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Comparative Review of Informed Consent as A Legal Safeguard in Healthcare: Perspectives from Indonesia and Other Countries

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Abstract

Informed consent serves as a fundamental ethical and legal mechanism to uphold patient autonomy and safeguard against medical malpractice. This evolving concept provides an opportunity to assess the weaknesses and effectiveness of informed consent mechanisms as a form of legal protection in Indonesia compared to other countries. This paper aims to compare the role of informed consent as a legal safeguard in healthcare services in Indonesia and other countries. This study employed a comparative legal research method using both normative-comparative and functional approaches, supported by literature searches across four major electronic databases. The included materials consist of peer-reviewed empirical studies, legal analyses, policy reports, and case studies. In Indonesia, informed consent is governed by various legal instruments, including the newly enacted Law No. 17 of 2023. However, implementation faces challenges related to cultural values, paternalistic practices, and limited health literacy. In many developing countries, collective decision-making norms and resource constraints further hinder compliance with international standards. Meanwhile, developed countries face challenges related to complexity, variability in practice, and the influence of advanced technologies on patient comprehension. The results have implications to ensure ethically and legally effective patient protection through a culturally adaptive approach, capacity strengthening, simplification of informational materials, and the use of communication technologies.

Keywords
Comparative Law, Healthcare, Informed Consent, Legal Safeguard.

1. Introduction

The process of educating patients about the advantages, disadvantages, and available options of a surgery or medical intervention is known as informed consent. Informed consent is a fundamental component of modern healthcare law and ethics, with a moral and legal obligation to ensure that patients understand and voluntarily consent to medical treatment (Shah et al, 2024). To obtain valid informed consent requires assessing the patient's understanding, developing clear medical recommendations and justifications, and documenting the process. Health workers should emphasize active patient participation in decision-making and avoid any form of pressure for patients to get agreement for clinical recommendations (Morton et al., 2024).

However, the application of the principle of informed consent becomes more complex in emergency situations, where life-threatening conditions often prevent patients (especially unconscious patients) from giving consent, so medical personnel must act quickly without explicit consent to save the patient's life (Pont et al, 2025). Thorough documentation of informed consent is very important, especially in high-risk medical procedures because it serves as legal protection for doctors and can reduce potential legal disputes (Putra et al, 2024).

Informed consent protects patients from unnecessary medical treatment and also provides legal protection for medical personnel against malpractice claims. However, due to institutional, historical, and cultural differences, the concept and application of informed consent can vary significantly between different legal systems. For example, the UK takes a jurisprudential approach by shifting the duty to disclose information that patients would reasonably want to know, through a threshold of "material risk" as established in Montgomery v. Lanarkshire Health Board (Balasingam et al, 2022).

In contrast, Germany's Patients' Rights Act of 2013 explicitly regulates informed consent and requires full disclosure of information. Indonesia, as a country with an emerging health law system, has revised its provisions on informed consent through Law No. 17 of 2023 on Health, incorporating aspects of informed consent into a broader framework of health rights. This development provides an opportunity to evaluate the weaknesses and effectiveness of informed consent mechanisms as a form of legal protection in Indonesia, when compared to the legal systems of more developed countries (Mubarak et al, 2024)

Sugiarti (2010) stated about informed consent in Indonesia and the United States, Indonesia adheres to the Continental European system while the United States uses the Anglo Saxon legal system formed from custom (common law). Research by Bolcato et al., (2024) compared informed consent in health services among Italy, France, England, Nordic Countries, Germany, and Spain. Pakpahan et al.'s research (2021) compared the laws of patients who are victims of plastic surgery malpractice in Indonesia and South Korea. Based on the literature search, no published literature review was found regarding the discussion of informed consent in Indonesia and with developed and developing countries in the world. Therefore, further writing is needed to obtain a comparative evaluation of the use of informed consent. Based on these problems, the purpose of the study was to compile a narrative review with the title "Comparative Review of Informed Consent as A Legal Safeguard in Healthcare: Perspectives from Indonesia and Others Countries". This research aims to identify best regulation practice and give recommendation policy that can improve patient's protections and legal clarity in clinical practice.

2. Methods

The research method was designed as comparative legal research, combining two main approaches: a normative-comparative approach to compare the legal framework, including laws, government regulations, professional guidelines, and court decisions on informed consent in Indonesia and comparator jurisdictions in other countries; and a functional approach to evaluate the implementation and enforcement of informed consent mechanisms in healthcare practices in each country.

The authors conducted a multi-stage search on four major electronic databases (PubMed, ScienceDirect, ProQuest, and Google Scholar) to collect literature on informed consent as a legal protection in healthcare. Search strings were constructed using Boolean operators and adapted to the syntax of each platform. Core keywords included "informed consent", "legal safeguard", "healthcare", "Indonesia", "regulatory framework", "patient rights", 'bioethics', and "comparative law". To

ensure comprehensive coverage, the authors also applied snowballing techniques to all eligible articles.

Authors submit peer-reviewed empirical studies, legal analyses, policy reports, and case studies published in English or Indonesian. Eligible works address the design, implementation, or enforcement of informed consent mechanisms in Indonesian healthcare settings and at least one other national jurisdiction. The authors exclude conference abstracts, commentaries, editorials, and pure ethics essays without legal analysis.

The selection of comparative jurisdictions in other countries was based on similarities and differences in health system structures and regulatory frameworks as well as the availability of primary and secondary legal documents. Primary legal materials included the text of laws, government regulations, health professional guidelines, and court decisions while secondary legal materials included academic articles, policy reports, and case analyses. This approach ensures adequate data coverage for both normative and functional analysis.

3. Results

The legal system governing informed consent in Indonesia is based on a number of important laws and regulations. Undang-Undang No. 36 of 2009 on Health, Peraturan Pemerintah No. 32 of 1996 on Health Workers, Undang-Undang No. 29 of 2004 on Medical Practice, and Undang-Undang No. 8 of 1999 on Consumer Protection are the main foundations that regulate the concept of informed consent. These regulations emphasize that informed consent is a fundamental right of patients, by requiring health workers to provide sufficient information regarding treatment options, risks, and available alternatives (Siregar et al, 2024).

The legislative framework emphasizes the importance of patient autonomy as well as the obligation of medical personnel to ensure that patients have understood the information needed before making medical decisions. This is reinforced by the Minister of Health Decree No. 290/MENKES/PER/III/2008 which specifically regulates the procedure for informed consent. Unlike the Anglo-Saxon legal system adopted by countries such as the United States, Indonesia's legal system is rooted in the Continental European legal tradition. In the United States, doctors are legally required to provide all information necessary for patients to make informed medical decisions.

The legal protection of informed consent was further strengthened with the enactment of Undang-Undang No. 17 of 2023 on Health. This law emphasizes the importance of standardizing the process of giving consent as well as the urgency of comprehensive information transparency. In addition, this law also regulates the implementation of informed consent in medical emergencies and public health emergencies, to ensure that patients' rights are respected (Indina et al., 2023).

However, the implementation of informed consent in Indonesia still faces various challenges. One of the main obstacles is the lack of effective communication and adequate understanding between patients and health workers. Many patients do not fully understand the treatment options available, which can lead to misunderstandings and lower the level of trust in the healthcare system (Hatta et al, 2024). In addition, the paternalistic mindset that is still dominant among medical personnel in Indonesia is also a barrier. Many health practitioners believe that medical decisions should be made entirely by medical personnel and patients should not be burdened with complex medical information. This approach has the potential to raise ethical and legal issues and reduce the principle of patient autonomy (Desdiani, 2024).

Cultural settings also influence the implementation of informed consent in Indonesia. Values such as harmony and respect for authority are highly upheld in Indonesian culture, which may inhibit patients from questioning medical personnel's

decisions. These cultural dynamics can make it difficult for patients to express their right to informed consent (Cipta et al., 2024). Various efforts have been made to improve the practice of informed consent, including educational initiatives for patients and health workers aimed at increasing public understanding of patients' rights and the importance of clear communication in medical care. However, structural barriers that interfere with the effective implementation of informed consent in Indonesia still require further attention (Risdawati, 2024).

Informed consent is the basic process by which a competent individual voluntarily consents to medical intervention or research participation after receiving and understanding comprehensive information regarding the nature, purpose, risks, benefits, and alternatives of the proposed procedure (Creed-Kanashiro et al., 2005). Informed consent rooted in principles dating back to ancient Egyptian and Greek civilizations has evolved into a legal and ethical mandate codified in modern bioethics guidelines, such as the Council for International Organizations of Medical Sciences (CIOMS) and the Nuffield Council on Bioethics, which emphasize not only clear disclosure, but also cultural and contextual adaptation of consent procedures both written and oral to ensure genuine and voluntary agreement in various settings (Willis, 2003).

In developing countries, informed consent relates to an entrenched framework of cultural norms, resource limitations, and ethical requirements that differ from the individual-centered paradigm of Western models (Chaar et al., 2025). Rather than relying entirely on personal decisions, consent processes often involve community stakeholders, utilize oral communication, and apply adaptive documentation to bridge literacy gaps and respect local hierarchies. For example, empirical evidence suggests that as many as 40-60% of clinical trial participants in sub-Saharan Africa obtain preliminary approval from a village chief or council of elders before giving individual consent, confirming the importance of collective governance (Krogstad et al., 2010). However, there are structural constraints to the implementation of such systems, such as a lack of interpreter services, uneven regulatory oversight and power imbalances between providers and patients that can undermine standardized ethical protections (Mayer, 2002).

Western bioethics positions informed consent on the foundation of individual autonomy, assuming literacy, understanding of biomedical concepts, and social emphasis on self-determination. In many developing countries, these assumptions do not hold. In rural Ghana, the research team routinely presented study protocols to village chiefs and councils of elders, whose consideration of the community's welfare was the cornerstone before approaching potential participants individually. This hierarchical step ensures community support, but risks excluding the voices of special populations, especially among women and youth. In Kenya, elders commonly translated clinical details into agricultural metaphors to enhance the understanding of participants with limited formal education. While such mediation builds trust, it can also introduce variation in delivery, potentially masking important information about risks or the voluntary nature of participation (Nahler, 2009).

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can also introduce variation in delivery, potentially masking important information about risks or the voluntary nature of participation (Nahler, 2009).

Legally, informed consent has been enshrined in the laws of many developing countries, such as Indonesia's LAW No. 17 of 2023 which emphasizes comprehensive disclosure of patient information, while Bangladesh enforces consent as an ethical obligation as well as a legal mandate. However, gaps in enforcement persist. In Pakistan, systemic inefficiencies and low stakeholder awareness often hinder consistent implementation, highlighting the urgent need for capacity strengthening and more robust oversight mechanisms for the framework to function at the frontline of healthcare (Kurniawan & Chandra, 2024).

As such, despite clear legal mandates, the implementation of informed consent in developing countries often stalls at the first step, which is ensuring patients truly understand what they are agreeing to. Consent documents are often written in dense medical terminology and complex sentence structures, which can be overwhelming for individuals with limited formal education. In Uganda, researchers found many participants struggled to follow the scientific jargon-laden consent forms, leaving them unclear about study procedures and potential risks. Similarly, surgical patients in Tanzania reported that explanations of benefits and complications were inadequate so they did not feel properly informed before consenting to surgery. This lack of understanding not only undermines patient autonomy, but also exposes clinicians and institutions to ethical and legal vulnerabilities (Abraham & Mathias, 2024).

Cultural practices around health decision-making also add another layer of complexity. In many societies, especially in South Asia and some parts of Africa, individual choices are incorporated into wider family or community deliberations. Sociocultural factors such as gender disparity and religious beliefs also play a significant role in the exercise of informed consent (Bandewar, 2003). In Pakistan, it is common for family members (generally male relatives) to be actively involved in consent discussions, ask questions, and even veto treatment plans on behalf of patients. As described earlier, while this collective approach can build trust and shared responsibility, the same mechanism also risks negating the patient's own preferences, particularly for women or other vulnerable groups (Memon et al., 2024). Therefore, clinicians must navigate a careful balance between respecting cultural norms and protecting each person's right to make informed and voluntary choices (Hidig and Nour, 2024).

Patients must be provided with all relevant information about the medical procedure to be undertaken in order to give valid informed consent, which is based on the principle of patient autonomy. This information includes the type of procedure, potential risks, benefits, treatment alternatives, as well as the right to refuse the medical treatment. In countries such as the UK, legal developments show a shift from medical paternalism towards patient-centered care, as affirmed in the landmark judgment of Montgomery v. Lanarkshire Health Board (Milo, 2022).

In line with the ethical principle of respect for autonomy, the Montgomery judgment requires health professionals in the UK to inform patients of material risks that a reasonable person would consider significant. In the United States, informed consent is also required by law, with special arrangements in research involving human subjects as set out in the Belmont Report (McCormack, et al, 2018).

In many developed countries, informed consent is usually in writing, especially for elective procedures. For example, a European study in interventional cardiology showed that 88.4% of respondents always used a written consent form (Rajkumar et al., 2022). This practice is supported by legal regulations and professional standards that specifically address the format and content of consent documents (Bolcato et al., 2024).

Shared decision-making (SDM), which involves collaboration between patients and healthcare professionals in making informed decisions, is gaining increasing attention. This approach is particularly relevant in complex therapeutic situations with uncertain outcomes, such as cardiovascular disease care. The ethical framework underlying SDM strongly emphasizes patient autonomy and the provision of complete and understandable information (Tarantini et al., 2025).

However, the implementation of informed consent still faces a number of ongoing challenges, despite the legal and ethical framework that supports it. One of the main issues is the variation in practice, both between countries and between healthcare facilities within a country. For example, there are considerable differences in the quality of consent forms and the completeness of information provided to patients across Europe. The high complexity of information conveyed during the consent process is also a barrier (Mentzelopoulos et al., 2021). A comparison of informed consent practices in various developed countries is shown in Table 1.

Table 1. Comparasion Informed Consent Practices in Various Developed Countries

Country	Main Fitur Informed Consent	Challenges and Variability
United Kingdom	Emphasis on patient autonomy and SDM, influenced by the Montgomery decision.	Variability in practice across different healthcare settings
United States of America	Legally mandated with specific federal regulations; emphasis on patient understanding and volunteerism	Complexity in clinical trials and research settings
Germand and Poland	Clinicians perceive the legal framework as complicated but necessary, with challenges in balancing overload informations	The struggle to exclude vulnerable populations from research
Nordic Countries	Strong emphasis on patient-centered care and autonomy; integration of ethical guidelines into practice	Variability in the quality of consent forms and patient information

Legal provisions governing informed consent vary widely between countries, reflecting differences in cultural values, healthcare system organization, literacy levels, and regulatory traditions. The real effectiveness of any health legal framework depends on the ability to balance ethical principles, particularly respect for patient autonomy and protection of rights with practical challenges such as language barriers and collective decision-making mechanisms (Milo, 2022).

In many developed (high-income) countries, the legal framework emphasizes individual self-determination enforced through comprehensive written agreements. In the United States and much of Western Europe, patients or research participants are required to sign comprehensive consent documents detailing potential risks, benefits and alternatives, while Institutional Review Boards (IRBs) are responsible for monitoring compliance although these bodies sometimes face conflicts between participant protection and institutional liability. In the UK (including England, Wales, and Scotland), common law precedents particularly the Montgomery v Lanarkshire Health Board ruling confirm that clinicians must disclose all "material risks" and alternatives that patients would reasonably consider significant (Brunvand, et al, 2018).

Meanwhile, Italy, in its civil law system, codified informed consent through Undang-Undang No. 219/2017, placing it within a broader health rights framework to encourage shared decision-making between doctors and patients. Despite such progress, both common law and civil law jurisdictions still face a "law in theory versus practice" gap, as patients sometimes struggle to seek redress or navigate complex legal procedures. Norway offers an interesting variation; it generally favors true understanding over formal documentation, allowing oral consent in most

situations except high-risk interventions, reflecting the high level of public trust in healthcare providers and low medical litigation.

In contrast, in many developing countries (low to middle income), particularly in sub-Saharan Africa and parts of Asia, legal and ethical frameworks explicitly recognize the importance of collective structures in decision-making. Research protocols often require prior approval from community elders or elected gatekeepers before individual consent can proceed, reflecting social norms that favor collective deliberation over singular choices. High illiteracy and language diversity further limit the effectiveness of written forms, leading to alternatives such as verbal consent with witnesses, participant thumbprints or audiovisual explanations. IRB-equivalent regulatory oversight bodies may be scarce or lack enforcement authority; consequently, emphasis shifts from uniform documentation to rigorous assessment of participant understanding prior to enrollment.

In the European region, countries share strong laws informed by the European Convention on Human and Biomedical Rights, which requires transparent written disclosure (Orzechowski et al., 2021). Nordic countries, while legally similar, give more weight to shared decision-making, but still grapple with the nuances of consent involving minors and individuals with limited capacity (Stultiëns et al., 2007). In North America, both the United States and Canada adhere to the "wise patient" or "reasonable person" standard, which requires clinicians to disclose information that would be considered significant by the average patient (Symons et al., 2020). The Asia-Pacific region, represented by Australia and New Zealand, adopts similar common law principles to the UK and US, with a strong focus on patient empowerment through full disclosure.

In sub-Saharan Africa, legal frameworks are still at various stages of development: patient awareness of consent rights is low, and cultural and resource limitations often prevent meaningful implementation (Pittalis et al., 2023). Meanwhile, Latin American countries are progressively strengthening their consent laws to protect autonomy, but rural and marginalized populations still face barriers to fully exercising these rights.

Based on the literature, a number of basic principles underlie informed consent laws in various jurisdictions. Respect for patient autonomy remains paramount, affirming the right of every individual to make voluntary and informed decisions regarding their own health actions without coercion. This emphasis on self-determination has been reinforced in the UK through the historic Montgomery judgment, which shifted medical practice away from a paternalistic model towards an obligation for clinicians to disclose all risks and alternatives that a reasonable patient would consider material.

In South Africa, the provision of professional interpreter services alongside plain-language consent forms has markedly reduced language barriers and improved participant understanding (Chima, 2018). Rapid Ethical Assessment (REA) has also been adopted as a pragmatic mechanism to identify and address ethical gaps in real time. In Ethiopia, the application of REA has uncovered critical failures in communication and enabled researchers to adapt the consent process to the specific needs of the community, thereby better protecting participants' rights (Addissie et al., 2014).

Community engagement remains a cornerstone of robust consent practices. In genomic studies in sub-Saharan Africa, ongoing collaboration with community advisory groups has fostered trust, clarified the implications of research participation, and ensured equitable governance of biobanks and benefit sharing. Strengthening the capacity of health workers and researchers through targeted training is therefore essential. In Pakistan, specific programs that emphasize clear communication techniques and reinforce the ethical principles underlying informed

consent have been recommended to equip clinicians and researchers to facilitate truly informed and autonomous participant decisions (Creed-Kanashiro et al., 2005).

Closely related to autonomy is the obligation to provide appropriate information. The scope of required disclosure varies: in the United States, the "prudent patient" standard requires practitioners to share every fact that a rational person in the patient's position would consider significant (Symons et al., 2020). In contrast, some European countries adopt a collaborative disclosure model, where shared decision-making between the clinician and patient allows for customization of information according to individual needs (Orzechowski et al., 2021).

Legal standards for informed consent vary widely between jurisdictions, reflecting different legal traditions, healthcare structures and cultural expectations. In Europe, the mandatory requirement of consent is enshrined in both jurisprudence and legislation. Italian Law 219/2017 codifies patient rights and advance directives, placing informed consent within a broader health rights framework that emphasizes shared decision-making and allows for written or audiovisual documentation of consent. France relies on its Civil Code as well as two primary laws (Laws 303/2002 and 370/2005) to regulate patient information, withdrawal of consent, and the role of relatives and guardians, while Spain through Law 41/2002 establishes regional variations regarding the timing of delivery, the role of proxies, and the format of documentation.

The German Patients' Rights Act 2013, together with provisions in the Code of Professional Medicine, transformed the practice of consent from professional custom to binding law, requiring disclosure of treatment alternatives, key risks, and the right to refuse or withdraw consent. In the UK, guided by the Montgomery v Lanarkshire Health Board (2015) judgment and the Scottish Patients' Rights Act 2011, it requires disclosure of all "material risks" that a reasonable patient would consider significant, reflecting the common law emphasis on individual autonomy. In Nordic countries such as Finland, Iceland, Denmark, Norway and Sweden, patients' rights legislation since the 1990s stipulates that consent must be "complete, adequate and understandable," permits verbal consent for low-risk procedures, and lowers the age of consent in children based on maturity assessments (Orzechowski et al., 2021).

In contrast, regulations in Central and Eastern Europe show both conformity with international ethical guidelines and notable national variations. Germany, Poland and Russia all affirm informed consent in their constitutions or basic laws, referring to the Declaration of Helsinki as an ethical benchmark. However, there are differences: German law allows for electronic consent and only requires brief disclosure of some information, whereas Polish and Russian laws detail extensive information requirements including participant obligations, compensation mechanisms and data processing details and stipulate both oral and written disclosure. For vulnerable populations, all three countries require consent through legal representatives for adults without capacity and minors, but only Germany and Poland explicitly require assent from those capable of expressing an opinion, reflecting a stronger commitment to participant engagement. Neither Poland nor Russia stipulate an emergency enrollment procedure, while the German regulation requires subsequent consent as soon as possible (Orzechowski et al., 2021).

Rigorous assessment of the patient's capacity to give consent is also crucial. In England and Wales, the Mental Capacity Act 2005 sets out clear criteria and procedures for determining whether an individual can understand, retain and weigh relevant information to make a decision, as well as mechanisms for appointing a representative when capacity is lacking. In the United States, similar guarantees are set out in state laws, which require that consent comes from a person who can appreciate the nature and consequences of the proposed treatment. However, even the most comprehensive legal frameworks face practical obstacles. In sub-Saharan

Africa, for example, low patient literacy, cultural barriers and limited resources significantly impede the realization of genuine informed consent. Similarly, in Europe, the challenge often lies in adequately involving families and guardians when individuals lack capacity, exposing the gap between legal ideals and clinical realities (Orzechowski et al., 2021).

In Table 2, cultural and ethical dimensions shape the way consent is operationalized. In many African regions, traditions of collective decision-making can conflict with Western concepts of individual autonomy, requiring models of consent that respect collective values while protecting personal rights. In Asia, the interplay between family involvement and personal choice similarly requires careful ethical calibration to ensure patients maintain genuine consent (Hui Zhang et al., 2021).

Tabel 2. Differences in Health Legal Frameworks between Countries

Aspect	Italy (Hukum Sipil)	UK (Common Law)	Nordic Country	Developing Country
Legal Base	Law (Law 219/2017) + jurisprudence	Jurisprudence (e.g. Montgomery ruling)	Legislation with flexible consent provisions	Ethical guidelines + emerging national laws
Approval Model	Patient autonomy + medical partnership	Patient autonomy + shared decision making	Patient understanding comes first	Communal decision-making + individual consent
Documentation	Written consent required	Standardized written consent; digital tools	General verbal consent; written for special cases	Oral consent, thumbprint, audiovisual tools
Enforcement	Courts + legislation; practice gap	Courts; evolving standards; digital audits	High trust; minimal litigation	Limited regulatory capacity; ethics committees varied

Legal protection in healthcare is a multifaceted issue that encompasses the rights and responsibilities of patients, as well as healthcare workers. Legal protection involves a combination of national and international laws, ethical considerations, and practical measures to ensure safety, fairness, and quality in healthcare. Legal protection mechanisms are designed to protect the interests of all parties involved in health care, from the patients who receive services to the health workers who provide health services.

Legal protection for patients is primarily concerned with ensuring their right to receive safe and effective medical healthcare services. In Indonesia, Undang-undang No. 44/2009 on Hospitals outlines patients' rights to receive comprehensive healthcare services, including inpatient, outpatient, and emergency care. Patients are entitled to preventive and repressive legal protection, which includes measures to prevent harm and address complaints through legal channels (Awangga, 2023).

Furthermore, health workers also receive legal protection that includes preventive measures to avoid legal problems and repressive measures to deal with violations. National laws, such as LAW No. 36 of 2014, provide a framework to protect health workers from violence and legal repercussions while performing their duties. International Humanitarian Law also plays a role in protecting health workers, especially in conflict situations, although compliance is often hampered by a lack of awareness and understanding (Andayani & Kurniawan, 2023).

Informed consent serves as an important legal protection mechanism in the healthcare sector, protecting both patients and medical personnel. Informed consent is a formal agreement that ensures patients are fully informed about the medical procedure they are about to undergo, including its potential risks and benefits, enabling them to make an informed decision. This process not only upholds patient autonomy, but also provides legal protection for healthcare providers by documenting patient consent, which can be crucial in defending against malpractice claims (Kurniawan et al, 2023).

Informed consent is embedded in the legal framework of many countries, including Indonesia, where it is recognized as a fundamental component of healthcare law. Informed consent is mandated by laws such as LAW No. 17 of 2023, which emphasizes informed consent as a medical duty and patient right, ensuring comprehensive information is provided to patients. The legal position of informed consent is strong in civil law in Indonesia, which is seen as a manifestation of the therapeutic agreement. Violation of informed consent can lead to significant legal implications, including claims for damages and breach of contract (Kurniawan & Chandra, 2024).

For medical personnel which includes doctors and other healthcare providers, informed consent acts as a legal shield. This consent provides a sense of security when performing medical actions because it is written evidence of the patient's consent to the action thus protecting against potential lawsuits or lawsuits. In cases of malpractice claims, informed consent can be an important factor in legal defense, although it is not always the determinant of malpractice outcomes, as in a Supreme Court case, informed consent was not enough to protect doctors who committed dosing errors (Lazuardi & Marwiyah, 2023).

Informed consent is essential to protect patients' rights, ensuring they are informed about their medical condition and the procedure they are about to undergo. This process respects patients' right to self-determination and healthcare, allowing them to accept or refuse treatment based on comprehensive information. This process involves a detailed explanation of the diagnosis, treatment options, risks, and possible outcomes, so that the patient can make an informed decision and seek the opinion of other health professionals or a second opinion if needed (Hernoko et al., 2020).

Informed consent serves as an important legal protection in healthcare, ensuring that patients are fully informed about medical procedures and their potential risks before consenting to treatment. In Indonesia, informed consent is governed by a comprehensive legal framework, including LAW No. 17 of 2023, which emphasizes informed consent as both a medical duty and a patient right. This framework aims to address the issue of unequal access to healthcare and strengthen the national healthcare system, particularly in emergencies (Kurniawan & Chandra, 2024).

Despite the legal framework, Indonesia faces challenges in ensuring that informed consent is effectively implemented. Issues such as ineffective communication and the absence of detailed guidelines for various patient needs remain barriers (Masyuri et al., 2024). Healthcare professionals in Indonesia need to adapt to the evolving legal landscape and ensure that informed consent processes are transparent and inclusive. This includes addressing language barriers and providing support for vulnerable populations. Indonesia's legal system must also balance the rights of individual patients with the interests of public health, particularly in emergencies or extraordinary events. This requires ongoing legal and ethical considerations (Kurniawan et al, 2024).

4. Discussion

In the context of Indonesia's hierarchical and communal culture, healthcare decisions are often influenced by social relations. Patients tend to defer to the

authority of medical personnel instead of asserting their autonomy, and families often play a central role in decision-making. In addition, spiritual and religious views also influence acceptance of medical procedures. Spiritual healing and alternative therapies are often prioritized before seeking conventional medical services, making it difficult for health workers to balance cultural expectations and legal demands (Prihandono et al, 2023).

Although Indonesia has a legal regulation informed consent, its implementation in the field still faces many challenges. One of the main problems is the lack of understanding from both patients and health workers regarding patients' rights. This can reduce the effectiveness of informed consent and undermine public trust in the healthcare system. Cultural factors that emphasize harmony and obedience to authority can also hinder effective communication and patient freedom of decision-making. Therefore, a more contextual and sensitive approach to Indonesian cultural values needs to be developed to support the principles of informed consent. Improving the implementation of informed consent in Indonesia in the future can be done through the expansion of education and awareness programs for patients and health workers. These programs should emphasize the importance of clear communication as well as the moral and legal principles underlying informed consent. In addition, further studies on cultural and social factors that influence the implementation of informed consent in Indonesia are needed to develop more effective intervention strategies (Irawati et al, 2020). Such time pressures not only undermine the ethical integrity of consent, but can also compromise clinical outcomes when patients proceed with treatment without full awareness of possible complications or therapeutic alternatives (Mihiretu et al., 2024).

These challenges, including limited patient understanding, the dynamics of collective decision-making, and acute resource constraints point to the urgent need for a comprehensive legal framework with plain and clear language materials, clinician training in culturally sensitive communication, and institutional support to provide adequate time and resources for the consent process. To overcome these barriers, interventions must be carefully tailored to local conditions. In rural African communities, for example, the application of community-based participatory methods that formally engage traditional leaders and gatekeepers in consent dialogues has proven effective in adapting research procedures to local governance structures (Ede et al., 2023).

Patients often have difficulty in understanding complex medical information, especially when probabilistic models or advanced technologies such as Artificial Intelligence (AI) are used. This can hinder patients' ability to make truly informed decisions (Günther, 2024). Furthermore, vulnerable groups such as individuals with cognitive impairment or low health literacy face additional barriers that weaken their ability to give informed consent, emphasizing the importance of tailored communication strategies to preserve patient autonomy (Jawa et al., 2023). In emergency situations, the need to provide immediate medical intervention makes the informed consent procedure much more complicated. The ethical and legal implications of implied consent are still debatable and require careful consideration, although some countries allow this practice in life-threatening situations (Rajkumar et al., 2022).

The integration of AI in healthcare brings both opportunities and challenges to the implementation of informed consent. On the one hand, AI can improve patient understanding through the provision of personalized and easily accessible information; but on the other hand, it also raises concerns about the potential reduction of patient autonomy. Proposed regulations on the use of medical AI emphasize the importance of a legal framework that strikes a balance between innovation and the protection of patients' rights. Efforts to improve informed consent procedures are ongoing, including through the development of standardized

consent forms, improved patient education, and the use of multimedia to facilitate understanding. Furthermore, the importance of cultural sensitivity in the informed consent process is now increasingly recognized, especially in the context of international clinical trials (Millum et al, 2021).

Informed consent is an important pillar of legal protection in Indonesia's healthcare system, ensuring that patients are adequately informed about medical procedures before making independent medical decisions. The recent enactment of LAW No. 17 of 2023 has provided a stronger foundation for informed consent by emphasizing comprehensive information sharing as a patient right and medical obligation. The law mandates that the informed consent procedure begins with the provision of information about medical treatment that enables patients or their legal representatives to consent to or refuse such treatment (Hernoko et al., 2020).

The following recommendations relate to the implications of informed consent as legal protection as a policy or for the strengthening of the Indonesian legal system. Regulatory reconstruction is recommended to emphasize fairness, transparency, and inclusiveness, including mandatory use of digital documentation and enhanced communication technologies. Support systems such as interpreters or visual aids should be integrated into the legal framework to assist vulnerable populations, ensuring informed consent reflects the patient's true choices. Strengthening the legal system could involve clearer regulation of advanced medical procedures and decisions regarding the discontinuation or delay of life-sustaining treatment, which are not outlined in detail in current legislation (Kurniawan et al, 2023).

Legal policies have a positive impact on human rights protection, but barriers to policy implementation remain, necessitating civil society engagement and international support (Jaman, et al, 2023). In addition, comparative studies with informed consent practices in the United States also show the importance of comprehensive information and the potential consequences of non-compliance to inform future health policy formulation (Siregar et al., 2024).

5. Conclusion

This research confirms that informed consent is an important legal protection instrument in the practice of health care. However, its implementation is highly influenced by the legal system, cultural norms, and institutional capacity in each country. Based on this study, the main problems identified in Indonesia include the lack of uniformity in informed consent practices, weak communication between health workers and patients, and suboptimal legal protection for patients and service providers. This is in contrast to practices in developed countries that have adopted approaches that emphasize patient autonomy and information transparency, as well as systematic digital documentation.

In this study, the practical implication can be a comprehensive improvement by building an informed consent approach that is adaptive to local culture, but still upholds the universal principles of medical ethics. Strategic steps that can be taken include strengthening the capacity of health workers in effective communication and empathy, simplifying information materials to be easily understood by all patient groups, and integrating communication technology to strengthen informed consent documentation. In addition, it is necessary to strengthen legal regulations and supervision, update evidence-based policies, and increase legal awareness for the wider community. Through this approach, it is hoped that the practice of informed consent in Indonesia can become more ethical, effective, and provide equal legal protection for patients and health workers. The limitations of this study include the number of countries for comparison, which may affect the generalizability of the findings. Recommendations for future research are to conduct empirical studies that focus on the legal framework that oversees informed consent both in Indonesia and several other countries.

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