

INFORMED CONSENT AS A PREVENTIVE MEASURE AGAINST MEDICAL MALPRACTICE AT THE SAMBI COMMUNITY HEALTH CENTER, WEST KOTAWARINGIN, PANGKALAN BUN, CENTRAL KALIMANTAN

Muhammad Erman Subarkah¹, Zahir Rusyad², Endang Kusuma Astuti³

¹Student of the Master's Program in Law, Master's Program in Law, Postgraduate Program, Universitas Widyagama Malang

²Master's Program in Law, Master's Program in Law, Postgraduate Program, Universitas Widyagama Malang

³Master's Program in Law, Master's Program in Law, Postgraduate Program, Universitas Widyagama Malang

Abstract

The research method used was empirical legal research (sociolegal research). The study location was the Sambu Community Health Center in West Kotawaringin. The data types and sources were primary data collected from the field through interviews and observations, while secondary data were collected from the literature. Qualitative data analysis techniques with steps of data reduction, data presentation and drawing conclusions/verification. The research results for the ethical aspect showed a high level of understanding (72 responses, or 51.4%), indicating that healthcare workers established good communication with patients by providing information regarding the medical procedures performed. Regarding the legal aspect, a high level of understanding (72 responses, or 52.1%), indicating that the handling of medical procedures adhered to the guidelines of Law No. 17 of 2023, which stipulated that healthcare workers provided patients with the opportunity to consent to the medical procedures they received and provided informed consent documents. Preventive efforts for healthcare workers showed a high level of understanding (SSP), with 69 responses, or 49.2%. Efforts include training and workshops to prevent medical negligence for healthcare workers.

Keywords: Informed consent, Preventive Measures, Medical Negligence.

Abstrak

Metode penelitian yang digunakan adalah penelitian hukum empiris (penelitian sosiologis-hukum). Lokasi penelitian adalah Pusat Kesehatan Masyarakat Sambu di Kotawaringin Barat. Jenis dan sumber data meliputi data primer yang dikumpulkan dari lapangan melalui wawancara dan observasi, sedangkan data sekunder dikumpulkan dari literatur. Analisis data kualitatif dilakukan dengan langkah-langkah pengurangan data, penyajian data, dan penarikan kesimpulan/verifikasi. Hasil penelitian untuk aspek etika menunjukkan tingkat pemahaman yang tinggi (72 tanggapan, atau 51,4%), menunjukkan bahwa tenaga kesehatan menjalin komunikasi yang baik dengan pasien dengan memberikan informasi mengenai prosedur medis yang dilakukan. Mengenai aspek hukum, tingkat pemahaman yang tinggi (72 tanggapan, atau 52,1%), menunjukkan bahwa penanganan prosedur medis sesuai dengan pedoman Undang-Undang Nomor 17 Tahun 2023, yang mengatur bahwa tenaga kesehatan memberikan kesempatan kepada pasien untuk memberikan persetujuan terhadap prosedur medis yang diterima dan menyediakan dokumen persetujuan yang terinformasi. Upaya pencegahan bagi tenaga kesehatan menunjukkan tingkat pemahaman yang tinggi (SSP), dengan 69 tanggapan, atau 49,2%. Upaya tersebut meliputi pelatihan dan lokakarya untuk mencegah kelalaian medis bagi tenaga kesehatan.

Kata kunci: Persetujuan yang terinformasi, Langkah-langkah pencegahan, Kelalaian medis.

INTRODUCTION

Law No. 17 of 2023 defines health workers as individuals who are committed to the health sector and possess professionalism, knowledge, and skills obtained through higher

education. For certain types of work, a special license is required to carry out health efforts. Health workers include clinical psychologists, nurses, midwives, pharmacists, public health workers, environmental health workers, nutritionists, physiotherapists, medical technicians, biomedical engineers, traditional health practitioners, and other health professions as determined by the Minister.

Based on Law Number 17 of 2023 concerning Health, health services include all activities and/or series of activities provided directly to individuals or communities with the aim of caring for and improving the health of the community through promotive, preventive, curative, rehabilitative, and/or palliative approaches. Health services are provided through various facilities organized by the central government, local governments, and/or communities. One example of a health service facility is a hospital. Hospital

Hospitals serve as health care facilities that provide comprehensive individual services and offer inpatient care, emergency services, and outpatient care in accordance with Government Regulation No. 47 of 2021 of the Republic of Indonesia.

The work of doctors has certain characteristics, including a very intimate relationship based on a high level of trust. Patients must have confidence in the skills of the doctors who treat them. However, over time, this situation has begun to change due to various developments in many aspects of life. With the increase in public knowledge and awareness of personal health responsibilities, the trust that was previously focused on the abilities of doctors themselves has now shifted to their scientific expertise. There is an awareness among the public to demand a more balanced relationship and no longer be completely dependent on doctors. Husein Kerbala explains that in addition to trust no longer being directed solely at doctors, but also at the quality of medical science, changes in the dynamics of the doctor-patient relationship have occurred due to a new trend that states that health does not only mean freedom from disease, but also includes physical, mental, and social well-being, as well as an increasing number of regulations that provide legal protection for patients.

Therefore, it appears that the interaction between doctors and patients is not limited to medical aspects, but also contains social, legal, and economic dimensions.

In Indonesia, the case of Dr. Setyaningrum in the 1980s was an important moment in raising public awareness of the importance of balance in the relationship between doctors and patients. Since that incident, there has been a transformation in the patient-doctor relationship, from a paternalistic one to a more collaborative one. Patients are now more

aware of their rights, including the right to obtain information and the right to give informed consent.

Many new cases have emerged since the Dr. Setyaningrum incident, in which patients or their families have sued and demanded compensation from medical personnel for various cases of negligence. A clear example of this phenomenon can be seen in the recent cases of “The Family of Baby Jared-Jayden and Omni Hospital” and “The Family of Baby Ismi and Borromeus Hospital.” From this, it is clear that a good understanding of informed consent is essential as a step Prevention of medical negligence. The author focuses on this issue, namely what and how “Informed consent is a preventive measure against medical negligence.”

At the Sambi Kotawaringin Barat Community Health Center, which the author observed, the informed consent forms for inpatients and emergency patients who need stabilization when referred are incomplete. The staff there only wrote medical records and informed consent forms for inpatients in a book. Medical records and informed consent forms for inpatients and emergency patients who needed to be stabilized when referred were not available because the Sambi Community Health Center was an outpatient community health center. It was only on May 20 May 21 and 22, 2024, during the implementation of the Sambi Community Health Center accreditation survey, the medical records and informed consent documents were completed. This is stated in the Indonesian Minister of Health's decree number HK.01.07/MENKES/165/2023 CONCERNING COMMUNITY HEALTH CENTER ACCREDITATION STANDARDS.

From this point, it is clear that the concept of informed consent is crucial as a preventive measure against medical errors. This is the issue the author wishes to discuss: what is “Informed Consent” and how does it function as a preventive measure against medical errors?”

METHOD

This research is an empirical study based on law. The method used in this empirical legal research is known as field research, which analyzes existing legal regulations and examines the realities that occur in society. In this context, the research aims to observe the actual circumstances or real conditions in society with the aim of collecting the necessary facts and data. Once the necessary data has been collected, the next step is to identify the problem, which will ultimately lead to a solution to the problem.

The approach applied in this study is an empirical legal approach, also known as socio-legal research. In this case, the research was conducted at the Sambi Kotawaringin

Barat Community Health Center to investigate the laws related to informed consent and to understand how informed consent can serve as a preventive measure against medical negligence.

The sampling technique used in the preparation of this thesis is non-probability sampling, with a focus on purposive sampling, where the selection of samples is based on specific objectives. This means that the researcher selects samples according to certain criteria, with the hope that the samples meet the relevant properties or characteristics to understand and answer the issues that are characteristic of the population being studied.

The research location was at the Sambu Kotawaringin Barat Community Health Center. The types and sources of data used in this study included primary data obtained through interviews and field observations, as well as secondary data from literature sources. Data analysis was conducted qualitatively by following steps such as data reduction, data presentation, and conclusion drawing or verification.

RESULTS AND DISCUSSION

A. Ethical and Legal Aspects Informed consent

1. Ethical Aspects of Informed Consent

Informed consent is permission or consent given by a patient or their family to a doctor to perform medical procedures, such as physical examinations and various other tests to establish a diagnosis, provide therapy, administer injections, assist in childbirth, administer anesthesia, perform surgery, and provide follow-up care in the event of complications, among other things. The word “informed” relates to the provision of information or explanation. Thus, it can be concluded that informed consent is permission or consent given by the patient (or authorized family) to the doctor to perform medical procedures, after the doctor has provided comprehensive information about the procedure.

Usually, patients experience illnesses or injuries that require intervention from a doctor for treatment. Based on the provisions in Article 1 point 23 of Law Number 17 of 2023 concerning Health, a patient is defined as an individual who receives health services from medical personnel and/or health workers. In terms of professional ethics, the doctor's responsibility to the patient is outlined in the Medical Code of Ethics (KODEKI) established through the Decree of the Executive Board of the Indonesian Medical Association (IDI) Number 111/PB/A.4/02/2013, namely: Article 14 A doctor is required to be sincere and use all of his knowledge and skills for the benefit of the patient, and if he is unable to perform an examination or treatment, he must refer the patient to a doctor

who has the necessary expertise after obtaining the consent of the patient or his family. Article 15 Every doctor must provide patients with the opportunity to always interact with their family and advisors, including in matters of worship and/or in resolving their personal problems.

Law of the Republic of Indonesia Number 17 of 2023 concerning Health is an important step in efforts to improve the health system in Indonesia. This law emphasizes the importance of patient rights, including informed consent, and regulates various aspects of health service delivery to ensure fair, equitable, and quality access for the entire community. Informed consent is an integral part of this Law, which emphasizes the importance of informed consent from patients before medical procedures are performed. This concept reflects the principle of autonomy and the right of patients to make decisions based on sufficient information about their medical care.¹

The obligations of Medical Personnel and Health Workers are regulated in Articles 274-275 of Law No. 17 of 2023 concerning Health, which stipulates that Medical Personnel or Health Workers in carrying out their practice must: a. Provide Health Services in accordance with professional standards, professional service standards, established operational procedures, professional ethics, and the health needs of Patients; b. Obtain consent from the patient or their family for any actions to be taken; c. Maintain the confidentiality of patient health information; d. Create and maintain records and/or documents regarding examinations, treatments, and actions taken; and e. Refer patients to other medical personnel or health workers who have the relevant competence and authority.

In addition, doctors have an obligation to have knowledge and skills appropriate to their profession. After obtaining a medical degree and license to practice, they are expected to have abilities and expertise equivalent to the standards of doctors in general. If someone is a specialist, it is expected that their abilities will be measured against specialist standards in their field. 2) A doctor is expected to use their knowledge and skills carefully, reasonably, and thoroughly, as other doctors would normally do in similar situations and conditions. 3) A doctor is required to exercise the best judgment. They are also human beings who can make mistakes while performing their duties, as long as these mistakes do not fall into the category of gross negligence.

Based on the results of the questionnaire on the ethical aspect of informed consent, which discusses whether health workers have ensured that patients do not feel coerced and can make decisions to accept medical treatment/care, it can be concluded

¹ Undang-Undang Nomor 17 Tahun 2023

that health workers are very knowledgeable (SSP) with 72 responses or 51.4% of respondents answering that they are very knowledgeable. Healthcare workers have established good communication with patients by providing information about the medical procedures performed, healthcare workers are open to patients regarding the medical procedures provided, and healthcare workers have ensured that patients do not feel coerced into accepting medical procedures or treatment. Meanwhile, the health department always reminds health service providers such as community health centers and hospitals to provide the best service for patients.

2. Legal aspects of informed consent

Hermien Hadiati Koeswadji explains that therapeutic transactions are relationships between doctors and patients that determine the most appropriate treatment methods for patients, and both parties must comply with existing regulations. Once the transaction has been carried out, the rights and obligations of each party must be fulfilled. The relationship between doctors and patients in therapeutic agreements is related to human rights, including the right to self-determination and the right to obtain explanations and information regarding their health. The agreement requires a type of communication known as therapeutic communication, which is an interpersonal interaction between nurses and clients that allows both parties to understand each other.

Therapeutic transactions are a form of professional relationship between doctors and patients based on the principles of good faith and mutual trust. This relationship emphasizes the importance of open communication and a shared commitment to achieving optimal treatment goals, with the interests and safety of the patient as the top priority. This concept is in line with Article 1313 of the Civil Code, which states that an agreement is an act whereby one or more persons bind themselves to one or more other persons.²

Consent for medical treatment does not always require a written document. In minor medical situations, consent can be seen from the patient's body language, such as lying down for a doctor's examination or nodding when being explained about the medication being administered. According to Mikhaela F. L. Tapada, quoted from Hanafiah and Amir, there are five conditions that must be met for Medical Consent

² Endang Kusuma. 2019. *Transaksi Terapeutik (Dalam upaya pelayanan Medis di RS)*. Bandung. PT Citra Aditya Bakti.

(Informed Consent) to be considered valid based on the guidelines from The Medical Defense Union contained in the book “Medico legal Issues in Clinical Practice”, namely: 1. Given willingly; 2. Given by an individual capable of making an agreement; 3. An explanation of the procedure to be performed has been provided so that the patient understands the necessity of the procedure; 4. It relates to a specific matter; 5. The procedure is performed in the same context.

In addition to the above conditions, there are two fundamental conditions in a legal relationship for informed consent to be considered valid, namely:

The material condition is considered important because without this condition, medical consent is impossible, as this condition is the basis for the formation of a legal relationship between the doctor and the patient.

The material requirements of informed consent consist of three aspects, namely: 1. There is a medical procedure 2. It is carried out in accordance with the applicable rules in medical science 3. There is consent from the patient.³

In terms of legal liability for errors or negligence committed by doctors against patients, hospitals are also legally responsible for all problems arising from the negligence of doctors, because doctors are health workers who operate under the auspices of hospitals. Based on Law of the Republic of Indonesia Number 17 of 2023 concerning Health, it is stated that “Hospitals are legally responsible for all losses caused by negligence committed by doctors.” Thus, mistakes made by doctors within the scope of the hospital are the responsibility of the hospital. This provision applies to public hospitals, which are government-owned institutions, as well as to doctors who work as permanent doctors at these hospitals. Thus, actions taken by doctors are considered to be actions taken on behalf of the hospital, If a patient files a claim against a doctor for a mistake made, the hospital will be responsible for the doctor's actions and will compensate the patient. If the mistake results in significant harm, such as the death of the patient or permanent, irreparable disability, the hospital will hold further discussions with the medical committee to evaluate the doctor's mistake. This discussion will include an assessment of the level of loss and the type of compensation that is appropriate. In this case, the hospital is responsible for errors that occur in the implementation of the medical treatment agreement. The decision regarding compensation will be made by the hospital together with the medical committee through deliberation. Based on this decision, the hospital will provide payment for

³ Viona W. Rusnita. 2024. Pertanggungjawaban pidana terhadap kelalaian medis yang dilakukan oleh dokter dalam persepektif hukum kesehatan di indonesia. Skripsi. Universitas Andalas Padang

losses incurred due to negligence or errors by doctors in the implementation of medical treatment.

In terms of informed consent, it discusses whether health workers give patients the opportunity to consent to the medical treatment they receive and whether health workers are prepared to accept legal consequences if they do not meet the requirements. From these results, it can be concluded that health workers are aware (SP) with 72 responses or 52.1%.

From these results, it can be concluded that in terms of legal aspects, health workers are aware, with 72 responses or 52.1% of the questionnaire results. These results show that health workers at the Sambi Kotawaringin Barat Community Health Center (Puskesmas) refer to the guidelines of Law No. 17 of 2023 in their handling of medical procedures, namely that health workers give patients the opportunity to consent to the medical procedures they receive. health workers already understand the contents of informed consent and have provided informed consent documents to patients to give them the opportunity to understand and sign the documents, and in the event of medical negligence and legal claims, health workers are prepared to face legal consequences.

B. Informed Consent as a Preventive Measure Against Medical Malpractice

The application of informed consent in healthcare is crucial in healthcare services. Informed consent occurs when a patient or their closest family member gives consent for a medical procedure after receiving a comprehensive explanation of the procedure. This consent serves to protect the patient and also provides legal protection for doctors in the event of a possible error, which could have negative implications.

The interaction between doctors and patients is a professional relationship (doctor) with individuals receiving services (patients). This relationship forms the basis for all aspects of medical practice, both in the diagnosis and treatment of patients. When patients choose a particular doctor to treat their health problems, it means that they entrust the management of their illness completely and are confident that the doctor will not take any action without their consent. The trust given by the patient is a responsibility, so in treating patients, doctors act according to their best knowledge and abilities, and follow medical ethics, moral norms, and applicable laws. The legal relationship between doctors and patients must be built on a solid foundation.⁴

⁴ Veronica Komawalati. 2002. Peranan *Informed consent* dalam Transaksi Terapeutik (Persetujuan dalam Hubungan Dokter dan Pasien). Cetakan ke-2. Bandung. PT Citra Aditya Bakti

Preventive measures discuss preventive actions or medical actions taken by health workers to avoid high risks to patients, and from the results it can be concluded that health workers are Very Knowledgeable (VK) with 69 responses or 49.2%. The efforts made by healthcare workers to prevent negligence in medical procedures include always participating in and updating their knowledge through training and workshops to prevent negligence by healthcare workers. They work as a team and always coordinate with the team regarding the procedures performed. In addition, healthcare workers already understand the steps or procedures to take if negligence occurs, and health centers always apply the work principles instilled in healthcare workers to always be able to anticipate medical actions that cause high risks.

CLOSING

Research results on ethical aspects: With a very good understanding of the results (72 responses or 51.4%), health workers establish good communication with patients by providing information about the medical procedures performed. In terms of legal aspects, 72 respondents or 52.1% understood that medical procedures are carried out in accordance with Law No. 17 of 2023, which states that healthcare workers must give patients the opportunity to consent to medical procedures and provide them with informed consent documents. The results of preventive efforts by healthcare workers showed that 69 respondents or 49.2% understood very well. Efforts include training and workshops to prevent medical negligence among healthcare workers. Recommendations for the health department include the need for continuous and consistent evaluation of community health centers to ensure compliance with established standards. The health department also needs to conduct regular skills training to ensure that health workers remain competent in providing health services. Recommendations for health workers at community health centers include the need for caution and thoroughness in their work and in carrying out services based on established service standards, as well as the expectation that they always participate in skills training conducted by the health department.

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REGULATIONS:

- Peraturan Menteri Kesehatan Republik Indonesia Nomor 3 Tahun 2025 Tentang Penegakan Disiplin Profesi Tenaga Medis Dan Tenaga Kesehatan
- Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan Peraturan Menteri Kesehatan Republik Indonesia 1438/MENKES/PER/IX/2010 tentang Standar Pelayanan Kedokteran