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# Legal Protection for Patients Undergoing Orthopedic Surgery from The Perspective of Equity and Sustainability in Health Care

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**Abstract**

In healthcare practice, orthopedic surgical procedures are frequently performed on patients with serious injuries, such as work-related accidents or traffic accidents, which require immediate medical attention. However, postoperative complications are often perceived as medical malpractice, potentially leading to disputes between patients and medical personnel. This situation highlights the lack of clarity regarding the boundary between medical risk and medical negligence, which can give rise to legal liability. This study aims to (1) analyze the legal framework regarding patient protection in orthopedic surgery within the Indonesian healthcare legal system, and (2) examine the boundary between medical risk and malpractice, as well as its implications for healthcare providers' liability from the perspectives of equity and the sustainability of healthcare services. The research method used was a normative legal study employing both a statutory and a conceptual approach. The results of the study indicate that legal protection for patients undergoing orthopedic surgery is related to the recognition of patients' rights, the implementation of patient safety measures, and the obligation of medical personnel to provide clear medical information through informed consent. Compliance with professional standards and medical service standards serves as the basis for distinguishing between acceptable medical risks and medical negligence categorized as malpractice. Therefore, strengthening medical service standards, ensuring transparency of information, and establishing fair dispute resolution mechanisms are necessary to guarantee patient protection while also providing legal certainty for medical personnel in delivering equitable and sustainable healthcare services.

## INTRODUCTION

The 1945 Constitution of the Republic of Indonesia states that health is a fundamental right and an integral component of human well-being. Patient rights are classified as human rights derived from the right to self-determination (Nagieh, n.d.). In this context, orthopedic surgery, as part of specialized healthcare services, plays a strategic role in treating musculoskeletal disorders, such as bone injuries, joint abnormalities, and degenerative conditions that directly affect patients' mobility, productivity, and quality of life. Along with advancements in medical technology and increasing public demand, orthopedic surgery has experienced a significant rise in both procedural complexity and the number of patients treated (Asshiddiqie, 2020).

The high complexity of orthopedic surgical procedures is accompanied by potential risks that cannot be ignored, such as postoperative complications, medical procedure failures, and the possibility of medical errors. These conditions place patients in a vulnerable position, thereby requiring adequate legal protection. From a health law perspective, the relationship between patients and medical personnel in orthopedic surgery is not merely a therapeutic relationship but also a legal relationship that gives rise to rights and obligations for the parties involved (Koeswadji, 2016). Patients have the right to receive complete, honest, and transparent information regarding the medical procedures to be performed, including risks and treatment alternatives, as well as the right to provide informed consent. On the other hand, healthcare providers have an obligation to perform procedures in accordance with professional standards, service standards, and the principles of patient safety (Ameln, 2017).

In practice, various problems are still frequently encountered, revealing a gap between normative regulations (das sollen) and empirical reality (das sein). These problems include the suboptimal implementation of informed consent, limited communication between medical personnel and patients, an imbalance in bargaining power between the parties, and the emergence of alleged malpractice cases that lead to legal disputes (Udi Sampurna, 2020). Furthermore, the suboptimal oversight and law enforcement mechanisms in the healthcare sector exacerbate the condition of patients' legal protection, particularly in high-risk medical procedures such as orthopedic surgery (Pound, 2017).

Issues concerning patient legal protection in orthopedic surgery are also closely linked to the principle of equity in healthcare. Equity requires that every individual has an equal right to access quality healthcare without discrimination, whether based on social status, economic status, or geographic location. However, the reality in Indonesia reveals disparities in access to orthopedic services, particularly between urban and rural areas, a shortage of specialist medical personnel, and inequities in healthcare financing. These conditions have the potential to create injustice in the fulfillment of health rights, which ultimately weakens legal protection for patients.

On the other hand, the concept of sustainability in healthcare is becoming increasingly important in addressing the challenges of the modern healthcare system. Sustainability encompasses not only the continuity of care but also safe, efficient, responsible, and long-term medical practices that prioritize patients' conditions. In the context of orthopedic surgery, sustainability includes the quality of medical procedures, patient recovery, and the optimal use of healthcare resources. Therefore, the patient legal protection system must be able to integrate sustainability principles by promoting accountability among medical personnel and healthcare institutions.

The novelty of this research lies in its integration of equity and sustainability perspectives into the analysis of patient legal protection in orthopedic surgery. Unlike previous studies that focus narrowly on individual liability or procedural compliance, this research examines how legal protection mechanisms can simultaneously achieve three objectives: (1) protecting patients from harm and ensuring access to justice as a manifestation of equity; (2) providing legal certainty for healthcare providers so they can practice without fear of unjust criminalization, thereby supporting the sustainability of the medical profession; and (3) ensuring the continuity of safe, efficient, and high-quality orthopedic services as part of the sustainability of the healthcare system. This research also provides a systematic analysis of

implant-related liability under Law Number 17 of 2023, including the interaction between health law, civil law, particularly product liability, and consumer protection law.

Based on the above explanation, this study aims to analyze the forms and mechanisms of legal protection for patients undergoing orthopedic surgical procedures within Indonesia's health law system, identify gaps between normative regulations and actual practice, and formulate a legal protection model oriented toward the principles of equity and sustainability in healthcare services.

This study employs a normative legal methodology, which focuses on the examination of legal norms found in legislation, legal doctrine, and legal literature. All legal materials were collected through a literature review and analyzed qualitatively using legal interpretation to produce systematic, logical, and comprehensive arguments in addressing the research questions (Soekanto, 2018).

## RESEARCH METHODOLOGY

This study employs a normative legal research method designed to systematically analyze legal norms, regulations, and doctrines relevant to patient protection in orthopedic surgery in Indonesia. The research integrates both a statutory approach and a conceptual approach to address the research objectives comprehensively.

1. Statutory Approach

   The statutory approach involves a detailed examination of primary legal materials, including Law No. 17 of 2023 on Health, the 1945 Constitution of the Republic of Indonesia, Minister of Health Regulations on patient safety, medical records, and medical device standards. These legal sources provide the normative foundation for understanding patients' rights, the obligations of healthcare professionals, and standards for medical service provision.

2. Conceptual Approach

   The conceptual approach explores the theoretical framework surrounding medical risk, malpractice, patient protection, equity, and healthcare sustainability. It involves reviewing legal doctrines, scholarly literature, and case studies to clarify the boundary between acceptable medical risks and medical negligence and to understand its implications for healthcare providers' liability.

3. Data Collection

   Data were collected through a comprehensive literature review of legal texts, scientific publications, professional guidelines, and previous research related to medical law, patient rights, orthopedic surgery, and healthcare service standards. Sources include books, journal articles, government regulations, and other authoritative references.

4. Data Analysis

   The collected materials were analyzed qualitatively using legal interpretation and doctrinal analysis. The analysis focused on identifying patterns, gaps, and consistencies in legal provisions and their application to orthopedic surgical practice. Emphasis was placed on evaluating how legal norms regulate patient protection, informed consent, professional standards, and liability mechanisms.

5. Outcome

   The methodological framework enables a systematic assessment of the legal landscape governing orthopedic surgery in Indonesia. It provides insight into how healthcare professionals can distinguish between legitimate medical risks and malpractice, ensuring both patient protection and sustainable, equitable healthcare delivery.

## RESULTS AND DISCUSSION

### Legal Provisions Regarding Patient Protection in Orthopedic Surgery Within the Indonesian Healthcare Legal System

Legal protection for patients undergoing orthopedic surgery is an integral part of Indonesia's healthcare legal framework, which is inseparable from the recognition of the right to health as a human right. In a constitutional context, Article 28H paragraph (1) of the 1945 Constitution of the Republic of Indonesia affirms that every person has the right to healthcare, which is further elaborated in Law No. 17 of 2023 on Health as the latest regulation comprehensively governing the national health system. Orthopedic surgery, as a form of specialized medical care, is characterized by high risks, whether in terms of invasive procedures, the use of medical devices, or the potential for postoperative complications. Therefore, its regulation is not merely technical-medical in nature but also involves a legal dimension that demands robust legal protection standards for patients, who are often in a vulnerable position. From a health law perspective, the relationship between doctors and patients in orthopedic procedures is not merely contractual, as reflected in a therapeutic agreement, but also represents a public law relationship involving the state's responsibility to ensure the safety and quality of healthcare services (Budi Sampurna, 2017b).

Legally, regulations on patient protection in orthopedic surgical procedures in Indonesia are currently based primarily on Law No. 17 of 2023 on Health, which has integrated various previous provisions, including regulations related to hospitals, thereby providing a more comprehensive framework regarding patient rights, the obligations of medical personnel, and health service standards focused on safety and quality of care (Siregar, 2023). In an operational context, various subsidiary regulations, such as the Minister of Health Regulation on patient safety and medical records, further strengthen the technical aspects of patient protection through provisions on medical accountability, information transparency, and continuity of care. However, despite regulatory unification, there remains potential fragmentation of standards at the implementation level, particularly in high-risk orthopedic surgery practices that require more integrated and specific standards. Therefore, policy harmonization and the strengthening of technical regulations are necessary to achieve more comprehensive legal certainty for patients and healthcare professionals, in line with the principles of legal protection in modern healthcare services.

In practice, legal protection for patients undergoing orthopedic surgery depends heavily on the fulfillment of patients' rights, particularly the right to information and informed consent for medical procedures. The principle of informed consent is a manifestation of respect for patient autonomy, whereby every medical procedure must be based on consent given consciously after the patient has received complete information regarding the diagnosis, procedure, risks, benefits, and alternative treatments. This obligation is explicitly regulated in

Article 276 paragraphs (1) and (2) of the 2023 Health Law, which states that every healthcare service must obtain the patient's consent after a complete explanation has been provided. Additionally, Article 293 of the 2023 Health Law stipulates that such consent may be given in writing or orally, depending on the type of medical procedure performed. In the context of orthopedic surgery, informed consent becomes increasingly crucial given the high risks associated with the procedure, such as surgical failure, infection, and even permanent disability. Therefore, negligence in obtaining informed consent may result in legal liability, whether under civil law as a breach of contract or tort, and under certain conditions may even lead to criminal liability.

Patient protection is also closely linked to the application of professional standards and medical service standards in orthopedic procedures, which are now comprehensively regulated under Law No. 17 of 2023 on Health. Healthcare professionals, particularly orthopedic specialists, are required to practice in accordance with professional standards, service standards, and standard operating procedures to ensure safe, high-quality care that prioritizes patient safety as part of fulfilling the right to health. In the context of healthcare facilities, the law also emphasizes the importance of implementing a patient safety system as part of integrated and sustainable clinical risk management and healthcare governance (Hanafiah & Amir, 2016). Thus, patient protection depends not only on the individual competence of medical personnel but also on an institutional system that encompasses oversight, accreditation, and comprehensive quality assurance of services. Any violation of these standards may result in legal consequences in the form of administrative sanctions, ethical sanctions, professional disciplinary actions, or other forms of legal liability.

In the development of modern orthopedic surgical practices, the use of implants or prostheses has become an integral part of medical procedures, particularly in the treatment of fractures, joint reconstruction, and joint replacement. Orthopedic implants may include pins, plates, screws, or joint prostheses such as knee and hip replacements, which function to replace or support damaged anatomical structures. Legally, the use of implants in medical procedures raises more complex legal consequences than conventional medical procedures, as it involves patient safety, medical device standards, and multi-party liability encompassing medical personnel, healthcare facilities, and medical device manufacturers (Notoatmodjo, 2017).

The issue of implants and prostheses is particularly relevant because their use carries specific risks, such as implant failure, infection, biomaterial incompatibility, prosthesis loosening, mechanical damage, and the need for revision surgery. Therefore, legal protection for patients in orthopedic procedures must include a guarantee that the implants or prostheses used meet safety, quality, and efficacy standards and are applied in accordance with medical indications by competent medical personnel. Under current regulations, business activity standards and product or service standards in the health subsector are now referenced in Ministry of Health Regulation No. 11 of 2025 on Business Activity Standards and Product/Service Standards in the Implementation of Risk-Based Business Licensing for the Health Subsector. Thus, discussions regarding the use of orthopedic implants must be framed within compliance with the latest health product and service standards. On the other hand, documentation of the use of such implants must also be accurately reflected in medical records, in accordance with the obligations regarding the maintenance of medical records as stipulated in Ministry of Health Regulation No. 24 of 2022 on Medical Records (Tutik, 2020).

Technical regulations regarding medical devices, including orthopedic implants, are set forth in ministerial health regulations, including Ministry of Health Regulation No. 11 of 2025 on Business Activity Standards and Product/Service Standards for the Implementation of Risk-Based Business Licensing in the Health Subsector, as well as regulations related to the distribution and supervision of medical devices. In this context, every implant used must have marketing authorization, meet national and international standards, and be used according to medical indications by competent healthcare professionals. This obligation is also closely related to the responsibility of healthcare facilities to ensure that the devices used have been clinically tested and are safe for patients.

From a patient protection perspective, the use of orthopedic implants requires stricter adherence to the principle of informed consent. This is due to the invasive and long-term nature of implants, as well as potential risks such as implant failure, infection, the body's reaction to foreign objects, and the need for revision surgery. Therefore, patients must be provided with complete information regarding the type of implant used, its benefits, risks, lifespan, and potential complications. This obligation is legally mandated under Law No. 17 of 2023 on Health, particularly regarding consent for medical procedures, which emphasizes the importance of transparency and patient autonomy in medical decision-making (Sasongko, 2020).

In practice, the use of orthopedic implants also opens the possibility of legal disputes, particularly when implant failure occurs and affects the patient's condition. The legal issues that arise often concern whether such failure constitutes an acceptable medical risk or negligence. Furthermore, in certain cases, legal liability does not rest solely with the physician but may also involve the medical device manufacturer under the framework of product liability. Thus, the legal liability regime regarding the use of orthopedic implants is complex and involves the interplay of health law, civil law, and consumer protection law.

On the other hand, advancements in orthopedic implant technology, including the use of biomaterials and robotics-based technologies, require regulatory adaptations that are responsive to innovation. The state must ensure that every technological advancement in orthopedics remains within a legal framework that guarantees patient safety and legal certainty for medical personnel. In this context, strengthening oversight systems, medical device certification, and medical audits is crucial for preventing malpractice risks and continuously improving the quality of healthcare services.

Legal regulations regarding implants and prostheses in orthopedics are an integral part of the patient protection system, which requires a multidimensional approach encompassing regulatory, medical practice, and law enforcement aspects. Moving forward, more specific and integrated regulatory frameworks are needed to anticipate technological advancements and minimize the potential for legal disputes in orthopedic surgical practice.

From the perspective of legal liability, orthopedic surgical procedures may give rise to liability under various legal regimes, namely civil, criminal, administrative, and ethical. In civil law, the relationship between a doctor and a patient within a therapeutic contract may give rise to liability in the event of a breach of contract or an unlawful act, as provided for in Article 1365 of the Civil Code. Criminally, medical negligence resulting in serious injury or death may be prosecuted under the provisions of the Criminal Code, such as Articles 474 and 475. Meanwhile, from an administrative perspective, medical personnel may face sanctions from

the Indonesian Medical Council or health authorities if they violate licensing regulations and practice standards (Soekanto, 2018). On the other hand, violations of the medical code of ethics may also be addressed through ethical mechanisms by the Medical Ethics Honorary Council. Thus, the system of legal accountability in orthopedic practice is multi-layered and aims to provide comprehensive protection for patients.

Legal protection for patients undergoing orthopedic surgery must also be viewed from the perspective of fairness and equitable access to healthcare services. In practice, disparities in access to orthopedic services still exist, particularly for people in remote areas or vulnerable groups such as patients with limited financial means and disabilities. In this context, the state has an obligation to ensure that every citizen has equal access to healthcare services, as mandated by Law No. 17 of 2023 on Health. Furthermore, the national health insurance system through BPJS Kesehatan serves as a crucial instrument in ensuring access to orthopedic services, although in practice it still faces various challenges, such as limited facilities and long waiting times. Therefore, patient protection is not merely a legal matter but also involves public policy aspects that ensure distributive justice in healthcare services (Nasser, 2019).

From a sustainability perspective, patient protection in orthopedic surgery must encompass the sustainability of healthcare services from the preoperative stage through the surgical procedure to postoperative care. The concept of continuity of care is essential to ensure that patients receive consistent, high-quality care (Asyhadie, 2021). Furthermore, advancements in medical technology within the field of orthopedics, such as the use of implants and robotic technology, also require adaptive legal frameworks to continue ensuring patient safety. In this regard, the state must ensure that technological innovations do not compromise patients' legal protection but instead strengthen a healthcare system that is safe, effective, and sustainable.

In practice, various issues and regulatory gaps remain regarding patient protection in orthopedic surgery. One of the main issues is the absence of regulations specifically governing orthopedic practice, meaning that relevant provisions remain scattered across various general regulations. Additionally, ambiguity remains in distinguishing between reasonable medical risks and malpractice, which often leads to disputes between patients and medical personnel. On the other hand, oversight and enforcement mechanisms for medical practices are not yet optimal, so they do not fully provide a deterrent effect or maximum protection for patients. This situation highlights the need for a more comprehensive and integrated reformulation or refinement of regulations (Sudirta, 2020).

To strengthen patient protection, a patient-centered legal approach is needed, placing the patient at the center of the healthcare legal system. This approach emphasizes the importance of transparency, accountability, and patient participation in every stage of healthcare delivery. Additionally, integrating a legal accountability system that encompasses civil, criminal, administrative, and ethical aspects is key to creating an effective protection system. The digitization of medical records, the strengthening of medical audits, and technology-based oversight can also serve as solutions to improve service quality and minimize the risk of disputes. Thus, strengthening legal protection for patients in orthopedic surgical procedures depends not only on existing legal norms but also on effective implementation oriented toward justice and legal certainty (Moeloek, 2018).

Another important aspect of patient protection is the existence of effective and fair medical dispute resolution mechanisms. Under the Indonesian legal system, medical disputes do not always have to be resolved through litigation in court; they can also be addressed through non-litigation mechanisms, such as mediation and resolution through the Professional Disciplinary Board (MDP) (Guwandi, 2019). These mechanisms provide a pathway for faster and more efficient dispute resolution that is oriented toward restoring the relationship between patients and healthcare providers. However, in practice, challenges remain, such as the public's limited understanding of complaint mechanisms and restricted access to dispute resolution bodies. Therefore, strengthening the medical dispute resolution system is a crucial component of patient protection efforts.

Advances in information technology and digitalization in the healthcare sector also have implications for patient legal protection, particularly regarding the management of medical data. Electronic medical records, as part of modern healthcare systems, must be managed in accordance with the principles of patient data confidentiality and security. This aligns with the provisions of Law No. 27 of 2022 on Personal Data Protection, which governs the protection of personal data, including health data as a category of sensitive information. In the context of orthopedic surgery, patient medical data, such as radiology results, surgical history, and postoperative conditions, constitute information that must be protected from misuse (Akbar, 2021). Thus, patient protection encompasses not only medical procedures but also the protection of personal data as part of patients' right to privacy.

In addition, the government's role as a regulator and supervisor is crucial in ensuring patient safety during orthopedic surgeries. Through the Ministry of Health and related agencies, the government has a duty to oversee healthcare practices, including through hospital accreditation mechanisms, medical personnel certification, and service standard evaluations. This oversight function is not merely administrative; it also aims to ensure that every healthcare facility meets patient safety standards. In this regard, strengthening technology-based oversight functions, such as patient safety incident reporting systems, is a strategic step toward improving the quality of healthcare services nationwide.

Patient protection in orthopedic surgery must be aimed at achieving substantive justice, not merely formal compliance with legal norms (Rahardjo, 2016). This means that the law must be able to provide tangible protection for patients, especially in the face of the power imbalance between patients and medical personnel, who possess greater knowledge and authority. Therefore, a more humanistic and responsive approach is needed in the enforcement of health law, one that does not focus solely on sanctions but also on prevention and public education. Thus, the health legal system in Indonesia is expected to provide more effective and equitable protection for patients undergoing orthopedic surgery.

Ultimately, strengthening legal protection for patients undergoing orthopedic surgery requires synergy among comprehensive regulations, effective implementation, and legal awareness among all parties involved. Harmonizing various laws and regulations, enhancing the capacity of medical personnel, and strengthening oversight systems are key to creating a safe and high-quality healthcare system. Furthermore, active public participation in understanding patients' rights and responsibilities is also a crucial factor in achieving optimal legal protection. Thus, patient protection in orthopedic surgery is not solely the responsibility of medical personnel or hospitals but a shared responsibility among the state, healthcare

providers, and the public in realizing a fair, inclusive, and sustainable healthcare system.

**The Boundary Between Medical Risk and Medical Malpractice and Its Implications for the Liability of Healthcare Professionals from the Perspective of Equity and Sustainability in Healthcare Services**

The distinction between medical risk and medical malpractice is a fundamental issue in healthcare law because it determines whether healthcare providers can be held legally liable for their actions. In healthcare practice, every medical act carries risks that cannot be entirely avoided, even when performed in accordance with professional standards and due care. Therefore, distinguishing between medical risk and malpractice is essential to ensure legal certainty and proportional protection for both healthcare providers and patients. Clarity regarding this boundary also serves to prevent the criminalization of medical acts that are, in fact, still within the bounds of professional practice (Budi Sampurna, 2017a).

Medical risk is essentially an inherent consequence of any medical procedure performed in accordance with professional standards and standard operating procedures. Medical science is probabilistic in nature; therefore, the outcome of a medical procedure cannot be guaranteed with absolute certainty but can only be pursued to the best of the healthcare provider's ability (Ohoiwutun, 2021a). In this context, the legal relationship between healthcare providers and patients is more appropriately characterized as a "best-effort obligation," not a "result obligation." Consequently, as long as healthcare providers have acted in accordance with applicable standards, the resulting risks cannot serve as grounds for legal liability.

Conversely, medical malpractice constitutes a violation of professional standards committed by medical personnel that results in harm to the patient (Jenie, 2019). Malpractice can manifest in various forms, such as diagnostic errors, procedural errors, negligence in patient care, or failure to provide adequate information. The key element distinguishing medical malpractice from medical risk is the presence of fault or negligence, which indicates a failure to meet the duty of care. Therefore, the presence of fault is a key factor in determining the legal liability of medical personnel.

Distinguishing between medical risk and medical malpractice has important implications for ensuring balanced legal protection for patients and healthcare providers. As recipients of healthcare services, patients have the right to safety, security, and transparent information regarding the medical procedures to be performed. However, this protection should not be interpreted as imposing absolute liability on healthcare providers for every resulting consequence. Therefore, the law must be able to place both parties in a position proportionate to their respective rights and obligations (Hanafiah & Amir, 2017).

The information gap between patients and healthcare providers is one of the factors influencing perceptions of medical risk and medical malpractice. Patients generally lack adequate medical knowledge, so they tend to evaluate the final outcome without fully understanding the process and risks inherent in medical procedures. In this context, informed consent serves as a crucial tool to ensure equity, as it provides patients with the opportunity to understand the medical procedure to be performed along with its associated risks. Consequently, if a previously explained risk occurs, it cannot automatically be classified as medical malpractice.

In modern orthopedic surgical practice, the distinction between medical risk and malpractice has become increasingly complex due to the use of implants or prostheses as part of medical procedures. Orthopedic implants, such as plates, screws, and joint prostheses, serve to restore the patient's anatomical structure and function, but at the same time carry inherent risks such as infection, implant failure, prosthesis loosening, or the need for revision surgery. In this context, not every implant failure can be considered malpractice, as such failures may occur as part of medically acceptable risks, provided that the procedure was performed in accordance with professional standards and operational procedures.

The use of implants or prostheses also expands the scope of liability, as it involves not only healthcare providers but also healthcare facilities and the legal aspects of medical devices themselves. Under the framework of Law No. 17 of 2023 on Health, every medical device must meet the principles of safety, quality, and benefit and be used in accordance with medical indications. Therefore, in the event of patient harm, a comprehensive analysis must be conducted to determine whether the incident constitutes medical risk, medical negligence, or medical device failure.

In this context, the use of implants or prostheses requires stronger application of the principle of informed consent. Patients must be provided with complete information regarding the type of implant, the risk of failure, potential complications, and the need for follow-up procedures such as revision surgery. Without such transparency, the information gap between patients and medical professionals may widen further and potentially lead to disputes. Therefore, if a risk that has been adequately explained subsequently occurs, it cannot automatically be classified as medical malpractice.

From a legal liability perspective, disputes related to implants or prostheses exhibit characteristics of multi-layered liability, in which liability may arise under various legal frameworks. In this context, medical records play a crucial role as evidence to assess whether medical procedures were performed in accordance with applicable standards. Comprehensive documentation regarding the type of implant, the procedure performed, and postoperative evaluations serves as an important basis for distinguishing between medical risk and medical malpractice (Budianto, 2018a).

The distinction between medical risk and malpractice is determined through ethical and disciplinary mechanisms by authorized bodies, such as the Professional Disciplinary Council (MDP) (Ohoiwutun, 2021b). This body plays a crucial role in assessing whether medical actions have complied with professional standards. The assessments conducted are technical and science-based, thereby providing more objective legal certainty. The existence of this mechanism also serves as an effort to prevent the criminalization of healthcare professionals.

From the perspective of healthcare sustainability, the lack of clarity regarding the boundary between medical risk and malpractice can have significant consequences, one of which is the emergence of defensive medicine (Budianto, 2020). Healthcare professionals may take excessive measures or avoid high-risk cases to prevent potential legal claims. This situation has the potential to increase healthcare costs and reduce the quality of care provided to patients. Therefore, clarity regarding the distinction between medical risk and malpractice is essential for maintaining the sustainability of the healthcare system.

Legal uncertainty can also erode healthcare professionals' trust in the existing legal system. This can lead to a decline in their motivation and performance in providing healthcare

services. In the long term, such conditions can undermine the stability of the healthcare system, particularly in the face of challenges posed by shortages of healthcare professionals and the growing demand for public healthcare services. Therefore, regulations are needed that can provide legal certainty while also protecting the medical profession.

In the context of health law reform, there is a need to strengthen regulations that can balance the interests of patients and healthcare professionals. Additionally, the development of non-litigation dispute resolution mechanisms, such as medical mediation and restorative approaches, is crucial for reducing the litigation burden. These approaches not only provide faster and more efficient solutions but also preserve the relationship between patients and healthcare professionals. Consequently, the healthcare system can operate fairly, equitably, and sustainably (Ohoiwutun, 2021c).

From the perspective of modern health law, determining the boundary between medical risk and malpractice cannot be separated from a standards-based approach that emphasizes the conformity of medical actions with applicable professional and service standards. These standards are dynamic and continue to evolve alongside advances in medical science and technology (Nasser, 2018). Therefore, the assessment of a medical act must consider the specific circumstances at the time the act was performed, including available facilities and the patient's clinical condition. This approach is essential to ensure that the law remains flexible and relevant to evolving medical practices.

In the context of the burden of proof, the doctrine of res ipsa loquitur is often relevant in medical malpractice cases, particularly when the harm suffered by the patient could not logically have occurred without some form of error (Budianto, 2018b). However, this doctrine must be applied with caution so as not to blur the line between medical risk and malpractice. The burden of proof must still be based on expert testimony and comprehensive medical analysis. Thus, the judicial process can produce fair and science-based rulings.

With regard to the principle of equality, the state plays a crucial role in ensuring that patients have access to adequate information and legal protection. This includes providing a transparent complaint system and educating the public about their rights and obligations in healthcare services. On the other hand, the state must also provide protection to medical personnel so they can practice their profession without undue pressure resulting from legal threats. Thus, equality can be substantively realized within the healthcare system (Syafriana, 2017).

From a sustainability perspective, the development of the healthcare system must be directed not only toward resolving disputes but also toward preventing medical disputes from occurring. One approach that can be taken is improving communication between healthcare providers and patients, as well as implementing clinical risk management. Effective communication can reduce the potential for misunderstandings, while risk management can minimize the likelihood of medical errors. This approach is a crucial component in creating high-quality and sustainable healthcare services (Khairiyah, 2023).

Advances in healthcare technology also influence the dynamics of drawing the line between medical risk and malpractice. The use of technologies such as electronic health records and telemedicine can improve the quality of care but also introduces new risks that must be anticipated. Therefore, adaptive regulations are needed to ensure that the use of technology remains consistent with the principles of patient safety and legal certainty. This demonstrates

that healthcare law must continue to evolve in line with changing times.

Ultimately, the boundary between medical risk and malpractice must be understood as a spectrum requiring comprehensive analysis of legal, medical, and social aspects. Clarity regarding this boundary is not only crucial for determining the liability of healthcare professionals but also for ensuring the realization of fair, equitable, and sustainable healthcare services. Without such clarity, the legal system risks creating uncertainty that harms all parties. Therefore, a comprehensive, adaptive, and equitable legal framework is needed to regulate healthcare practices in Indonesia.

## CONCLUSION

The legal framework governing patient protection in orthopedic surgery within Indonesia's healthcare legal system is fundamentally based on Law No. 17 of 2023 on Health, which comprehensively regulates patients' rights, the obligations of healthcare professionals, and healthcare service standards. Normatively, patient protection is affirmed through Article 276 paragraphs (1) and (2), which require that every healthcare procedure obtain the patient's informed consent after a full explanation has been provided, as well as Article 293, which regulates the form of such consent. Furthermore, aspects of safety and service quality are reflected in provisions concerning the obligation of healthcare professionals to practice in accordance with professional standards, service standards, and standard operating procedures, as well as the obligation of healthcare facilities to implement patient safety systems as part of clinical risk management. In the context of orthopedic implant use, further regulation is reinforced by technical provisions in Minister of Health Regulation No. 11 of 2025 on Business Activity Standards and Product/Service Standards for the Implementation of Risk-Based Business Licensing in the Health Subsector, as well as Minister of Health Regulation No. 24 of 2022 on Medical Records, which requires the accurate documentation of medical procedures. However, regulations that remain scattered and do not specifically address orthopedic practice may create legal uncertainty. Therefore, harmonization and the strengthening of more integrated regulations are necessary to ensure optimal legal protection for patients undergoing orthopedic surgery.

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