



## Criticality of informed consent: Understanding the legal protection of health workers at Andi Makkasau Parepare Regional Hospital

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### Abstract

This study aims to analyze informed consent regarding the legal protection of health workers at the Andi Makkasau Parepare Regional General Hospital. Informed consent is an approval for medical action through a communication process between the doctor and the patient regarding the agreement on the medical action that the doctor will carry out on the patient. The research method used is a normative juridical qualitative research method with a descriptive approach. The data collection techniques were literature studies, interviews, and fieldwork practices. The research results show that, in general, informed consent at the Andi Makkasau Parepare Regional General Hospital has been implemented optimally and is by the SOP (Standard Operational Procedure) at the hospital, and there is also General Consent, namely the general consent of new patients. Having informed consent that has been carried out optimally and in accordance with existing hospital regulations can protect the health of workers and medical personnel in carrying out medical procedures on patients. The suggestions given by researchers are that health workers and medical personnel must provide information regarding the existence of informed consent procedures and that they must fully understand the applicable laws and regulations, especially regarding health and existing regulations in hospitals.

**Keywords:** Informed consent, health staff

### Introduction

Health is the most essential part of human life. The person's health condition influences a person's productivity and activities. With health, people can think well and can carry out activities optimally. When someone's health is disturbed, they will do various things to get healthy again. One way is to seek treatment and receive medical treatment at available health services facilities such as community health centers, clinics, and hospitals. (Wardhani 2014) [7].

As mandated in the 1945 Constitution of the Republic of Indonesia, "Health is a human right and one of the elements of prosperity that the ideals of the Indonesian nation must realize." Therefore, every activity and effort to raise the highest level of health for the people must be carried out by the principles of non-discrimination, protection, participation, and sustainability, which is very urgent for the formation of human resources, national competitiveness, increasing resilience, and national development. (Gustina, Fauziah, and Agustina 2022) [1].

According to Law Number 17 of 2023 concerning Omnibus Law Health, article 267 regulates the Rights and Obligations of Patients. In the therapeutic contract, the patient has certain rights and obligations. Provide complete and honest information about health problems to the doctor who is treating him.

1. Comply with the doctor's advice and instructions.
2. Please comply with the provisions that apply at health service locations, whether hospitals, health centers, or other health service locations.
3. It is providing service compensation for services received. Is obliged to fulfill the things that have been agreed upon or the agreements made.

Consent given by the patient or his family based on information and explanation regarding the action to be carried out on the patient is called Informed Consent. The

relationship between informed consent and the medical action to be carried out by the doctor is that informed consent is the main component that supports the medical action. Because voluntary consent given by the patient by signing an informed consent is one of the subjective conditions for the occurrence or validity of an agreement if the patient fulfills at least three elements, namely sufficient disclosure of information provided by the doctor, the patient's competence in giving consent and voluntary (without coercion/pressure) in giving consent, for this reason, filling out the informed consent must be complete and correct. In this case, the function of the announced consent agreement in question is an agreement between the doctor and the patient to carry out medical procedures.

In the explanation of Law Number 17 of 2023 concerning Omnibus Law on Health, it is stated that, in principle, the person concerned has the right to approve or reject medical treatment. However, if the patient concerned is under the means, approval or refusal for medical treatment can be given by the closest family, including husband/wife/biological mother, biological children, or siblings. At the Andi Makkasau Parepare Regional General Hospital, Informed Consent is needed by health workers and medical staff to be used as a sign of approval for surgery and anesthesia, which have the potential to cause medical disputes or as legal protection for medical staff who carry out the procedure.

A health worker is anyone who dedicates themselves to the health sector and has knowledge and skills through education in the health sector for a specific type, requiring authority to carry out health efforts. As a health service facility, through doctors and other health workers, each hospital has a goal: improving public health. (Rezki Pebrina, Najwan, and Alissa 2022) [5].

Based on research conducted by the author at the Andi Makkasau Parepare Regional General Hospital. In reality, it

shows that the implementation of informed consent regarding the legal protection of health workers has almost no problems and has been implemented optimally. However, the delivery of the results of the patient's condition by the health workers still needs to be clarified, resulting in miscommunication between the patient's family and the health workers at Andi Regional Hospital. Makassar Parepare. Therefore, health workers must always continuously provide information about the patient's condition to the family.

### Research methods

The type of research in this writing is a Normative Juridical research method, which is studied using a statutory approach (the statute approach), meaning that a problem will be seen from the legal aspect by examining statutory regulations, in addition to the method using library research (library *research*), namely by analyzing library materials related to the above problems. (Juliardi, B., et.al, 2023) <sup>[2]</sup> A written normative juridical research is also examined from various aspects such as theoretical, philosophical, comparative, structure or composition, consistency, general explanation and explanation of each article, formality, and binding force. A law and the language used are legal. (wahwahi; and Anissa; 2020)

### Discussion

#### a. Informed Consent Concept

Informed consent comes from the word "informed," which means having received an explanation, and the word "consent," which means having given consent. <sup>10</sup> Thus, what is meant by informed consent is consent arising from information considered explicit by the patient regarding a medical action that will be carried out to him in connection with the need for diagnosis and health therapy.

In the Regulation of the Minister of Health of the Republic of Indonesia number 290/Menkes/Per/III/2008 concerning Approval of Medical Procedures, it is determined that informed consent is translated into Approval of Medical Procedures, which is regulated in Chapter I Article 1 which determines that consent is given by the patient or their closest family after receiving a complete explanation of the medical or dental procedures that will be carried out on the patient. (Nadira and Khairunnisa 2023) <sup>[3]</sup>.

So, informed consent can be interpreted as the approval given by a patient to a doctor for a medical action to be carried out after receiving clear information about the action. Consent to medical treatment is a unilateral statement by the patient or their legal representative that contains approval for a plan of medical or dental action proposed by a doctor or dentist after receiving sufficient information to be able to make an approval or refusal. (Wahyudi; and Anissa; 2020) <sup>[6]</sup>.

An agreement is considered valid if:

- a. The patient has been explained/information
- b. The patient or their legal representative is competent (competent) to provide a decision/consent
- c. Consent must be given voluntarily.

According to Veronika Komalawati, 2002, informed consent is an agreement or approval of the patient regarding the doctor's medical efforts after the patient receives information from the doctor regarding the efforts.

Medical treatment that can be done to help him, accompanied by information about all the risks that may occur.

In connection with the explanation above, informed consent is not just about getting an informed consent form signed by the patient or his family. Still, approval for medical treatment is an intensive communication process to achieve a common perception about whether or not an action, treatment, or medical care can be carried out. So informed consent is a process, not just getting a signature on an action consent sheet.

#### 1. Forms of Informed Consent

Informed consent must be taken every time a medical procedure is carried out, regardless of the action's size. According to the Ministry of Health (2002), Informed Consent is divided into 2 (two) forms:

##### a. Implied or deemed to have been given (Implied Consent)

#### Under Normal Circumstances

Implied consent is the consent given by the patient implicitly, without an explicit statement. The doctor captures the signal for this statement from the patient's attitude and actions.

#### In an Emergency (Emergency)

Implied consent in another form is if the patient is in an emergency and the doctor requires immediate action. If the patient cannot give consent and his family is not there, the doctor can take the best medical action according to the doctor. Article 4, paragraph (1) of Minister of Health Regulation Number 29 of 2008 concerning Approval of Medical Procedures states, "In emergencies, to save the patient's life and prevent disability, approval of medical procedures is not required."

#### Expressed (Expressed Consent)

Expressed consent is an agreement expressed verbally or in writing if what will be carried out is more than the usual examination and action procedures. In such circumstances, it is best to tell the patient first what action will be taken to avoid misunderstanding.

#### 2. Purpose of Informed Consent

The purpose of Informed Consent, according to J. Guwandi, is

- a. Protecting patients against unnecessary doctor's actions
- b. Providing legal protection to doctors against unexpected and negative consequences (wahyudi and Anissa, 2020) <sup>[6]</sup>.

#### 3. Informed Consent Function

- a. Respect for the dignity of patients as human beings
- b. Promotion of the right to self-determination
- c. To encourage doctors to exercise caution in treating patients
- d. Avoid fraud and misleading by doctors
- e. Enables more rational decisions to be made
- f. Encourage public involvement in medical and health issues
- g. As a process of public education in the fields of medicine and health

#### 4. Benefits of Informed Consent

- a. Helps smooth medical procedures.

- b. Reduces side effects and complications that may occur.
- c. Accelerates the recovery and healing process of disease.
- d. Improving service quality.
- e. Protects midwives from possible lawsuits.

### 5. Informed Consent as an Agreement

An agreement, word, or medical approval will arise after the patient is given an explanation regarding the disease he is suffering from and the consequences that can be predicted according to medical science in terms of treatment. Then, the patient accepts his condition to be treated; for this treatment, the patient gives permission or consent, called informed consent. The patient has the right to refuse and permit treatment. Informed consent is a tool to enable self-determination to function in physicians' practice.

### Legal Protection Concept

According to Setiono, legal protection is an action or effort to protect society from arbitrary actions by authorities, not by the rule of law, to create order and tranquility to enable humans to enjoy their dignity.

#### 1. Objectives of Health Law

Health law aims to create an orderly society, creating order and balance. By achieving order in society, human interests are hoped to be fulfilled and protected (Mertokusumo, 1986).

#### 2. Characteristics of Health Law

- a. It is a set of provisions that are directly related to health services
- b. Health law stipulates the rules of civil law, criminal law, and state administrative law

### Health Worker Concept

A health worker is any person who dedicates themselves to the health sector and has a professional attitude, knowledge, and skills through higher education, which, for certain types, requires the authority to carry out health efforts. (Law No. 17 of 2023)

#### 1. Various Roles of Health Workers

- a. As a communicator
- b. As a motivator
- c. As a facilitator
- d. As a counselor

#### 2. Types of Health Resources

##### a. Medical personnel consisting of

1. Dokter
2. Dentist

##### b. Health Workers consisting of

1. Clinical Psychologist
2. Nursing Personnel
3. Midwifery center
4. Pharmacy center
5. Center for Public Health
6. Environmental Health Workers
7. Tenga Nutrition
8. Physical Therapy Personnel
9. Medical Technician
10. Biomedical Engineering Staff
11. Traditional Health Workers
12. Other Health Workers appointed by the minister

### Emergency Condition Concept

An emergency is a situation in which the sufferer requires an immediate medical examination; if not carried out, it will have fatal consequences for the sufferer (Ministry of Health of the Republic of Indonesia, 2009).

Conditions that must be treated immediately in the ER

1. Heart Attack and Cardiac Arrest
2. Physical injury resulting from an accident
3. Difficulty breathing
4. Strokes
5. Poisoning

Every hospital must have informed consent, just as Andi Makkasau Regional Hospital has general consent, an available consent form, and an integral part of the medical record. Broad consent is an approval form that the patient or their closest family must fill out after receiving a complete explanation regarding the health services that will be provided to the patient related to the hospital's examination, care, and treatment process.

Mutual consent is written evidence of agreement or agreement regarding matters relating to the express provisions of patient care and medical services.

1. Several general consent procedures at the Andi Makkasau Parepare Regional General Hospital must patients and their families, namely must carry out:
  - a. Consent to care, treatment, and release of information
  - b. Patient's belongings (if the patient's belongings are lost, the hospital is not responsible)
  - c. Desire for privacy
  - d. Administration
  - e. Hospitalization information
  - f. Patient rights and obligations
2. The problems in conveying general consent by health workers to the patient's family need to be more accurate in their delivery. It is often thought that the patient's family needs to be given adequate information by health workers.
3. The resolution effort in conveying general consent is that in this problem, the hospital must better maintain general consent and be more apparent in providing information about the patient's condition. The hospital will provide information repeatedly to the patient and the patient's family from the moment the patient enters the house. Illness until the agreement between the patient's family and the hospital, in the emergency room or treatment room, until the patient goes home, and until the patient must complete his obligations in the form of general consent. General consent will be maintained as a guideline or general agreement between the patient and the hospital. If there is no general consent, there will be a debate between the patient and the hospital, leading to a discussion of missed communication or what is often called malpractice.

Based on the results of fieldwork practice at the Andi Makkasau Parepare Regional General Hospital, to fill out the informed consent, the doctor in charge and health workers will first explain the procedures involved in the informed consent. There are several reported consent procedures at the Andi Makkasau Parepare Regional General Hospital, including:

Every time an invasive operation or other invasive procedure is carried out, a DPJP (Patient Responsible Doctor) must be carried out as the person responsible for the patient who will carry out the action and provide informed consent in advance regarding:

- a. Diagnosis
- b. Patient condition
- c. Procedures for the objectives of the action to be implemented
- d. Benefits and risks of action
- e. The name of the person performing the action
- f. Possible alternative actions
- g. Possible unexpected results
- h. Possible outcomes if no action is taken

The role of informed consent in protecting health workers is vital because having informed consent will protect health workers from patient complaints. Every action will have risks and unexpected events because we don't know that every time it is carried out; the important thing is that we have been given information about the benefits and risks of the action, as long as the patient and family have understood the informed consent which will protect health workers and proof that it has been given. Information.

Problems That Occur in Emergency Situations at the Andi Makkasau Parepare Regional General Hospital. In this problem, the author looks at an accident case in which the patient had an accident that resulted in broken bones and a hard impact on the head, making the patient unconscious. In an emergency like this, the patient needs help, and family or close relatives do not accompany the patient. The hospital immediately took action without the consent of the patient and the patient's family because the condition made it impossible to ask for permission. If serious action was not taken, it would threaten the patient's life, and the patient would not be helped, so the medical policy was implemented to take action because of the patient's condition. Which is quite severe and requires medical action, and it is a doctor's responsibility to help people in any situation.

Each procedure has stages, and the patient is first taken to the triage room for examination and then taken to the surgical resuscitation room for follow-up. The triage room is a particular room for the process of sorting and selecting patients based on disease burden and prioritizing treatment after arriving at the hospital to identify them into one of the following categories:

1. With emergency signs (Emergency Signs)
2. With priority signs (Priority Signs)
3. No signs of emergency or priority

The medical team can explain the patient's condition after the treatment and action process is complete and the patient is conscious. The hospital also makes an official report and a statement from an emergency patient who was an accident victim. After that, the hospital also consents to approve the action on the patient. If the patient agrees to the action being carried out by the medical officer, the patient must also sign the informed consent. In contrast, the conscious, family, and witnesses must sign the informed consent.

When an emergency action occurs, the hospital can defend itself. The basis for the hospital to protect itself is with medical records, the actions taken, and the diagnosis, and the nursing committee or medical committee officers will

discuss and explain whether the actions taken were correct. According to the rules or not, if viewed from medical law, which is linked to the doctrine of informed consent, then what is an emergency can be done without the permission of the patient or the patient's family because an emergency is a situation where:

1. There is no further opportunity to ask for informed consent, either from the patient or the closest family member (next of kin)
2. There's no more time to procrastinate
3. An action must be taken immediately
4. To save the patient's life or limb

The law can enter in cases like this. Still, the medical staff has been sworn to do everything according to their professional oath and by existing regulations in hospitals according to the law, namely:

1. Law Number 17 of 2023 concerning Health
2. Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning Approval of Medical Procedures
3. Civil Code Article 1354

The core of solving problems lies in the patient's medical record data because medical record data is essential for patients and health workers, so having medical record data can help defend and protect health workers and the profession.

### Conclusion

Studies at the Andi Makkasau Parepare Regional General Hospital show that the informed consent procedure has been implemented optimally by applicable Standard Operating Procedures. This informed consent provides complete information to patients about the risks, benefits, alternatives, and consequences of refusal before carrying out medical procedures. The importance of informed consent in protecting health workers from accusations of malpractice or other violations is legally recognized by internal hospital regulations and applicable health laws. Through informed consent and General Consent, health workers can carry out their duties by complying with procedures established legally and sustainably.

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