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LEGAL ASPECTS OF INFORMED CONCENT IN HEALTH SERVICES

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Abstract

Informed consent is one of the main pillars in legal protection for patients in health services. Consent given by patients after obtaining adequate, honest, and understandable information about the medical action to be taken, is a legal and ethical requirement for every medical intervention. In the context of Indonesian law, the regulation regarding informed consent has been explicitly regulated in Law Number 29 of 2004 concerning Medical Practice, Law Number 17 of 2023 concerning Health, and Regulation of the Minister of Health Number 290 of 2008 concerning Consent to Medical Actions. This study uses a normative juridical method with a conceptual and legislative approach, aiming to examine how legal regulations regarding informed consent are applied in medical practice, as well as the form of legal accountability of medical personnel if there is a violation of the procedure.
The results of the study show that although the legal framework on informed consent in Indonesia is quite comprehensive, its implementation in the field still faces various obstacles, ranging from the lack of understanding of medical personnel regarding their legal obligations, weak patient education, to minimal supervision and law enforcement. Violation of the informed consent procedure can result in legal liability in three areas at once: civil, criminal, and administrative. Therefore, there needs to be a policy reformulation that is more adaptive to the development of health technology and increased legal literacy for both patients and health workers, in order to make informed consent a substantive legal protection instrument in national health service practices.

Keywords: *Informed Consent, Health Law, Patient Rights, Medical Responsibility*

INTRODUCTION

The development of modern medicine today presents various forms of technological progress and very complex therapeutic methods. Along with this progress, the relationship between health workers and patients is no longer paternalistic, but rather demands a more egalitarian relationship, based on the principle of respect for the autonomy of individual patients. In this context, the concept of Informed Consent becomes an important pillar in the practice of health services. Informed consent is not just an administrative formality, but a concrete manifestation of respect for the patient's human rights to determine for themselves the medical steps that will be taken for themselves, after first obtaining sufficient, honest, and understandable information.(Fazizullah, Marlina, and Sahlepi 2022)

Etymologically, informed consent can be translated as consent given after obtaining information. In the medical field, this term refers to a patient's consent to a medical procedure after receiving a complete explanation of the diagnosis, purpose of the procedure, possible risks, alternative procedures, and possible outcomes (prognosis). At the normative level, this concept reflects the principle of autonomy in bioethics, which requires doctors to respect the patient's choices and rights in making decisions regarding medical interventions. Therefore, the application of informed consent is an absolute requirement for the legality of medical procedures and is an ethical and legal foundation in medical practice in a country with the rule of law such as Indonesia.(Harahap, Kusuma, and Gurning 2024)

In the context of national law, the existence of informed consent has been accommodated in various laws and regulations. Law Number 29 of 2004 concerning Medical Practice, especially Article 45, emphasizes that every medical action must be preceded by the consent of the patient or his/her legitimate family, after being given a complete explanation. The explanation must include aspects of diagnosis, procedures to be performed, the purpose of the medical action, risks and complications that may arise, alternative actions, and prognosis. This provision is then strengthened

more technically in the Regulation of the Minister of Health of the Republic of Indonesia Number 290 of 2008 concerning Consent to Medical Actions, which expressly regulates the form, procedures, and requirements for the validity of informed consent.

Law Number 17 of 2023 concerning Health as the latest regulation in the health sector in Indonesia also emphasizes the importance of patient consent in every form of individual health service. Article 293 paragraph (1) of this Law states that every health service action carried out by medical personnel or health workers must obtain patient consent. In the event of an emergency, where the patient is unable to give consent and there is no family or guardian who can give consent, medical action can still be carried out based on the professional considerations of health workers. However, outside of these conditions, the obligation to obtain informed consent remains absolute, and ignoring this procedure can have serious legal implications.(Rahmadsyah and Sidi 2023)

In principle, informed consent is a manifestation of legal protection for patients. This is closely related to patient rights as regulated in various regulations, including the Medical Practice Law, the Health Law, and Law Number 44 of 2009 concerning Hospitals. Patients have the right to receive correct, clear, and honest information about their health condition and medical action plans. They also have the right to ask for a second opinion, to refuse unwanted medical actions, and the right to obtain a copy of their own medical records. On the other hand, medical personnel are obliged to explain completely, not misleadingly, and according to the patient's intellectual capacity, so that decision-making is truly based on informed choice.

Legally, informed consent can be either verbal or written. However, for high-risk medical procedures, regulations require written consent to be legally valid. Minister of Health Regulation No. 290 of 2008 states that high-risk medical procedures such as surgery, anesthesia, and the use of drugs that have serious side effects must obtain written consent. This written consent is not only for the legal protection of medical personnel, but also as a legal document that can be used as evidence in resolving medical disputes in the future.(Salsabila, Nugroho, and Gusthomi 2024)

From a civil law perspective, the absence or invalidity of informed consent can be qualified as a form of breach of contract or an unlawful act (onrechtmatige daad), as regulated in Article 1365 of the Civil Code. If a patient suffers a loss due to a medical procedure performed without valid consent, the patient can file a lawsuit for damages against the doctor or health facility concerned. This lawsuit can be in the form of a civil claim based on medical negligence or even a violation of the patient's rights. In some cases, the hospital can also be held liable as an institution (corporate liability), if there is evidence of procedural negligence in ensuring the protection of patient rights.

Meanwhile, in criminal law, the consequences of ignoring the informed consent procedure can lead to criminal liability, especially if the medical action carried out without consent results in serious injury or death of the patient. Article 440 of the Health Law Number 17 of 2023 explicitly stipulates that medical personnel who commit negligence that causes serious injury can be punished with a maximum prison sentence of 3 years and/or a maximum fine of IDR 250 million, while if it causes death, the threat becomes 5 years in prison and/or a fine of IDR 500 million. In addition, criminal provisions also apply to unlicensed medical practices, as referred to in Article 439 of the Health Law, which threatens the perpetrator with imprisonment and significant fines.

In practice, various legal cases related to informed consent have emerged and become important jurisprudential material. One of them is a court decision against a dentist who performed an implant procedure without written consent from the patient, even though the action is a medical procedure that poses a risk. The court stated that the action violated professional ethics and became the basis for administrative sanctions against the perpetrator. On the other hand, there are also decisions that show the importance of informed consent documents as evidence of defense. In the case of a lawsuit against a hospital in West Jakarta (Selfy vs. RS Kedoya case), the court rejected the patient's lawsuit after it was proven that the patient had signed a medical consent form, so there was no sufficient basis to declare malpractice.

Cases like these show that informed consent is not merely an administrative ritual or bureaucratic formality, but rather a vital legal mechanism to protect both parties: patients and medical

personnel. On the patient's side, this procedure ensures that the rights to information and personal autonomy are respected. Meanwhile, for health workers, the existence of a consent document can be an important evidence in facing allegations of malpractice or medical negligence.(Prince 2024)

However, the implementation of informed consent in the field does not always run ideally. There are a number of substantive and technical obstacles that make the effectiveness of this concept still questionable. Substantive obstacles arise when the explanation given by medical personnel is too technical, not transparent, or does not match the patient's level of understanding. This causes patients to give consent not because they really understand, but rather because they feel forced or helpless. Technical obstacles also occur when the informed consent documentation procedure is not carried out in accordance with applicable regulations, for example not signed, not legally documented, or even filled in by another party.

Another crucial issue is when there are differences in interpretation between patients and doctors regarding the substance of the information provided. In many cases, medical personnel assume that the explanation has been given adequately, while the patient feels otherwise. This creates disputes that are quite difficult to prove, especially if the documentation is incomplete or inaccurate. Therefore, it is necessary to strengthen legal mechanisms, supervision of professional ethics, and legal education for health workers and the community so that the implementation of informed consent truly reflects the expected ethical and legal principles.

Based on this background, it is important to examine the legal aspects of informed consent in health services in Indonesia, especially in relation to the fulfillment of patient rights, the obligations of medical personnel, and the form of legal responsibility in the event of a violation of procedures. The focus of the discussion in this article will be directed at two main issues: (1) How is the legal regulation regarding informed consent in Indonesian legislation and how is it implemented in medical practice? (2) What is the form of legal responsibility of medical personnel in the event of a violation of informed consent procedures, both from a civil and criminal legal perspective?

METHOD

This study uses a normative legal method, namely a legal research approach that focuses on the analysis of written legal norms that regulate informed consent in health services in Indonesia.(Yam 2022)The main data sources used are primary legal materials, such as Law Number 17 of 2023 concerning Health, Law Number 29 of 2004 concerning Medical Practice, and Regulation of the Minister of Health Number 290 of 2008 concerning Consent to Medical Actions, as well as secondary legal materials in the form of legal literature, scientific journals, and relevant court decisions. This study was analyzed qualitatively with a conceptual and legislative approach, in order to systematically understand how legal norms regulate the rights and obligations of the parties in the process of consent to medical actions and the form of legal accountability if there is a violation of the informed consent procedure.

RESULTS AND DISCUSSION

Legal Regulations Regarding Informed Consent in Indonesian Legislation and How to Implement It in Medical Practice

Informed consent in health care practices in Indonesia is not only a medical ethics issue, but has become part of the positive legal regime that regulates the relationship between medical personnel and patients. In the Indonesian legal system, informed consent or approval of medical procedures is a legal instrument that is inherent in the principle of respect for human rights, especially the right to bodily integrity and personal autonomy. Thus, regulations regarding informed consent not only

function as a guideline for medical professional ethics, but also as a legal standard that determines whether or not a medical procedure is valid.(Njoto 2011)

Normatively, legal regulations regarding informed consent in Indonesia can be traced through various laws and regulations, both in the form of laws, government regulations, and ministerial regulations. The main legal framework that is used as a reference is Law Number 29 of 2004 concerning Medical Practice. Article 45 of this Law states explicitly that every medical action carried out by a doctor or dentist on a patient must be preceded by consent, which is given after the patient has received a complete explanation. This explanation must at least contain information about the medical diagnosis, the procedure to be carried out, the purpose of the action, the risks and complications that may arise, other alternative actions (if any), and the prognosis for the patient's condition. This regulation affirms the principle that the patient is a legal subject who has the right to determine whether a medical action can be carried out on his body or not.(Siyen, Hadi, and Asriwati 2020)

The obligation to obtain consent for medical procedures is further described in more detail in the Regulation of the Minister of Health of the Republic of Indonesia Number 290 of 2008 concerning Consent for Medical Procedures. This regulation is a direct derivative of Article 45 of the Medical Practice Law and regulates the procedures for implementing informed consent in medical practice in a more technical manner. Article 1 number 1 of the Minister of Health Regulation explains that consent for medical procedures is consent given by the patient or his/her immediate family after receiving a complete explanation regarding the medical procedures to be performed by health workers. This explanation includes the diagnosis, type and purpose of the procedure, risks, complications, and other alternatives, as also emphasized in the Law. The Minister of Health Regulation also distinguishes between oral and written consent, and stipulates that for high-risk procedures, consent must be given in writing.

In addition to Law 29 of 2004 and Minister of Health Regulation 290/2008, strengthening of norms on informed consent can also be found in Law Number 17 of 2023 concerning Health, which is the latest regulation and replaces the previous Health Law (Law No. 36 of 2009). Article 293 paragraph (1) of Law 17/2023 emphasizes that every individual health service action must obtain the patient's consent. In its explanation, this consent is referred to as a form of recognition of the patient's right to accept or reject medical action based on information provided by medical personnel. Furthermore, this law also regulates criminal sanctions for medical personnel or health workers who, due to their negligence in carrying out medical actions, cause serious injury or death, which in practice can involve failure to comply with informed consent procedures.(Indonesia 2003)

Harmonization between legal regulations and medical ethics principles shows that the regulation of informed consent is not only aimed at protecting patient rights, but also to create legal certainty and protection for medical personnel. In practice, the existence of a valid informed consent document is a form of legal protection for doctors from malpractice claims. This document serves as evidence that the patient has understood and agreed to the medical actions that will be carried out on him. Therefore, informed consent has a two-way dimension: on the one hand protecting patient autonomy, on the other hand becoming a legal shield for medical personnel.

Although the normative regulation on informed consent in Indonesia is quite adequate, implementation in the field still faces a number of challenges. In various studies and field reports, it was found that the process of implementing informed consent is often not carried out in its entirety as mandated in the regulation. For example, the explanation given by medical personnel to patients is often too technical or not fully understood by the patient. Even in some cases, patients or their families are only asked to sign a consent form without proper explanation. This is certainly contrary to the spirit of the legal regulation which requires informed consent, not just consent alone.(Country 2001)

The information gap between doctors and patients is one of the main factors causing the low quality of informed consent implementation. Patients are often in a subordinate position, do not have sufficient medical understanding, and feel psychologically pressured by the doctor's authority. In such conditions, the consent given tends to be passive and does not reflect an autonomous decision. This is exacerbated by the paternalistic culture in Indonesian medical practice which tends to position

doctors as authoritative figures, so that explanations to patients are less than optimal. As a result, even though the consent procedure has been carried out administratively, the essence of informed consent as a form of protection of patient rights has not been achieved.

Another problem lies in the documentation aspect. In practice, not all hospitals or health care facilities have adequate standard operating procedures (SOPs) regarding the implementation and documentation of informed consent. Many medical consent forms do not meet legal standards because they do not include information that should be conveyed to the patient. There are even cases where the signature on the informed consent document is not given by the patient or his/her family, but by another party who does not have legal authority. This condition not only endangers the patient's legal position, but also places medical personnel at great legal risk.

From the aspect of supervision, it can be said that the regulation of sanctions for violations of informed consent procedures is still ineffective. Although the Health Law has regulated criminal and administrative sanctions, the implementation of law enforcement is still very limited. Most violations of informed consent are only discovered when there is a legal dispute or malpractice that causes serious losses. In fact, ideally the monitoring mechanism for the implementation of informed consent procedures should be carried out preventively and continuously by professional organizations, hospitals, and health service supervisory institutions. Unfortunately, there is no effective complaint mechanism and legal audit to ensure that every medical action has gone through a legitimate informed consent procedure.(Hasan 2015)

However, there have been some advances in the practice of hospitals and health care facilities in implementing the concept of informed consent. Several hospitals have implemented accreditation standards that require the implementation of informed consent as part of the service quality indicators. Accreditation from the Hospital Accreditation Committee (KARS) and international accreditation such as the Joint Commission International (JCI) encourage hospitals to implement written, documented, and evidence-based informed consent procedures. In addition, training in medical ethics and law that is beginning to be required in the medical education curriculum also provides hope that the next generation of doctors will be more aware of the importance of legal and ethical aspects in obtaining medical consent.

However, this progress is not evenly distributed. In various regions, especially in primary health facilities (FKTP) such as community health centers or small private clinics, the implementation of informed consent procedures is still not up to standard. This is due to various factors, such as limited human resources, lack of medical law training, and the absence of binding written SOPs. In this context, the state through the Ministry of Health and professional organizations such as the Indonesian Doctors Association (IDI) and the Indonesian Hospital Association (PERSI) needs to expand regulatory and educational interventions so that the implementation of informed consent is not just a formality, but is truly implemented as substantive legal protection.(Ritonga, Hasibuan, and Zarzani 2024)

Legal regulations on informed consent also need to be continuously updated in line with technological developments and health service models. For example, in the era of telemedicine and online health consultations, how informed consent procedures are implemented is still a matter of debate. The Regulation of the Minister of Health Number 20 of 2019 concerning the Implementation of Telemedicine between Health Service Facilities does state that patients must still be given adequate information, but the documentation mechanism has not been regulated in detail. This opens up room for legal uncertainty, especially if there is a dispute over medical actions carried out online. Thus, legislation and regulations related to informed consent must be adaptive to developments in the era and new models of interaction between patients and health workers.

In the broad framework of a state of law, informed consent is a manifestation of the principles of legality, respect for human rights, and procedural justice in medical services. The state is obliged to ensure that citizens are not treated arbitrarily in any medical action. Therefore, regulations regarding informed consent must be designed comprehensively and their implementation must be maintained through effective monitoring mechanisms. Public education is also important so that patients

understand that they have the right to know, refuse, or ask for clarification regarding the medical actions to be carried out. Without legal awareness on both sides, informed consent will remain an administrative procedure and lose its ethical and legal meaning.

Thus, it can be concluded that the legal regulation on informed consent in the Indonesian legal system has been quite clear and comprehensive, both in the form of laws and technical regulations. However, its implementation in the field still faces serious challenges, both in terms of substance, procedure, and the legal culture of society and medical personnel. Systematic efforts are needed from various parties to ensure that informed consent truly becomes an instrument for protecting patient rights and legal protection for health workers in medical service practices in Indonesia.

Forms of Legal Responsibility of Medical Personnel in the Event of Violation of Informed Consent Procedures, Both from a Civil and Criminal Law Perspective

Informed consent in health care practice is not only a form of respect for patient human rights, but also a means of legal protection for medical personnel. When the informed consent procedure is carried out legally and in accordance with legal principles, medical personnel have legal protection if unavoidable medical complications occur. However, on the other hand, failure to fulfill the legal obligation to obtain informed consent legally can have serious legal consequences for medical personnel. Violation of this procedure has the potential to result in liability in various legal areas, especially in civil law and criminal law, and does not rule out the possibility of being subject to administrative or ethical sanctions by professional organizations.

From a civil law perspective, violations of the informed consent procedure are generally qualified as a form of default or unlawful act (onrechtmatige daad), as regulated in Article 1365 of the Civil Code (KUHPerdata). This article states that "every unlawful act, which causes loss to another person, requires the person whose fault causes the loss, to compensate for the loss." In the context of the doctor-patient relationship, if the doctor performs a medical procedure without the patient's valid consent, then the action can be considered a violation of the law, because there is no contractual basis or free will of the patient as the party affected by the action. Thus, the doctor or hospital can be sued by the patient or his/her family to pay compensation for material or immaterial losses.(Sidi and Putra 2022)

The legal relationship between a doctor and a patient in many literatures is categorized as a civil contract based on a therapeutic agreement, in which the doctor is obliged to carry out professional actions in accordance with medical and legal standards. In this contract, if the patient gives consent without sufficient understanding due to incomplete or misleading explanations, then the agreement is considered defective, and does not meet the subjective requirements as referred to in Article 1320 of the Civil Code. Even in several court decisions, it has been emphasized that the consent given by the patient is only valid if it is given freely, without pressure, and is based on complete information that can be understood by the patient. Therefore, if informed consent is given manipulatively, unilaterally, or administratively without a valid explanation, then it can be categorized as voidable consent which has legal consequences in the form of an obligation to compensate for the medical party who acts unlawfully.

This civil liability can be requested not only to individual doctors, but also to hospitals as institutions. This is in line with the principle of vicarious liability, namely institutional responsibility for the actions or negligence of medical personnel working under the responsibility and management of the hospital. In the context of Indonesian law, Article 29 of Law Number 44 of 2009 concerning Hospitals stipulates that hospitals are legally responsible for all losses caused by the negligence of medical personnel working under them. Therefore, if a legal dispute occurs due to the failure to carry out the informed consent procedure legally, the hospital as an institution can be sued civilly and held accountable to pay compensation for the losses experienced by the patient.(Darwaman, Sidi, and Saragih 2023)

In addition to civil aspects, violations of informed consent procedures can also result in criminal liability, especially if the medical action taken without consent causes serious injury, disability, or even death of the patient. Criminal law has a repressive and corrective function against any action that violates the law and poses a danger to individual rights, including the right to bodily integrity and life. In this case, Law Number 17 of 2023 concerning Health has explicitly regulated criminal sanctions against medical personnel who are negligent in health services.

Article 440 of the 2023 Health Law states that "Any medical and/or health worker whose negligence results in a patient experiencing permanent disability or serious injury shall be subject to a maximum imprisonment of 3 (three) years and/or a maximum fine of IDR 250,000,000.00 (two hundred and fifty million rupiah). If such negligence results in death, the criminal threat increases to 5 (five) years in prison and/or a maximum fine of IDR 500,000,000.00 (five hundred million rupiah)." This provision indicates that negligence in health care procedures, including failure to obtain consent for medical treatment, can be subject to criminal sanctions if it has fatal consequences.(Sustainable 2023)

In addition, Article 439 of the same Law threatens criminal penalties for anyone who practices medicine without a license as a medical professional. Although not directly related to the issue of informed consent, this article is relevant in the context of violations of the limits of competence and authority in medical services, which are often associated with procedural failures, including ignoring informed consent. In the context of criminal liability, proving the elements of negligence (culpa) and the causal link between medical actions carried out without consent and the consequences caused are central points in the judicial process.

In court practice, a number of cases have shown how violations of informed consent procedures have become the basis for criminal charges against medical personnel. One actual example is the liposuction case in Depok that occurred in 2024, where a patient died as a result of a medical procedure performed at a beauty clinic without a valid consent procedure. In the court's decision, the doctor in question was sentenced to 1 year and 4 months in prison because he was proven to have performed medical procedures without meeting the standards of care and legal procedures, including negligence in obtaining informed consent. This case sets a precedent that administrative and substantive failures in the medical consent process are not only ethical errors, but also constitute a violation of criminal law that can threaten the freedom of the perpetrator.

In addition to civil and criminal legal consequences, medical personnel who violate informed consent procedures can also be subject to administrative sanctions and professional discipline. Based on Articles 50–53 of the Medical Practice Law, doctors who are proven to have violated professional standards and codes of ethics can be subject to sanctions by the Indonesian Medical Council (KKI), ranging from warnings, suspension of practice permits, to permanent revocation of practice permits. Professional organizations such as the Indonesian Doctors Association (IDI) also have the authority to impose ethical sanctions on their members who violate ethical norms, including non-compliance with the principle of informed consent. These ethical sanctions, although not juridical in the criminal or civil sense, have serious reputational and professional impacts on the career sustainability of medical personnel.

From the perspective of state administrative law, hospitals or health care facilities can also be subject to administrative sanctions if they are proven to have systematically ignored the implementation of informed consent procedures. These sanctions include warnings, suspension of operational permits, revocation of permits, or administrative fines, as stipulated in Article 341 and Article 410 of the 2023 Health Law. This provision shows that accountability is not only individual, but can also be corporate if violations are committed in a structured and repeated manner.(Yolanda, Saragih, and Tanjung 2024)

However, in assessing legal responsibility for violations of informed consent procedures, the principle of caution in proof must still be upheld. Not all medical failures that cause adverse consequences can be automatically attributed to violations of informed consent. In some cases, medical complications can occur even though informed consent procedures have been carried out

legally. Therefore, the court must carefully examine the extent to which consent has been given, whether the information provided is sufficient and understood by the patient, and whether there is an element of negligence or intent on the part of medical personnel in carrying out their legal obligations.

In an effort to prevent such legal liability, the implementation of informed consent procedures must be part of the risk management system in every health care facility. Hospitals and clinics need to prepare clear standard operating procedures (SOPs) regarding the implementation of informed consent, train medical personnel in effective communication with patients, and provide consent forms that comply with legal standards. Equally important is good recording and documentation as evidence of the implementation of the procedure, including in the form of integrated electronic medical records. Doctors must record that information has been given to the patient, state the contents of the explanation, who provided and received the information, and proof of the patient's consent in the form of a valid signature or electronic recording.

Thus, legal liability for violations of informed consent procedures is a complex and multidimensional legal reality. Medical personnel, hospitals, and all health service providers are required to understand and comply with applicable legal provisions, so that the principles of law, ethics, and professionalism can go hand in hand. Amidst increasing public awareness of patient rights, as well as increasing cases of medical malpractice lawsuits, the informed consent procedure should no longer be viewed as merely an administrative procedure, but must be made the main pillar in maintaining the legality of medical actions and public trust in the health service system in Indonesia.

DISCUSSION

A study of the legal aspects of informed consent in health services in Indonesia shows that there is a fairly complete and systematic normative formulation. This can be seen from the existence of regulations at various levels of legislation, starting from Law Number 29 of 2004 concerning Medical Practice, Law Number 17 of 2023 concerning Health, to Regulation of the Minister of Health Number 290 of 2008 which explicitly regulates the form, requirements, and procedures for implementing consent for medical actions. These provisions expressly state that medical personnel are required to provide honest and complete explanations to patients as a basis for conscious decision-making. This finding confirms that the Indonesian legal system has recognized informed consent as a substantive legal right of patients, not just an administrative completeness.

However, based on the analysis of implementation in the field, the author found that there is still a serious gap between legal regulations and their implementation. One of the main findings is that the implementation of informed consent is often still a mere formality. Patients are often only asked to sign a form without being given an adequate understanding of the content and implications of the medical actions to be carried out. Communication between doctors and patients is often not two-way, but rather one-way, dominated by medical authorities. This causes the consent given by patients to tend not to meet the element of "informed" as required by law.

Another important finding is the weak supervision and law enforcement against violations of informed consent procedures. The author did not find any regular audit mechanisms carried out by supervisory institutions, either at the ministerial level or professional organizations, to ensure that informed consent procedures are carried out according to legal standards. Most cases of violations only surfaced after a serious incident or lawsuit occurred. This indicates that the preventive aspect of legal regulation is still not optimal. In addition, sanctions against procedural violations are also more ethical and administrative in nature, while criminal enforcement tends to be selective and difficult to prove because it requires a strong causal link between procedural failure and medical consequences.

From the perspective of legal responsibility, the author's findings show that many doctors and hospitals still do not fully understand the meaning and legal consequences of informed consent. Many of them consider it only as a supplementary document to medical records, whereas legally, informed consent is a statement of free will that can be the main evidence in a malpractice or negligence lawsuit. Even in the context of criminal law, failure to obtain valid informed consent can be qualified as a

form of negligence that results in criminal penalties if it results in serious injury or death. Ignorance of these implications can increase legal risks, both for medical personnel individually and health care institutions corporately.

In addition, the author also noted that there has been no harmonization of regulations in facing new challenges, such as telemedicine practices, the use of artificial intelligence in diagnosis, and the development of aesthetic medical procedures that are rampant in non-hospital clinics. In this condition, the informed consent procedure becomes more complicated and requires regulatory innovation to continue to guarantee the protection of patient rights without hindering the progress of health services. The author considers that a revision of Permenkes 290/2008 or the development of new technical guidelines for informed consent in digital and non-conventional practices is urgently needed.

Sociologically, the author also found that the legal culture of Indonesian society is still weak in affirming the right to medical information. Many patients feel helpless before medical authorities and do not question the doctor's explanation due to ignorance or fear. In this case, informed consent will not have substantive meaning if the patient himself is not aware that he has the right to ask, refuse, or ask for a second opinion. Therefore, strengthening patient legal literacy is an inevitable need in increasing the effectiveness of the implementation of informed consent.

CONCLUSION

Based on the results of a legal study of laws and regulations and implementation practices in the field, it can be concluded that informed consent is an essential legal component in health services in Indonesia. Its presence is not merely an administrative procedure, but a legal instrument that guarantees protection of basic patient rights, especially the right to autonomy, bodily integrity, and complete medical information. Regulations regarding informed consent have been explicitly regulated in Law Number 29 of 2004 concerning Medical Practice, Law Number 17 of 2023 concerning Health, and detailed in the Regulation of the Minister of Health Number 290 of 2008. These three regulations consistently place informed consent as a legitimate requirement for medical action, by requiring a thorough explanation to the patient before the action is taken, especially for medical actions that have high risks.

However, in practice, the implementation of informed consent in various health care facilities is still not optimal. The author found a tendency towards formalistic implementation, where patients are only asked to sign a form without being given adequate, clear, and understandable information. The imbalance in the relationship between doctors and patients, low patient legal literacy, and weak monitoring systems for the implementation of this procedure increase the potential for violations of patient rights which have serious legal implications. In the event of a violation of the informed consent procedure, medical personnel can be held accountable in three legal areas at once, namely civil, criminal, and administrative. In civil law, such violations can be categorized as breach of contract or unlawful acts. In criminal law, negligence without valid consent can result in imprisonment if it causes serious injury or death. Meanwhile, in administrative and ethical law, medical personnel can be subject to sanctions by professional institutions and health authorities.

Therefore, informed consent must continue to be understood and implemented not only as a legal obligation for medical personnel, but also as a concrete form of protection and respect for the dignity of patients as autonomous legal subjects. Consistent enforcement of this procedure will strengthen the health service system based on ethics, accountability, and procedural justice. In the future, regulatory updates are needed that are responsive to the challenges of modern health services, strengthening the hospital supervision and accreditation system, and increasing legal education for both medical personnel and the wider community so that the implementation of informed consent is truly effective and meaningful in national health practices.

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