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Medical Risk Assessment, Medical Errors, And Legal Accountability

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Abstract: Healthcare services are inherently complex and challenging activities, particularly in terms of medical risks and the potential for medical errors or malpractice. Medical risks, medical errors, and malpractice in healthcare are interconnected concepts that are interesting to examine together, as all three can have negative consequences for the patient's body. Therefore, it is essential to explore them further to distinguish between them clearly. This research aims to examine the legal aspects of the relationship between medical risk, medical error, and malpractice, as well as the potential legal liabilities that may arise in medical practice. The approach used is normative juridical, with primary sources including legislation, legal principles, and relevant scholarly literature. The findings suggest that medical risks are inherent consequences of any medical action, which cannot always be avoided, and do not imply negligence if performed in accordance with professional standards, ethics, and operational procedures. In contrast, medical errors refer to unintentional mistakes in the implementation or planning of medical actions, which still need to be evaluated to prevent recurring adverse impacts. Medical malpractice occurs when there is an element of negligence and a violation of professional standards that results in harm to the patient, potentially leading to both criminal and civil legal liability. By clearly distinguishing between medical risk, medical error, and malpractice, this research highlights the importance of therapeutic communication, the application of informed consent principles, and the need for balanced legal protection that balances both patient safety and medical personnel protection.
Keywords: Medical risk, Medical error, Malpractice, Legal liability, Healthcare services.

1. Introduction

Health is one of the fundamental needs crucial for a nation. Recognizing its significance, governments formulate and implement policies aimed at ensuring the health of individuals and communities. The importance of health directly impacts the quality of human resources, serving as a pivotal factor in addressing poverty and fostering economic growth. To achieve these objectives, governments aim to facilitate access to healthcare services through expanded healthcare delivery systems and the provision of social health insurance. However, the implementation of healthcare services is not without challenges. One significant issue is the emergence of legal disputes, often involving allegations of malpractice due to medical risks or errors. Such cases typically arise from adverse outcomes of healthcare services, including disability or death, without clear causal explanations.

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. 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. Transparency is both a right and a duty. Patients are obliged to provide complete and honest information about their health conditions, which, in turn, serves as a right for physicians to receive, enabling them to determine the most appropriate course of action. This obligation is explicitly stated in Article 276 of Law No. 27 of 2023 on Health, which mandates that "patients are required to provide complete and honest information about their health problems."

Patients who perceive themselves as harmed by healthcare services often attribute blame to medical professionals, accusing them of committing offenses against bodily integrity or life by causing injury or death due to alleged negligence. In reality, many adverse outcomes in healthcare arise from uncontrollable factors, including medical risks that are mistakenly attributed to doctor errors. Given that health is a fundamental human right protected by law, and that the right to life is equally paramount, the existence of legal frameworks governing medical practice is not only necessary but crucial. Moreover, legal regulations addressing the conduct of healthcare professionals—particularly actions leading to deteriorating health or death that could have been avoided with greater care or professional adequacy—are indispensable.[1]

There are instances where the expectations of patients and physicians diverge from desired outcomes. Unexpected complications or unexplained adverse conditions may arise. Physicians cannot guarantee successful treatment outcomes or an absolute absence of risks. Healthcare, being an inherently uncertain field, is subject to various possibilities, including medical risks that emerge during care delivery. Consequently, a physician's role is to provide the best effort, not a guaranteed result.

While medical risks cannot be entirely controlled, it is essential to communicate these possibilities to patients to prevent misunderstandings and unwarranted accusations of negligence against doctors or nurses [2]. Similarly, while medical errors may occur, they must not be dismissed or left unaddressed. Errors, although inherent to human nature, must not be tolerated if they occur repeatedly. Corrective measures should be taken to prevent recurrence, relying on accountable knowledge and professional standards.

Patient safety is a critical component of healthcare delivery. Its prominence is fueled by a growing body of literature highlighting the high incidence of treatment errors and widely publicized cases of medical mistakes that have heightened public concern over the safety of modern healthcare services. Medical risks, medical errors, and malpractice share a commonality in their potential to negatively impact outcomes, necessitating a structured and unified approach to their analysis [3]. Therefore, this study aims to explore and clarify the interplay between medical risk assessment, medical errors, malpractice, and their associated legal responsibilities.

Malpractice and medical risk, while also highlighting the complexity of public understanding and the lack of precise juridical formulations regarding medical risk in Indonesian legislation. Another study conducted by Rohadi et al.4 focused primarily on legal protection for the medical profession following the enactment of Law No. 17 of 2023 on Health, particularly in cases involving alleged malpractice. This research examined the legal liability of doctors in criminal, civil, and professional ethical contexts, emphasizing the importance of public education to prevent misunderstandings between medical risk and malpractice.

The researcher contributes by addressing existing gaps through a more holistic and analytical approach. This study not only differentiates between medical risk, medical error, and malpractice from legal and ethical perspectives but also systematically outlines the legal contractual relationship between doctors and patients as a critical foundation for identifying

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[1] Miha Šepec, "Medical Error – Should It Be a Criminal Offence?," *Medicine, Law & Society* 11, no. 1 (April 25, 2018): 47–66, https://doi.org/10.18690/2463-7955.11.1.47-66.(2018).

[2] Abdul Kolib, "Analisis Yuridis Perbandingan Risiko Medis Dengan Kelalaian Medis," *AL-MANHAJ: Jurnal Hukum Dan Pranata Sosial Islam* 2, no. 2 (July 22, 2020): 238–54, https://doi.org/10.37680/almanhaj.v2i2.481.

[3] Brenda Langkai, "Malprkatik Medis Dalam Perkara Pidana," *Lex Administraum* 11, no. 5 (2023).

[4] https://doi.org/10.24843/KS.2024.v12.i11.p02

the forms of legal liability. Moreover, the research places strong emphasis on the importance of transparent communication, patient education about risk, and accurate documentation through informed consent. A key strength of this study lies in its clear differentiation of the three concepts-medical risk, medical error, and malpractice-in terms of definitions, legal causality, elements of fault, and the resulting criminal or civil liability. It also proposes more operational theoretical boundaries between medical risk, medical error, and malpractice within the Indonesian legal system.

2. Method

The research method employed in this study is the normative juridical approach, where legal norms, including statutory regulations, legal principles, and legal theories, serve as the primary framework. The study adopts a descriptive-analytical specification. The initial phase involves a regulatory review and systematic literature review. During this phase, the research team examines the existing conditions by referencing relevant literature and statutory regulations. This research does not involve direct field studies. Data collection is conducted through document analysis. The collected data is analyzed using a normative qualitative approach, where the data is systematically, logically, and effectively presented in well-structured sentences without overlap. The findings from the discussion are synthesized inductively to address the research questions and objectives, providing comprehensive answers to the issues at the core of the study.

3. Results and Discussion

3.1 Medical Risk in Health Law

Medical risks would not arise if no treatment or medical actions were undertaken during healthcare or nursing services provided through therapeutic transactions. Although the occurrence of medical risks in healthcare services is minimal, nearly every medical procedure inherently involves some degree of risk. 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 [5]. 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.

The relationship between doctors and patients is legally characterized as an equal relationship. 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[6]. From a legal perspective, Article 1 of Law No. 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, Based on this, doctors

[5] Jr, Sidney T. Bogardus, "Perils, Pitfalls, and Possibilities in Talking About Medical Risk," *JAMA* 281, no. 11 (March 17, 1999): 1037, https://doi.org/10.1001/jama.281.11.1037.

[6] Herbert M. Adler, "The Sociophysiology of Caring in the Doctor-Patient Relationship," *Journal of General Internal Medicine* 17, no. 11 (November 2002): 883–90, https://doi.org/10.1046/j.1525-1497.2002.10640.x.

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.

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*.[7] This legal relationship grants both the patient and the doctor rights and obligations. *Inspannings verbintenis* 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.

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. 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 [8], following the patient's recovery of consciousness, informed consent is then sought.

It is emphasized in Article 293 Paragraph (9) of Law No. 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. 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.

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 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. Article 1329 of the Civil Code states that every person is

[7] Anggraeni Endah Kusumaningrum, "Analisis Transaksi Terapeutik Sebagai Sarana Perlindungan Hukum Bagi Pasien," *YUSTISIA MERDEKA : Jurnal Ilmiah Hukum* 5, no. 2 (December 16, 2019), https://doi.org/10.33319/yume.v5i2.35.

[8] Syahrul Machmud, *Penegakan Hukum Dan Perlindungan Hukum Bagi Dokter Yang Diduga Melakukan Medikal Malpraktek*, 1st ed. (Bandung: Mandar Maju, 2008).

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. 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.

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 and Robert if informed consent is not given, it constitutes a crime.[9] 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.

Law No. 17/2023, Article 293, states that every individual healthcare service performed by medical personnel and healthcare workers must receive consent. 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 carries risks, so consent is mandatory, whether the action is minor or major.

Consent, whether given in writing or orally, must be obtained before any medical action is taken. However, written informed consent is mandatory when the procedure is invasive and/or carries high risks. If the patient is deemed incapable of providing consent, consent can be given by a representative, with one of the healthcare providers or medical staff as a witness. Consent is given after the patient is made aware of the potential medical risks and grants permission to the doctor to perform the therapeutic action.[10].

Informed consent is a form of equality between the patient and the doctor [11]. It is ensured that patients claim their right to participate in decision-making regarding healthcare

[9] Robert D Miller, "The First Medical Informed Consent Statute - Deseret (1851): The Use of Laws Requiring Consent to Discourage Disfavored Medical Procedures," *MINDS@UW*, 2020.

[10] Riza Alifianto Kurniawan, "RISIKO MEDIS DAN KELALAIAN TERHADAP DUGAAN MALPRAKTIK MEDIS DI INDONESIA," *Jurnal Perspektif* 18, no. 3 (2013).

[11] Ukilah Supriyatin, "HUBUNGAN HUKUM ANTARA PASIEN DENGAN TENAGA MEDIS (DOKTER) DALAM PELAYANAN KESEHATAN," *Jurnal Ilmiah Galuh Justisi* 6, no. 2 (November 19, 2018): 184, https://doi.org/10.25157/jigj.v6i2.1713.

options.[12]. 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 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. 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.[13].

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.

3.2 Medical Risk Cannot Be Penalized

Every action we take always carries a risk that must be faced. To avoid this risk, we could choose not to do anything, but even then, it cannot guarantee that the risk will be eliminated, nor can we avoid it by simply doing nothing. To prevent risks from occurring, one must think carefully and prudently.

Legally, medical risk is not clearly defined, but in the Indonesian Dictionary (KBBI). risk can be defined as an undesirable (harmful, dangerous) consequence of an action or behavior. Another definition of risk is a deviation from the expected outcome or a potential aspect of loss [14]. Meanwhile, "*medis*" (medical) originates from Latin and Greek, and generally refers to diagnosis and surgery . "*Medis*" relates to or is associated with medicine. Another view is that the medical terminology system is used to organize a list of medical terms for diseases, symptoms, and procedures [15]. The definition of medical risk is a situation that cannot be anticipated beforehand or a condition where preventive measures can no longer be taken [16]

Understanding the information provided by doctors to patients is crucial in preventing misunderstandings or allegations of negligence. To avoid the perception that every outcome

[12] 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 (May 31, 2017): 264–84, https://doi.org/10.1163/15718093-12341410.

[13] Marc D. Ginsberg, "Informed Consent: No Longer Just What the Doctor Ordered? Revisited.","Akron Law Review 52, no. 1 (2019).

[14] Opan Arifudin, Udin Wahrudin, and Fenny Damayanti Rusman, *Manajemen Risiko* (Bandung: Widina, 2020).

[15] H.F Rommony, "Evaluasi Kesesuaian Penggunaan Terminologi Medis Pada Penulisan Diagnosis Lembar Resume Medis Berdasarkan ICD-10 Di RSU Haji Surabaya (Studi Literatur)" (Disertasi, STIKES Yayasan RS Dr. Soetomo Surabaya, 2021).

[16] Guwandi, *Hukum Medik (Medical Law)* (Jakarta Fakultas Kedokteran Universitas Indonesia: UI, 2004).

that does not meet expectations is always seen as malpractice, it is important to recognize that in medical practice, unfavourable results may occur due to[17]:

1. The natural course of a disease;
2. Complications of diseases that are unrelated to the healthcare services provided by the doctor at the time;
3. Unavoidable risks, including those that cannot be foreseen and those that are known but deemed acceptable due to their low probability and already understood and agreed upon by the patient or their family. Even risks with a high probability must be undertaken if it is the only viable course of action.
4. Errors due to patient variations. This opinion 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 history. 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[18].

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.

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[19]. Inherent risks arise from the medical procedures performed 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 Iniura* 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.

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. 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. Medical risks occur during healthcare services

[17] (Ari Yunanto dan Helmi, 2010)

[18] Barry F Furrow et al., *Health Law, Cases, Materials and Problems*, 3rd ed. (America: West Publishing Co, 1997).

[19] Michel Daniel Mangkey, "Perlindungan Hukum Terhadap Dokter Dalam Memberikan Pelayanan Medis," *Lex et Societatis* 2, no. 8 (2014).

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[20], [21]. 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 (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 of the person[22]. 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. According to Bambang professional standards consist 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. 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 [23]

Law No. 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.

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

[20] Bambang Poernomo, *Hukum Kesehatan Pertumbuhan Hukum Eksepsional Di Bidang Pelayanan Kesehatan* (Yogyakarta: Aditya Media, 1991).

[21] Brenda Langkai, "Malprkatik Medis Dalam Perkara Pidana."

[22] Anny Isfandyarie, *Malpraktek & Resiko Medik (Dalam Kajian Hukum Pidana)* (Jakarta: Prestasi Pustaka, 2005).

[23] Bambang Poernomo, *Hukum Kesehatan Pertumbuhan Hukum Eksepsional Di Bidang Pelayanan Kesehatan*.

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.

3.3 The Intersection of Medical Error and Malpractice

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. 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.

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

1. 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[24]. According to the Institute of Medicine (IOM) report titled "*To Err is Human*": medical error is 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). [25][26],[27]
2. 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[28].
3. Medical error can also be defined as a failure in the mechanisms used to acquire and process information relevant to the task at hand.[29]

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[30]:

1. 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.

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[24] Jawahar Kalra, "Medical Errors: An Introduction to Concepts," *Clinical Biochemistry* 37, no. 12 (December 2004): 1043–51, https://doi.org/10.1016/j.clinbiochem.2004.08.007.

[25] A. R Holder, *Medical Errors*, 1st ed. (ASH Education Program Book, 2005).

[26] Šepec, "Medical Error – Should It Be a Criminal Offence?"

[27] Ethan D. Grober and John M.A. Bohnen, "Defining Medical Error," Canadian Journal of Surgery 48, no. 1 (2005).

[28] Nataliia V. Nikitchenko et al., "A MEDICAL ERROR: DOES LAW HELP OR HINDER," *Wiadomości Lekarskie* 72, no. 4 (April 2019): 697–701, https://doi.org/10.36740/WLek201904137.

[29] Stephen M. Casner, "To Err Is Human, to Be Error-tolerant Is Divine. Human Error, James Reason. Cambridge University Press, New York, 1990. No. of Pages 302. ISBN 0-521-306-698 (Hardback) and 0-521-314-194 (Paperback). Price US $54.95 (£42.50) and US $21.95 (£13.95) Respectively," *Applied Cognitive Psychology* 6, no. 5 (September 13, 1992): 456–57, https://doi.org/10.1002/acp.2350060510.

[30] Rodziewicz, Thomas L, and John E. Hipskind, "Medical Error Prevention," *Stat Pearls Publishing*, 2020.

2. 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.

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 [31].

The category of errors must be determined operationally before an investigation is conducted, and every deviation should be clearly stated [32]. 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.

From the explanation above, the writer can conclude 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. 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[33]. 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 reasons are presented against the criminalization of medical errors for healthcare professionals, including: (1). Uncertainty of Standards. In healthcare, there is often a lack of certainty due to various limitations. Doctors are frequently required to make difficult decisions because there is no definitive answer that is 100% correct. (2). Justification and Rationale. From a utilitarian perspective, the application in medical professions explains that the benefits of certain actions outweigh the risks. Therefore, justification is acceptable when the benefits of a treatment or procedure are greater than the potential risks. In certain situations, actions may be justified or forgiven. (3). Defensive Medicine. Defensive medicine occurs primarily due to the fear of legal liability, not directly for clinical reasons. Healthcare providers may conduct unnecessary tests or procedures to avoid potential lawsuits rather than for clinical necessity. And (4) Criminal Penalty as a Last Resort. Criminal penalties do not solve problems or eliminate errors in healthcare services. If negligence is truly proven, criminal penalties should be used as a last resort. According to Law No. 17/2023, Article 310, when healthcare professionals are suspected of making errors in their profession that

[31] Barry F Furrow et al., *Health Law, Cases, Materials and Problems*.

[32] Elizabeth A. Allan and Kenneth N. Barker, "Fundamentals of Medication Error Research," *American Journal of Health-System Pharmacy* 47, no. 3 (March 1, 1990): 555–71, https://doi.org/10.1093/ajhp/47.3.555.

[33] Šepec, "Medical Error – Should It Be a Criminal Offence?"

cause harm to patients, disputes arising from these errors should first be resolved through alternative dispute resolution outside of court.

The word "error" carries a negative stigma because it can create feelings of guilt, fear, or a lack of confidence in doctors or healthcare professionals, especially when the error enters the legal realm. Punishment is not an effective solution; however, in certain circumstances, it can provide a resolution if it is clear that negligence occurred. One solution is to maintain a culture focused on patient safety and to implement appropriate solutions, rather than perpetuating a culture of blame, silence, or punishment. Building a safer system to reduce the likelihood of errors and mitigate their impact on patients is crucial[34]. Organizations should recognize that errors should not be silenced, but rather addressed with a focus on improving systems, viewing medical errors as challenges to overcome in the pursuit of patient safety.

Patient safety is a philosophy that underpins quality improvement [35]. According to the explanation in Article 219 of Law No. 17 of 2023 on Health, patient safety is crucial because it represents a framework of organized activities aimed at building a culture, processes, procedures, behaviors, technology, and environments within healthcare services. These efforts are consistently and sustainably designed to reduce risks, minimize avoidable harm, prevent potential errors, and mitigate the impact when incidents occur involving patients.

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. 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.

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

[34] Ethan D Grober and John M A Bohnen, "Defining Medical Error," *National Library of Medicine* 48, no. 1 (February 2005).

[35] Olivier Guillod, "Medical Error Disclosure and Patient Safety: Legal Aspects," *Journal of Public Health Research* 2, no. 3 (December 27, 2013), https://doi.org/10.4081/jphr.2013.e31.

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 error and malpractice have fundamental differences, but they are often difficult to distinguish, particularly in a legal context. A medical error is an unintended mistake in medical service, while malpractice involves negligence that is either intentional or a disregard for professional standards.

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