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A Legal Comparison of Informed Consent and a Conceptual Analysis of Doctor Protection in Medical Practice in Indonesia

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ABSTRACT

This study examines the increasing number of patient complaints against doctors, particularly those addressed to the Professional Disciplinary Council, highlighting concerns related to deviations from medical management standards. One key aspect of medical practice is the proper execution of informed consent and informed refusal, which are essential before performing medical procedures. This study conducts a conceptual analysis and legal comparison of informed consent and informed refusal practices across several countries with advanced medical systems. The focus is on understanding the legal frameworks of these countries and how they ensure patient protection through these consents. The paper also explores the potential for medical actions by doctors to be categorized as medical fraud and discusses possible legal approaches for handling such cases. The research utilizes a normative juridical method, analyzing primary, secondary, and tertiary legal materials. It also includes a comparative law study of the Anglo-Saxon and continental European legal systems, along with an exploration of Indonesian law, particularly in the context of the overlap between general law (*jure generali*) and special health law (*jure specialis*) as well as relevant regulations. The findings offer insights into how different legal frameworks address informed consent and refusal, with implications for improving patient safety and legal accountability in medical practice.

INTRODUCTION

In medical law, informed consent is a legal requirement for any medical treatment, where the healthcare provider explains to the patient the risks, benefits, and alternatives of a procedure or intervention (Koch, 2018). The principle is that patients have the right to make choices about whether, when, and by whom medical procedures will be performed. This consent can be given orally, in writing, or nonverbally, as long as the individual understands the treatment or examination; although, in an emergency, informed consent can be ignored.

The history of informed consent is rooted in the development of medical ethics and the recognition of the rights of individuals in medical research and treatment. This concept of medical ethics and recognition of individual rights has experienced dark times, which later resulted in the concept of informed consent as we know it today.

Along with human awareness of basic human rights manifested in Human Rights law whose human values are universally embraced, informed consent is included as a basic human right to determine oneself and to obtain the treatment one prefers.

In the tradition of world health law, it is recognized that informed consent must be carried out in the Netherlands, which is regulated in the *Medisch tuchtrecht*, and in British health law, there is also an emphasis on the importance of informed consent (J. Guwandi, 2007a). Similarly, New Zealand's health law, which emphasises the need for informed consent, is set out in the *Health and Disability Commissioner Act 1994* (Health and Disability Commissioner, 2024).

Informed consent in Indonesian law is regulated by several laws both in health law, such as Law No. 17 of 2023 concerning Health, Government Regulation No. 28 of 2024 concerning Implementation Regulations of Law No. 17 of 2023 concerning Health, and Regulation of the Minister of Health No. 3 of 2025 concerning the Enforcement of Discipline of Medical Personnel and Health Workers.

Informed consent is also regulated in other laws, such as article 25 of the *Deklarasi Universal Hak Asasi Manusia* (*DUHAM*), Law No. 11 of 2008 concerning Information and Electronic Transactions, articles 1313, 1320, 1338 of the Civil Code, Regulation of the Minister of Health No. 290 of 2008 concerning Approval of Medical Measures, Indonesian Medical Code of Ethics (*KODEKI*), and Supreme Court Decisions No. 25 K/Pdt.Sus/2009 and No. 204 K/Pdt.Sus/2012—rules that strengthen the need for informed consent.

Since countries in the world, including Indonesia, have implemented informed consent as a requirement for doctor–patient relationships, informed consent has become a requirement in the international legal tradition that must be carried out in both the continental European and Anglo-Saxon legal traditions.

In addition to making informed consent, *informed refusal* is also required. *Informed refusal* is a concept related to the patient's right to refuse medical treatment after receiving adequate information about the diagnosis, prognosis, procedure, risks, benefits, and alternatives to be performed.

The gap between informed consent and *informed refusal* lies in the decision-making process regarding the patient's medical care. Informed consent occurs when a patient consents to a medical procedure or intervention; on the other hand, *informed refusal* refers to the patient's decision to refuse a particular treatment after being provided with all the necessary information (Bester et al., 2016).

The fundamental difference from the law of engagement is that informed consent is created between doctor and patient on what the doctor will do in medical action, where both legal subjects are capable of making a legal commitment. In *informed refusal*, the patient as one of the legal subjects rejects the doctor-patient relationship's efforts to carry out the medical plan, so there is no agreement and legal obligation between doctor and patient (Irvani Imbiri & Wahyu Andrianto, 2023).

Therefore, if such a conflict occurs, the doctor must respect the patient's refusal by providing an alternative treatment that the patient can agree to or, under certain conditions, by not taking any medical action against the patient, on the condition that the patient understands the medical and legal consequences and is responsible for the refusal.

Informed refusal of the patient is closely related to the patient's conflict of beliefs about treatment, the cost of treatment, the risk of treatment, or the consideration of other alternative treatment preferences that the patient and their family are considering. In this situation, the doctor must give the patient autonomy to make their own choice.

When a patient refuses, the doctor is obliged to make clear and complete documentation of the patient's refusal. It often happens that doctors ignore documentation of the patient's refusal, which can lead to medical disputes. Documentation carried out by doctors in *informed refusal* situations will be useful for legal protection.

Informed consent and *informed refusal* in certain conditions may not be required by the doctor. In Indonesian civil law, in the situation of an incompetent patient according to the category of articles 433, 1330 of the Civil Code—so that they cannot communicate, are cognitively incompetent, or are underage—and in health law article 293 paragraphs (7), (8), (9) Law No. 17 of 2023 concerning Health, where the patient is incompetent, there is no family representing the patient, and the emergency room, informed consent and *informed refusal* are not required by a doctor in performing medical procedures.

Another article that overrides informed consent is article 295 paragraph (1), which explains that government action programs require approval, but with a note in paragraph 2 stating that actions must still be informed to the people who receive health services.

In the field of health, there are three aspects that doctors must adhere to in practice: ethics, discipline, and law (J. Guwandi, 2007a). The rise of medical disputes in Indonesia often stems from doctors not carrying out informed consent and informed refusal with the correct procedures, which may result in ethics, discipline, and legal violations.

Article 308 of Law No. 17 of 2023 concerning Health and Government Regulation No. 28 of 2024 concerning Implementation Regulations of Law No. 17 of 2023 concerning Health also state that medical disputes must receive the recommendation of the Assembly, which is temporarily mandated to the Professional Disciplinary Council. One of the evaluations carried out by the Panel before issuing recommendations regarding medical disputes is to examine whether or not there is informed consent and *informed refusal*. If both have been managed properly by the doctor, it will bring benefits in medical disputes.

From the facts of the trial, the completeness of making informed consent and *informed refusal* in accordance with the correct procedure benefits doctors, where this documentation can form the *ratio decidendi* (reason for the judge's consideration) and *ratio legis* (common sense, or reason/reason which is the basis) for the panel judges in assessing disputes.

In civil law, the therapeutic transactions of doctor and patient must meet the principles of legality, balance, timeliness, good faith, honesty, prudence, openness, human rights, and autonomy of the patient. These principles are what doctors must implement in practice. Evidence in medical civil law, after informed consent and *informed refusal* are documented, can be used as evidence at trial.

Considering the importance of documenting informed consent and *informed refusal*, if the hospital or health service agency does not provide proper documentation, it is highly recommended for doctors to take the initiative to document independently to protect themselves from legal threats that may arise.

Medical fraud is something that must be avoided in medical practice when providing treatment, carrying out medical intervention actions, and other treatment efforts. Medical fraud in developed countries and in Indonesia today is a serious matter that has become a legal problem in the medical world.

Medical fraud refers to fraudulent or misleading practices in health services to gain financial compensation by deceitful means in order to obtain a favorable position for the perpetrator. Medical fraud can consist of incorrect or deliberately misleading information, claims, or documentation in medicine, medical services, or the imposition of medical costs. Medical fraud often occurs at various levels in the healthcare system, including doctors, insurance companies, patients, and even in government programs.

It can thus be concluded that informed consent, *informed refusal*, and avoiding medical fraud in the therapeutic relationship between doctor and patient are essential anticipatory measures to protect the doctor's reputation, rights, and finances.

A study by Bester et al. (2016) emphasizes differences between informed consent and *informed refusal* in the context of patient medical decision-making. However, this research is limited regarding practical and legal applications in developing countries, including Indonesia, which have unique legal systems. This study fills the gap by introducing the positive legal context in Indonesia and its influence on medical practice and medical disputes.

Furthermore, research by Irvani Imbiri & Wahyu Andrianto (2023), which analyzes the relationship between informed consent and *informed refusal*, provides insight into patients' rights in refusing medical procedures. However, it has not discussed in depth the impact of the application of these two concepts on the avoidance of medical fraud, especially in Indonesian legal practice. This research fills the gap by highlighting how the implementation of informed consent and *informed refusal* can protect doctors from potential legal disputes, as well as the role of documentation in protecting both the rights of legal and medical professions.

This study aims to identify the legal sources underlying the implementation of informed consent and *informed refusal* in Indonesia and provide legal protection for doctors in carrying out medical practice. The practical benefit of this study is to provide a clear understanding for doctors and healthcare facilities regarding their legal obligations in carrying out informed consent and *informed refusal*, in order to avoid the risk of medical lawsuits. Theoretically, this research contributes to the theory of health law in the doctor–patient relationship and enriches normative legal concepts related to the implementation of law in Indonesian medical practice.

METHODS

The research method used in this study is a *normative juridical* method, which is an approach that aims to analyze applicable legal norms through legal sources such as laws, regulations, legal doctrines, and other literature. This research aims to understand, interpret, and evaluate law based on positive legal texts. According to Assoc. Prof. Rio Christiawan, *normative* research focuses on legal conditions that experience emptiness, ambiguity, or *antinomy* (conflict) that can cause legal uncertainty. The steps in this method include the identification of legal objectives, interpretation of the law, analysis of the linkages between regulations, and evaluation of the impact of the law on individuals and society.

The author also applies the *comparative legal* method, which is an approach that compares legal regulations, systems, or practices between two or more jurisdictions to find similarities, differences, and potential applications in the national legal system. The purpose of this approach, as explained by Rio Christiawan, is to produce recommendations on *normative* legal issues under study. The stages in this method include determining the research topic, describing the comparative legal system, identifying similarities and differences, and applying comparative results to enrich and reflect on the Indonesian legal system. In this context, a comparison is made between the *common law* (United Kingdom and New Zealand) and *civil law* (Netherlands and Indonesia) legal systems.

This research is conducted in the form of a *doctrinal law* study, which analyzes written legal materials (statutes), precedents (*case law*), and doctrines that develop in legal practice. The study also examines the laws produced by legislative, executive, and relevant international law institutions. The research was carried out systematically and hierarchically, using interpretive and textual analysis methods that are qualitative and hermeneutical. This approach aims to build a deep understanding of the legal principles that apply and are relevant to the issues under study, particularly in the field of health law.

The data sources in this study consist of three categories of legal materials. Primary legal materials include the 1945 Constitution, laws, government regulations, presidential regulations, as well as international treaties and conventions that have been ratified by Indonesia. Secondary legal materials include legal literature such as textbooks, monographs, dissertations, theses, and articles from reputable national and international legal journals. Meanwhile, tertiary legal materials are in the form of research aids such as regulatory indexes, court decision catalogs, and legal bibliographies that are used to strengthen and facilitate the search for relevant legal sources.

RESULTS AND DISCUSSION

Legal sources underlying informed consent and informed refusal

General Law

The definition of the Informed Consent Theory, a medical consent that arises after the patient is given an explanation of his illness and the consequences that can be taken into account according to medical science, after which the patient gives permission to be treated. (Supreme Court of the Republic of Indonesia, 1992) In the context of the general contract law of articles 1313 and 1320 of the Civil Code, informed consent arises after there is a consent agreement between the doctor and the patient.

The theory of informed consent is a basic principle of medical ethics and discipline that explains the need to respect the patient's autonomy and the patient's right to make decisions based on his or her own preferences to receive the treatment to be performed on him/her.

From the definition of informed refusal theory, the condition of this theory is that patients obtain adequate information about their medical condition, regarding proposed treatments, risks, benefits, and other treatment alternatives. From this information, it is expected that the patient will voluntarily give approval for medical measures.

The legal principles of informed consent theory in civil law (Burgerlijk Wetboek) include:

i. Both legal subjects are considered capable and have sufficient cognition to make legal agreements, not categorized as incompetent persons in article 1330
Ii. The patient is not in custody as categorized in article 433.

Iii. Agreement on an act that is halal and does not violate the applicable law in Indonesia, in article 1320
Iv. The agreement does not arise from error, coercion or fraud, as described in article 1321.
v. The agreement does not harm a third party as described in article 1340

Failure to carry out informed consent can cause the following legal, ethical and disciplinary consequences:
i. Violation of Patient Rights: Please note that patients have the right to receive clear and comprehensive information about the diagnosis, risks, benefits, and alternatives before they agree to the medical measures to be performed.
Ii. Malpractice: Patients can file a malpractice lawsuit if they feel that the medical procedure performed is not up to the expected standard or does not get proper informed consent before the procedure is performed.
Iii. Physical or Psychological Harm: the patient may postulate physical and/or psychological harm to the medical treatment provided but without his consent.
Iv. Ethical and disciplinary sanctions for doctors.

Meanwhile, informed consent is in a special law (legi specialis) that requires informed consent and its implementation rules are regulated in Law No. 17 of 2023, Government Regulation No. 28 of 2024 concerning Implementing Regulations of Law No. 17 of 2023 concerning Health and Regulation of the Minister of Health No. 3 of 2025 concerning the Enforcement of Discipline of Medical Personnel and Health Workers
In order to protect the legal protection of doctors, doctors are required to comply with the following articles, where patients are given the opportunity: Law No. 17 of 2023 concerning Health., 2025)
i. Article 4 (f) is about determining the health services that he needs independently and responsibly.
Ii. Article 4 (h) accepts or rejects part or all of the relief measures that will be given to him after receiving and understanding the information about the action in full.
Iii. Article 4 (j) obtains information about his/her health data, including data on actions and treatments that his/her has or will receive from medical personnel and/or health personnel.
Iv. Article 293 (1 to 12) the patient receives a medical explanation and approval of the health service action that must be taken.
v. Article 274 letter b about the patient's consent to the action to be given.
Vi. Article 276 letter b on adequate medical explanation.
Vii. Article 276 letter d concerning patient approval or rejection except in the context of the prevention of infectious diseases and the management of KLB or Outbreaks;

In addition to informed consent, there is a so-called negative informed consent. Negative informed consent is an agreement between a patient's doctor that results in an agreement that is unlawful, for example, if the doctor issues and states information that is not in accordance with the patient's health condition, so that it can be threatened with punishment under article 267 paragraphs (1) and (3) of the Criminal Code or article 395 paragraph (1) of the 2023 Criminal Code.

Another example is the agreement between the doctor and the patient in the abortion attempt, where the agreement to carry out this abortion is prohibited in several laws, namely; Article 60, PS

428 (1a) (2) (3), PS 429 paragraph (1) (2) of Law No. 17 of 2023 concerning Health, article 348 of the Criminal Code or article 409, 463 paragraph (1), 464 paragraph (1a), (2), (3), article 465 paragraph (1) (2) of the 2023 Criminal Code, which brings criminal charges for both the doctor and the patient, However, if it turns out that the pregnancy that arises is the result of rape and an indication of a medical emergency as mandated in Article 429 (3), then it is not punishable. (Government Regulation Number 28 of 2024 concerning Implementation Regulations of Law Number 17 of 2023 concerning Health, 2024)

Special positive law

In the second half of 2023, the government passed a new Health Law known as Law No. 17 of 2023 concerning Health. The passage of this law is legally referred to as omnimbus. Omnimbus law is defined as a rule that consists of many contents, (Rio Christiawan, 2022) so this new rule contains a lot of other rules contained in it.

With the passage of Law No. 17 on Health 2023, this Law repeals 10 other laws, namely:

i. Law No. 4 of 1984 concerning Infectious Disease Outbreaks
Ii. Law No. 29 of 2004 concerning Medical Practice
Iii. Law No. 36 of 2009 concerning Health
Iv. Law No. 44 of 2009 concerning Hospitals
v. Law No. 20 of 2013 concerning Medical Education
Vi. Law No. 18 of 2014 concerning Mental Health
Vii. Law No. 36 of 2014 concerning Health
Viii. Law No. 38 of 2014 concerning Nursing
Ix. Law No. 6 of 2018 concerning Health Quarantine
x. Law No. 4 of 2019 concerning Midwifery.

Therefore, Law No. 17 concerning Health 2023 is named as an omnibus Law in the health sector, which repeals the ten Laws into one Law No. 17 of 2023 concerning Health, whose content includes the ten old laws. In addition, the implementing regulations are regulated in Government Regulation No. 28 of 2023 concerning Implementation Regulations of Law No. 17 of 2023 concerning Health and Regulation of the Minister of Health No. 3 of 2025 concerning the Enforcement of Discipline of Medical Personnel and Health Workers.

For the record, medical law is a law that has characteristics and specificities. (Rio Christiawan, 2021) So this law is sui generis, the meaning of the law can only be understood by the community in it, unlike the common law. Therefore, legal and medical practitioners want a special medical court or at least strengthen the norms of the medical council's recommendations as a recommendation to determine whether or not there is medical malpractice.

This is understandable given the sui generis nature of health law, where the judgment of medical actions carried out is very complex, difficult and medically technical. The doctor's concern about the general court who does not have a medical background, although supported by expert witnesses, is worried that it is difficult to digest complex and difficult medical technical matters.

Health law generally regulates: the legal subjects of the obligations and responsibilities of health workers including; government, doctors, patients, nurses, roles of pharmaceutical services, healthcare institutions, healthcare practices, medical licensing and medical ethics.

Broadly speaking, health law explains:

i. The role of the government as a regulator in the health sector.
Ii. Rights and Obligations of doctors.
Iii. Patient Rights and Obligations.
Iv. Medical research involving human subjects.
v. Medical practice licensing.
Vi. Safety of medical products
Vii. Quarantine, unusual events and outbreaks
Viii. Human Resources
Ix. Medical Technology
x. Medical information service system

Medical Ethics: Such as healthcare, patient confidentiality, conflicts of interest, impact of technology in the field of health and medical research.

The concept of informed refusal

Informed refusal is a patient's right that is protected by law. The idea of informed refusal is a basic human right or more commonly known as a human right starting from an idea that focuses on human beings as an individual in achieving the main goal of human life (Hermien Hadiati Koeswadji, 1998) and basic human rights initially only concern the individual. (Moh. Hatta, 2013)

Based on the above idea, human beings are free individuals who have the right to determine themselves (autonomous) in accordance with the main purpose of their lives. Therefore, respect for patients as individuals who can determine themselves must be respected in accordance with their human rights without coercion in accordance with article 1321 of the Civil Code.

The right to refuse to receive medical procedures by patients is protected in article 4 (h) and article 276 letter d of Law No. 17 of 2023 concerning Health. In this article, it is stated that patients have the right to refuse or agree to the medical treatment they will receive, except in the context of infectious diseases or outbreaks. (Law Number 17 of 2023 concerning Health, 2023)

The conditions that can be implemented informed refusal are that the patient in making decisions that can be considered, must be given complete, understandable information, given proposed treatment options, potential risks, benefits, and alternatives that may be implemented by the doctor.

The patient's refusal in informed refusal brings legal consequences to the patient who refuses the refusal, as the refusal of medical action is the patient's responsibility. (Irvani Imbiri & Wahyu Andrianto, 2023) However, the doctor-patient relationship is not broken and doctors are obliged to provide alternative treatment that is preferred by the patient and still give their best efforts. J. Guwandi in his book revealed that the procedure for refusal of medical action by patients can be used by doctors to protect themselves, with the following procedures:

i. Provision of information by the doctor regarding the medical measures taken.
Ii. The patient stated that he refused to be carried out by the doctor for him.
Iii. The doctor is obliged to provide information about the consequences and risks that will occur and that the patient will bear if he refuses such medical treatment.
Iv. If the patient still remains in his or her stance to refuse the medical treatment to be given, the doctor has the right to ask the patient to fill out and sign the refusal letter.

v. If the patient is not willing to sign the rejection letter then the doctor can record the event in the patient's medical records.
Vi. The record contains that the patient still refuses to undergo medical treatment and refuses to sign the refusal letter that has been given.

The concept of informed consent and informed refusal in various countries

Dutch law regulated in Medisch tuchtrecht provides the principle of informed consent that must be followed by doctors. (F. A. G. Wood, 2006) Medicsh tuchrecht in the medical contract section states that doctors are legally and ethically obliged to inform patients about the nature, goals, benefits, risks, and alternative medical treatments expressed by doctors.

The purpose of Informed consent in general in the world of international medicine is that physicians should also communicate medical information in a caring and compassionate way. If these requirements are met, the clinician-patient relationship will be founded on trust and alliance. (Falagas et al., 2009) From the above quote, the purpose of informed consent is to obtain/find trust and cooperation between doctors and patients.

Informed consent in New Zealand is a legal right and moral right (De Luca, 2003) as regulated in the Health and Disability Commissioner Act 1994 and the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996. The Health and Disability Commissioner Act 1994 mandates the right of patients to access health services, with an emphasis on comprehensive information received by patients regarding the health services to be provided by doctors.

In the UK, informed consent is an important principle in medical care and research. This requires voluntary and informed consent from the patient who has the capacity to give consent, is legitimate, if the participant/patient is informed, is free and can withdraw at any time. (NHS England, 2023)

From the comparison of informed consent in several countries and Indonesia, it can be drawn the following common principles of informed consent theory:

i. Informed consent requires patients to have the freedom to make decisions voluntarily and without coercion.
Ii. Open communication between doctors and patients regarding planned medical information, treatment methods, risks, impacts and alternative treatments.
Iii. Providing clear and comprehensive information to patients regarding their medical condition. The doctor must be sure that the patient understands the course of action.
Iv. A joint doctor-patient decision that collaboratively respects the patient's values, preferences and priorities as a priority.
v. Document this informed consent agreement, both from the results of discussion, development, patient rejection and recording of medical records, which is the accountability and transparency of the doctor.

From this equation, it can be concluded that its implementation in Indonesia has followed international standards and is in accordance with the tradition of international health law.

Efforts to avoid medical fraud in various legal perspectives in Indonesia.

Some actions that can be categorized as potential medical fraud: (dr. Ika Komar Dhanudibroto, Sp.JP (K), 2025a)

a) Not doing informed consent and convincing that there is no informed refusal.
b) If there is an informed refusal from the patient, steps must be taken in accordance with the procedure.
c) The doctor must be sure of the patient's understanding of the action to be taken and its side effects, including the possibility that the patient will become disabled or not return to normal as before the medical procedure was performed.
d) Not making a patient's health certificate that is not in accordance with the patient's health condition can be threatened with criminal penalties of the Criminal Code Ps. 267 (1) or ps 395 (1) of the 2023 Criminal Code.
e) The obligation for doctors to make medical records and to store and maintain medical records is mandated in article 296 (1) (3) (4) and (5) of Law No. 17 of 2023 concerning Health.
f) False documentation: doctors falsify medical records, test results, or other documentation to support false claims or to defraud patients, insurance companies, or other regulatory bodies, as provided for in articles 263 (1) and (2) of the Criminal Code or article 498 of the Criminal Code of 2023.
g) Prescription fraud: In this case a doctor knowingly prescribes an unnecessary drug, falsifies a prescription, or engages in illegal activities related to a particular substance, which is regulated in article 263 (1) and (2) of the Criminal Code.
h) Identity Theft: Medical fraud such as the theft or misuse of a patient's personal information, such as insurance details or medical records, to fraudulently obtain medical services or prescription drugs, this is regulated in article 67 paragraphs (1) and (3) regulated in Law Number 27 of 2022 concerning Personal Data Protection (PDP Law).
i) Potential criminal threats regarding the confidentiality of patients' health, regarding examinations, care and actions that have been taken, which are regulated in ps 274 (c and d), ps 296 (5), ps 301 (1) of Law No. 17 of 2023 concerning Health.
j) Obstructing the patient's right to access medical records: article 4 (i), article. 276 (e) and article 297 (2) of Law No. 17 of 2023 concerning Health.
k) Obstructing the rights of persons in article 4 (1) letters a to k. Law No. 17 of 2023 concerning Health.
l) Avoid practicing medicine which is categorized as an error in Indonesian criminal and civil law.

Avoiding Guilt and Medical Errors

Indonesia's current health law is positively correlated with universal health law regarding culpa and medical error. Culpa can be the basis for criminal liability if the perpetrator is deemed not to meet the reasonable scientific standards of a doctor acting in good faith. There are several types of culpa that the author researches that can be categorized as having an impact on legal consequences for doctors, including:

i. Negligence in terms of not seeing the future that should be considered necessary, in this case the doctor does not imagine exactly or does not imagine at all what will happen from his actions.
Ii. Culpa in the case of lack of necessary caution, in this case the doctor is not obedient in carrying out the proper and correct standard operating procedure/medical guide line. (Topo Santoso, 2023)

Some experts also divide culpa into categories of understanding: conscious forgetfulness (bewuste culpa) and unconscious forgetfulness (onbewuste culpa). In bewuste culpa, the perpetrator is aware of the possibilities that can arise but he is convinced that the possibilities that arise can be overcome. For example, an interventionist doctor in cardiology inserts a large number of stents, he realizes that there will be a possibility of complications such as accute thrombosis or possible complications but he is confident that he is able to overcome the possibility that it does not happen, but then what is thought happens that the doctor previously believed could be overcome.

In unconscious forgetfulness (onbewuste culpa), the doctor does not imagine the possibility that will happen, even though the perpetrator should have imagined the impact arising from his actions. So it can be concluded that the doctor's "ignorance" of the impact arising from his actions can give rise to criminal threats. This second type of culpa is related to the understanding of the risks of an action taken by one doctor with another, the impact is already known while the other is not understood the risk.

Medical error must be defined in the sense of a process that fails and that is clearly related to the consequences of negative outcomes. The errors that arise cannot be viewed from a legal point of view but must still be viewed from the scope of medicine and by the medical profession, therefore this medical error is in the realm of gray. (J. Guwandi, 2007b)

Failure of therapy can be in the form of:

i. Surgical procedures such as complications, medical accidents, allergies from anesthesia, risky surgeries, and the patient's condition is full of risks.
Ii. Medication administration: under-use of medication, overuse of medication, inappropriate medication, undesirable drug reactions and no medication that can be used in patient therapy. (J. Guwandi, 2007b)

The author divides medical errors into two categories, the first medical error caused by doctors and second, by medical equipment. In medical errors caused by doctor's therapy, it can be categorized as onbewuste culpa, because the doctor should be able to imagine the impact arising from the therapy he provides.

In contrast to the malfunction of the health equipment system or malfunction in the equipment during the action, in this situation it cannot be categorized as culpa because such a situation cannot be held accountable to the doctor, but the responsibility of the health service agency. The elements of the element of culpa, subjective and objective elements carried out by the doctor cannot be fulfilled.

Perfect Informed Consent and Informed Refusal

The perfection of informed consent and informed refusal has at least been legal protection for doctors because it is protected by general law (jure generali) articles 433, 1320, 1321 and 1330 of the Civil Code, articles 304, 359, 360 (Criminal Code, n.d.), article 474, article 475 (1) (2) of the 2023 Criminal Code, Regulation of the Minister of Health No. 290 of 2008 concerning the Approval of Medical Measures, article 25 of the Universal Declaration of Human Rights (DUHAM).

Special law (jure specialis) article 440 paragraph (1) (2) of Law No. 17 of 2023 concerning health, and will receive protection from the threat of ethical sanctions from the Indonesian Medical Code of Ethics, discipline from the Doctor Disciplinary Council.

Prevention and Solution

Avoiding Assault and Battery Actions

In Indonesian health law, assault and battery are also known as two different acts, assault in medical law is, the crime of treatment without informed consent, doctors will be prosecuted if they treat patients without consent for example surgeons perform surgical operations on patients without consent (Sentencing Council, 2018) or doctors who perform dangerous acts, for example cardiac intervention specialists perform dangerous intervention actions such as ignoring the treatment of previous patients who took blood thinners that caused bleeding, so they could be threatened with punishment. (dr. Ika Komar Dhanudibroto, Sp.JP (K), 2025b)

Battery is a deliberate unlawful act that involves unlawful, dangerous, or violating the patient's dignity by a doctor (Legal Match, 2020) in a conscious or unconscious state of the patient, and abandoning the patient. An example of a case that has occurred in Indonesia is a nurse or doctor who physically abused a female patient who was in an unconscious and abandoned condition so that he could be threatened with articles 290 paragraph (1), 294 (2) number 2 of the Criminal Code or 415 (a), 418 (a) (b), 423, 428 paragraphs (10, (2), (3) and 431 of the 2023 Criminal Code. (2023 Law on the Criminal Code, 2023)

The context of Battery also includes cases where doctors perform medical procedures that are different from those that have been approved by the patient, which has the potential to give rise to the threat of lawsuits under articles 1365 and 1371 of the BW. (Civil Code, n.d.)

Countermeasures and Ways Out

In an effort to overcome and make a way out of the shackles of law, ethical sanctions and discipline, doctors must seek to understand what is required in their practice by: upgrading medical knowledge, due to new scientific findings that are developing rapidly. Unwillingness to improve oneself can have an impact, medical measures are not in accordance with the updating of medical measures.

Ensuring that informed consent and informed refusal have been carried out perfectly, as well as carrying out medical actions appropriately and correctly in accordance with standard operating procedures such as in the medical guide line, making medical records, storing them and keeping them confidential for means of communication, information between doctors and patients, administrative functions and legal functions because medical records are evidence in the event of disagreements/demands from patients, and as legal protection for doctors. (Hermien Hadiati Koeswadji, 1998)

Granting patients access to obtain medical records as required by law. Consult with other doctors who better understand the patient's disease, in order to enforce the diagnosis and prognosis of medical action in the patient.

Understand the legal rules related to medical practice, such as Law No. 17 of 2023 concerning Health, other positive laws and external factors where this factor focuses on the globalization orientation of criminal law where the development of theory and practice of one country can affect other countries. (Heliany et al., 2023).

CONCLUSION

This research shows that the obligation to carry out *informed consent* has been regulated in various international rules such as the *Declaration of Human Rights*, as well as in positive laws and

health laws in various countries, including Indonesia, the Netherlands, New Zealand, and the United Kingdom. *Informed consent* has become a medical legal tradition that doctors must adhere to in their practice.

In addition, to avoid medical dispute lawsuits, doctors need to carry out legal protection by ensuring that *informed consent* and *informed refusal* are conducted correctly, avoiding negative *informed consent*, and steering clear of the practice of medical fraud, *culpa*, assault, and battery. Doctors are also expected to follow the applicable medical guidelines in the implementation of health services.

The suggestion from this study is that hospitals and other health facilities provide more intensive training on the implementation of *informed consent* and *informed refusal* for medical personnel, as well as develop a good documentation system to minimize legal risks that can arise due to negligence in the implementation of medical procedures.

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