves healthcare services provided to patients in need of medical care. Medical professionals (doctors/dentists) are obligated to provide care to patients without requiring their consent in emergency situations. Such conditions may arise at the beginning or during the legal relationship. Once the patient regains consciousness, consent is subsequently obtained. This situation does not fall under *resultaatverbintenis* (obligation of result) but remains an obligation of maximum and diligent effort by the doctor,[33] following the patient's recovery of consciousness, informed consent is then sought.

It is emphasized in Article 293 Paragraph (9) of Law Number 17/2023 that in situations where a patient, as referred to in Paragraph (6) is incapacitated and requires emergency action but no party is available to provide consent, such consent is not required.[34] Actions are taken in the patient's best interest, as determined by the medical or healthcare professional providing care. Subsequently, information regarding the actions taken must be conveyed to the patient once they regain capacity or to their representative when present. Nonetheless, as a form of patient protection, the patient retains the right to file a claim, which can be proven in court or before a disciplinary/ethical medical board.[35]

Second, the doctor-patient relationship arises from an obligation based on a contract or agreement. Article 1320 of the Indonesian Civil Code outlines the elements of an agreement, which are: (1) The existence of mutual consent from

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[31] Janetty Janetty, "Kajian Yuridis mengenai Inspanning Verbintenis dan Resultaat Verbintenis di Bidang Kedokteran Bedah Plastik dengan Tujuan Estetika," *Jurnal Spektrum Hukum* 19, no. 2 (2022): 124. See also, Sumeru and Tanawijaya, "Inspanning Verbintenis dalam Tindakan Medis," 502.

[32] Anang Riyan Ramadianto, "The Deviation of Informed Consent Practices: Understanding the Inspanning Verbintenis and Legal Aspects," *Jurnal Ilmiah Dunia Hukum* 4 no. 2 (2023): 58.

[33] Syahrul Machmud, *Penegakan Hukum dan Perlindungan Hukum bagi Dokter yang Diduga Melakukan Medikal Malpraktek* (Bandung: Mandar Maju, 2008), 70; Hendradiana and Gunarto, "The Legal Renewal of Malpractices," 77; Sukmawan and Khisni, "Legal Protection of Health Worker," 265.

[34] King-Jean Wu et al., "Court Decisions in Criminal Proceedings for Dental Malpractice in Taiwan," *Journal of the Formosan Medical Association* 121, no. 5 (2022): 904. See also, Tringale and Hattangadi-Gluth, "Truth, Trust, and Transparency," 4. See also, Ramadianto, "The Deviation of Informed Consent," 59.

[35] Gede Dicky Wahyu Putra Sudarta et al., "Corrective Justice for Medical Personnel Who Violate the Law: Where Is the Professional Organizations Involvement?," *Jurnal Dinamika Hukum* 23, no. 2 (2023): 386.

those binding themselves. When the patient expresses their condition and the doctor responds, this is where the agreement begins; (2) Capacity to form an obligation.[36] Article 1329 of the Civil Code states that every person is authorized to create an obligation, unless they are declared incapable of doing so. Further, Article 1330 specifies that those incapable of making an agreement include minors, individuals placed under guardianship, and married women in matters determined by law, as well as anyone prohibited by law from entering certain agreements; (3) A specific subject matter. In the doctor-patient contract, the object of the obligation is the doctor's maximum and diligent efforts in accordance with established standards.[37] Therefore, the patient or their family cannot demand a cure, and the doctor cannot guarantee one, as healthcare services involve probabilities of other factors that may affect the patient's condition, such as medical risks; (4) A lawful cause. Article 1335 of the Civil Code states that agreements without a cause, or based on a false or unlawful cause, have no binding power. Article 1337 specifies that an unlawful cause is one prohibited by law or that contradicts decency or public order.[38]

The explanation above can clearly be concluded that the doctor-patient relationship exists due to the mandate of law and an obligation arising from the healthcare needs of the patient and the responsibilities as healthcare professionals, with this agreement being documented in the medical consent. Informed consent is an agreement that must be provided; in fact, according to Miller[39] if informed consent is not given, it constitutes a crime. The application of legal requirements for consent based on information (informed consent) is carried out to protect the public and prevent allopathic treatment or both, marking a significant step in the development of healthcare law regulations.[40]

Law Number 17/2023, Article 293, states that every individual healthcare service performed by medical personnel and healthcare workers must receive

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[36] Aria Chandra Gunawan et al., "Tinjauan Hukum Pidana Terhadap Tindakan Malpraktek dalam Bidang Kesehatan atau Medis," *UNES Law Review* 6, no. 2 (2023): 5390.

[37] Anggraeni Endah Kusumaningrum, "Analisis Transaksi Terapeutik Sebagai Sarana Perlindungan Hukum Bagi Pasien," *Yustisia Merdeka: Jurnal Ilmiah Hukum* 5, no. 2 (2019): 8. See also, Amiati et al., "Navigating Ambiguity: Critiques of Indonesia's," 96; Ukilah Supriyatin, "Hubungan Hukum antara Pasien dengan Tenaga Medis (Dokter) dalam Pelayanan Kesehatan," *Jurnal Ilmiah Galuh Justisi* 6, no. 2 (2018): 188.

[38] Franklin G. Miller and Alan Wertheimer, "The Fair Transaction Model of Informed Consent: An Alternative to Autonomous Authorization," *Kennedy Institute of Ethics Journal* 21, no. 3 (2011): 205.

[39] Robert D. Miller, "The First Medical Informed Consent Statute Deseret (1851): The Use of Laws Requiring Consent to Discourage Disfavored Medical Procedures," *Minds@UW*, October 7, 2020. Retrieved in July 23, 2025 from https://minds.wisconsin.edu/handle/1793/80622.

[40] J. A. Bulen Jr., "Complementary and Alternative Medicine," *Journal of Legal Medicine* 24, no. 3 (2003): 331.

consent.[41] The consent must include adequate explanation covering, at a minimum, the diagnosis, indications, the healthcare actions performed and their purposes, the risks and potential complications, alternative actions and their risks, the risks if no action is taken, and the prognosis after receiving treatment. In this article, the term "risk" is mentioned multiple times, emphasizing the crucial point that healthcare services are inherently associated with medical risks, including medical alternatives. Every action and alternative action carry risks; therefore, consent is mandatory, whether the procedure is minor or major.[42]

Consent, either written or verbal, must be obtained before any medical procedure is performed. Written informed consent is mandatory if the procedure is invasive and/or high-risk. If the patient is deemed incapable of giving consent, consent can be given by a proxy, with a healthcare provider or medical staff member acting as a witness. Consent is granted after the patient is aware of the potential medical risks and gives permission to the physician to perform the therapeutic procedure.[43]

Informed consent is a form of equality between the patient and the doctor.[44] It is ensured that patients claim their right to participate in decision-making regarding healthcare options.[45] This decision forms a legal relationship between the patient and doctor as a therapeutic transaction. Another question is whether informed consent can prevent negligence claims. Identifying the issue of proving informed consent is one of the first matters to consider. Upon reviewing decisions from other jurisdictions, it is stated that the evidence of informed consent cannot

[41] Ana-Maria Chepestru, "The Crime of Mass Disorder in the Criminal Laws of the Commonwealth of Independent Member States." *Sci. Annals Stefan cel Mare Acad. Ministry Internal Aff. Republic Mold.* 17, no. 4 (2023): 245. See also, Fitra Deni et al., "Juridical Analysis of Therapeutic Transactions as a Form of Agreement between Doctors and Patients," *Jurnal Akta* 10, no. 3 (2023): 210.

[42] Katz Aviva L. et al., "Informed Consent in Decision-Making in Pediatric Practice," *Pediatrics* 138, no. 2 (2016): 5. See also, John Coggon and José Miola, "Autonomy, Liberty, and Medical Decision-Making," *Cambridge Law Journal* 70, no. 3 (2011): 524; I. Glenn Cohen et al., "The Legal and Ethical Concerns That Arise from Using Complex Predictive Analytics in Health Care," *Health Affairs* 33, no. 7 (2014): 1141.

[43] Riza Alifianto Kurniawan, "Risiko Medis dan Kelalaian Terhadap Dugaan Malpraktik Medis di Indonesia," *Perspektif* 18, no. 3 (2013): 148. See also, Teddy Asmara, "Criminal Sanctions against Pharmacists Who Sell Antibiotic Drugs without a Doctor's Prescription: In Perspective of Health Law in Indonesia," *Journal of Legal, Ethical and Regulatory Issues* 24, no. 8 (2021): 3.

[44] Elisabeth Sundari and Anny Retnowat, "The Limits Access of Medical Records in Indonesia and a Broader Propose to Support Patients in Malpractice Claims," *Journal of Law and Sustainable Development* 11, no. 12 (2023): 6. See also, Supriyatin, "Hubungan Hukum antara Pasien dengan Tenaga Medis," 189; Deni et al., "Juridical Analysis of Therapeutic Transactions," 212.

[45] Barbara Von Tigerstrom, "Informed Consent for Treatment: A Review of the Legal Requirements," *Journal SOGC* 23, no. 10 (2001): 953. See also, Birkeland, "Informed Consent Obtainment," 269.

determine right or wrong when proving malpractice cases based on negligence in providing care and treatment. The fact that a patient may have consented to a procedure with known risks does not automatically absolve the doctor of responsibility.[46] However, if the doctor is negligent in assessing the patient's suitability for the procedure, the informed consent may still be an issue. In such cases, if the plaintiff can prove the connection between the doctor's failure to disclose risks and the injury suffered, and that the undisclosed risk materialized, informed consent may not provide a defense against a malpractice claim.[47]

An agreement is necessary in healthcare services with a focus on patient safety, where an organized framework is implemented to build a culture, processes, procedures, behaviors, technologies, and environments in healthcare services consistently and sustainably. This framework aims to reduce avoidable hazards, prevent the likelihood of errors, and minimize the impact when incidents occur, with the goal of reducing risks to patients.[48]

3.2. Medical Risks Without Negligence Should Not Result in Punishment

Every action carries inherent risk. Choosing inaction does not eliminate risk, as even doing nothing can still result in unintended consequences. Risk remains an unavoidable aspect of any decision, and it must be addressed through careful and prudent consideration.[49] In the Indonesian legal context, the definition of medical risk is not clearly established. Generally, risk is understood as an undesirable or harmful consequence resulting from an action or behavior. It can also be described as a deviation from the expected outcome or the potential for loss. The term "medical" originates from Latin and Greek, commonly associated with diagnosis and surgical procedures. It relates specifically to the field of medicine. Another interpretation views medical terminology as a systematic classification of terms related to diseases, symptoms, and procedures. Accordingly, medical risk can be defined as a condition that cannot be predicted with certainty or a situation where preventive measures are no longer effective in avoiding harm.[50] Understanding the

[46] Aibek Seidanov et al., "Crimes in Medical: A Criminological Perspective on Causes, Conditions and Prevention," *Pakistan Journal of Criminology* 16, no. 3 (2024): 7.

[47] Marc D. Ginsberg, "Informed Consent: No Longer Just What the Doctor Ordered? Revisited," *Akron Law Review* 52, no. 1 (2018): 52.

[48] Thaddeus Mason Pope, "Patient Decision Aids Improve Patient Safety and Reduce Medical Liability Risk," *Maine Law Review* 74, no. 2 (2022): 74. See also, Paul McGivern and Natalia Ivolgina, "Legal Liability in Informed Consent Cases: What Are the Rules of the Game?," *McGill Journal of Law and Health* 7, no. 3 (2013): 133; Jaime Staples King and Benjamin W. Moulton, "Rethinking Informed Consent: The Case for Shared Medical Decision-Making," *American Journal of Law & Medicine* 32, no. 4 (2006): 430.

[49] Janet T. Thomas, "Informed Consent through Contracting for Supervision: Minimizing Risks, Enhancing Benefits," *Professional Psychology: Research and Practice* 38, no. 3 (2007): 223.

[50] J. Guwandi, *Hukum Medik (Medical Law)* (Depok: Universitas Indonesia Press, 2019), 70.

information provided by doctors to patients is crucial in preventing misunderstandings or allegations of negligence. To avoid misperceiving every unsatisfactory outcome as malpractice, it is crucial to understand that unfavorable results may arise from the natural course of illness, unrelated complications, unavoidable or acceptable risks (whether foreseeable or not), and patient-specific variations.[51] Even high-risk actions may be justified if they are the only viable option and have been acknowledged and accepted by the patient or family through informed consent.[52]

This argument states that doctors cannot be held responsible for errors caused by patient variations. Their knowledge about specific patients emphasizes that each patient is a unique individual, not merely a combination of chemical and physical factors but also a product of their personal variations. If an unfavourable outcome occurs, the error is not due to intentional scientific ignorance but rather the unavoidable lack of knowledge about environmental "contingencies." Injuries resulting from this lack of knowledge stem from many diseases that remain unknown and numerous treatment techniques that still cause harm, such as cancer chemotherapy, which produces substantial side effects.[53]

Medical risks can occur at any time, whether during minor or major healthcare services. For example, an allergic reaction to certain medications or a surgical case involving two individuals of different ages: one aged 20 years and the other 60 years. Despite the same standard procedures and type of health issue, the outcomes may differ due to the age difference. The younger individual may recover safely, while the 60-year-old could experience more severe health complications or even death.[54]

The occurrence of medical risks during healthcare services can be categorized into risks related to treatment (inherent risks, hypersensitivity risks, and complications that occur suddenly and unpredictably) and *volenti non fit injuria* or assumption of risk.[55] Inherent risks arise from the medical procedures performed

[51] Mengxiao Wang et al., "The Role of Mediation in Solving Medical Disputes in China," *BMC Health Services Research* 20, no. 1 (2020): 7.

[52] Ari Yunanto and Helmi S. H., *Hukum Pidana Malpraktik Medik, Tinjauan dan Perspektif Medikolegal* (Yogyakarta: Penerbit Andi, 2024), 34.

[53] Robert L. et al., *Health Law: Cases, Materials and Problems* (Leiden: West Academic Publishing, 2013), 38. See also, McGivern and Ivolgina, "Legal Liability in Informed," 135; Birkeland, "Informed Consent Obtainment," 270.

[54] Gilbert Kodilinye and Natalie Corthésy, "General Defences," In *Commonwealth Caribbean Tort Law* (London: Routledge, 2022), 407.

[55] Michel Daniel Mangkey, "Perlindungan Hukum terhadap Dokter dalam Memberikan Pelayanan Medis," *Lex et Societatis* 2, no. 8 (2014): 3. See also, Michelle Madden Dempsey, "The Volenti Maxim," In *the Routledge Handbook of the Ethics of Consent, ed. Peter Schaber and Andreas Müller* (London: Routledge, 2018), 188; Wen Cai, "The Philosophical Basis for the Evolution of the

during healthcare services. Hypersensitivity risks occur because individuals may react differently to treatments or procedures, with the body overreacting to foreign substances, leading to hypersensitivity. Sudden and unpredictable complications are situations where patients may appear to recover or improve but then suddenly deteriorate or even pass away. *Volenti non fit injuria* or assumption of risk refers to medical risks that are already known before a medical procedure is performed. If such risks have been explained to the patient or their family and they consent to the procedure, the risks that were previously predicted and occur are considered as part of this assumption of risk. [56]

As previously mentioned, medical risks can occur in both minor and severe cases, manifesting as changes in form, minor injuries, or even death. When comparing medical risks to medical negligence, both can result in suffering, injury, or death, and both have a causal relationship.[57] However, there is one fundamental difference between medical risks and medical negligence: medical risks do not involve negligence, whereas medical negligence clearly involves elements of carelessness.[58] Medical risks occur during healthcare services performed in accordance with applicable standards and procedures. It is relatively straightforward to distinguish between medical risks and medical negligence. Medical risks involve no negligence or errors during medical actions, with services provided according to operational standards, professional standards, and medical standards.[59] On the other hand, medical negligence clearly includes elements of carelessness, with a causal relationship between the act and the resulting harm.

Negligence, as stipulated in Articles 359 and 360 of the Indonesian Penal Code (*Kitab Undang-Undang Hukum Pidana* or KUHP), contains the following elements: the presence of negligence, the existence of specific acts, the resulting severe injury or death of another person, and a causal relationship between the act and the death

Doctrine of Assumption of Risk in Anglo-American Law: A Liberal Perspective," *Beijing Law Review* 16, no. 2 (2025): 1024.

[56] Anton Van Loggerenberg, "An Alternative Approach to Informed Consent," *South African Law Journal* 135, no. 1 (2018): 56. See also, Jodi Gardner, "Rethinking Risk-Taking: The Death of Volenti?" *Cambridge Law Journal* 82, no. 1 (2023): 111; Sylvester C. Chima, "Evaluating the Quality of Informed Consent and Contemporary Clinical Practices by Medical Doctors in South Africa: An Empirical Study," *BMC Medical Ethics* 14, no. 1 (2013): 3.

[57] Shah Hussain et al., "Modern diagnostic imaging technique applications and risk factors in the medical field: a review," *BioMed research international* 22, no. 1 (2022): 5164970.

[58] Piotr Stępniak, "Medical Error and Negligence as a Premise of Liability for Damage Caused to Patients," *Journal of Health Inequalities* 7, no. 2 (2021): 133. See also, Oyebode, "Clinical Errors and Medical Negligence," 328.

[59] Bambang Poernomo, *Hukum Kesehatan: Pertumbuhan Hukum Eksepsional di Bidang Pelayanan Kesehatan* (Yogyakarta: Aditya Media, 1997), 38. See also, Langkai, "Malpraktik Medis Dalam Perkara Pidana," 7.

of the person.[60] If a patient has been treated in accordance with standard medical procedures but ultimately suffers severe injury or dies, and it has been proven that no negligence exists in the causal relationship, this constitutes a medical risk. Conversely, if a patient suffers severe injury or death as a result of healthcare services provided below medical standards, this indicates medical negligence.

Negligence occurs due to a lack of caution in medical actions, while medical risks involve no element of negligence. In contrast, malpractice clearly contains elements of negligence, where the actions fall below the predetermined professional standards. Some provide detailed professional standards consisting of the following elements: 1) exercising diligence and care; 2) adhering to medical standards; 3) possessing average capability under similar conditions; 4) employing comparable efforts; and, 5) performing medical actions for concrete purposes.[61]

Failure to meet the first point constitutes negligence, as it reflects an omission of duty that results in harm or a clear causal relationship. Furthermore, if medical services do not include the elements of medical standards outlined above, they fall into the category of "negligence." In criminal law, medical errors may lead to criminal liability if the doctor is found negligent.[62]

Law Number 1 of 2023 regarding the Criminal Code specifies negligence by doctors or healthcare workers in Article 474, Paragraph (1), which states that any person who, due to negligence, causes another person to suffer injuries resulting in illness or an inability to perform their duties, livelihood, or profession for a certain period is subject to imprisonment for a maximum of one year or a fine of up to Category II. The explanation of this article does not provide a clear definition of negligence, but generally, negligence refers to actions where the perpetrator does not intend for the consequences of their actions, such as death or injury. However, in concrete situations, it is often difficult to determine whether an action qualifies as negligence. As such, the definition of negligence is left to the judge's discretion when evaluating the case.[63]

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[60] Anny Isfandyarie, *Malpraktek dan Resiko Medik dalam Kajian Hukum Pidana* (Jakarta: Prestasi Pustaka, 2005), 43.

[61] Nuzul Abdi et al., "Tanggungjawab Hukum Rumah Sakit Terhadap Tindakan Medis Dokter," *Journal of Science and Social Research* 5, no. 3 (2022): 629. See also, Bambang Poernomo, *Hukum Kesehatan: Pertumbuhan Hukum,* 47.

[62] Kartina Pakpahan et al., "Perbandingan Perlindungan Hukum Pasien Korban Malpraktek Bedah Plastik di Indonesia dan Korea Selatan," *Jurnal IUS Kajian Hukum dan Keadilan* 9, no. 1 (2021): 221. See also, Istiana Heriani et al., "Legal Protection of Patient Rights in Indonesia," *Sriwijaya Law Review* 3, no. 1 (2019): 76; Deri Mulyadi et al., "Medical Negligence Dispute Settlement in Indonesia," *Indian Journal of Forensic Medicine & Toxicology* 14, no. 4 (2020): 1235; Teddy Asmara, "Criminal Sanctions against Pharmacists," 5.

[63] Gigih Sanjaya Putra, "Implikasi Tanggungjawab Hukum Atas Tindakan Malpraktik yang Dilakukan Oleh Tenaga Medis di Indonesia," *Muhammadiyah Law Review* 4, no. 2 (2022): 129.

Doctors are expected to act responsibly in carrying out the professional duties entrusted to them. In other words, information about medical risks must be clearly communicated to and understood by the patient or their family, while negligence must be avoided by doctors or dentists. Based on the explanation above, medical personnel are not held accountable if they have provided information about potential risks, adhered to professional, medical, and operational standards, and if the worsening condition or death was proven to be due to medical risks. In such cases, doctors cannot be subjected to criminal or civil penalties.[64]

3.3. Distinguishing Medical Error from Malpractice in Healthcare Legal Frameworks

It is not an easy task to provide an opinion on medical error. The term "medical error" is a medical term often used by healthcare professionals to describe mistakes in the medical field. Medical errors are a complex issue due to the difficulty in uncovering their root causes.[65] If the cause of a medical error can be identified, future occurrences may be prevented. One approach to ensuring such incidents do not recur is to recognize the incident and provide appropriate solutions, rather than assigning blame or imposing punishment.[66]

Medical errors are categorized based on the medical actions performed. These errors predominantly occur in the healthcare sector.[67] Various definitions of medical errors have been drawn from the medical field. Below are several definitions of medical error provided by experts:

a. Medical error was first introduced in 1869 by Rudolf Virchow, who defined it as a mistake caused by deviations from the established rules of the medical profession due to inadequate care.[68] According to the Institute of Medicine (IOM) report titled "To Err is Human": medical error is

[64] Hargianti Dini Iswandari and Sanjana Hoque, "Reconceptualizing Legal Arrangement on the Doctor-Patient Relationship in Indonesia," *Law Reform* 18, no. 1 (2022): 58. See also, Koto and Asmadi, "Pertanggungjawaban Hukum Terhadap Tindakan Malpraktik," 183; Shipman, "The Role of Communication," 436.

[65] Handoyo Prasetyo et al., "Reconstruction of Criminal Design Based on Strict Liability Theory for Hospitals in Cases of Medical Malpractice Against Patients," *Jurnal Suara Hukum* 6, no. 2 (2024): 331.

[66] Suwito Suwito et al., "Human Rights Perspectives on Resolving Medical Malpractice Cases through Penal Mediation in Indonesia," *Jambura Law Review* 5, no. 2 (2023): 281. See also, Ni Wayan Eka Mustika et al., "Restorative Justice Settles Health Disputes between Patients and Hospitals from an Inclusive Justice Perspective," *Jurnal IUS Kajian Hukum dan Keadilan* 11, no. 3 (2023): 425;

[67] Hildayastie Hafizah and Surastini Fitriasih, "Urgensi Penyelesaian Dugaan Kesalahan Medis Melalui Restorative Justice," *Jurnal USM Law Review* 5, no. 1 (2022): 213.

[68] Jawahar Kalra, "Medical Errors: An Introduction to Concepts," *Clinical Biochemistry* 37, no. 12 (2004): 1046. See also, Torsten Riotte, "Medical Negligence in Nineteenth-Century Germany," In *Progress and Pathology, ed. Melissa Dickson, Emilie Taylor-Brown, and Sally Shuttleworth* (Manchester: Manchester University Press, 2020), 56.

described as a discrepancy between planned actions and actions performed, or the use of an incorrect plan to achieve a goal (errors in execution and errors in planning).[69]

b. In the European Union, medical accidents are understood as: 1) unplanned, unexpected, and undesirable events, usually with adverse consequences; 2) acts or omissions with potentially negative consequences for the patient, which would be judged as wrong by knowledgeable and skilled peers at the time of the incident, regardless of whether any negative consequences actually occurred.[70]
c. Medical error can also be defined as a failure in the mechanisms used to acquire and process information relevant to the task at hand.

Considering the above definitions, a medical error refers to an unintended, unintentional action when providing medical services, regardless of whether it results in injury or not. There are two main types of errors in medical error. The first is negligence occurs when an action that should have been taken is neglected. For example, failing to secure a patient to a wheelchair or not stabilizing a stretcher before transferring a patient. The second is action errors occur when an incorrect action is taken. For instance, administering a medication that could cause an allergy in the patient or failing to label laboratory samples correctly, leading to mix-ups with patients.[71]

Patient injuries resulting from poor quality of care can be categorized into two sources of injury. First, intentional or reckless actions, which can be seen as deviations from professional practice norms based on knowledge, standards, or applicable laws to prove fault. Second, negligence, which is the failure to exercise caution on certain occasions, even when the doctor is skilled and trained. This may also include systematic failures due to an inability to keep up with advancements in medical knowledge or not receiving adequate education overall.[72]

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[69] Angela Roddey Holder, "Medical Errors," *Hematology* 5, no. 1 (2005): 505. See also, Ethan D. Grober and John M. A. Bohnen, "Defining Medical Error," *Canadian Journal of Surgery* 48, no. 1 (2005): 39; Debra Hardy Havens and Lizbet Boroughs, "To Err Is Human: A Report from the Institute of Medicine," *Journal of Pediatric Health Care* 14, no. 2 (2000): 77.

[70] Nataliia V. Nikitchenko, "A Medical Error: Does Law Help or Hinder," *Wiadomości Lekarskie* 72, no. 4 (2019): 698. See also, Elena Toader et al., "Vulnerabilities in the Medical Care," *Procedia Social and Behavioral Sciences* 12, no. 2 (2013): 936; Bulen Jr., "Complementary and Alternative Medicine," 334.

[71] Rodziewicz and Hipskind, "Medical Error Prevention," 21. See also, Mulyadi et al., "Medical Negligence Dispute Settlement," 1236; Grober and Bohnen, "Defining Medical Error," 40.

[72] Aisyah Meidian Sulaeman and Hudi Yusuf, "Standard Pelayanan Fasilitas Kesehatan (Rumah Sakit) Bagi Pasien Menurut Undang-Undang," *Jurnal Intelek Dan Cendikiawan Nusantara* 1, no. 2 (2024): 2599. See also, Schwartz et al., *Health Law: Cases, Materials and Problems*, 43; Putra, "Implikasi Tanggungjawab Hukum," 130.

The category of errors must be determined operationally before an investigation is conducted, and every deviation should be clearly stated.[73] Reflecting on the definitions in medicine, it should be drawn into the legal context where medical errors and malpractice are closely related. Unlike medical risks, which are easily distinguished, as explained earlier, medical errors can occur without any negative outcomes for the patient. For example, a mistake in administering medication with no negative consequence for the patient. Should this be punished? However, not all individuals will experience the same outcome, as negative consequences may arise in some cases. Therefore, whether there is a negative outcome or not from a medical error, an evaluation of the actions must be conducted.[74]

From the explanation above, it can be concluded that if there is a clear harm caused to the patient as a result of the medical error (whether the error occurred without prior evaluation or was clearly negligent with fatal consequences), then this can be held accountable legally for justice.[75] This aligns with Miha Sepec's statement that what can be blamed in a medical error are cases of negligence leading to fatal or serious consequence.[76] This includes ignoring proper medical principles, clearly making a mistake, abusing patient rights for treatment, failing to adhere to professional standards, or failing to take actions that could have easily been avoided.

Several arguments are presented against the criminalization of medical errors by healthcare professionals, including: the first is uncertainty of standards.[77] In healthcare, there is often a lack of absolute certainty due to various limitations. Physicians are frequently required to make difficult decisions without a definitive, 100% correct answer. The second is justification and rationale. From a utilitarian

[73] Elizabeth A. Allan and Kenneth N. Barker, "Fundamentals of Medication Error Research," *American Journal of Hospital Pharmacy* 47, no. 3 (1990): 555. See also, Delbon, "The Protection of Health," 99.

[74] Abdul Kolib, "Analisis Yuridis Perbandingan Risiko Medis Dengan Kelalaian Medis," *AL-MANHAJ: Jurnal Hukum Dan Pranata Sosial Islam* 2, no. 2 (2020): 245. See also, Koto and Asmadi, "Pertanggungjawaban Hukum Terhadap Tindakan Malpraktik," 187; Bulen Jr., "Complementary and Alternative Medicine," 336.

[75] Julius Roland Lajar et al., "Akibat Hukum Malpraktik Yang Dilakukan Oleh Tenaga Medis," *Jurnal interpretasi hukum* 1, no. 1 (2020): 10. See also, Sulistini et al., "Medical Disputes on the Concept," 106; Nofianto, "The Legal Protection of Patients," 63; Anton Van Loggerenberg, "An Alternative Approach," 56; Gharaibeh, "The Impacts of Applications," 378.

[76] Jan-Paul Knaak and Markus Parzeller, "Court decisions on medical malpractice," *International journal of legal medicine* 128, no. 6 (2014): 1053. See also, Šepec, "Medical Error Should It Be a Criminal Offence?," 56; Miller and Wertheimer, "The Fair Transaction Model," 207; Chima, "Evaluating the Quality of Informed," 5.

[77] Eli Y. Adashi and I. Glenn Cohen, "Criminalizing medical errors will undermine patient safety," *Nature Medicine* 28, no. 11 (2022): 2242. See also, Adler, "The Sociophysiology of Caring," 886; Firdaus and Hidayat, *The Role of Informed Consent,* 36.

perspective, actions in the medical field are often justified when the benefits outweigh the risks.[78] Thus, certain procedures or treatments may be acceptable, even if risky, when their potential benefits are greater than the possible harm. In specific situations, such actions may be considered justified or forgivable. The third is defensive medicine. This arises mainly from fear of legal consequences rather than clinical necessity. Healthcare providers may perform excessive tests or procedures to avoid litigation, rather than to benefit the patient clinically.[79] The fourth is criminal penalty as a last resort. Criminal penalties are not effective solutions for addressing or preventing errors in healthcare. If professional negligence is indeed proven, criminal sanctions should be considered only as a final measure. According to Article 310 of Law Number 17 of 2023, when healthcare professionals are suspected of making professional errors that harm patients, such disputes should initially be resolved through alternative dispute resolution mechanisms outside of court.[80]

Errors carry a negative stigma because they can instill guilt, fear, or a lack of trust in doctors or healthcare professionals, especially when the error enters the legal realm. Punishment is not an effective solution; however, in certain circumstances, punishment can provide resolution when negligence is clearly present.[81] One solution is to maintain a culture focused on patient safety and implement appropriate solutions, rather than perpetuating a culture of blame, silence, or punishment. Building safer systems to reduce the likelihood of errors and mitigate their impact on patients is crucial. Organizations must recognize that errors should not be silenced but rather addressed with a focus on system improvement, viewing medical errors as challenges to be overcome in the effort to achieve patient safety.

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[78] Nadia N. Sawicki, "The conscience defense to malpractice," *California Law Review* 108, no. 4 (2020): 1286. See also, Mulyadi et al., "Medical Negligence Dispute Settlement," 1239; Grober and Bohnen, "Defining Medical Error," 44.

[79] Laura VanPuymbrouck et al., "Explicit and implicit disability attitudes of healthcare providers," *Rehabilitation psychology* 65, no. 2 (2020): 101. See also, Ferguson et al., "Malpractice in Emergency Medicine," 663; Robertson and Brit Long, "Suffering in Silence," 404; Ludewigs et al., "Ethics of the Fiduciary," 63.

[80] Albertus D. Soge, "Analisis Penanganan Kesalahan Profesi Medis dan Kesehatan Dalam UU Nomor 17 Tahun 2023 Tentang Kesehatan Menurut Perspektif Hukum Kesehatan," *Jurnal Hukum Caraka Justitia* 3, no. 2 (2023): 154. Koto and Asmadi, "Pertanggungjawaban Hukum Terhadap Tindakan Malpraktik," 187. See also, Suwito et al., "Human Rights Perspectives," 283; Deri Mulyadi et al., "Medical Negligence Dispute Settlement," 1237; Mustika et al., "Restorative Justice Settles Health," 427; Iswandari and Hoque, "Reconceptualizing Legal Arrangement," 61; Prasetyo et al., "Reconstruction of Criminal Design," 335.

[81] James S. Barry et al., "Is medical error a crime? The impact of the State v. Vaught on patient safety," *Journal of Perinatology* 42, no. 9 (2022): 1273.

Patient safety is the underlying philosophy of quality improvement.[82] Based on the explanation in Article 219 of Law Number 17 of 2023 concerning Health, patient safety is crucial because it is a framework for organized activities aimed at building a culture, processes, procedures, behaviors, technology, and environment in healthcare.[83] These efforts are designed to consistently and continuously reduce risks, minimize avoidable losses, prevent potential errors, and mitigate the impact of incidents involving patients.[84]

Moreover, it must be emphasized that errors should not be equated with negligence, as errors often involve indirect components and may stem from limitations in medical practice. Many adverse events are caused by medical errors, and a significant portion of these errors is actually preventable. Such errors can occur anywhere and at any time during the healthcare service process. The consequences range from minor or no harm to severe and fatal outcomes for patients. It is important to recognize that a certain level of error is inevitable in all human tasks, particularly in healthcare services.[85] The root causes of many human errors are often attributed to unknown and systemic factors inherent in healthcare systems, especially within the complexity of modern healthcare services.[86]

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[82] Imelda Ika Aprilia and Redha Vebrina, "Analisis Hukum Terhadap Manajemen Risiko Hukum dan Keuangan Rumah Sakit: Korelasi Dengan Tuntutan Ganti Rugi dalam Pelayanan Kesehatan," *Proceeding Masyarakat Hukum Kesehatan Indonesia* 1, no. 01 (2024): 162. See also, Guillod, "Medical Error Disclosure," 183.

[83] Melanie Widjaja et al., "Tanggung Jawab Hukum Dokter Terhadap Tindakan Malpraktik," *Innovative: Journal of Social Science Research* 3, no. 3 (2023): 5790. See also, Prictor, "Where Does Responsibility Lie?," 8; Hendradiana and Gunarto, "The Legal Renewal of Malpractices," 78; Birkeland, "Informed Consent Obtainment," 270; Langkai, "Malpraktik Medis Dalam Perkara Pidana," 9.

[84] Absarani Maharani Effendi, "Pandangan Dalam Hukum Kesehatan Pada Kasus Malpraktik," *Jurnal Ilmu Hukum Prima* 6, no. 2 (2023): 258. See also, Heriani Istianaet al., "Legal protection of patient," 80; Koto and Asmadi, "Pertanggungjawaban Hukum," 188; Iswandari and Hoque, "Reconceptualizing Legal Arrangement," 65; Henny Saida Flora, "7 Tanggung Jawab Dokter," 7; Kass and Faden, "Ethics and Learning Health," 4.

[85] Yusuf Daeng et al., "Analisis Yuridis Malpraktik Medis dan Dampak Pidananya," *Innovative: Journal of Social Science Research* 3, no. 6 (2023): 3415. See also, Levinson et al., "Developing Physician Communication Skills," 1314; Jolly et al., "Evaluation of a Simulation," 73; Mostafapour et al., "Beyond Medical Errors," 9.

[86] Marsono Budi Ujianto and Wijaya Wijaya, "Tanggung Jawab Hukum Dokter Terhadap Gugatan Pasien Dalam Pelayanan Kesehatan di Rumah Sakit," *Jurnal Juristic* 1, no. 01 (2020): 56. See also, Grober and Bohnen, "Defining Medical Error," 44; Finkelstein et al., "When a Physician Harms," 332; Kalra, "Medical Errors: An Introduction," 1048; Nikitchenko et al., "A Medical Error," 699; Šepec, "Medical Error Should it Be a Criminal Offence?" 54; Kusumaningrum, "Analisis Transaksi Terapeutik," 9.

4. Conclusion

Medical risk is an inseparable part of healthcare services because every medical action carries potential risks, even though efforts to minimize these risks are made carefully in accordance with professional standards and ethics. The legal relationship between doctors and patients is equal, based on a legal commitment in the form of a therapeutic transaction. This involves the rights and obligations of both parties, reflected in the medical action consent or informed consent. Medical risks in healthcare must be managed through transparent communication, the implementation of procedures according to standards, and legal protection that is mutually beneficial for both patients and healthcare professionals.

Medical risk is a condition that cannot be fully avoided in healthcare, as medical actions always carry the potential for unintended consequences, even when performed according to professional standards. Medical risk differs from medical negligence because medical risk does not involve negligence. The legal implications of medical risk mean that a doctor cannot be criminally charged for medical risk if they have followed operational, professional, and medical standards, and provided complete explanations to the patient or their family about the potential risks. On the other hand, medical negligence can result in criminal charges if it is proven that the doctor failed to meet their obligations, such as being inattentive, careless, or not following standard procedures. Medical errors and malpractice have fundamental differences, but they are often difficult to distinguish, especially in a legal context. A medical error is an unintentional error in medical care, while malpractice involves intentional negligence or a disregard for professional standards.

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