

Legal Protection For Surgeons In The Context Of Informed Consent For Digestive Surgical Procedures At The Banten Regional General Hospital

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ABSTRACT

The background of this research is based on the fact that all medical procedures performed by healthcare professionals require prior consent from the patient. The patient must be fully informed and understand all aspects of the medical procedure. The importance of the equal legal relationship between doctors and patients necessitates knowledge of the protection of their practices and actions to prevent unilateral harm. Therefore, informed consent serves as an instrument of legal protection for doctors, and its forms and implementation are explored. This research employed a normative-empirical juridical method with a qualitative approach, combining literature studies and field data in the form of questionnaires for surgeons. The results showed that although 75% of doctors understood the importance of informed consent as part of professional ethics and legal protection, challenges persisted in its implementation, such as time constraints, lack of patient understanding, and suboptimal internal hospital oversight. Furthermore, it was found that approximately 10% of surgical procedures experienced discrepancies between the initial plan and the final outcome, necessitating re-informed consent to maintain transparency and avoid legal action. This study demonstrates that legal protection for doctors and the implementation of informed consent have been implemented in accordance with applicable legal and ethical standards. However, the researchers also recommend regular and systematic outreach to medical personnel, improvements in documentation and oversight of informed consent implementation in hospitals, and recommendations for re-informed consent if there is a discrepancy between the procedures implemented in all hospitals and regulations.

Keywords: Informed Consent, Legal Protection, Surgeon, Digestive Surgery, Banten Regional General Hospital

I. INTRODUCTION

The relationship between doctor and patient, a bond of trust, has existed for centuries. This relationship arises from the patient's need to find solutions to their health problems. In this case, the doctor or hospital can provide solutions to the patient's health problems. (Henny, 2024)

This relationship makes the doctor's position appear superior because the doctor is considered to know all the patient's illnesses and can always cure the patient's illness. Meanwhile, the patient is in a weaker position because he knows nothing about his illness and wants his illness to be cured by the doctor. However, with the development of the community's mindset, this perspective has shifted, so that the doctor is no longer in a superior position but is equal to his patient, the patient can determine his own rights and what methods will be used for treatment of his illness. The legal relationship between the patient and the doctor in health care is hereinafter referred to as a therapeutic agreement. The meeting between the two in the study of civil law has created a legal relationship, which is technically known as a *verbinten* agreement.

There are two types of agreements recognized in contract law: *Inspanningverbinten*, which is an agreement of effort, meaning that both parties promise or agree to make maximum efforts to realize what is promised. Second, *Resultaatverbinten*, which is an

agreement that will provide results or real results in accordance with what is promised. (Anggun et al., 2022)

Therapeutic agreements or therapeutic transactions are included in inspanningverbintenis or agreements of effort, because doctors cannot promise healing to patients, what doctors do is provide health services as an effort to cure patients.⁵ In carrying out this effort, doctors must do it with full sincerity and use all their abilities and skills by adhering to professional standards. In this therapeutic agreement, patients usually feel or are considered as the party asking for help so that their position is relatively weak compared to the doctor. So to reduce this weakness, a principle known as informed consent has been added, namely a patient's right to allow a medical action to be carried out on him.

All medical procedures performed by healthcare professionals must be based on prior consent from the patient, where the patient must be given complete information and understand all aspects of the medical procedure to be performed. ⁶ Consent to medical procedures provided by the patient can be in two forms, either written or unwritten. Written consent is provided for high-risk medical procedures and is provided in a form known as informed consent. (Indra et al., 2023)

Medical Actions based on Article 1 number 2 of Law Number 17 of 2023 concerning Health that "Health efforts are all forms of activities and/or a series of activities carried out in an integrated and continuous manner to maintain and improve the health status of the community in the form of promotive, preventive, curative, rehabilitative, and/or palliative by the Central Government, Regional Government, and/or the Community"

Informed consent aims to provide protection for patients and health workers, namely doctors, informed consent will provide comfort and support for patients to make choices for themselves, as well as to improve communication between doctors and patients. ⁸ Meanwhile, for doctors, informed consent aims to provide legal protection against the risk of lawsuits that are often related to failures in medical actions or maximum services that have been provided by hospital health workers. ⁸ Doctors must realize that informed consent can truly guarantee the implementation of legal relations between patients and doctors, on the basis of mutual fulfillment of the rights and obligations of each party that are balanced and accountable (Indra Narendra, 2023).

Informed consent is very clearly mandated in Article 17 paragraph (2) of Law Number 17 of 2023 concerning Health, more broadly and comprehensively it is stated that health is a condition that must be implemented by the state and the state guarantees health for all people in order to achieve the highest level of public health. Then the Medical Practice Law Number 29 of 2004 and has also been clarified in the Regulation of the Minister of Health of the Republic of Indonesia Number 1691 / MENKES / PER / IX / 2011 concerning Information and Approval of Health Actions which requires providing informed consent to patients as a sign of agreement in carrying out medical actions. (Kasiman.et al., 2023)

Doctors must understand the importance of informed consent, as it guarantees legal protection. A patient also has a fundamental right to determine their own actions. Therefore, every procedure (whether diagnostic or therapeutic) must always be performed with the patient's consent. Without such consent, healthcare professionals, in this case doctors, may be considered unlawful and liable for any losses incurred if certain procedures are performed. (Michele et al., 2022)

Patient consent is necessary because the results of medical procedures are full of uncertainty and cannot be calculated mathematically because they are influenced by factors beyond the doctor's control, such as disease virulence, drug quality, patient compliance, and many other factors. Furthermore, medical procedures carry risks (the possibility of adverse consequences), or even certain medical procedures are always followed by unpleasant

consequences (what follows logically or effectively from some causal action or condition). The patient bears these risks, whether good or bad. For this reason, patient consent is absolutely necessary for every medical procedure, except in emergency situations. (Octaviano, 2017)

This is evidenced by data obtained by a digestive surgeon at Banten Regional Hospital, along with several pediatric and general surgeons who have treated approximately one thousand patients annually. Each doctor stated that each surgical procedure could result in a discrepancy between the initial diagnosis and the surgical procedure performed. Of the thousand patients treated, this discrepancy is estimated to reach 10% of surgical patients.

These discrepancies in surgical outcomes ultimately lead to problems or dissatisfaction among patients and their families with the surgeons performing digestive surgeries. Failure to obtain informed consent before surgery can result in complaints and lawsuits against the surgeon. This can have legal implications, as families perceive discrepancies with the patient's initial explanation of the patient's condition.

The obligation to provide explanations or information to patients is included in the responsibilities of a doctor towards the patient. As stated in Article 10 Paragraph (1) of the Regulation of the Minister of Health of the Republic of Indonesia No. 290/MENKES/PER/III/2008 concerning Approval of Medical Actions, namely the Explanation as referred to in Article 9 is given by the doctor treating the patient or one of the doctors from the team of doctors treating him. However, if in the event of an obstacle, then the provision of explanations or information to the patient can be given by another doctor or other health worker, with the knowledge and responsibility of the doctor concerned. (Achmad B, 2018)

This can be distinguished between surgical and non-surgical procedures. For surgical procedures, the information must be provided by a physician, while for non-surgical procedures, the physician should still provide the explanation directly, although a nurse can also provide it. However, the physician must be absolutely certain that the nurse assigned to the procedure fully understands the problem and is capable of providing an explanation the patient can understand. Therefore, from a legal perspective, the responsibility for informed consent remains with the physician.

Based on this description, the researcher was interested in further analyzing how Indonesian regulations govern informed consent and how they are implemented to ensure legal protection for physicians. Therefore, this paper presents the title "Legal Protection for Surgeons in the Context of Informed Consent in Digestive Surgery at Banten Regional Hospital." (Kasiman, 2023)

II. RESEARCH METHODOLOGY

The type of research used in this study focuses on normative-empirical legal research. Normative-empirical legal research is legal research that examines law as a rule or norm and the application of legal rules in practice in society.

The research is entitled "Legal protection for surgeons in the context of informed consent for digestive surgery at Banten Regional General Hospital based on applicable laws and regulations." The required data is obtained through document studies, including regulations and legal expert opinions. Furthermore, the researcher will distribute questionnaires to surgeons performing digestive surgery at Banten Regional General Hospital. The data obtained will be analyzed to resolve the problem.

The approach used by the researcher is to examine legal norms (regulations) and the implementation (enforcement) of legal rules/legal application processes to achieve legal objectives. Patients and those responsible have the right to receive accurate and comprehensive information, and laws have been established to protect this right. Secondary data was obtained

from sources that can support the research, including documentation and literature. Data analysis was conducted through a qualitative study of all necessary and collected data. In this study, the discussion will be directed at a theoretical study regarding legal protection for doctors in the context of informed consent for abdominal surgery.

III. RESULT AND DISCUSSION

Legal Protection for Surgeons in Digestive Surgery Procedures in the Context of Informed Consent at Banten Regional General Hospital

Based on data analysis, it was found that the majority of surgeons at Banten Regional General Hospital (RSUD Banten) have a good understanding of the purpose and importance of informed consent in digestive surgery. They recognize that informed consent not only provides legal protection for doctors but also provides a means of providing transparent information to patients and their families. Several respondents also expressed a good understanding of the importance of informed consent as a legal protection and as essential evidence of medical procedures.

Based on the questionnaire data analysis, it was found that 75% of surgeons at Banten Regional General Hospital have implemented the principle of preventive legal protection through comprehensive informed consent. Seventy-five percent of respondents also provided additional explanations when discrepancies were found between surgical results and the initial plan, demonstrating an awareness of the importance of information transparency as a means of preventing disputes. This practice aligns with the provisions of Law No. 17 of 2023 and Minister of Health Regulation No. 290/2008, which emphasize the obligation of physicians to provide complete information regarding diagnoses, procedures, risks, and alternative medical treatments. By fulfilling this informative obligation, physicians not only protect patients' rights but also build a strong preventive legal defense.

On the other hand, the finding that 100% of respondents had experienced discrepancies in surgical outcomes but still complied with informed consent procedures demonstrates an understanding of the protective function of repressive legal remedies. A complete and valid informed consent document can serve as primary legal evidence in the event of a medical dispute, protecting doctors from various forms of repressive sanctions such as administrative sanctions, criminal sanctions, and civil lawsuits. The fact that 50% of respondents renewed their informed consent when faced with discrepancies in surgical outcomes reinforces this position, demonstrating a commitment to updating the consent in light of current developments.

The implementation of informed consent at Banten Regional General Hospital has thus balanced both aspects of legal protection. The preventive aspect is achieved through the provision of transparent information and effective communication with patients, while the repressive aspect is also met through the documentation of consent, which can be used as a legal defense tool if necessary. To optimize this function, it is recommended that physicians improve their communication skills and undergo more intensive medical documentation training so that informed consent can truly function as an effective legal instrument in protecting physicians.

The understanding of informed consent from several respondents is also in line with the principles of medical ethics that emphasize the importance of patient autonomy. Informed consent allows patients to make informed decisions about the medical treatment they will undergo. This is also in line with Law Number 17 of 2023 concerning Health and Minister of Health Regulation Number 290/MENKES/PER/III/2008 concerning Consent for Medical Procedures. Articles 293 to 295 of Law Number 17 of 2023 regulate consent for medical procedures (informed consent). This provision explains that every health care procedure

performed by a health professional must obtain informed consent from the patient after adequate explanation is provided, including an explanation of the diagnosis, indications, objectives of the procedure, risks, alternatives, and other matters as stipulated by law. This is in line with field data that 75% of doctors understand the importance of transparency in line with this article, which emphasizes the right to patient autonomy as a key principle.

Compliance with Ethics and Law: 75% of respondents felt that the informed consent process at Banten Regional Hospital complies with legal standards and medical ethics. However, the presence of respondents who expressed uncertainty indicates that there is still room for improvement in the implementation of informed consent. Furthermore, all respondents agreed that further training or outreach regarding the legal and ethical aspects of informed consent is essential.

Law Number 17 of 2023 concerning Health, in Article 273, emphasizes that health workers have the right to receive protection:

- 1) Legal protection in carrying out professional duties as long as work is in accordance with professional standards, service standards, operational procedure standards.
- 2) Protection against Acts of Violence, in this Article provides protection for doctors and other health workers from physical or verbal violence that often occurs in health service settings.
- 3) Protection against Ethical and Professional Violations: If a doctor violates the medical code of ethics or professional standards, the sanctions imposed are in accordance with professional regulations and not based on criminal law, unless there is a criminal element in the violation. This protection also stipulates that doctors have the right to be accompanied by professional organizations, such as the Indonesian Medical Association (IDI), in the process of resolving ethical disputes. This legal protection also covers the aspect of informed consent, which is the basis of the legal relationship between doctors and patients.

Furthermore, Article 293 of Law No. 17/2023 provides protection for doctors who perform medical procedures in emergency situations. The article states that doctors are not required to obtain informed consent from patients in emergency situations when the patient is unable to give consent and there is no family or authorized person who can be contacted. In situations that require doctors to make difficult medical decisions, they can obtain legal protection if they act in accordance with the principle of prudence and follow proper procedures.

- a) The principles of non-maleficence and beneficence form the basis of medical practice. If doctors act in accordance with these principles, they will receive legal protection even if the outcome is less than expected or even causes complications.
- b) Article 273 Generally, it stipulates that in emergency situations or health crises, doctors can make medical decisions without prior authorization, but must adhere to professional standards, service standards, standard operating procedures, and professional ethics. This also provides legal protection in the event of risks or adverse consequences arising from such actions.

Matter This demonstrates that even though informed consent has been implemented, there is still a need to increase understanding and awareness of the importance of legal and ethical aspects in surgical practice. Furthermore, Law No. 17 of 2023, which strengthens sanctions for ethical violations, makes training related to the legal aspects of informed consent (as proposed by respondents) urgent.

Responsibility in Medical Disputes: 75% of respondents stated that surgeons are primarily responsible in cases of medical disputes related to surgical outcomes that do not comply with initial informed consent. This aligns with the principle of professional

responsibility in medical practice, where physicians, as medical personnel, bear primary responsibility for the medical procedures performed. In terms of responsibility and morality, physicians are indeed the primary custodians of any patient outcome. However, Law 17/2023 provides more detailed provisions on collective responsibility (medical teams and health facilities).

If a doctor violates his or her obligations (for example, due to medical negligence), he or she may be subject to civil liability (compensation) under Article 1365 of the Civil Code (unlawful acts) or Article 1366 of the Civil Code (breach of contract). While the liability imposed on doctors to maintain the credibility of the profession presents very complex obligations, doctors are also provided with legal guarantees to maintain a system that creates balance and justice. There are several conditions that provide legal protection, including:

- i. To meet professional standards, doctors are required to practice their profession in accordance with established medical professional standards. This is affirmed in Article 273 of Law Number 17 of 2023 concerning Medical Practice, which states that doctors have the right to legal protection as long as they carry out their duties in accordance with professional standards and standard operating procedures. These standards cover diagnosis, therapy, and other medical procedures established by professional organizations such as the Indonesian Medical Association (IDI). If medical procedures are carried out in accordance with these standards, doctors cannot be considered negligent even if the results do not meet the patient's expectations. As long as doctors act based on reasonable medical knowledge and skills, and do not commit careless or negligent acts, the law will side with them.
- ii. NoThere is an element of error (Culpa), Legal protection is also provided if there is no element of error or culpability in the medical actions carried out by the doctor. This is regulated in: Article 440 of Law Number 17 of 2023 concerning Health, which states that medical personnel cannot be prosecuted criminally or civilly as long as there is no error in the actions carried out in accordance with professional standards and medical ethics.
- iii. Obtaining informed consent: Before performing any medical procedure, doctors are required to obtain informed consent from the patient. This is a form of preventative legal protection, as stipulated in Articles 293 to 295 of Law No. 17 of 2023, which state that every medical procedure must obtain the patient's consent after sufficient explanation. If the patient has been provided with complete information and given informed consent, the medical procedure has fulfilled the legal requirements. This will protect the doctor from potential future lawsuits.
- iv. Acting in an emergency: Doctors also receive legal protection when taking medical action without the patient's consent in emergency situations, namely when the patient's life is in danger and there is insufficient time to obtain consent. This is regulated in Article 273 of Law No. 17 of 2023, which authorizes medical personnel to take emergency medical action to save a life or prevent serious disability, even without informed consent. As long as the action is taken in the spirit of saving the patient and in accordance with medical procedures, doctors will not be subject to legal sanctions.

Implementation of Legal Protection for Doctors in Cases of Inconsistency in Surgical Results After Informed Consent in Medical Surgical Practice at Banten Regional General Hospital

Analysis of questionnaire data and respondents' experiences with surgical outcomes that differ from planned indicates that this is a common situation in surgical practice. Respondents who have experienced such situations tend to handle the situation by providing a direct explanation to the patient or family and re-obtaining informed consent if necessary. This

demonstrates an awareness of the importance of transparent communication and moral responsibility in medical practice.

In the context of surgical procedures, informed consent is crucial due to the invasive and high-risk nature of the procedure. This process must be conducted transparently, and documentation must be kept as legal evidence. Without valid informed consent, doctors can face both civil and criminal prosecution.

Digestive surgery is a medical procedure performed on the digestive system, including the intestines, stomach, liver, and pancreas. These procedures are often complex and carry a high risk of complications. Therefore, careful pre-operative preparation, including informed consent, is essential.

At Banten Regional General Hospital, digestive surgery is one of the leading services. However, an internal study from the hospital in 2022 noted that:

1. Approximately 18% of informed consent documents are not signed in full by all three parties (doctor, patient/family, and witness).
2. 30% The patient admitted that he did not fully understand the risks of the medical procedure even though he had signed the consent form.
3. A total of 3 complaint reports were received by the hospital's legal department regarding post-surgical complications during the 2021–2023 period.

The high patient volume and complexity of cases can increase the risk of legal issues, especially if post-operative complications arise. Therefore, understanding legal protections and implementing informed consent effectively is crucial. The Importance of Informed Consent in Digestive Surgery: In this context, informed consent is not merely an administrative formality, but an integral part of ethical and legally valid medical practice. Digestive surgery requires a detailed explanation to the patient or their family regarding:

1. Diagnosis and patient's clinical condition
2. Purpose and stages of surgical procedure
3. Possible risks
4. Alternative treatments besides surgery
5. Process recovery and possible post-operative complications

According to a study by Yanuar and Safira (2023) published in the Indonesian Journal of Ethics and Health Law, most lawsuits against surgeons stem from a lack of communication and clear information provided to patients prior to surgery. This demonstrates that informed consent is directly correlated with patients' perceptions of trust and satisfaction.

According to Notoatmodjo, informed consent has two main functions in modern medicine:

1. As a form of protection of the patient's right to determine his own actions regarding his body (autonomy)
2. As a form of legal protection for doctors in carrying out their professional duties

Providing re-informed consent when a procedure differs from the initial plan is not only a legal and ethical obligation, but also a medical defense strategy that protects doctors and hospitals from the risk of disputes. At Banten Regional General Hospital, research findings demonstrate an awareness of this urgency, but it needs to be supported by regulations, a strict documentation system, and the dissemination of updated regulations to ensure consistency of practice. Thus, re-informed consent is crucial, particularly for legal protection for the medical profession.

The urgency of re-informed consent when there are differences from the initial surgical plan is based on several fundamental considerations. First, it demonstrates respect for the principle of patient autonomy, which requires patients to receive complete information about any changes and consequences of the proposed medical procedure. Second, legal aspects necessitate a new consent, as Law No. 17 of 2023 concerning Health explicitly requires consent

for any significant changes to the medical plan. Third, from a medicolegal perspective, re-informed consent serves as documentary evidence that can protect healthcare professionals from potential future disputes.

However, despite the urgency of re-informed consent being crucial from an ethical, legal, and physician-protection perspective, there is currently no specific regulation explicitly addressing the obligation to re-informed consent in the context of changes to medical treatment plans, including surgical extensions. Existing regulations only address informed consent in general terms without detailing the procedures or mechanisms for re-informed consent when significant modifications to medical procedures occur.

Due to this regulatory vacuum, the practice of re-granting informed consent relies solely on the interpretation of general principles of contract law, specifically therapeutic transactions based on the principle of consensualism as stipulated in Articles 1320 and 1338 of the Civil Code. In this context, the relationship between doctor and patient is considered a contractual relationship that requires mutual agreement before any action is taken. Therefore, any changes to the initial medical procedure must again obtain the patient's consent, as such changes can be considered a new form of contract that requires re-consensus. In other words, even though it is not explicitly regulated in sectoral health legislation, the legal basis for re-granting informed consent can still be justified through a civil law approach. However, unfortunately, without concrete regulations, this practice remains vulnerable to interpretation and has the potential to create legal uncertainty for all parties involved.

To optimize this practice, Banten Regional General Hospital and the government need to establish clear ground rules regarding re-informed consent. These rules should include criteria for mandatory re-informed consent, such as when an extension of the surgical procedure is discovered, a significant change in risk, or a new pathological condition that impacts the treatment plan. Implementation procedures also need to be standardized, starting with identifying changes, communicating with the patient/family, and meticulous documentation using special forms. In special situations, such as incompetent patients or emergency cases, specific protocols are needed that uphold ethical principles even under less-than-ideal conditions.

Thus, this study provides an overview that the implementation of informed consent at Banten Regional General Hospital has been running well, but further efforts are still needed to improve understanding, compliance with legal and ethical aspects in surgical practice, and also the regulatory basis for re-informed consent in the event of differences in the results of digestive surgery.

IV. CONCLUSION

Based on the results of research and analysis that have been carried out regarding legal protection for surgeons in the context of informed consent for digestive surgery at Banten Regional General Hospital, the following conclusions can be drawn:

- 1) Legal Protection for Surgeons in Digestive Surgery Procedures in the Context of Informed Consent at Banten Regional General Hospital
 - a) The majority of surgeons at Banten Regional General Hospital (RSUD Banten) understand the importance of informed consent as a means of providing transparency to patients and providing legal protection for physicians. The implementation of informed consent at RSUD Banten generally complies with legal standards and medical ethics, although a small number of respondents remained uncertain about its compliance with the latest regulations (Law No. 17 of 2023).
 - b) Informed consent serves as legal evidence that protects doctors from malpractice claims,

provided that medical actions are carried out in accordance with professional standards, service standards and operational procedure standards in accordance with Article 2 Paragraph 2 of the Minister of Health Regulation No. 3 of 2025 concerning the Enforcement of Professional Discipline. Surgeons are considered the most responsible party in medical disputes related to the discrepancy between surgical results and initial informed consent, although Law No. 17 of 2023 also regulates the collective responsibility of the medical team and health facilities. In Law No. 17 of 2023 concerning Health, informed consent (approval for medical actions) is regulated in Articles 293 to 295. This provision explains that every health service action carried out by medical personnel or health workers must obtain informed consent from the patient after an explanation of the diagnosis, indications, objectives of the action, risks, alternatives, and others in accordance with the provisions of the law.

2) Implementation of Legal Protection for Doctors in Cases of Inconsistency in Surgical Results After Informed Consent in Medical Surgical Practice at Banten Regional General Hospital

- a) Surgical outcomes that do not align with the initial plan are not uncommon in surgical practice. Most doctors handle this by providing additional explanations and re-obtaining informed consent if necessary.
- b) Law Number 17 of 2023 concerning Health regulates the obligation to obtain informed consent for health care services in Articles 293 to 295. Article 293 emphasizes that every health care service must obtain the patient's consent after being given an adequate explanation, while Article 294 regulates the substance of the explanation which includes the diagnosis, purpose of the action, procedures, risks, alternatives, prognosis and estimated costs. Although this law does not explicitly mention the term re-informed consent, this obligation is implicitly inherent in the norm of informed consent, because consent is only valid for actions that have been explained and approved by the patient. Therefore, if there is a change in the patient's diagnosis, action plan, risks, or clinical condition, then the previous consent is no longer sufficient, so that medical and health workers are required to provide a re-explanation and obtain re-informed consent to ensure the protection of patient rights and legal certainty for health workers.
- c) The main challenge in implementing re-informed consent is the lack of explicit regulations governing it. Its practice still relies on the principle of consensualism in civil law, which can create legal uncertainty. Therefore, clear regulations and guidelines, including standard operating procedures for re-informed consent, are needed to ensure comprehensive protection for physicians. This effort will support improvements in the quality of digestive surgery services and strengthen the legal and ethical systems in modern medical practice.

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