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Legal Aspects in Implementing an Informed Consent System in Patient Health Practices

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ABSTRACT

This research explores the legal aspects related to the implementation of the Informed Consent System in patient health practice. This system is a crucial ethical foundation in the relationship between medical personnel and patients, ensuring thorough understanding before patients consent to medical procedures or research. The research focus includes analysis of legal requirements, authority rights, and legal consequences related to Informed Consent. Additionally, this research investigates recent developments in health law, such as data protection and patient privacy regulations, and explores legal cases that can shape the framework for practice. By detailing the legal aspects involved, this research aims to provide a holistic view of the implementation of the Informed Consent System, strengthen regulatory compliance, and encourage a better understanding of rights and responsibilities in healthcare practice. It is hoped that the implications of this research will provide solid guidance for health practitioners and researchers in ensuring legal and ethical compliance in administering Informed Consent.

Keywords:
Health Law, Medical, Informed Consent

1. Introduction

Medical record systems and informed consent practices summarize two important aspects in the delivery of health services. The medical record, as the center of patient health information, is the basis for clinical decision making, care coordination, and long-term monitoring. Meanwhile, informed consent creates an ethical and legal basis for interactions between patients and healthcare providers, ensuring that patients have full understanding and provide conscious consent to the medical procedures to be performed.

In the modern era, where developments in information technology have dominated the health sector, the importance of having an efficient and structured medical record system has become increasingly profound. Medical records are not just a collection of data, but also a detailed representation of a patient's health journey. Successful management of medical records not only influences daily health care but also plays a role in health policy, medical research, and evaluation of treatment effectiveness.

In this context, legal aspects emerge as a critical basis for ensuring the integrity, confidentiality and appropriate access to medical records. Legal interests not only include the protection of patient health data but also concern the professional responsibilities of health service providers. As the complexity

of the laws governing the management of medical records increases, a deep understanding of the legal significance becomes imperative for health practitioners and related parties.

Implementing a legally oriented medical record system is not only an ethical obligation, but also determines the overall quality of health services. Therefore, in-depth research regarding the legal aspects of medical record management is an urgent need to ensure that health practices are within the limits of legal norms and provide adequate protection for all parties involved. Thus, this research will comprehensively discuss the legal aspects of administering a medical record system, with a special focus on the general context of medical records and the practice of informed consent in health practice.

2. Literature review

1. Definition of Informed Consent

*Informed Consent*is a term commonly used in medical practice, referring to the consent given by a patient to a doctor to carry out a medical procedure after receiving adequate explanation. Although this term is often used, the essential understanding of Informed Consent is not always well understood by doctors, so its application is sometimes carried out inadequately.

Some doctors still sometimes delegate requests for approval for medical treatment to nurses, midwives or anesthetists, without providing adequate explanations to the patient or his family. In such situations, patients may simply be asked to sign a consent form without adequate understanding of the procedure to be performed, the procedure for carrying it out, and the potential risks that may arise. Even though it may be considered trivial, consent to medical procedures without adequate explanation from a doctor can be considered a procedural defect from a legal perspective. This means that the agreement does not have strong legal force and has the potential to give rise to medical disputes.

The definition of informed consent itself consists of two words, namely "informed" which means an explanation or information has been given, and "consent" which means agreement to do something. So, Informed Consent can be interpreted as approval given by the patient after receiving an explanation from the doctor concerned. By law, every medical action must obtain consent from the patient, and this consent must be given after the patient has received adequate explanation. This explanation includes at a minimum the diagnosis, procedure for the medical action, the purpose of the action, alternative actions, risks and complications that may occur, as well as the prognosis for the action to be carried out.

According to Minister of Health Regulation 290/2008, informed consent is approval given by the patient or family after receiving a complete explanation regarding the medical action that will be carried out on the patient. The obligation to obtain approval for medical procedures, both legally and morally, is an obligation for doctors. This is regulated in legislation, such as Article 45 paragraph (1) of Law Number 29 of 2004 concerning Medical Practice, and the Indonesian Medical Code of Ethics (KODEKI). Through this agreement, doctors respect the patient's human rights, especially the right to self-determination and the right to health care.

2. Elements of Informed Consent

The elements included in informed consent, as confirmed by the code of medical and research ethics, emphasize that consent must arise from the patient's free will (voluntarium) and must be an answer to information that is appropriate to the actual situation. Informed consent must be true and in accordance with the understanding of the patient and medical staff, and must originate from the free

decision of a competent individual. The elements of informed consent in question include competence, delivery of information, understanding of information, and freedom and consent.

1) Competence (Competence to Consent):
   Competence, in the context of informed consent, is more accurately described as a presupposition rather than an element. It refers to the initial conditions that are the basis for acting voluntarily, due to understanding the importance of information. A patient is considered competent if he is able to make decisions about treatment by considering all relevant factors. Competency includes understanding procedures, considering risks and benefits, and the ability to make decisions in accordance with knowledge, values, and personal goals.
2) Submission of Information (Disclosure of Information):
   Information delivery standards involve providing sufficient information so that a person can make an informed decision (informed choice). These standards can be standards of medical professional practice, average standards that a reasonable patient would want to know, and subjective standards that take into account the special needs of patients with certain diseases. The information presented must be in accordance with general medical practice and take into account the patient's ability to understand the information.
3) Understanding Information (Comprehension of Information):
   Information comprehension involves the patient's ability to understand the information provided. This condition can be limited if the information provided is not clear, or if there are communication difficulties between the patient and medical personnel. Therefore, good communication between patients and doctors is key in ensuring adequate understanding of information.
4) Freedom and Consent (Voluntary Consent):
   Freedom in the context of informed consent means that a person can make decisions without any external coercion or pressure. Although pure freedom from outside influence is difficult to achieve, information must be conveyed without threat or manipulation. The consent given must be completely voluntary and not forced by medical authorities. This includes the patient's right to refuse treatment if desired.
5) Refusal of Medical Treatment (Informed Refusal):
   Patients also have the right to refuse certain medical procedures as a form of autonomy. Refusal should be based on competence, adequate information, understanding, and patient freedom. However, this refusal must be considered in the context of the patient's best interests and not as a form of suicide.
6) The importance of understanding and acknowledging these elements in informed consent is key to ensuring that patients have control over decisions regarding their medical care.

3. Informed consent and juridical law

*Informed consent*and juridical law are closely related to medical practice, especially in relation to malpractice. Malpractice, which was defined by Valentin V as negligence on the part of a doctor or nurse in using the level of expertise and knowledge in treating and caring for patients, is often related to the principle of informed consent and standards of medical professional practice. In cases of suspected malpractice, the elements generally examined involve informed consent and the standards of medical professional practice followed by the doctor.

1) Informed Consent and Legal Dimensions:
   Informed consent is very important in medical procedures, especially those categorized as extraordinary means, because they involve legal dimensions. In criminal law, there are articles that regulate the abolition of punishment for criminals, and this law also applies to the medical profession. However, there are special factors in medicine, such as risk of treatment, medical accident or misadventure, non-negligent error of judgment, voluntary non-fit inura, and contributory negligence.
2) Special Factors in Medicine:
   - *Risks of Treatment*: The inherent risks in every medical procedure, such as allergic reactions or complications, are inherent elements that cannot always be avoided by doctors. In this situation, the doctor cannot be blamed as long as he has acted carefully and complied with the standards of medical professional practice and informed consent.
   - *Medical Accident or Misadventure:*Unforeseen medical accidents that are not the purpose of the action are also factors that must be considered in malpractice cases. This cannot always be avoided by doctors.
   - *Non-negligent Error of Judgment*: Errors in clinical judgment are a human thing, and in legal science it is known as the adage "errare humanum est." The principle of respectable minority rule also applies, where doctors are not considered to have committed negligence if they choose treatment methods that are recognized in the medical world.
   - *Volenti Non Fit Inura:*This doctrine states that someone who knows the risk and is willing to bear it cannot sue if the risk occurs. Examples in the field of sports such as boxing or martial arts, are also applied in several high-risk operations.
   - *Contributory Negligence:*Unreasonable behavior on the part of the patient, which results in loss or injury to him, can be a contributing factor in malpractice cases. In this case, the patient's negligence can be the basis for removing the penalty on the part of the doctor.
3) Assessment of Medical Professional Practice Standards:
   According to Chin Keow V, the standard of practice of the medical profession is measured by educated people in their usual profession, not by the smartest experts. Doctors are considered to meet the standards if they have carried out their knowledge according to educated people of the same level and are reasonable. In malpractice cases, this assessment is the basis for determining whether the doctor has committed an act of negligence or medical error.

The importance of informed consent and compliance with medical professional practice standards is key in avoiding malpractice. In the context of juridical law, a judicial process involving expert witnesses is necessary to ensure that the abolition of sentences or abolition of sentences is carried out in accordance with justice and in accordance with the norms applicable in the medical profession.

4. Principles of Health Lawand Basis for Implementing Informed Consent

Health law regulates legal provisions related to health maintenance and services and their implementation. The two main parties regulated in this health law are service recipients (patients) and service providers (health organizations and infrastructure). This legal aspect includes the relationship between the provider and recipient of health services.

1) Health Law as a Foundation for Medical Practice:

Health law establishes the legal framework that regulates the relationship between providers and recipients of health services. Principles such as legality, balance and good faith are recognized as the main foundation. Law no. 36 of 2009 concerning Health details these principles, including humanity, justice and respect for the rights and obligations of patients.

2) Basics of Implementing Informed Consent in Medical Practice:
   Informed consent is a legal obligation in medical practice. Article 45 paragraph (1) of Law Number 29 of 2004 and Article 56 paragraph (1) of Law Number 36 of 2009 emphasize that every medical action must be preceded by the patient's consent after receiving adequate information. RI Minister of Health Regulation Number 290/Menkes/Per/III/2008 also emphasizes the importance of patient consent for all medical procedures.
3) Legal Principles in Medical Practice and Health Services:
   Legal aspects in medical practice and health services include principles such as humanity, ethics, professionalism, benefits, justice, equal rights and patient protection. Law no. 29 of 2004 and Law no. 36 of 2009 confirms these principles, providing a basis for medical practice based on moral and ethical values.
4) Hospital Management Law and Its Role in Health Services:
   Hospitals, as providers of health services, have a legal basis for implementation that involves human values, ethics, benefits, justice and patient protection. These principles are stated in Law no. 44 of 2004 concerning Hospitals, creates the legal basis for hospital operations and services.

Aspects of health law, especially related to medical practice, informed consent, and the role of hospitals in providing health services. Moral, ethical and legal principles are recognized as the main foundation, making good understanding and implementation the main key in maintaining the quality of service, rights and safety of patients. Law no. 29 of 2004, Law no. 36 of 2009, and Law no. 44 of 2004 is the main basis for health practice in Indonesia.

5. Fulfillment of Patients' Rights and Legal Protection

Fulfillment of patients' rights and legal protection in informed consent is an important aspect of the Indonesian health system, which is based on human rights principles. The 1945 Constitution underlines the right of every person to live in physical and spiritual prosperity, including the right to a healthy environment and health services. The state is required to be responsible for providing adequate health service facilities.

Human rights related to informed consent involve the right to self-determination, which includes the right to privacy and one's own body. The right to information (The Right to Information) is implemented through informed consent. Articles 28 A and F in the 1945 Constitution stipulate the right to live and defend life, as well as the right to communicate, obtain information and develop oneself.

*Informed consent*should be based on the patient's knowledge and competence. Some hospitals and physicians have developed consent forms that include all information and are recorded in the patient's medical record. Patients should receive all information in an objective and free manner, allowing time for consideration before making a decision. In an emergency, doctors may prioritize life-saving measures without an informed consent process. However, life-saving procedures must remain in accordance with high standards of service and professionalism.

Other health rights include the right to live physically and spiritually healthy, enshrined in consumer protection laws. This right includes the right to detailed information about the illness suffered, the right to choose and obtain goods/services in accordance with the guarantee promised, the right to hear opinions and complaints, and the right to receive compensation if the goods/services do not comply with the agreement.

3. Method Study

According to Soerjono Soekanto, a method can be defined as a process or systematic way to understand a problem through structured steps. Research, as a tool that humans use to strengthen, develop and develop knowledge, involves involvement in the process.

1. Research Specifications

The method applied is analytical descriptive, which describes the applicable laws and regulations related to legal theories and the practice of implementing positive law related to the responsibilities of administering the Medical Record System and Informed Consent. Descriptive research aims to detail certain phenomena related to theory and address problems that arise.

2. Approach Method

The method applied in this research is the normative juridical method, a deductive approach that uses theory as a starting point for answering research questions. This research will analyze articles in statutory regulations related to responsibility for administering medical record systems and informed consent.

In the context of normative research, a conceptual approach is used to understand concepts such as responsibility for administering a medical record system and informed consent. These concepts are the basis for producing norms in the rule of law.

3. Research Stage

a) Literature Research: Involves literature study to collect secondary data, including primary and secondary legal materials related to the responsibility for administering the medical record system and informed consent.
b) Field Research: Conducted by interviews and direct observation of health workers in hospitals to support literature study.

4. Data Collection Techniques

a) Primary Legal Material: Involves binding legislation such as the 1945 Constitution, Law No.29 of 2004, Law No.36 of 2009.
b) Article 2 paragraph (1) RI Minister of Health Regulation Number 290/Menkes/Per/III/2008
c) Secondary Legal Materials: Involves law books and legal works from various sources.
d) Tertiary Law Materials: Includes dictionaries, encyclopedias, indexes, and cumulatives.

5. Data Collection Tools

a) Literature Study: Search for and collect secondary data such as statutory regulations, scientific journals, and scientific articles related to the implementation of medical record systems and informed consent.
b) Field Study: Using interview techniques with health workers to obtain primary data.

6. Data Analysis

a) The choice of analysis must be appropriate to the type, research objectives, and nature of the data collected.
b) Qualitative descriptive analysis is used to group, select, and connect data from field research with theories and laws that have been studied.

4. Results and Discussion

1. Findings Regarding Legal Aspects in Implementing a Medical Record System for Compliance with Regulations

Findings related to legal aspects in the implementation of medical record systems highlight several key aspects in the practice of health institutions. It can be seen that most health institutions have demonstrated a good level of compliance with legal regulations governing the management of medical records. By complying with established requirements, such as the Health Insurance Portability and Accountability Act (HIPAA), Law Number 36 of 2009 concerning Health, and related local regulations, health institutions demonstrate seriousness in maintaining the security and confidentiality of patient data.

However, the findings also highlight challenges in implementing legal aspects, especially those related to the privacy and security of patient data. Some institutions face obstacles in effectively implementing this aspect of the law. Therefore, further efforts are needed in the form of additional training and allocation of adequate resources to ensure that full understanding and compliance with legal regulations can be achieved.

When it comes to evaluating legal documents, such as patient consent letters and medical record management policies, there is variation in quality. Recommendations are provided to improve clarity and thoroughness in related legal documents. This is important to ensure that the patient consent process is well documented and complies with applicable legal standards.

Thus, these findings emphasize the importance of strengthening the implementation of legal aspects in the implementation of the medical record system through concrete steps, such as increasing understanding, training and improving the quality of legal documents.

2. Legal position in the relationship between doctor and patient

The legal position in the relationship between a doctor and a patient, where the doctor acts as a provider of treatment to patients who need it. This relationship is based on a sense of trust and is referred to as a therapeutic transaction.

*Informed consent*is an agreement to the medical action that will be carried out by the doctor to the patient, which can be in verbal or written form. It involves communication between the doctor and the patient regarding the medical procedure and its purpose. Signing an informed consent form is simply confirmation of a previous agreement. Patients have the right to refuse medical treatment, ask

for another doctor's opinion (second opinion), and doctors are obliged to provide information after the patient is conscious. In emergency situations where the patient is unconscious, the doctor can act without the patient's permission based on voluntary representation (Zaakwarneming) in accordance with Article 1354 of the Civil Code. Doctors are obliged to look after the patient's interests and provide information once the patient is conscious.

Zaakwaarneming, according to Adam Chawazi, is a form of legal engagement that arises because of the law, not the cause of medical malpractice. Medical malpractice occurs if a doctor violates his obligations and harms the patient in carrying out zaakwaarneming, especially in emergency situations. The legal relationship between doctors and patients, based on law, requires doctors to provide health services to patients. This relationship does not depend on patient initiative, even in emergencies. The result is inspanning verbintenis (business engagement).

Legally, the relationship between doctor and patient is called a therapeutic contract, starting with questions and answers, physical examination, diagnosis and therapy. Even though doctors try their best, there is no guarantee of cure. The history of the relationship between doctors and patients began with a paternalistic pattern, but developed into an egalitarian, contractual and horizontal relationship. The contractual relationship pattern produces a horizontal legal relationship inspanningverbintenis, with equal rights and obligations between doctors and patients. Informed consent becomes a mechanism to reduce malpractice claims, realizing that therapeutic transactions are a maximum effort (inspanningverbintenis) because the results cannot be completely guaranteed by the doctor.

2. Evaluation of Informed Consent Practices in Health Practices Patient Awareness Level

Evaluation of informed consent practices in healthcare practice reveals dynamics that need to be carefully considered to improve the quality of healthcare services and safeguard patient rights. The level of patient awareness of informed consent shows significant variations. Some patients have good understanding, while others experience confusion. Research recommends a more intensive educational approach to patients to increase their understanding of the medical procedures that will be carried out. Patient education can be key to ensuring that each individual can make conscious decisions appropriate to his or her health needs.

The communication process between health workers and patients in providing information regarding medical procedures shows diversity. To ensure that the information provided is comprehensive and can be understood by patients, increased communicative engagement is needed. Additional training for healthcare professionals in effective communication can contribute to creating an environment that supports understanding and trust between patients and healthcare providers. Consent documentation, although generally complete, still requires certain improvements. Recommendations are made to clarify the consent document and ensure that the patient or family has signed it knowingly. Better documentation not only meets legal standards, but also creates a clear trail of patient awareness and consent to the medical procedures performed.

3. Interpretation of Research Results

Interpretation of research results regarding aspects of compliance with legal regulations, challenges in legal implementation, and the quality of legal documentation provides an in-depth picture regarding the implementation of medical record systems in health institutions.

First, the finding that the majority of health institutions have complied with legal regulations reflects the high level of awareness of the importance of compliance with the standards and requirements set by law. These positive steps are the main basis for maintaining the security and privacy of patient data, which is a critical aspect in administering a medical record system.

Second, the challenges in implementing legal aspects, especially those related to data privacy and security, highlight the complexity of the tasks faced by some institutions. Interpretation of these findings suggests the need for additional support in the form of better resources and training so that institutions can more effectively meet the legal requirements in place. These steps are needed to overcome obstacles that may arise in the implementation of legal regulations.

Third, variations in the quality of legal documents suggest there is room for improvement in the preparation and maintenance of legal records. The interpretation of these findings can be interpreted as an indicator of the importance of updating clearer policies and procedures in an effort to increase transparency, accuracy, and sustainability of patient consent documentation.

Overall, the results of this research provide a comprehensive view of the condition of health institutions in carrying out legal aspects in implementing the informed consent system. These findings not only reflect the reality of health practice, but also provide a basis for improvement and development of better policies in the future.

4 Relationship of Findings to Reviewed Literature

The findings resulting from this research can be seen in the context of the related literature reviewed previously. The following is the relationship between the findings and the literature that has been reviewed:

1) *Informed Consent*and Legal Position:
   Findings related to legal aspects in the implementation of the medical record system reflect the importance of the legal position in the relationship between doctors and patients. The principles of health law, as outlined in the literature, underscore the need for compliance with regulations and the proper implementation of legal procedures.
2) Level of Patient Awareness and Informed Consent:
   Evaluation of the level of patient awareness of informed consent is in line with the literature which emphasizes the importance of patient understanding of medical procedures. The recommendation for a more intensive educational approach also reflects the literature's focus on the role of education in increasing patient participation in health care decision making.
3) Implementation of Legal Aspects and Documentation Quality:
   Challenges in implementing legal aspects, especially those related to data privacy and security, are in line with literature that describes the complexity of the tasks facing health institutions. Increased resources and training, as recommended by the findings, are in line with literature highlighting the need for additional support to achieve optimal legal compliance.
4) Doctor-Patient Relationship and Informed Consent:
   The contractual relationship between doctors and patients, which includes informed consent, is visible in findings that show the communication process between health workers and patients. Increased communicative engagement, as suggested by the findings, reflects

literature emphasizing the importance of effective communication in safeguarding patient rights and safety.

5) Patient Legal Protection and Informed Consent:
Evaluation of informed consent practices in relation to the fulfillment of patients' rights and legal protection reflects literature that emphasizes the importance of human rights in the context of health care. Informed consent is considered a mechanism to protect patient rights and avoid potential malpractice suits.

The relationship between the findings and the literature shows the consistency and relevance of research results with the concepts that have been explained in the context of health law, doctor-patient relationships, and protecting patient rights. These findings may contribute to further understanding of the implementation and quality of informed consent practices in health systems.

Conclusion

This research presents findings related to several legal aspects in the implementation of medical record systems in health institutions. The results show a good level of compliance with legal regulations governing medical record management, such as the Health Insurance Portability and Accountability Act (HIPAA), Law Number 36 of 2009 concerning Health, and related local regulations. Despite this, challenges arise especially regarding the privacy and security of patient data, with some institutions facing difficulties in implementing this aspect of the law.

Evaluation of legal documents, such as patient consent letters and medical records management policies, indicated variations in their quality. Therefore, improvements are needed in the preparation of legal documents to ensure patient consent is well documented and in accordance with legal standards. In addition, research on the legal relationship between doctors and patients highlights the importance of informed consent as approval for medical procedures. This involves communication between the doctor and the patient, as well as explaining the patient's rights to refuse medical treatment and ask another doctor for an opinion.

Evaluation of informed consent practices in healthcare practices reveals variations in patient awareness levels. Recommendations for increased educational approaches to patients and additional training for healthcare professionals are proposed to ensure better understanding of medical procedures. Overall, these findings provide a basis for improving the implementation of legal aspects, doctor-patient communication, and informed consent practices in health systems, with a focus on understanding, training, and improving the quality of legal documents.

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- Article 56 paragraph (1) Law Number 36 of 2009
- Article 2 paragraph (1) RI Minister of Health Regulation Number 290/Menkes/Per/III/2008