

## **POST-OPERATIVE: BETWEEN INFORMED CONSENT, RISK, AND LEGAL LIABILITY**

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### **ABSTRACT**

This study evaluates legal responsibility in postoperative medical services related to informed consent procedures. Hospitals are obliged to provide quality, fair and equitable health services. Informed consent is key in the doctor-patient relationship, affirming the patient's right to obtain complete information about medical procedures, alternatives, risks, and prognosis. The transformation of the health system in Indonesia emphasizes the importance of written consent before medical action. The research method uses a normative juridical approach with descriptive analysis to examine legal issues related to informed consent. The results showed that informed consent in Indonesia is regulated in Law No. 29 of 2004 concerning Medical Practice and Law No. 36 of 2009 concerning Health. Lack of information provided by health workers can have legal consequences. Standard Operating Procedures (SPO) and professional ethics are important guidelines for health workers in providing medical services. Article 1365 of the Civil Code regulates the obligation to compensate for losses due to unlawful acts. The complaint mechanism to the Indonesian Medical Discipline Honor Council (MKDKI) is a means for the public to file complaints related to medical services. Thus, this study emphasizes the importance of transparency and understanding in informed consent to improve the quality of medical services and the protection of patient rights.

**Keywords:** Informed consent, medical services, legal responsibility, patient rights, medical risks, professional ethics, Standard Operating Procedure.

### **INTRODUCTION**

Health Law regulates the rights and obligations of individuals and communities regarding health services. Hospitals have an obligation to provide quality, fair, and equitable health services to everyone at a cost that is affordable to the community as well as quality services. In addition, hospitals must not differentiate between individuals or groups from all levels of society. The rights and obligations of health workers are also regulated in health law, including the right to terminate the relationship with a patient if they deem that their cooperation is no longer useful.

Community empowerment is a crucial factor in supporting the delivery of structured health services. Involving various aspects, health services aim to achieve the highest degree of public health. Health care is an activity provided to individuals and communities by the government with the aim of preventing and curing individual and community diseases (Subiakso et al., 2023). The community also plays a role in organizing health services through participation in health service activities and public health efforts.

Indonesia's health system transformation aims to promote a healthy and strong Indonesian society through primary care, referral services, health security, funding, human resources, and health technology. This transformation requires the support of regulatory transformation that aims to fulfill people's rights, create laws that focus on disease prevention, and develop health innovations.

The Health Law is directly related to the provision of health services, including hospitals. It regulates the definition and scope of hospital actions, as well as the rights and obligations of individuals and communities regarding health services. Community empowerment is also an important factor in the delivery of health services. Transformation of the health system in Indonesia is also being carried out to promote a healthy and strong society through various prevention efforts and the development of health innovations.

In the therapeutic transaction between a doctor and a patient, respect for the patient's human rights, including the right to self-determination and the right to information, is a determining factor in the success of the relationship. The right to self-determination reflects the principle that every individual has the freedom to make decisions regarding his or her own medical treatment. Patients have the right to give consent or refuse a medical procedure after receiving adequate information from the doctor, so they have control over decisions that affect their own health and destiny.

Furthermore, the right to information emphasizes the importance of patients getting clear information about their health condition, proposed medical procedures, as well as available treatment options. Doctors have a responsibility to provide explanations that patients can understand, so that they can make informed decisions appropriate to their health needs.

In medical services, the role of the hospital does not focus directly on the implementation of medical actions, but rather on the appointment of doctors who will provide these services to patients. This medical service process is often referred to as a therapeutic transaction. By applying these principles, medical services can be more effective, meaningful, and in accordance with the needs and desires of patients (Arben, 2020).

According to Aprilyansyah (2020), in medical science, patients are no longer considered as objects, but as subjects who have an equal position with doctors. This is reflected in the need for Informed Consent before making healing efforts, in accordance with the provisions of Law No. 29 of 2004 concerning Medical Practice. Every medical action must obtain consent from the patient after the doctor provides an explanation that includes a

diagnosis of the patient's medical condition and the medical procedure to be performed. The goal is for the patient to have sufficient understanding to make informed decisions that are in accordance with their health needs.

Information that should be provided to patients includes medical procedures, alternatives, risks, complications, and prognosis. When high-risk medical procedures are performed, alternative treatments and associated risks should be considered and explained to the patient (Tampil et al., 2023). Risks and complications that may occur during or after the procedure should also be transparently conveyed to the patient. In addition, the prognosis or expected outcome of the procedure and its long-term impact should also be conveyed to the patient.

Written consent, signed by the person entitled to give consent, is a further step to ensure understanding and agreement between the patient and the healthcare provider (Busro, 2018). It is a form of professional responsibility and medical ethics to provide sufficient information to patients so that they can make informed decisions about the medical treatment to be performed so that, in the process of medical care, doctors and patients work together to find the most appropriate therapy for the patient. The relationship between doctors and patients is considered a respectful partnership, where the position of the patient is considered equal to that of the doctor (Mariyani, 2020). By holding these two basic rights, open and transparent communication between doctors and patients is key to ensuring patient safety and satisfaction during the medical treatment process.

Based on various controversial cases related to the discrepancy between informed consent and factual medical actions, this study aims to evaluate legal responsibilities in medical services, especially regarding postoperative informed consent procedures. In this evaluation, we will refer to the provisions contained in Law No. 29 of 2004 concerning Medical Practice. The main objective is to understand the extent to which hospitals and medical professionals comply with the regulations and legal obligations related to obtaining informed consent from patients after surgery.

The importance of informed consent in health care is increasingly emphasized, especially with the existence of Article 37 paragraph 1 of Law No. 44 of 2009 regarding Hospitals. The article states that "every medical intervention performed in a hospital environment must obtain prior consent from the patient and their family." This emphasizes the need for transparent communication between medical parties and patients, where patients and their families must obtain adequate information about the medical procedures that will be carried out.

Such consent must be based on a clear understanding of the risks, benefits and alternatives of the planned medical action. Informed Consent is not just a formality, but a form of ethical responsibility in medical practice (Chaeria et al., 2020). Thus, this regulation creates a legal foundation that mandates that every step in medical practice in hospitals requires valid consent from patients and their families.

## METHODS

This study uses a normative juridical approach with an analytical descriptive method to examine the legal responsibility of medical services in providing incomplete Informed Consent. This approach is based on analyzing the problem through legal principles and positive legal norms.

The research method consists of two stages. First, a literature study. Secondary data was collected from various sources, including primary legal materials such as laws, secondary legal materials such as books, articles, and scientific journals, and tertiary legal materials such as dictionaries. Second with qualitative juridical analysis. The data and regulations obtained were analyzed qualitatively to achieve an in-depth understanding of the issue of incomplete Informed Consent.

This study resulted in two main points. The first is an overview of the legal responsibilities of medical services in providing complete and comprehensive Informed Consent information. The second is a legal aspect analysis by analyzing legal aspects relevant to Informed Consent, including related regulations and underlying legal principles.

This qualitative analysis is expected to provide a better understanding of the law related to incomplete Informed Consent so that it can assist in dispute resolution and improving the quality of medical services.

## RESULTS AND DISCUSSION

Informed Consent in Indonesia is the consent given by the patient or next of kin after receiving a thorough explanation of the medical or dental procedure to be performed. Regulations related to Informed Consent are regulated in several laws, including Law No. 29 of 2004 concerning Medical Practice, Law No. 36 of 2009 concerning Health, and Regulation of the Minister of Health of the Republic of Indonesia Number 290/Menkes/PER/III/2008 concerning Consent for Medical Actions. According to Law No. 29 of 2004, Informed Consent is an obligation that must be fulfilled by health workers before performing medical actions. This emphasizes the importance of providing complete information to patients or their families, so that they can make conscious and knowledge-based decisions. In addition, Law No. 36 of 2009 on Health also emphasizes the patient's right to obtain clear and adequate information about the medical procedures that will be undergone.

Regulation of the Minister of Health of the Republic of Indonesia No. 290/Menkes/PER/III/2008 provides further guidelines regarding the consent of medical treatment, by requesting that the information conveyed to the patient should consist of the risks, benefits, and alternatives of medical treatment. The aim is to provide understanding to patients so that they can make the most appropriate decision according to their personal needs and values. As such, Informed Consent is a legal formality, and

represents the ethical and human rights principles of healthcare in Indonesia. The provision of clear and transparent information to patients is key to safeguarding the patient's right to autonomy and ensuring that any medical action is carried out with informed consent (Filia, 2019).

Law No. 36/2009 on Health has the main objective of increasing awareness, willingness, and ability to live a healthy life for every individual. The doctor's obligation is to provide a clear explanation of various aspects related to the patient's health condition. This includes the diagnosis that has been made, the medical procedure to be performed, the purpose of the action, the alternative treatment options available, as well as the risks and complications arising from the medical action. The accuracy and completeness of the information provided is very important, as failure to do so may be considered a violation of the law. If the doctor does not meet the standards for the delivery of correct medical information, then the patient's consent to medical treatment may be considered invalid and may have legal consequences. For this reason, doctors are required to carry out the procedures for delivering medical information correctly so that patients have an adequate understanding before agreeing to the medical action to be carried out.

The validity of medical actions should be in line with Standard Operating Procedures (SPO) in the health care sector, which are regulated in the regulation of the Indonesian Minister of Health No. 1438/Menkes/PER/IX/2010 concerning Medical Service Standards. The creation of SPOs aims to ensure that various work processes carried out routinely can run efficiently, effectively, uniformly, and safely. This is done to improve the quality of health services through the application of established standards. With the SPO, it is expected that all steps in medical practice can be carried out according to predetermined guidelines, so as to provide better and consistent services. These standards not only regulate aspects of efficiency and effectiveness, but also refer to patient safety and efforts to achieve consistency in the application of medical procedures. Therefore, compliance with SPOs is an important key to ensuring that medical practices achieve the highest standards in terms of validity and quality.

Medicine must carry out actions with validity in accordance with Standard Operating Procedures (SPO) in the field of health services, as regulated by the regulation of the Indonesian Minister of Health No. 1438 / Menkes / PER / IX / 2010 regarding Medical Service Standards. The creation of Standard Operating Procedures (SPO) aims to ensure that various work processes carried out routinely can run efficiently, effectively, uniformly, and safely. Through the implementation of SPO, it is expected to improve the quality of health services by ensuring that every step taken by medical personnel is in accordance with applicable standards. In other words, SPO is a guide that ensures that medical practice is carried out consistently and measurably, so as to provide optimal health services to the community.

Professional health workers focus on all their behaviors and steps in providing services to the community or patients based on professional standards. For this reason, it is

important for every type of health worker operating in various health facilities or facilities to have a code of conduct or professional ethics as the basis for their practice. The Professional Code of Ethics, or often referred to as a reference for action, must be formulated by the relevant professional organization or association.

Therefore, professional ethics is an important foothold that ensures that every interaction of health workers with patients or the community is carried out with a sense of responsibility and honesty (Lethy et al., 2023). The rules regarding the professional standards of health workers are regulated in Government Regulation No. 32 of 1996. Every medical personnel in carrying out their obligations is expected to comply with the norms of the health worker profession. The Minister then sets professional standards for these health workers. Specialized health workers in carrying out their professional duties have the responsibility to respect patient rights, maintain the confidentiality of the patient's identity and personal health information, provide information related to the condition and steps to be taken, seek consent for actions to be taken, and create and maintain medical records.

The form of liability that can be imposed on the hospital based on Law No. 29 of 2004 regarding Medical Practice is explained in Article 66 paragraph (1) of the Medical Practice Law. This article regulates a condition in which an error occurs involving health services, especially those performed by doctors. In this case, if there are complaints or dissatisfaction with the health services provided by the doctor, every individual who knows or feels harmed by the error has the right to file a complaint.

This complaint mechanism is directed to the Chairman of the Indonesian Medical Discipline Honor Council (MKDKI). MKDKI has an important role as an institution that handles the ethics and discipline of the medical profession. This means that individuals who feel aggrieved have a forum to voice their complaints regarding errors in health services performed by doctors. These complaints can consist of various aspects, such as improper diagnosis, unprofessional medical actions, or violations of medical ethics. This reflects the legislator's efforts to provide protection to the public regarding health services and maintain ethical standards in medical practice. With this complaint mechanism in place, it is expected to improve accountability and quality of health services, as well as provide assurance that any errors that occur will be addressed with appropriate disciplinary action.

Article 1365 of the Civil Code stipulates that any act that is contrary to the law, and causes harm to another person, requires the perpetrator of the act to compensate for the loss. This law is present to protect the rights and obligations when someone commits an act, whether it is a mistake, negligence, or lack of care. The element of fault can be divided into two, namely intentional fault and fault due to lack of care, with both having the same legal consequences. Article 1365 of the Civil Code confirms that both intentional and negligent acts have equal legal consequences, namely that the perpetrator must be responsible for compensating all losses arising from unlawful acts. Losses in civil law can be divided into

two categories, namely material losses and immaterial losses. Material loss refers to losses that can be measured in real and concrete terms. Meanwhile, immaterial loss refers to the loss of future benefits or profits. In practice, the determination of compensation for immaterial losses is often the task of the judge, so there are difficulties in determining the amount of immaterial compensation to be awarded, because this is highly dependent on the subjectivity of the judge who decides. The regulation of Article 1365 of the Civil Code is to uphold justice and protect the rights of individuals who are neglected due to unlawful acts. However, the interpretation of the amount of damages, especially in terms of immaterial losses, shows the challenge of maintaining consistency and objectivity, as it depends on the judge's more subjective judgment.

Article 1365 of the Civil Code ensures that any individual who engages in unlawful conduct and causes harm shall be liable for damages. Damages arising from a tort may consist of both material and immaterial damages, or even a combination of both. The types of damages recognized in the civil law realm consist of general damages and special damages.

General damages refer to a generally applicable form of damages, comprising situations involving tortious conduct. The Civil Code regulates the provision of general damages through articles 1243-1252. These articles specify that general damages may involve various forms, including damages and interest. These articles provide a legal basis for determining the amount and type of damages that can be received by a party who suffers a loss as a result of a tort. Punitive damages consist of any form of loss that can be calculated financially, such as property damage, medical treatment costs, or lost income. Meanwhile, interest may be applied in addition to compensate for time or monetary value lost during the damages settlement process. This means that general damages are a mechanism that involves the obligation of the party who committed the tort to compensate the injured party for the losses suffered. Through the articles set out in the Kuhperdata, the legal system provides a clear framework for assessing and determining the number of general damages in various legal cases.

Specialized indemnification refers to a form of indemnification that is limited to losses arising out of specific engagements. In this case, the indemnity does not comprise all types of losses, but only those related to the specific agreement or agreement that has been made between the parties involved. This means that if there is a breach or non-compliance with the specific engagement, the injured party is only entitled to compensation for limited and specific losses in accordance with the terms of the agreement. For example, in a business contract, the party that breaches the agreement may be required to pay specific damages that have been specified in the agreement. These damages consist of financial or other losses that are explicitly described in the contract. This means that the concept of special damages ensures that the reimbursement provided relates only to losses arising from the specific breach of the agreement, while limiting the liability to a pre-agreed scope.

Any legal violations that occur in the practice of medicine can be resolved through civil legal remedies. The settlement process can be done through various channels, including non-litigation, negotiation, mediation, and litigation. The litigation route, which is a process in a civil court, is regulated by Law No. 29 of 2004 regarding medical practice, specifically in Article 66 paragraph (1). According to this provision, any individual who knows or feels harmed by the actions of a doctor or dentist in carrying out medical practice may file a complaint in writing to the Chairman of the Indonesian Medical Disciplinary Honor Council. This complaint must consist of information on the identity of the complainant, the name and address of the doctor's practice, as well as the time, action taken, and reason for the complaint. The submission of the complaint does not remove the right of every individual to report alleged criminal acts to the authorities or file a civil lawsuit for losses incurred to the court. This means that individuals who feel aggrieved have the option to choose the most appropriate resolution path, either through the medical ethics and discipline process or through more formal civil or criminal legal channels.

The Indonesian Medical Discipline Honor Council (MKDKI) uses several legal mechanisms in resolving ethics cases. Here are some of these mechanisms. MKDKI is authorized to receive complaints from various sources, including patients, doctors, and other professional organizations. These complaints are then evaluated to determine whether there is a disciplinary violation that needs to be followed up. After a complaint is received, MKDKI conducts an examination and investigation of the doctor suspected of committing the offense.

This examination is conducted by MKDKI members consisting of doctors and legal experts, who are responsible for evaluating whether there are mistakes made by doctors in the application of discipline. If a violation is found, MKDKI can determine sanctions in the form of giving a written warning, recommendation for revocation of STR/SIP, and/or obligation to attend additional education or training. These sanctions aim to ensure that doctors understand and respect professional ethics and discipline. MKDKI is also responsible for conducting periodic supervision of doctors to ensure that they remain compliant with professional ethics and discipline. This is important to prevent misconduct and maintain professionalism in the practice of medicine. MKDKI often cooperates with the Indonesian Medical Ethics Honor Council (MKEK) and other institutions in addressing issues of professional discipline violations. This coordination helps in resolving cases more effectively and ensures that all disciplinary violations are properly identified and followed up.

By using these mechanisms, MKDKI can ensure that doctors uphold ethics and professionalism in medical practice, so that patients are protected and public trust in medical services is maintained. Thus, MKDKI examines and provides decisions on complaints relating to the discipline of doctors and dentists (Indaryanti et al., 2023). If the examination finds ethical violations, the Indonesian Medical Disciplinary Honor Council

forwards the complaint to the professional organization. The decision of the Indonesian Medical Disciplinary Honor Council is binding on doctors, dentists, and the Indonesian Medical Council. The decision can be in the form of being declared not guilty or giving disciplinary sanctions. Disciplinary sanctions as referred to in Article 69 in paragraph (3) of Law No. 29 of 2004 regarding medical practice can be in the form of giving a written warning; recommendation for revocation of registration certificate or license to practice; and/or obligation to attend education or training at medical or dental education institutions.

Informed Consent, risk, and legal responsibility after surgery are important aspects of medical services. MKDKI has an important role in ensuring that doctors uphold ethics and professionalism in the postoperative Informed Consent process so that patients are protected and public trust in medical services is maintained.

MKDKI ensures the ethics and professionalism of doctors in the Informed Consent process with several important steps. First, MKDKI is responsible for upholding the discipline of medicine and dentistry, including ensuring that doctors follow the Indonesian Code of Medical Ethics (KODEKI) which regulates professional behavior and ethics in medical practice. KODEKI instructs doctors to always make independent decisions and maintain professional behavior in the highest measure, as well as avoiding acts that are self-praising.

Secondly, MKDKI has the duty to receive complaints, examine, and decide on cases of doctor disciplinary violations that are filed. This is important in ensuring that doctors provide clear and transparent information to patients about the risks, benefits, and alternatives to existing medical measures, so that patients can make informed and conscious decisions. Thus, MKDKI ensures that doctors uphold ethics and professionalism in the Informed Consent process, so that patients are protected and public trust in medical services is maintained.

Thirdly, MKDKI has the authority to determine whether or not there is an error in the application of medical science and determine disciplinary sanctions. This helps in ensuring that doctors respect patients' rights and provide clear and transparent information about the medical procedures to be undergone. With clear and fair procedures, MKDKI can maintain professionalism and ethics in medical practice, including in the Informed Consent process.

Finally, MKDKI also plays a role in providing protection to patients, maintaining the quality of doctors, and maintaining the honor of the medical profession. This is important in ensuring that doctors provide correct and complete information to patients, so that patients can make informed decisions and are protected from risks that may arise. Thus, MKDKI ensures the ethics and professionalism of doctors in the Informed Consent process, so that patients can get quality and safe health services.

Based on this description, hospital management should provide periodic training and certification for health workers on informed consent procedures and professional ethics. Implementation of an information system that allows a complete track record of the informed consent process, including written documentation signed by the patient. Internal audit measures in place. By conducting periodic internal audits to assess compliance with SPOs and informed consent procedures, and taking corrective action when violations are found. Provision of counseling services to help patients understand medical information, action alternatives, risks, and prognosis in more depth before giving consent

## CONCLUSION

Informed consent, a legal agreement, is an important cornerstone of medical care, especially post-surgery. Behind this consent lies a complex legal liability for doctors and hospitals.

This study has shown potential legal violations in the Informed Consent process, where the information provided to patients and families may be inadequate. This is categorized as unlawful and illegitimate, contrary to the Standard Operating Procedure (SOP) and the Indonesian Ministry of Health regulation No. 1438/Menkes/PER/IX/2010. This incomplete information stems from suboptimal doctor-patient communication. Therefore, this study emphasizes the importance of improving the quality of communication to ensure correct and compliant Informed Consent.

Furthermore, this study highlights the responsibility of doctors in providing clear information about risks to patients' families. This lack of clarity can be categorized as a violation of Informed Consent and potentially ensnare doctors with legal consequences. Based on its role, Law No. 29 Year 2004 on Medical Practice and related regulations are present to protect victims of malpractice. Patients are entitled to compensation for medical negligence, in line with the purpose of law to provide certainty, justice, and expediency.

This study serves as a reminder for doctors and medical personnel to carry out their duties responsibly and transparently in the Informed Consent process. Hospitals are also encouraged to improve the quality of their services for patient satisfaction and the achievement of their vision and mission. The government needs to actively socialize the rights of patients in obtaining proper health services. This understanding will empower people to fight for their rights, especially if they suffer losses due to medical negligence.

This study provides suggestions for further research to enrich the understanding of the legal responsibility of postoperative medical services, with a focus on the optimal implementation of Informed Consent. Through deeper analysis, further studies are expected to produce useful recommendations for hospitals, doctors, and patients, for the realization of quality, safe, and responsible medical services.

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