
Implementation of Informed Consent by HealthCare Professionals to Ensure Patient Safety in Hospitals

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ABSTRAK

Penyelenggaraan pelayanan kesehatan dapat dipandang dari tiga subyek yaitu Pemakai, Penyelenggara, serta Penyandang dana pelayanan kesehatan. Bagi pemakai jasa pelayanan kesehatan, kualitas pelayanan lebih terkait pada dimensi ketanggapan petugas memenuhi kebutuhan pasien, kelancaran komunikasi petugas dengan pasien. Pelaksanaan Informed Consent haruslah mencerminkan asas umum pemerintahan yang baik karena hal tersebut berkaitan terhadap administrasi pemerintah. hal tersebut perlulah diperhatikan karena untuk menjaga marwah profesi kedokteran dan/ atau tenaga kesehatan, marwah rumah sakit penyedia layanan serta marwah hak dari pasien itu sendiri. Keadaan gawat darurat Informed consent tetap merupakan hal yang paling penting walaupun prioritasnya diakui paling bawah. Prioritas yang paling utama adalah tindakan menyelamatkan nyawa. Budaya keselamatan yang kuat tidak hanya menjadi inti untuk mengurangi bahaya terhadap pasien, tetapi juga penting untuk menyediakan lingkungan kerja yang aman bagi petugas kesehatan.

Kata Kunci: Informed Consent, Tenaga Kesehatan, Keselamatan Pasien, Rumah Sakit

ABSTRACT

The implementation of health services can be seen from three subjects, namely Users, Organizers, and Presentation of health funds. For health service users, service quality is more related to the dimensions of staff responsiveness in meeting patient needs, smooth communication between staff and patients. The implementation of Informed Consent must reflect good general governance because it is related to government administration. This needs to be taken into account because it is to maintain the dignity of the medical profession and/or health workers, the dignity of the hospital providing services and the dignity of the rights of the patients themselves. emergency department Informed consent The

situation remains the most important thing even though the priority is acknowledged to be the lowest. The most important priority is action to save lives. A strong safety culture is not only central to reducing harm to patients, but is also essential to providing a safe work environment for healthcare workers.

Keywords: Informed Consent, Health Workers, Patient Safety, Hospitals

INTRODUCTION

The fulfilment of human protection efforts has long been discussed, both in Indonesia and internationally. Humans are God's perfect creation because they are equipped by their creator with reason, feelings and will. Intellect is a tool of thinking, as a source of science and technology in modern times like this. With reason, humans judge what is right and what is wrong, as a source of truth value.

Health services are one of the rights guaranteed in the 1945 Constitution which must be realised by increasing the degree of health services as high as possible. Hospitals and health workers are one form of effort to improve the degree of health services to citizens. Hospitals according to Government Regulation No. 47 of 2021 are health service institutions that provide comprehensive individual health services that provide inpatient, outpatient and emergency services.

Effective and efficient health services so that patients avoid physical and material losses; and patients have the right to obtain information which includes the diagnosis and procedure for medical action, the purpose of medical action, alternative actions, risks and complications that may occur, and prognosis of the actions taken and the estimated cost of treatment; as well as giving consent or refusing action to be taken by medical personnel for their illness. So that the patient or the patient's family can file a claim for compensation against the hospital or hospital doctor, who acts in error or negligence in health services.

Good relationships with all parties who play a role in health services can make it easier to achieve common goals, namely healing and patient satisfaction. The interaction of nurses with patients is needed in the nursing service process in order to achieve closeness and kinship. The relationship between doctors and patients in health law is regulated in accordance with Permenkes No. 290 of 2008 concerning Approval of Medical Actions (PTK) established in the

bond of therapeutic transactions, in the sense that each party, namely providing services and receiving services, has rights and obligations that must be respected by the other party. It is in such ties that Medical Action or what is now called Medical Action Approval (PTK) arises. The doctor (team of doctors) has the obligation to carry out the best diagnosis, treatment, and medical action according to their (their) thoughts and considerations, and on the other hand, the patient or the patient's family has the right to determine the approval or rejection of the treatment or medical action they have undergone.

The implementation of Informed Consent must reflect the general principles of good governance because it relates to government administration. This needs to be considered because it is to maintain the dignity of the medical profession and / or health workers, the dignity of the service provider hospital and the dignity of the rights of the patient himself. The law of informed consent in each country has its own regulations such as for example in the United States, England, and France adhering to the Anglo Saxon legal system, namely using a court formed from custom (Common Law) which develops and becomes widely used through jurisprudence or judge decisions (Rule of Law).

The implementation of Informed Consent law also cannot be separated from the principle of Patient Safety. Patient safety is a top priority in the provision of health and nursing services in hospitals (K.A., 2003). Injury, disability, and even death are future threats to patients, especially paediatric patients, because they are not yet able to realise and express the dangers of actions that are not or incorrectly carried out by health services. Patient safety discipline is a coordinated effort to prevent harm caused by the health care process to patients. This discipline aims to prevent and reduce risks, errors, and losses that occur to patients during the provision of health services. In the Regulation of the Minister of Health of the Republic of Indonesia Number 11 of 2017 concerning Patient Safety, it is stated that patient safety is a system that makes patient care safer, including risk assessment, identification and management of patient risk, incident reporting and analysis, the ability to learn from incidents and their follow-up, and implementation of solutions to minimize the incidence of risk and prevent injury caused by errors due to carrying out an action or not taking action that should be taken.

There has been research on Inform Consent that has been carried out, among others, first, Achmad Busro in 2018 with the title "Legal Aspects of Medical Action Approval (Inform Consent) in Health Services" the results of his article are The application of informed consent, between doctors and patients should be mutually aware that each party has rights and

obligations that must be upheld. Second, Etyan Ariyani Susilowati, Wardah Yuspin, Absori in 2021 with the title Compliance of Medical Personnel Against the Implementation of Informed Consent: A Lawsuit Prevention Study for Medical Disputes Compliance of Medical Personnel Against the Implementation of Informed Consent: A Lawsuit Prevention Study for Medical Disputes with the results of his research that the compliance of medical personnel in the implementation of informed consent has not been carried out in accordance with the existing SOP, so that medical personnel are still negligent in carrying out their duties in the administrative field, namely completing medical record documents, especially informed consent sheets. That with the existence of these 2 (two) studies, the author is interested in making research on the application of informed consent to realise patient safety in public and private hospitals.

PROBLEM FORMULATION

From the background of the problem, the following problems can be formulated:

What is the role of Informed Consent in Patient Safety efforts at the Hospital?

The purpose of this study is an effort to determine how far health workers understand Informed Consent as a Patient Safety Effort.

RESEARCH METHOD

The research method used is the Doctrinal research method, namely by collecting related regulations, books, previous studies and related journals. Secondary data includes legal materials in the form of primary legal materials and secondary legal materials.

DISCUSSION

The relationship between patients and health care providers has a legal basis, this can be seen in Article 1367 of the Civil Code "A person is not only responsible for losses caused by his own actions, but also for losses caused by the actions of those who are his dependents or caused by people who are under his supervision". Furthermore, when the losses suffered by patients due to actions taken by nurses are fatal, this is where legal problems arise, especially in the civil law section. This can be seen in Article 1365 of the Civil Code regarding unlawful acts (PMH) which reads "Every act that violates the law and brings harm to another person,

obliges the person who causes the loss because of his fault to replace it".

Informed Consent comes from the Latin word *Consentio* which means consent, permission, approve, give permission / authority to someone who does something. Informed means information that has been given (English). "*Consensio / Consentio*" (Latin) becomes "consent" (English) which means approval, permission, approval, giving permission (approval of authority) to someone to do something (Guwandi, 2003). Consent literally means consent, or more specifically "permission". So Informed consent is an agreement or permission by the patient or family who has the right to a doctor to carry out medical actions on the patient, such as physical examination and other examinations to establish a diagnosis, give medicine, make injections, assist in childbirth, perform anesthesia, perform surgery, perform follow-up in case of difficulty, etc. (Rosyida, 2021). Furthermore, the word Informed is related to information or explanation. It can be concluded that Informed Consent is an agreement or permission by the patient (or entitled family) to the doctor to carry out medical action on him, after the doctor has given him complete information or explanation about the action.

There are 2 kinds of informed consent, namely : (Amri, 1997)

1. Implied Consent (dianggap diberikan)

Generally, implied consent is given under normal circumstances, meaning that the doctor can capture the approval of the medical action from the gesture given / done by the patient. Similarly, in emergency cases where the doctor requires immediate action while the patient is unable to give consent and his family is not present, the doctor can take the best medical action according to the doctor.

2. Expressed Consent (dinyatakan)

Can be expressed orally or in writing. In medical actions that are invasive and contain risks, doctors should obtain written consent, or what is commonly known in hospitals as an operating licence.

The functions of Informed Consent are as follows:

1. Promotion of the right to individual autonomy;
2. Protection of patients and subjects
3. Prevention of fraud or coercion;
4. Stimulate the medical profession to conduct self-introspection;
5. Promotion of rational decisions;

6. Involvement of society (in promoting the principle of autonomy as a social value and providing oversight in biomedical investigations).

Informed Consent itself according to the type of action / purpose is divided into three, namely: (Samil, 2001)

1. Those for research purposes (patients are asked to become research subjects);
2. Those aimed at finding a diagnosis;
3. Those aimed at therapy.

In an emergency Informed consent is still the most important thing although its priority is recognised as the lowest. The highest priority is life-saving measures. Although still important, Informed consent should not be a barrier or obstacle to the implementation of emergency care because in a critical situation where the doctor is racing with death, he does not have enough time to explain until the patient fully realises his condition and needs and gives his decision. The doctor also does not have much time to wait for the patient's family to arrive. Even if the patient's family is present and then does not agree to the doctor's actions, then based on the doctrine of necessity, the doctor must still carry out medical action. This is outlined in the regulation of the Minister of Health of the Republic of Indonesia Number 290 / Menkes / Per / III / 2018 concerning approval of medical actions, that in an emergency situation no Informed Consent is required.

Authority is the main requirement in performing a medical action. Article 16 Permenkes RI No. 26 of 2019 concerning Regulations for the implementation of Law No. 38 of 2014 concerning nursing. Benchmarks or guidelines regarding the fulfilment of health which is a human right and is one of the elements of welfare that must be realised in accordance with the ideals of the Indonesian nation as referred to in Pancasila and the 1945 Constitution. The implementation of quality services in the health sector certainly cannot be separated from the quality of human resources who become health service providers as referred to in Article 25 of Law No. 36 of 2006 concerning Health, that health service providers must also have and meet minimum qualifications in the provision of health services to patients.

Article 52 of Law No. 36 of 2009 Concerning Health, which states that health services consist of individual health services and public health services. Health services according to this Law include activities with promotive, preventive, curative, and rehabilitative approaches. Public health services are generally organised together in an organisation and must even include

the potential of the community and prevent disease and the main target is the community as a whole. In addition to health services, there are also medical services where this service includes all efforts and activities in the form of prevention (Preventive), treatment (Curative), improvement (Promotive), and recovery (Rehabilitative) of health based on an individual relationship between experts in the field of medicine and individuals who need it.

In essence, informed consent is a communication process between a doctor and a patient regarding an agreement on medical action that the doctor will take against the patient. The signing of a written informed consent form is only a confirmation of what has been agreed upon previously. The purpose of a complete explanation is for the patient to determine his own decision according to his own choice (informed decision). Therefore, the patient also has the right to refuse the recommended medical treatment. The patient also has the right to seek the opinion of another doctor (second opinion), and the treating doctor. . Juridically, a nurse is actually not authorised to carry out the "informed consent" process. This is the duty of the doctor, and if there is a delegation of authority, then the doctor must be sure that the nurse who is given the task really understands the problem and is able to provide an explanation that is understood by the patient. Therefore, from a legal perspective, the responsibility for informed consent remains with the doctor.

The legal consequences if someone violates the provisions of the law then the person will be held legally responsible, which means the legal consequences of the act of deviation committed by the nurse. That the legal consequences in health services can be divided into three:

1. Administrative Legal Responsibility Administrative legal responsibility is internal to the professional organisation of nurses.

The Indonesian National Nurses Association, especially on the issue of upholding professional ethics. The institution that oversees nursing ethical issues in the articles of association of the Indonesian National Nurses Association (PPNI) described in CHAPTER IX is the Nursing Ethics Honour Council (MKEK). Article 188 of Law No. 36 of 2009 concerning Health states that if health workers and health facilities carry out services not in accordance with the law, the relevant ministry can take administrative action.

2. Civil Law Liability

In therapeutic transactions, nurses and patients have the same liability position. A lawsuit to hold a nurse liable under the Health Services Act, will be fulfilled if the following elements are present:

- a. Therapeutic contact between the health worker and the client/patient;
- b. Inappropriate health services;
- c. The patient suffers harm as a result of the health worker's actions.

A breach of law that constitutes facts can be sued, even though there is no agreement between the two parties, and there must be 4 conditions met:

- a. The existence of a loss by the client/patient;
- b. There was a mistake;
- c. The fault and the loss are causally related;
- d. The act is unlawful.

3. Criminal Law Liability

Nurses who perform work that is not in accordance with the standards of the nursing profession and make deviations in their practice, means that they have committed errors / negligence. Nurses who commit errors or negligence will be sued for civil compensation and if they have fulfilled the criminal requirements, they can be prosecuted under criminal law.

Patient safety, according to WHO is the reduction of unnecessary risk of harm associated with health services to the minimum acceptable level. Acceptable minimum refers to the collective notion of the current knowledge provided, the resources available, and the context in which the care provided is considered against the risk of non-treatment or other treatment.

The opposite is an adverse event. The Harvard Medical Practice Study defines KTDs as injuries caused by medical management (not the underlying disease) that prolong hospitalisation, cause disability at discharge or both (Lumenta, 2021). Meanwhile, the Institute for Healthcare Improvement defines as unintentional physical injury that results from or is contributed to by medical services (including the absence of medical services previously indicated to be performed), that requires additional monitoring, treatment, or hospitalization, or that results in death (Network, 2019).

The rules on patient safety are more clearly found in Law No. 44 of 2009 concerning Hospitals. Article 2 states "Hospitals are organized based on Pancasila and are based on the values of humanity, ethics and professionalism, benefits, justice, equal rights and anti-discrimination, equity, protection, and patient safety, and have a social function". In addition to the law, the Minister of Health also issued a Ministerial Regulation on Patient safety in 2011, namely Permenkes RI Regulation Number 1691 / MENKES / PER / VIII / 2011 concerning hospital patient safety. In this regulation, several definitions related to patient safety are mentioned, among others: 1) Hospital patient safety, 2) Patient safety incidents, 3) Adverse events, 4) Near-injury events, 5) Non-injury events, 6) Potential injury conditions, 7) Sentinel events, 8) Patient safety incident reporting.

It is difficult for hospitals to avoid adverse events (AEs). However, the occurrence of an AE does not necessarily indicate negligence or error. There are many instances where an AE is not actually a mistake. For example, in cases where certain drugs are administered that result in "patient injury" in the sense of a consequence of the treatment such as the occurrence of complications. KTDs are part of patient safety incidents (PSE). IKP is an event or situation that can cause or has the potential to cause harm (illness, injury, disability, death, etc.) that should not occur. Events that do not reach the patient (near misses) can occur due to an error in performing an action (commission) or not taking an action that should have been taken (omission) that can injure the patient, but serious injury does not occur due to luck, prevention or warning.

In terms of health law, the patient's relationship with the doctor as a party has rights and obligations that are respected. In this bond, the problem that is often encountered is the issue of consent to medical treatment. Generally, ordinary people consider the form that needs to be signed before undergoing surgery is just a formality, while on the other hand most doctors are lazy to provide information about what kind of medical action will be carried out and its risks. The fact that the presence of informed consent is often not seen as something that has a strategic position even though this informed consent has an important bargaining position both from the perspective of health service providers and from the perspective of health service users. The dilemmatic reality is how law enforcement relates to this informed consent given the absence of specific arrangements regarding this matter.

From a legal perspective, especially criminal law, the main issue between health law and criminal law is the existence of fault and negligence. To determine whether or not the act

embraces the element of error, it must be proven through a medical approach. This is because the liability of doctors in criminal law is closely related to the efforts made by a doctor (Nasution, 2005).

In this regard, the principle of legality 'no punishment without guilt' applies. It would be contrary to justice for someone to be sentenced when they are completely innocent. A person cannot be sentenced if he does not commit a criminal act, but even if he commits a criminal act, he cannot always be convicted.

Law Number 44 of 2009 concerning Hospitals, explains that a Hospital is a health care institution that organizes comprehensive individual health services that provide inpatient, outpatient and emergency services. The Legal Responsibility is that the Hospital is legally responsible for all losses caused by negligence committed by health workers in the hospital. Based on these rules, hospitals should also be responsible for negligence committed by health workers. Which means Health Workers include doctors, nurses and those related to the medical handling of patients to realize patient safety.

CONCLUSION

The development of a culture of safety is key to any sustained effort towards improving patient safety. Safety culture must permeate the attitudes, beliefs, values, skills, and practices of healthcare workers, managers, and leaders of healthcare organizations. A strong safety culture is not only core to reducing harm to patients, but also essential to providing a safe working environment for healthcare workers. This includes creating a psychologically safe work environment where healthcare workers can talk about patient safety and other issues without fear of negative consequences. Informed consent plays a very important role in avoiding medical disputes if something goes wrong in the future. Informed consent is not just an approval of the patient's will but it is also a form of commitment to protect the patient's rights from all medical actions that may be fatal to the patient to the stage that can eliminate the patient's life. The position of informed consent as an important matter for the protection of patients' rights in carrying out medical actions is considered very urgent because it concerns the body of every person. It must also be understood that the meaning of informed consent in the perspective of protecting patient rights is to prevent malpractice in medical actions performed by doctors. This means that doctors should act in accordance with the correct procedures, in

accordance with the provisions of operational standards determined by the medical organization.

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