A Case Study Informed Consent

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Review article

A case study of informed consent in Indonesian Law Number 29, 2004

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ABSTRACT

Background: *Informed consent is an agreement between the doctor/the provider of medical services and the patient/the recipient of medical services. This relationship between these parties has changed from a paternalistic to a contractual relationship due to technological shifts. Doctors are obliged to notify the patient of all the risks and benefits of a procedure while respecting their autonomy by not intervening the decision-making process. This article will look at three government and academic hospitals in Surabaya, as informed consent has to be practiced in all medical settings.* ***Purpose:*** *This study aims to review the role of informed consent according to Law Number 29, 2004.* ***Review:*** *This study aims to discuss the characteristics of informed consent under Law Number 29, 2004, because there are too few articles addressing this issue. It also explains the roles of the patient and the doctor/dentist in informed consent according to this piece of legislation.* ***Conclusion:*** *According to Article 184, informed consent provides vital evidence that can be used to hold doctors and dentists legally accountable because it contains information about standard operating procedures (SOPs) that medical professionals are legally required to follow. Guidelines for informed consent are given in Law Number 29, 2004, Article 45, paragraph 2.*

Keywords: *medical action agreement; doctor-patient relationship; paternalistic-contractual; medical information; medicine*
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INTRODUCTION

The fourth paragraph in the introduction of the 1945 Constitution of the Republic of Indonesia and the Body of the 1945 Constitution in article 28A states that the national goal of the Indonesian people is to protect the entire Indonesian nation and fellow Indonesian citizens by making contributions in advancing public welfare and education while protecting freedoms and maintaining peace and social justice. Article 28A explains the right of every citizen to access health services because health is key to protecting life in general.[1,2]

As providers and recipients of health services, doctors and patients share a unique relationship that has become the object of lengthy legal study about the responsibilities of, and protections for, both parties. One of issues that makes these concerns necessary is that of medical malpractice. Indictments for malpractice can be submitted by the public against a medical professional who is deemed to have abused their power to harm a patient, sometimes causing pain, injury, physical disability, or death.[3]

Disputes can occur if doctors are negligent in carrying out their legal responsibilities, as this may lead to a violation the patient's rights, causing them to demand justice. Justice must be proportional whenever there is a dispute between the two parties.[4,5]

To avoid disputes around healthcare, doctors must be responsible, as outlined in Law No. 29, 2004. Accountability

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must be based on the principle of social justice for patients whose rights are violated and doctors who must be held responsible for the patient's condition. The principle of social justice discussed here is the concept of proportional justice laid out in the introduction of the 1945 Constitution of the Republic of Indonesia mentioned above.[6]

The objective of this article is to explain the characteristics of informed consent under Law Number 29, 2004, concerning medical practice and the responsibilities of medical professionals by analyzing a combination of case studies and providing a narrative review of published articles. The aim of reviewing literature already published on this topic is to provide an overview of informed consent and the legal nature of the doctor–patient relationship. This article will look at three informed consent procedures from three different hospitals (referred to as Hospitals A, B, and C) in Surabaya to assess how strictly they conform to the guidelines laid out in paragraph 2 in Article 45 of Law Number 29, 2004.

There have been a number of examples of improper implementation of informed consent in dental care in Indonesia since the implementation of this law. The first case discussed here occurred in 2010, when a dentist mistakenly extracted a patient's tooth, causing them to be charged with malpractice. The malpractice charge levelled against the dentist was negligence. Another case in 2016 involved a dentist's failure to inform their patient of the relevant medical risks before failing to successfully extract a tooth, leaving fragments of the tooth in the gum, the removal of which later required a further operation. A third case of dental malpractice happened in 2020, when a dentist left an open wound in a patient's mouth during an operation. The dentist was reported to the police and the dental discipline council before being given a five-year prison sentence.

The purpose of the narrative review is to see how informed consent under Law Number 29, 2004, is enforced in Indonesian dental practice. Giving informed consent under this law involves respecting the patient's autonomy and requires the doctor or dentist to carry out their duties in line with the SOP. This is necessary to avoid the improper implementation of informed consent in Indonesia by forming a contractual relationship, made possible by technological developments that change patient perceptions.

REVIEW

Law Number 29, 2004

According to Law Number 36, 2009, certain pieces of information must be given to the patient for their consent to qualify as informed: details regarding the diagnosis and suggested medical procedure, the purpose of the proposed procedure, details of any other medical action to be carried out that may affect the patient, an account of the risks associated with the procedure, and a prognosis.

Informed consent

Informed consent emerged to establish a change in the relationship between doctor and patient from a vertical, paternalistic relationship to a horizontal, contractual relationship. Informed consent is essentially a therapeutic agreement between doctors and patients based on the patient's health status. This can take two forms: implied consent (considered as given without being stated explicitly) and expressed consent (stated by the patient to the doctor). With treatments that pose a high risk of harm, informed consent must be given in written form. Doctors must prioritize the implementation of informed consent in their daily activities unless they believe that there are other people who are more competent and can provide assistance. For emergency care, informed consent does not need to be given, but if the patient or a family member is capable of receiving the necessary information and giving their consent, this must be carried out.

The therapeutic agreement of informed consent between doctor and patient is binding as soon as the agreement is signed. Once signed, it remains in effect until both parties consent to terminate the agreement. There are several principles that guide the implementation of informed consent, the most important of which is the principle of good faith. This is the principle that underlies the pre-negotiation stage before the contract or therapeutic agreement can be implemented. Therapeutic agreements between doctors and patients are based on mutual trust, but with that trust, there is responsibility and accountability that must be carefully considered by doctors when agreeing to perform medical interventions.

Responsibility in law has two facets, namely responsibility (verantwoordelijkheid) and liability (aansprakelijkheid). Liability refers to the position of a person or legal entity who must pay some form of compensation after a legal battle due to malpractice (liability with fault) or error (liability without fault), also known as risk responsibility (strict liability). The application of responsibility and liability requires a clear awareness of the relationship between the professional who has committed the crime and their employer. Article 2 of the Criminal Code states that criminal provisions in Indonesian legislation apply to anyone who commits an offense in Indonesia, including medical professionals.

Criminal law recognizes that crime in the health services can be justified and forgiven as outlined in jurisprudence, but this does not necessarily mean that justification and forgiveness can overturn criminal proceedings. The science of criminal law and jurisprudence gives specific reasons for the abolition of unwritten crimes based on justification and forgiving. Reasons for justification include when an unlawful act was regarded as lawful by the defendant. Regardless, the defendant's actions may still be unlawful, even if they are not criminal.

Informed consent acts as a piece of evidence that can be brought forth if ever there is a lawsuit filed by a patient against a doctor based on Article 184 of the Criminal Procedure Code, allowing the court to assess whether the

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doctor's actions can be considered negligent. Hence, it is important that informed consent is as thorough and accurate as possible, especially in matters relating to diagnosis, the patient's treatment plan, and the prognosis. Also, the informed consent form must be signed by a witness.

Literature search strategy

A search for studies on informed consent between doctor and patient was conducted from January to February 2022. A librarian with knowledge of medical referencing developed individual search strategies and retrieved citations from ScienceDirect, PubMed and Google Scholar. A mix of terms were used together to find the relevant literature ("Informed Consent AND Therapeutic Contract AND Doctor-Patient Relationship"). The search strategies used in each database will be explained in the next paragraph.

Criteria

The narrative review includes studies that examine Indonesian doctors' awareness of their legal responsibilities under Law Number 29, 2004. The following inclusion and exclusion criteria were used. The articles had to include a discussion of doctors and their patients, the therapeutic relationship they share, the contractual relationship they share, informed consent from the point of view of Indonesian law, and specific reference to paragraph 2 in Article 45 of Law Number 29, 2004. Articles were excluded if they had an abstract only or belonged to obscure, protected, or unassessed journals or papers. These criteria were based on technical issues and reliability.

Data Extraction

This study is based on descriptive data, including the legal points of view of the doctor and the patient. Table 1 shows how data was extracted from the 22 sources used in the narrative review. There are two kinds of study analyzed here: those that focus on the practice of dentists and doctors and those that focus on legal responsibility in the doctor–patient relationship. The former could be seen as being based on Law Number 29, 2004, and the application of informed consent. The latter could be seen as being based on the theory, legality, therapeutic agreement, legal liability theory, and medical treatment risks that guide the dentist/doctor's daily practice.

The description criteria were formulated by analyzing the contents of the informed consent contract for Hospitals A, B and C (concerning labelling, the consent body, level of detail, ease of interpretation, the purpose of medical action, alternatives and risks, the prognosis, details of the contract between the operator and patient, personal data, the number and details of the witnesses' present, and the full names of the operator and the patient; see Table 2).

The extraction of component data from the informed consent contracts in these three hospitals is detailed in Table 3. The author has categorized each of these requirements as very clear, clear enough, unclear, and very unclear based on how well they convey the criteria covered in paragraph 2 in Article 45 of Law Number 29, 2004. The data was extracted after reading and analyzing the informed consent forms of the three hospitals.

DISCUSSION

A description of the gold standard for informed consent can be found in paragraph 2 in Article 45 of Law Number 29, 2004, which discusses the issue of seeking approval for medical or dental interventions. Paragraph 1 of Article 45 states that every medical or dental action to be carried out by a doctor or dentist on a patient requires their approval. Paragraph 2 states that this consent must be given after the patient has received a complete explanation of the proposed medical procedure in line with the gold standard of informed consent, covering the diagnosis, the nature of the procedure, its purpose, its risks, any other alternative actions and associated risks, and a prognosis.[7,8]

Article 45, paragraph 4, explains that the approval mentioned in paragraph 2 can be given in writing or verbally. Paragraph 5 goes on to state that any medical or dental procedure that comes with a high risk must be given written approval and signed by the person permitted to give consent. Paragraph 6 explains the provisions relevant to the approval of medical or dental procedures as referred to in paragraphs 1–5, which are regulated by Ministerial Regulation.

A number of additional requirements were also identified in the published literature, namely: the category of risk that comes with the given medical action (high, medium, and low); the time, place, and date of the signing of the informed consent agreement; the number of witnesses who were present and participated in signing the informed consent form; a column with the full names of doctors, patients, and witnesses who were present at the time of signing.[9–11]

Based on the data in Table 1, it is clear that the informed consent procedure at Hospital A comes closest to the gold standard of informed consent outlined in Law Number 29, 2004. The informed consent procedures at Hospitals B and C are less clear and do not follow these guidelines as closely as Hospital A.

The four comparisons made in Table 2 address the fundamental issues that make informed consent one of the best ways to ensure proportional justice between doctors and patients. These comparisons are based on cases in dental treatment. Here, the dentists had to ensure that their medical treatment would not endanger their patients or involve medical malpractice. At Hospital B, the majority of labels and informed consent bodies do not clearly reflect a sufficiently rigorous informed consent procedure. The label section of Hospital B does not clearly state the location as given by the Surabaya City Government because the font is too small. This is important because the label must clearly state where the informed consent was given so that

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Table 1. Data extraction process from 22 references used in narrative review

	Reference																					%
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	Sign
Related to practice of both dentist/ doctor in medicine	✓	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	-	✓	-	-	✓	-	✓	✓	72.7
Law No. 29 of 2004	✓	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	-	✓	✓	✓	-	✓	✓	✓	✓	✓	86.3
Informed consent	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	✓	-	✓	✓	✓	✓	✓	90.9
Related to the position of a doctor-patient relationship	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	-	✓	✓	✓	✓	✓	86.3
Covenant theory	✓	✓	✓	✓	-	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	-	✓	✓	✓	-	✓	✓	81.8
Legal aspect	✓	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	✓	-	✓	-	✓	-	✓	-	✓	✓	77.2
Therapeutic agreement	✓	-	✓	✓	✓	✓	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	✓	86.3
Legal liability theory	✓	-	✓	-	-	✓	✓	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	81.8
Medical treatment risks	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100

Table 2. Informed consent analysis of three hospitals (Hospital A, Hospital B, and Hospital C) in Surabaya

Description	Hospital A	Hospital B	Hospital C
Informed Consent Label	Very clear	Very Unclear	Very clear
Informed Consent Body			
Detailed information on the action (diagnosis and medical procedures) that will be carried out	Very clear	Very Unclear	Clear enough
Ease of interpretation of the purpose of medical action in detail info on the action to be taken	Very clear	Very Unclear	Very Unclear
Details of other alternative actions and the risks of medical treatment that can occur after the procedure is carried out	Very Unclear	Very clear	Very Unclear
Prognosis of the medical action to be taken	Very clear	Very Unclear	Very Unclear
The contract between the operator and the patient on the points to be held	Very clear	Very Unclear	Very Unclear
Informed Consent person data	Very clear	Unclear	Very clear
Closing			
Informed Consent detail contract time	Very clear	Very clear	Unclear
Number of witnesses involved in the Informed Consent signing process	Very clear	Very clear	Very clear
The full name of the operator and patient in the Informed Consent	Very clear	Very clear	Very clear

Table 3. Extracting data of informed consent taken from three hospitals based on component mentioned in paragraph 2 article 45 Law Number 29, 2004

Component mentioned in paragraph 2 article 45 Law Number 29, 2004	Informed consent of Hospital A	Informed consent of Hospital B	Informed consent of Hospital C
Medical diagnosis and procedures	✓	-	✓
The purpose of the medical action taken	✓	✓	-
Alternative courses of action and their risks	✓	✓	-
Risks and complications that may occur	-	✓	-
The prognosis for the action taken	✓	-	-

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the necessary documentation can be found in the patient's medical record if a legal issue arises.[12–14]

The informed consent body of Hospital B is also unclear, except for the detailed description of the relevant risks of a procedure. In the detail section of action info, information on relevant risks, the prognosis, and the contract between the operator and the patient lacks clarity. As such, some of the important parts of the informed consent form are not clear enough to meet the gold standard of informed consent as required by Law Number 29.[15]

These sections are important because the purpose of informed consent is to inform the patient about all of the proposed medical actions and to ensure that the patient is protected by law and can refuse any medical procedure they do not feel comfortable with. Doctors are not allowed to perform medical actions in any form without the consent of the patient. According to SK PB IDI Number 319/PB/A4/88, all relevant information must be given to the patient in its entirety, and the doctor must not withhold any such information. This must include all the potential advantages and disadvantages of planned medical treatments.[16,17]

The signatures are an important part of the contract because they confirm that all the necessary information has been exchanged, including that which relates to competence, the delivery of information, the patient's understanding of the information they have received, and the patient's right to approve of or reject proposed medical procedures.[18,19]

These checks must be made in an informed consent form because there is never a guarantee that medical treatment will come without side effects or risk. Even the most seemingly benign medical treatment, such as the administration of a commonly used drug, can pose a risk that may result in the patient suffering from an unforeseen reaction. In addition, the signatures on the contract help guarantee the patient's autonomy, as they can refuse to sign the document if they do not want to take the treatment. If the patient is later dissatisfied with their treatment, the doctor may be subject to charges under the KUHP, articles 359 and 360, which include reference to legal proceedings for negligence (culpa).[20]

The informed consent procedure at Hospital C is equally unclear and lacking in rigor compared with the gold standard of informed consent. In particular, there is a lack of clarity regarding the ease of interpretation, the information provided on the proposed treatment, the level of risk, and the agreement between the doctor and the patient stating that the doctor has fully informed the patient regarding their condition and the potential effects of the treatment.[8,21]

This lack of clarity on such important medical issues can endanger not just the patient, but the reputation of the medical professionals involved by undermining the effectiveness of the agreement. Correctly and clearly established informed consent that adheres to the principle of proportional justice is needed for the student medical professionals at these facilities to protect themselves and their patients in the future.[20,21]

Moreover, Hospital C's informed consent form only contains reference to the place and date it was signed by the patient, omitting the exact time. The signing of the informed consent agreement indicates that the five requirements of informed consent have been fulfilled and that the patient's right to autonomy in giving their consent for medical action without coercion from other parties has been granted.[19,20]

Hospital C's procedure is also unclear in laying out the information that should be conveyed to the patient regarding the proposed treatment, the prognostic risks of the treatment, and the contract between the doctors and the patient. These are important matters in adhering to the gold standard of informed consent and ensuring proportional justice between doctors and patients.[21]

In contrast, Hospital A provides a good example of informed consent that is clear, safe, and adheres to the gold standard of informed consent. As such, it acts as an effective therapeutic agreement between the doctor and the patient, thereby allowing both parties access to proportional justice. However, Hospital A's form is lacking when it comes to details about the informed consent body, precisely in the absence of a detailed section on the risks associated with proposed treatments. It is crucial that patients are given a detailed account of the relevant risks because they allow the patient to consider all possible advantages and disadvantages of treatment before consenting to it. This also helps to avoid conflict between patients and doctors if patients are later dissatisfied with the outcome of the treatment.[19]

The missing pieces of information in the informed consent forms from Hospitals B and C could lead to acts of negligence (culpa) because they fail to set out the professional standards and code of ethics necessary to ensure that the patient is properly informed when they give their consent.[8,18,22,23]

Though important, informed consent procedures should not prevent doctors from acting quickly to save someone's life in an emergency, and doctors should always provide first aid when necessary. They may carry out the informed consent procedure later on with the patient or a family member for any further treatments. Nonetheless, a doctor or dentist providing emergency care must still comply with the applicable SOPs.[22,24–27]

The gold standard of informed consent is an important starting point in evaluating the informed consent procedures of health facilities (faskes) on a large scale. This can help improve patient and doctor safety and the quality of health services in Indonesia while minimizing the occurrence of patient–doctor lawsuits and conflicts.[28–30]

In conclusion, informed consent, based on guidelines given in paragraph 2 in Article 45 of Law Number 29, 2004, provides crucial evidence in medical cases, as stated in Article 184. It is used to ensure the legal accountability of doctors and dentists because it contains information about their adherence to SOPs when providing diagnoses, treatments, and relevant treatment information.

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