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Research Article

# Application of the Informed Consent Principle in Civil Law: A Case Study of Reduction Operations and Internal Fixation

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**Abstract**

This article describes the application of the principle of informed consent in civil law, focusing on case studies of internal reduction and fixation operations (ORIF). The research method uses a normative legal approach by analyzing related laws and regulations, related court decisions, and relevant legal literature. Interviews with medical legal practitioners and experienced physicians were conducted to gain practical insight into doctor-patient agreements in ORIF actions. The importance of a holistic and adaptive approach in implementing the principle of informed consent in Indonesia not only covers legal aspects, but also considers cultural, social, and economic factors. This requires active involvement from all relevant parties, as well as increased awareness of patient rights and physician responsibilities. By understanding these challenges, we can improve informed consent systems in the context of ORIF, create a more transparent healthcare environment, and safeguard the principles of patient well-being in medical practice. The results of this study are expected to contribute to a further understanding of the complexities of civil law in the context of informed consent, strengthen ethical principles in medical practice, and provide guidance for stakeholders, including physicians and medical law practitioners with a focus on ORIF actions.

**Keywords:** Privat Law, informed consent, ORIF

## INTRODUCTION

The rapid growth in medical practice, especially in areas of orthopaedic surgery such as internal reduction and fixation surgery (ORIF), highlights the need for a better understanding of the legal aspects of doctor-patient agreements. Informed Consent, as an ethical and legal principle, aims to actively involve patients in the decision-making process regarding their medical care.

The ORIF procedure, which involves reuniting broken bones using an internal fixation device, is a procedure that needs to provide clear information to the patient. The procedure is often complex, with risks and benefits that must be fully understood by the patient before surgical approval can be granted.

In the modern medical world, the relationship between doctor and patient not only covers clinical aspects, but also has a very important legal dimension. One crucial element of this legal framework is the application of the principle of informed consent, which ensures that patients have sufficient knowledge before consenting to a particular medical treatment. The importance of informed consent in ORIF actions lies not only in compliance with legal regulations, but also in the protection of the rights of doctors and patients, the principle of autonomy, and patient integrity. Therefore, this study aims to analyze in detail how the principle of informed consent is applied in the context of civil law, with a particular focus on the dynamics of the doctor-patient relationship in ORIF actions.

With a better understanding of the application of informed consent in this context, it is hoped that better use of informed consent can so as to, provide maximum protection of the rights of doctors, hospitals and patients while considering the needs of complex medical practices. This article will delve deeply into the application of the principle of Informed Consent in the context of civil law, focusing on case studies of Internal Reduction and Fixation Operations (ORIF).

## METHOD

The research method used in this article uses a normative legal approach by reviewing related laws and regulations, related court decisions, and relevant legal literature. In addition, interviews with experienced medical law practitioners and physicians were also conducted to gain practical insights regarding doctor-patient

agreements in ORIF actions, where the main focus is to collect, analyze, and synthesize information from various literature sources related to the application of informed consent in civil law, particularly through case studies of Internal Reduction and Fixation Operations (ORIF).

In this literature analysis, some of the objectives to be obtained are

1. Identify and summarize key concepts related to informed consent in the context of civil law.
2. Compare informed consent legal practices on ORIF actions across different jurisdictions, highlighting similarities, differences, and emerging trends.
3. Establish and analyze concrete case studies that address the application of informed consent to ORIF actions to provide in-depth insights.
4. Identify weaknesses or challenges that may arise in the application of informed consent to ORIF measures, based on literature findings.

By involving analysis from various literature sources, it is hoped that this article can present a comprehensive and accurate view of the application of informed consent in actions, especially ORIF.

## RESULT AND DISCUSSION

*Informed consent* is a very important concept in the context of civil law in Indonesia. However, there is no specific definition of *informed consent* in the Indonesian Civil Code or any particular law in Indonesia. In the Regulation of the Minister of Health of the Republic of Indonesia no 585 / Menkes / Per/XI / 1989 Article 1 states that informed *consent* is consent given by a patient or his family on the basis of an explanation of the media action that will be taken by the doctor against the patient. Information about the medical procedure must be provided to the patient, whether requested or not by the patient. In practice, *informed consent* is defined as consent given by a person (patient) after fully understanding relevant information about a medical action or intervention to be carried out by a medical party (doctor, nurse). This consent should be given voluntarily, without coercion, and once the patient has an adequate understanding of the risks, benefits, and possible alternatives.

Some principles that can form the basis for the definition of *informed consent* according to civil law in Indonesia include:

1. Full understanding

Patients must clearly understand the information provided by the doctor regarding the medical action to be performed, including the risks and benefits.

2. Patient engagement

Patients have the right to be involved in decision-making regarding their medical care. The doctor should give the patient the opportunity to ask questions and provide input.

3. Openness and transparency

Doctors have an obligation to provide information openly and transparently. This includes disclosing all risks that may occur during or after a medical procedure.

4. Voluntary consent grant

Informed consent must be given voluntarily without any element of coercion or threat. The patient has the right to refuse or accept such medical measures.

In Indonesia, civil law that regulates the validity of Informed Consent in the context of medical actions, can be found in the Civil Code (KUHPercivil) and related laws and regulations. Some relevant provisions involving the legal requirement of Informed Consent between doctors and patients include:

1. Article 1365 of the Civil Code

This article states that every agreement must be made in good faith. In the context of *informed consent*, this indicates that physicians have an obligation to provide honest and transparent information to patients.

2. Article 1366 of the Civil Code

Mention that consent must be given freely, without coercion and without any element of guilt. This indicates that *informed consent* should be given voluntarily by the patient without pressure on the part of the physician.

3. Law Number 36 of 2009 concerning Health also regulates the right of patients to obtain true and clear information about medical procedures to be carried out.

The application *of good informed consent* is an integral part of ethical medical practice and contributes to the protection of patient rights in the Indonesian legal system. In addition, medical practitioners can also refer to ethical guidelines and regulations issued by IDI to ensure quality medical practice and integrity, can also form the basis for the implementation of *informed consent* in Indonesia.

There are 2 forms of *informed consent* in the legal context, which include

1. *Implied Consent*

A form of *informed consent that is* not spoken directly by the patient but is considered to exist based on the patient's actions or behaviors that show consent. In the case of an emergency while the doctor needs immediate action while the patient is unable to give consent and his family is not there, the doctor can take the best medical action according to the doctor.

2. *Expressed Consent* (dinyatakan)

A form of *informed consent* expressed orally or in writing. This is the most direct and explicit form of consent. In invasive and risky medical procedures, doctors should get written approval, or known in the hospital as a letter of approval for surgery.

3. *Presumed Consent*

A form of *informed consent* that assumes that patients will give consent unless they explicitly state otherwise. It can be used in the context of organ donation, where a person is considered to agree to become a donor unless they have stated otherwise.

4. *Informed Refusal*

A condition that occurs when a patient refuses medical treatment after receiving adequate information about its risks, benefits, and alternatives.

5. *Limited Consent*

A form of *informed consent* is consent given for a specific action or in a specific context, but not for all medical treatments or measures. For example, patients give special consent for a surgical procedure but not for other actions that may be required during surgery.

6. *Informed Assent (Asent)*

A form of *informed consent* used when patients who are immature or unable to give consent are expected to give consent after understanding the information provided.

ORIF (Internal Reduction and Fixation Surgery) is a surgical procedure generally performed in fracture cases that require stabilization and reunion of separated bone fragments. Specifically, ORIF is used to repair complex fractures or bones located in important areas of the body such as the femur, or upper arm (humerus), aiming to restore the normal anatomy of the bones and restore the function of the joints and limbs involved. This procedure is often necessary when the fracture cannot be treated conservatively (without surgery) or when the results of closed reduction are inadequate. The ORIF procedure involves two main stages:

1. Reduction

The first stage is reduction, where the doctor will manipulate the bone fragments to return them to their appropriate positions. This can be done behind closed (without surgery) or open (surgically).

2. Internal fixation

After reduction is performed, the doctor will use internal fixation devices such as bone nails, metal plates, or screws to stabilize and fuse bone fragments. This equipment is placed inside the body and may remain there for a period of time to support bone healing.

The decision to perform an ORIF is usually considered based on factors such as the type of fracture, location, number of fragments, and is generally made after careful medical evaluation. After the ORIF procedure, patients will usually undergo a rehabilitation program to restore strength and mobility and ensure optimal healing.

*Informed consent* has an important role in providing legal protection for both parties, doctors, and patients. ORIF is a complex surgical therapeutic procedure and has risks that include surgical risks and risks related to the installation of internal fixation equipment, therefore related to *informed consent* in the context of installing ORIF, several aspects of civil law that need to be considered are

1. The doctor has the responsibility to explain in detail the ORIF procedure, the associated risks, as well as possible alternative measures. The doctor needs to specifically address the risks associated with ORIF insertion, such as the risk of infection, nerve damage, or allergic reaction to the internal fixation material. Moreover. What includes possible complications, success rates, and the long-term impact of the procedure should also be explained
2. The patient must be actively involved in the decision-making process. Clinicians need to ensure that patients have the opportunity to ask questions, provide input, and understand the implications of their decisions.
3. *Informed consent* requires an explanation of possible alternatives to ORIF. Patients should understand the other options that can be taken and why ORIF is considered the best option in a particular case.
4. Consent must be given voluntarily without coercion. Patients should not feel compelled or threatened to give them *consent*.
5. The physician needs to carefully document the entire informed *consent process*, including discussions with the patient, questions asked by the patient, and agreement reached. The patient's signature on the *informed consent* form must be a valid expression of consent. The patient must be mature enough and mentally competent to give consent.

In the implementation of the therapeutic agreement of ORIF action there is significant legal responsibility involvement on the part of both the doctor and the patient. This can be seen in the following aspects, namely:

1. Legal responsibilities of the doctor:
    a. *Informed consent*

Physicians have an obligation to provide patients with adequate information regarding ORIF measures, including their risks, benefits, and alternatives. The success of *good informed consent* will help protect doctors from potential lawsuits.

b. Professional competencies and standards

Doctors are responsible for providing medical care in accordance with applicable professional standards. If the doctor does not meet this standard, he may be subject to legal liability.

c. Medical errors

If a medical error occurs during the implementation of ORIF attributable to negligence or improper actions of the doctor, the doctor may be subject to legal liability.

d. Medical documentation

Physicians have the responsibility to accurately record all aspects of care, including patient consent, procedures performed, and other medical records. Complete documentation can be important evidence in a legal context.

2. Legal responsibilities of the patient

a. Consent and compliance

The patient has the responsibility to give voluntary informed consent and comply with the doctor's postoperative instructions, including treatment and rehabilitation. Patient compliance can affect the outcome of the ORIF procedure.

b. Required information

Patients have the responsibility to seek the information necessary to make knowledge-based decisions. If the patient does not understand the information provided, he has the right to request further explanation from the doctor.

c. Report a complication or problem

The patient has the responsibility to promptly report any complications or problems that may arise after the ORIF procedure. Prompt reporting can enable early intervention and reduce the risk of more serious complications.

d. Dissatisfaction or lawsuits

If the patient feels that there was negligence or inadequate action on the part of the doctor resulting in harm or complications, the patient has the right to express dissatisfaction or, in some cases, file a lawsuit.

3. Insurance and legal claims

Doctors and patients, can have a role in filing insurance claims or legal claims. Doctors may have professional insurance to protect against malpractice claims, while patients may have relevant health insurance.

4. Etika dan norma profi

Doctors and patients are expected to comply with applicable medical ethical norms and laws that involve integrity, honesty, and openness from both parties.

One of the legal case analyses related to the ORIF Action quoted through the Supreme Court Decision number 120 / Pdt.G / 2019 / PN Ckr, dated May 20, 2019 against dr. AJS SpOT and RSUD B. Lawsuits occur due to the results of surgery that are not in accordance with patient expectations, feel worse than the condition before surgery, and there are surgical complications where the patient's hands experience pain and weakness due to abnormalities in the motor radix of the median and ulnar nerves the right and right radial nerve sensory radix. The existence of *informed consent* in this case protects the doctor as a defendant because there is written documentation that explains what may be the risks or effects of surgery and has been approved by the patient and his family (plaintiff).

*Informed consent* that meets the provisions in the Article of the Regulation of the Minister of Health of the Republic of Indonesia Number 280 of 2008 concerning Approval of Medical Actions which includes the diagnosis and procedures for medical action, the purpose of medical action, alternative actions and risks, risks and complications that may occur, and prognosis, can provide legal protection to the executor of medical action from unreasonable claims on the part of the patient,

and from the consequences of unexpected and negative medical actions, such as the risk of medical actions that are impossible to avoid even though doctors or medical action implementers have acted carefully and in accordance with the operational standards of medical professional procedures. It cannot be blamed, then, unless there is a grave mistake due to *negligence* or *ignorancy* which would not have been done so by other colleagues.

From this case, it can be a learning material about the importance of *informed consent* because it has the effect of legal protection for doctors and hospitals, if it has been done correctly, by minimizing the risk of lawsuits and providing a strong legal basis for perpetrators of medical actions, through

1. A strong legal basis for the existence of the consent document is proof that the patient has been given adequate information and has given consent for medical action.
2. Communication and education evidence.

Informed consent reflects the process of communication between doctors and patients. If the doctor in detail explains the risks, benefits, and alternatives of action, and the patient gives consent voluntarily, it provides evidence that the patient has been informed and understood.

3. Prevention of malpractice claims.

Patients who have been adequately informed and still choose to pursue medical treatment may find it difficult to prove that they are not fully aware of the risks involved.

4. Protection against tort claims

*Informed consent* can provide protection against claims that doctors acted without the patient's consent. Clear and written consent can help prove that the doctor acted according to the patient's will.

5. Accurate Documentation

*Informed consent* creates accurate and complete medical documentation. This document can be important evidence in legal defense, especially if the patient makes claims regarding unexpected results or complications.

6. Ethical Punishment and Professionalism

By adhering to the informed *consent process*, doctors demonstrate a commitment to medical ethics and professionalism. This creates a positive impression in the eyes of the medical institution and the judicial system. Adhering to *informed consent* also reflects that doctors adhere to the standards of the medical profession. This can be a key factor in supporting legal defenses.

7. Patient Involvement in Decisions

*Informed consent* creates patient involvement in decision making. Patients who feel they have control over their care may be more willing to cooperate and less likely to file legal claims.

It should be remembered that the legal protection provided by Informed Consent is not absolute, and there are other factors that may influence legal considerations, such as manifest malpractice, procedural errors, or violations of medical ethics. In addition, Informed Consent only provides protection to the extent that the process is conducted properly and in accordance with legal standards and medical ethics.

In Indonesia, some weaknesses or challenges in the application of *informed consent* to ORIF actions can cover various aspects. Some of these challenges may be general, while others may relate to specific medical and legal contexts in Indonesia. Here are some of the weaknesses or challenges of using *informed consent* faced in Indonesia, namely

1. Limitations of health literacy

The varying levels of health literacy in the community can be challenging. Patients with low literacy levels may have difficulty understanding the medical information provided.

2. Cultural and linguistic diversity

Indonesia has cultural and linguistic diversity. Properly communicating medical information and ensuring patient understanding amidst this diversity can be challenging.

3. Emergencies

In emergency situations, such as accidents that require immediate ORIF action, doctors may be faced with limited time to provide patients with comprehensive information.

4. Uneven health systems

Equitable access to health information and health services throughout Indonesia may not always be guaranteed. Patients in remote areas may face these accessibility challenges.

5. Family involvement

Families often play an important role in health decision-making in Indonesia. Challenges may arise in managing family involvement by ensuring respect for patients' autonomy rights.

6. Trust in Health workers

The level of public trust in health workers can affect how information is received. Low trust can make patients less likely to understand or accept the information provided.

7. Socioeconomic

Socioeconomic conditions can affect a patient's understanding of medical information. Patients with low income levels may have limited access to education and health information.

8. Complex laws and regulations

Complex health regulations and laws may be difficult for patients to understand. Doctors need to explain simply and ensure that patients understand the legal implications.

9. Ethical and cultural aspects

Ethical and cultural aspects of approaching patients for consent can vary. Approaching patients with local wisdom and medical ethics accepted in the community is important.

10. Inadequate documentation

Inadequate informed *consent* documentation can be a drawback. Poor documentation can be a problem if there is a lawsuit later on.

11. Understanding risks and benefits

Conveying information about the risks and benefits of ORIF effectively can be challenging, especially if patients do not have adequate medical understanding.

Addressing these challenges requires a holistic approach that considers the diversity of people and health systems in Indonesia. Doctors and medical teams need to establish strong communication with patients, provide information in easy-to-understand language, and ensure that *informed consent* is well understood by patients before the procedure is performed. In addition, focusing on approaches that are sensitive to local culture and context is also important.

## CONCLUSION

In the face of the complexities of civil law related to ORIF actions, the application of the principle of informed consent is key in ensuring the protection of patient rights and maintaining the integrity of medical practice. This case study highlights the importance of providing patients with comprehensive information prior to undergoing ORIF procedures, ensuring that they understand the risks, benefits and alternative options available.

In the context of civil law, the consent given by the patient must be based on a full understanding of the procedure to be performed. This creates a strong legal basis for involving patients in the decision-making process regarding their care. However, challenges arise primarily in managing cultural diversity, health literacy levels, and psychological conditions of patients. Efforts to ensure that the principle of informed consent is recognized and understood by all parties, including physicians, patients, and patients' families, is a must. Effective and ethical communication on the part of the doctor, as well as a willingness to listen to the patient's concerns, can improve the quality of understanding and trust.

The importance of a holistic and adaptive approach in implementing the principle of informed consent in Indonesia not only covers legal aspects, but also considers cultural, social, and economic factors. This requires active involvement from all relevant parties, as well as increased awareness of patient rights and physician

responsibilities. By understanding these challenges, we can improve informed consent systems in the context of ORIF, create a more transparent healthcare environment, and safeguard the principles of patient well-being in medical practice. These conclusions underscore the importance of collaboration between civil law, medical ethics, and health practice in building a solid foundation for sustainable, human rights-based patient care.

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