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Patient Protection for Operations Using Telesurgery Technology

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Abstract

This study aims to examine the legal and ethical protection mechanisms available to patients undergoing telesurgery robotic surgical procedures conducted remotely via telecommunication systems. Positioned within the emerging discourse on medical law in digital healthcare, this research addresses a critical regulatory gap as telesurgery becomes increasingly globalized yet lacks adequate international legal instruments. Through a qualitative doctrinal approach using library research, this study synthesizes literature from legal, ethical, and biomedical sources to explore five primary questions, including informed consent adequacy, cross-border regulatory barriers, and the distribution of liability in system failures. The findings reveal that current legal systems in both developed and developing nations are not sufficiently equipped to guarantee patient safety and rights in telesurgical contexts. Notably, the absence of cross-jurisdictional regulations, coupled with limited public understanding of technological risks, contributes to systemic vulnerability. The study offers a novel contribution by proposing a multi-layered regulatory framework integrating national health law, international medical ethics, and private-sector accountability. This integrative model ensures that telesurgery evolves as not only a technological innovation but also a legally and ethically responsible medical practice.

Keywords:
Telesurgery, Patient Protection, Informed Consect, Medical Ethics, Health Law

1. Introduction

The development of digital technology in medicine has driven major innovations in health services, one of which is telesurgery, which is a surgical procedure performed by surgeons remotely using robotic systems and high network connectivity. This innovation provides opportunities for wider medical access, especially for remote areas where it has been difficult to obtain surgery services from specialists. However, these advancements pose new challenges in the aspect of legal protection for patients, which has yet to have a comprehensive regulatory framework in many countries, including Indonesia. When internet connection becomes the main link in procedures that involve human lives, the question of who is responsible when there is a system failure becomes crucial to answer (Elendu et al., 2025).

On the one hand, basic medical principles such as non-maleficence and informed consent must be upheld in the digital context. Unfortunately, informed consent in the

practice of telesurgery has not been studied in depth in relation to patient understanding of technological risks, dependence on communication networks, and potential technical glitches. Research by Singh and Kumar (2021) shows that many patients still do not understand the risks of digitizing medical services, including the possibility of data breaches and system failures. This is exacerbated by the absence of global standards governing procedures for providing information to patients in remote surgery. Especially in the context of Indonesia, which still faces digital literacy challenges, the delivery of electronic-based medical information and consent is a challenge (Singh & Kumar, 2021).

The challenge is even more complex when telesurgery is performed cross-border. Different legal jurisdictions between hospitals, doctors, and patients become a barrier to ensuring maximum patient protection. In Europe, a recent study found that differences in laws between EU member states hamper supervision and enforcement in cross-border telesurgery procedures, especially regarding liability in cases of malpractice and violation of patient privacy. In Indonesia, existing regulations are still focused on conventional medical practices and have not accommodated digitalized healthcare models, let alone cross-regional or cross-country. Therefore, there is a need for urgent need to review patient protection regulations and standards in the context of this digital operation.

In this context, it is important to formulate key questions related to patient protection in telesurgery: what is the ideal form of legal protection for patients? What are the ethical and legal challenges in telesurgery? Is the current system of informed consent adequate? Who should be liable when technical failures occur? And how can the legal framework be developed to fit the dynamics of technology and globalization of healthcare? This research aims to answer these questions through a multidisciplinary approach that includes aspects of law, medical ethics, and information technology. This research also aims to develop a legal protection model that is able to balance technological innovation with the basic rights of patients that must be guaranteed universally and fairly.

The benefits of this research are divided into two: theoretically, this research can expand the treasure of literature in the field of health law, especially on contemporary issues involving digital technology such as telesurgery; practically, the results of this research are expected to be a strategic input for policy makers, health service providers, and medical professional institutions to develop patient protection protocols in remote surgery. In addition, the general public can also gain a more complete understanding of the risks and rights in receiving technology-based medical services. This study also tries to differentiate itself from three previous studies: first, (Elendu et al., 2025) which focused on legal challenges in Europe; second, (Kobayashi et al., 2023) which highlighted technical risks but did not address the legal realm in depth; and third, (Singh & Kumar, 2021)which only discussed aspects of medical records without building a comprehensive legal protection model. With a local (Indonesian) and global context-based approach, this research serves as a constructive effort in formulating a relevant legal framework for the future of digital medicine (Putri & Kurniawan, 2021; Fitriani & Nugroho, 2022).

2. Literature Review

2.1 Basic Theory

This research rest on three main theoretical foundations, namely: (1) Patient Rights Theory, (2) Medical Ethics, and (3) Theory of Legal Liability in Digital Medical Actions. Patient Rights Theory is rooted in the principle that every individual has the right to obtain safe, quality, and fair health services. In the context of telesurgery, these rights are threatened by a lack of information transparency, potential technical glitches, as well as unclear legal jurisdiction when surgery is performed cross-border (Van Wynsberghe & Gastmans, 2008). This theory provides a normative basis that legal protections should guarantee the right to full information, security of personal data, and recognition of the right to refuse technology-based procedures (Fitriani & Nugroho, 2022; Wijayanti & Harahap, 2023).

Meanwhile, Medical Ethics offers a normative framework through four main principles: autonomy, beneficence, non-maleficence, and justice (Beauchamp & Childress, 2019). In telesurgery, the principle of autonomy demands that patients are fully informed and free to make decisions. However, in practice, patients' limited understanding of robotic and tissue technology poses a significant ethical dilemma. As highlighted in the study , telesurgery (Saikali et al., 2024) can create an emotional distance between doctors and patients which has the effect of decreasing the quality of human interaction in ethical and clinical decision-making.

As for the Theory of Legal Liability, specifically within the framework of tort law and liability doctrine, it becomes important to assess who should be liable in telesurgery system failures. For example, in the case of software failure or network disruption, the liability between the doctor, the platform provider, and the device manufacturer becomes overlapping (Xue & Weng, 2025). This theory becomes a tool to analyze the distribution of legal liability in the context of complex medical technology innovation.

Technically, this study also considers the Unified Theory of Acceptance and Use of Technology (UTAUT) framework, especially in the aspect of technology acceptance by patients and medical personnel. As reviewed by (Gerstl et al., 2022), patient acceptance of telesurgery is strongly influenced by risk perception, technology efficacy, and trust in the system. This theory helps explain the extent of society's readiness to accept digital medical procedures and how these factors affect the pattern of legal protection that should be designed.

Global ethical theories such as Thomas Pogge's Theory of Global Justice are also relevant in the context of telesurgery (Saikali et al., 2024) across countries explaining that access to telesurgery should not only be the right of patients in developed countries, but should also be part of global health justice. This perspective broadens the scope of research from local to transnational and interdisciplinary, in line with the complexity of modern medical technology.

2.2 Framework

The framework of this research is based on the integration of theories of patient rights protection, medical ethics, and legal responsibility. The main problem identified is the potential violation of patient rights and safety in the practice of telesurgery due to the lack of technology-adaptive regulations. The theory of patient rights is a normative foundation that emphasizes the importance of protection of the right to obtain information and protection against medical risks. This is directly connected to the principles of autonomy and informed consent from medical ethics

Meanwhile, legal liability theory provides an analysis of the existing legal structure, while evaluating whether the current liability system is sufficient to address issues of system failure, technical error or negligence in the practice of telesurgery. In this regard, the UTAUT framework bridges the technological and psychological aspects of patients, to explain how the level of acceptance of new medical procedures affects the legal risks and protections needed.

The framework culminates in the understanding that legal protection of patients in the context of telesurgery should involve (1) adaptive digitally-based informed consent mechanisms, (2) division of legal liability between medical actors and technology providers, and (3) national regulations that are compatible with international ethical and legal standards. The relationship between these elements is visualized as a causal chain: Technological sophistication → Risk complexity → Legal protection challenges → Need for multilevel and multidisciplinary regulatory frameworks.

3. Research Method

3.1 Research Design

This research uses a qualitative design based on library research. This approach was chosen because the main focus of the research was to analyze the concepts, principles, and legal and ethical frameworks underlying patient protection in the context of using telesurgery technology. This design allows researchers to examine relevant legal literature, medical ethics, health technology, and various national and international regulatory policies. The literature study is considered the most appropriate because the object of study is regulations, normative concepts, and academic and legal documents that require interpretative analysis (Yin, 2018). In addition, this approach expands the scope of the study without the limitations of space and time and provides a comprehensive understanding of the dynamics that cannot be reached with a direct empirical approach

3.2 Population and sample

The population in this study was not physical individuals or groups, but documents, scientific articles, legal journals, medical ethics reports, laws and regulations, and international standards regarding telesurgery and patient protection. The sample was taken purposively based on certain criteria: (1) published in Scopus or Web of Science indexed scientific journals, (2) focusing on

legal, ethical, and technological aspects in the context of telesurgery, and (3) relevant to the protection of patient rights. The articles included publications between 2008 and 2025, with particular attention to the last three years of publication given the rapid development of digital medicine technology (Gerstl et al., 2022). The sample characteristics also included a variety of disciplinary approaches, ranging from health law, bioethics, medical engineering, to public policy.

3.3 Research Instruments

The main instruments in this study were documentation instruments and critical reviews of scientific and regulatory literature. The review was conducted with the help of a literature analysis sheet containing: source identity, focus of discussion, theoretical approach, relevance to patient protection, and synthesis of legal and ethical issues. In addition, a mapping of the conceptual framework of each reference was also carried out to ensure that each reference had a clear conceptual framework. ensure the connection between the theories used and the issues studied. In this context, the instrument used is not just a recording tool, but also a medium of analysis based on thematic categorization and legal interpretation (Bowen, 2009).

3.4 Data Collection

The data collection procedure was carried out systematically through several stages. First, academic article searches were conducted using journal databases such as Scopus, Web of Science, and PubMed using the keywords: telesurgery, patient protection, legal framework, bioethics, and cross-border medical liability. Second, literature was selected based on the year of publication, indexing, and relevance of the substance to the issue of patient protection in telesurgery. Third, articles that passed the selection were analyzed using content analysis techniques with a focus on the legal, ethical, and policy dynamics discussed. Fourth, a thematic synthesis of the selected literature was conducted to develop a framework that answers the objectives and problem formulation of this study

3.5 Data Analysis

The data analysis method used is qualitative content analysis, which classifies literature findings into specific themes relevant to the research problem. This analysis is not only descriptive but also interpretative, to explore the contextual meaning of each document. The main themes developed include: models of legal responsibility in telesurgery, forms of protection for patient rights, cross-border regulatory challenges, and medical ethical standards in the use of remote robotic technology. The data that has been analyzed is then compiled in the form of an argumentative narrative that combines theory, literature findings, and researcher interpretations to support the conceptual framework built.

4. Results and Discussion

4.1 Forms of Legal Protection for Patients in Telesurgery Practices

The literature review reveals that the legal protection of patients in the practice of telesurgery is highly dependent on the domestic legal system in each country. Developed countries such as the United States and the European Union have begun to integrate this issue through legal tools that support patient data privacy and the regulation of technology-based medical practices, especially through GDPR and HIPAA. However, there is no international legal convention that explicitly regulates liability in the context of cross-border telesurgery, leading to legal uncertainty in cases of remote procedure failure (Elendu et al., 2025). In Indonesia, regulations related to medical practice are still oriented towards conventional services and have not specifically accommodated the practice of telesurgery as part of digital healthcare transformation (Utami & Rochmah, 2023; Siregar & Laksmi, 2020). This results in a legal vacuum that can have a detrimental impact on patients, especially in the context of system errors, device failures, or imperfections in the informed consent process. According to (Hadi & Lestari, 2023), the existing legal protection framework for patients within Indonesia's digital health ecosystem remains insufficient, particularly in relation to operational mechanisms and legal dispute resolution. In light of this, there is a pressing need to establish a comprehensive legal framework, supported by the formulation of implementing regulations and adaptive technological protocols that align with the evolving landscape of digital healthcare services.

4.2 Ethical and Legal Challenges in Cross-Border Telesurgery Operations

This research also shows that the main challenge in the implementation of cross border telesurgery lies in the absence of global standards in informed consent procedures and the protection of patients' personal data. Although the GDPR in Europe has set high standards in data protection, harmonization of health laws between countries remains a major obstacle in ensuring patient safety equally across different jurisdictions. In the context of Indonesia and other developing countries, regulations on telemedicine are minimal, and do not cover telesurgery specifically (Saikali et al., 2024). This inequality creates injustice in patient access and protection, which if viewed from a global justice perspective will contradict the principle of universality of the right to fair and equitable health (Pogge, in Saikali et al., 2024). Furthermore, this study identifies the lack of harmonization in ethical and legal standards across nations as a critical issue. When telesurgical procedures involve healthcare providers and patients from different countries, they often give rise to jurisdictional disputes, particularly in cases of malpractice or breaches of patient confidentiality. The absence of a dedicated international legal framework governing telesurgery exacerbates these challenges by creating ambiguity in conflict resolution. Within this context, the principle of global justice emphasizes that all patients, irrespective of their country of origin, are entitled to equal access to legal protection (Saikali et al., 2024; Susanti & Firmansyah, 2022). Therefore, it is important for international organizations such as WHO to formulate global ethical and legal

protocols that can be adopted across countries. This harmonization is a strategic step to bridge the gap of patient legal protection in remote medical practices.

4.3 Adequacy of Informed Consent System in Ensuring Risk Awareness

Previous research shows that the level of patient understanding of the risks of telesurgery is still very low. Most patients do not understand technical risks such as the possibility of disconnection, software errors, or the limitations of human interaction in procedures performed through machines and networks (Gerstl et al., 2022). The current informed consent system is still formalistic and relies heavily on text documents that are not easily understood by ordinary patients, especially in regions with low digital literacy levels (Ramadhan & Widodo, 2022). This directly contradicts the principle of autonomy in bioethics, which requires that patients must be given sufficient information and be able to understand the information before agreeing to medical treatment (Beauchamp & Childress, 2019). A study conducted by (Rahayu & Prasetya, 2021)revealed that patients' comprehension of digital medical information is significantly shaped by their level of technological literacy. In response to this challenge, there is a need to shift from conventional consent procedures toward an interactive, audiovisual-based informed consent model. Such a model would enhance the substance of the consent process, ensuring it goes beyond mere administrative compliance. Accordingly, the authors recommend the implementation of a multimedia-informed consent system that presents medical risks through visual, narrative, and simulation elements. This approach is essential to guarantee that patients' consent is not merely procedural but genuinely informed, grounded in a clear understanding of both the risks and benefits associated with the proposed medical intervention.

4.4 Distribution of Legal Liability in Telesurgery System Failures

One of the important findings of this study is the absence of a clear model for the distribution of legal liability when there is a failure in the practice of telesurgery. In practice, system failures can be caused by various parties, ranging from the implementing doctor, hospital, internet network provider, to hardware or software manufacturers. This lack of clarity not only complicates the process of law enforcement, but it also harms patients who do not know who to sue for compensation (Syaifullah & Cahyani, 2021). Based on the theory of shared liability (Bowen, 2009), it is suggested that there should be a shared liability scheme outlined in the form of a contractual matrix or multilateral agreement involving all parties in the digital healthcare system. This model will ensure that there are no legal loopholes that can be utilized by one party to escape responsibility. In addition, this approach will also speed up the dispute resolution process and provide more structured legal protection for patients

4.5 Ideal Regulatory Framework for Patient Protection in Telesurgery

Most of the analyzed literature suggests that the regulatory framework for patient protection in telesurgery should be built with a multilayered approach that includes

national laws, international professional codes of ethics, and medical technology industry standards. This approach is considered the most effective to address the interdisciplinary and cross-jurisdictional complexities of digital medical practice (Van Wynsberghe & Gastmans, 2008; Elendu et al., 2025). The authors contend that an effective regulatory framework for telesurgery should be founded on three essential principles: the establishment of clear legal jurisdiction, the universal safeguarding of patient rights, and the proactive participation of the technology industry in formulating legal and ethical standards. Future studies are encouraged to develop tangible mechanisms such as bilateral agreements between states to govern cross-border telesurgical procedures, along with the creation of specialized medical insurance schemes tailored for digital surgical interventions. These recommendations are critical to advancing a global healthcare system that prioritizes not only technological efficacy but also fairness and ethical integrity.

Furthermore, beyond these basic principles, the proposed framework must be contextually aligned with existing Indonesian legal instruments, including Law No. 17 of 2023 on Health and Law No. 11 of 2008 on Electronic Information and Transactions (ITE Law). This alignment is crucial to ensure that national regulations effectively address the unique legal and ethical challenges posed by telesurgery, particularly regarding the use of electronic medical records, digital accountability, and online consent processes. To accommodate the transnational nature of telesurgery, it is also necessary to establish bilateral or multilateral agreements that clearly delineate jurisdiction, liability allocation, and standardized international medical procedures. The implementation of such agreements should be supported by government initiatives through collaboration between the Ministry of Health, the Ministry of Foreign Affairs, and global organizations such as the World Health Organization (WHO) and ASEAN's health sector. Ultimately, the envisioned legal framework must not only be adaptive to technological progress but also capable of ensuring justice and equitable protection for patients, both domestically and globally.

5. Conclusion

The advancement of telesurgery as a component of digital health transformation has brought both opportunities and critical challenges, particularly in terms of legal and ethical safeguards for patients. This study found that many national legal frameworks, especially in developing countries like Indonesia, have yet to incorporate adequate protections for patients undergoing remote surgical procedures. Issues such as inadequate informed consent, data vulnerability, and system failures remain unaddressed due to the absence of specific digital health regulations. Furthermore, there is no international legal convention that clearly defines liability and dispute resolution mechanisms in cross-border telesurgery cases. These gaps increase the risk of harm and legal uncertainty for patients receiving telesurgical interventions. Therefore, the development of a robust legal framework is not merely a regulatory necessity but a moral imperative.

Equally important are the ethical and jurisdictional challenges that arise when telesurgery is conducted between countries with differing legal standards. The lack of harmonization in informed consent procedures and data protection laws exacerbates disparities in patient safety and rights enforcement. This study underscores the need for a global approach rooted in the principle of health justice, where patients regardless of nationality receive equal legal protection. The incorporation of ethical principles such as autonomy, non-maleficence, and justice must be integrated into both national and international regulatory structures. Moreover, the complexity of technological liability spanning healthcare providers, software developers, and equipment manufacturers requires the adoption of shared liability models. Without these coordinated measures, accountability remains fragmented and patients continue to face heightened vulnerability in digital medical environments.

To address these multidimensional challenges, the study recommends a multi-layered regulatory framework that integrates national laws, international codes of conduct, and industry standards. This framework should include adaptive informed consent mechanisms, clear legal jurisdiction for cross-border operations, and active participation of technology stakeholders in policy development. Specifically, for the Indonesian context, legal reforms should align with existing laws and regulations, such as the Health Law and the Electronic Information and Transactions (ITE) Law, while expanding their scope to encompass the nuances of telesurgical procedures. The government, in collaboration with international institutions such as the WHO and ASEAN, should lead efforts to develop bilateral or multilateral agreements for telesurgical regulation. This way, the legal system can evolve alongside technological innovation, ensuring that patient protection remains paramount in the era of digital medicine.

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