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The Deviation Of Informed Consent Practices: Understanding The Inspanning Verbintenis And Legal Aspects

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Abstrak

This research has the main purpose to determine the legal protection of patients on the deviation of informed consent practices concerned in Inspanning Verbintenis and legal aspects. This article emphasizes normative juridical research with descriptive research specifications approach to understand the deviation that happened in medical field and the importance of Inspanning Verbintenis. This study used secondary data obtained from the literature and is described systematically from the Indonesian law, books, National and International journals, news, and previous research related to informed consent practices and the legal aspect. Previous research found that in specific cased a healthy patient, plastic surgery performed for aesthetic reasons is a Resultaat Verbintenis because it concentrates on the result in accordance with a certain arrangement made at the beginning between the doctor and the patient, namely the actual outcomes as anticipated. Hence, to avoid the deviation and missed conception, the Indonesian regulation system requires legal protection clearly. The planned consequence of the medical action may not be realized due to either Inspanning Verbintenis or Resultaat Verbintenis. Therefore, the goal of informed consent is to safeguard the patient against all medical procedures carried out without their knowledge.

Keywords: *Deviation, Inspanning Verbintenis, Resultaat Verbintenis.*

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1. Introduction

Health is very important and is the most valuable human asset because without health, humans cannot move and work. Health as a basic human need is a right for every citizen. This is the mandate of the 1945 Constitution of the Republic of Indonesia (1945 Constitution) Article 28H Paragraph (1) which is emphasized in the Law of the Republic of Indonesia Number 17 of 2023 Concerning Health (UU No. 17 of 2023) Article 4 J and K that, "obtain information about his/her health data, including actions and treatment that he or she has received or will receive from medical personnel and/or health workers; and get protection from health risks".[1]

[1] "Undang-Undang Kesehatan," UU Nomor 17 Tahun 2023.

The deviation of informed consent practices refers to situations where the process of obtaining informed consent, particularly in medical or research settings, does not adhere to established ethical and legal standards. Informed consent is a fundamental principle in medical ethics and research ethics, and it involves ensuring that individuals fully understand the potential risks, benefits, and alternatives of a medical procedure or research study before they agree to participate. There are some common deviations from proper informed consent practices: 1. Lack of Information: 2. Coercion: 3. Limited Comprehension: 4. Lack of Capacity: 5. Deception: 6. Failure to Disclose Conflicts of Interest: 7. Inadequate Documentation: 8. Research Without Consent: 9. Proxy Consent Issues: 10. Failure to Reconfirm Consent.[2]

Deviations occur when this reconfirmation is neglected. Deviation from informed consent practices is considered a serious ethical violation and may have legal consequences. To ensure the protection of individuals' autonomy and well-being, it is essential for healthcare providers, researchers, and institutions to strictly adhere to established informed consent guidelines and principles. This helps maintain trust and transparency in healthcare and research settings.

To prosper the nation, one of the most important factors is health development. Health development is aimed at increasing the ability to live a healthy life for every human being to create an optimal degree of health. Providing health services, there are several components that play a role, such as medical and health workers, health facilities, and patients. Medical personnel and health workers are parties who provide health services to cure certain diseases, while patients are parties who need health services.[3]

Doctors in terms of carrying out medical actions, namely an action that is diagnostic/therapeutic (determines the type of disease/cure) carried out on patients, where doctors try their best to carry out their duties and obligations to provide healing assistance for patients based on knowledge, abilities, and competencies it has. Meanwhile, based on Article 1 point 1 of Law Number 29 of 2004 concerning Medical Practice (Law No. 29 of 2004) the definition of a doctor is one of the main components of providing health services to the public who is permitted to carry out medical procedures because of their expertise in

[2]Bhatt Arun, "Protocol Deviation and Violation. Perspectives in Clinical Research" 3 (2012): 117, https://doi.org/10.4103/2229-3485.100663.
[3]Grenaldo Ginting, "Patents to Obtain Health Services in Hospitals From a Human Rights Viewpoint", UNSRAT Repository Vol. II No. 2 January-March 2014, Manado: Faculty of Law, University of Sam Ratulangi, p. 71-72.

disease and treatment. The series of activities carried out by doctors and dentists for patients in carrying out health efforts is called medical practice. Next based on Article 1 point 10 of Law no. 29 of 2004 the definition of a patient is any person who consults about his health problems to obtain the necessary health services either directly or indirectly from a doctor or dentist.

A Therapeutic Agreement is an agreement formed because of the legal relationship between a doctor and a patient. Legal relations are relationships between legal subjects or between legal subjects and legal objects, which are regulated by law. The conditions for a legal relationship to occur are a legal basis, namely legal regulations that regulate the relationship and the existence of a legal event, namely an event that brings consequences regulated by law.[4]

Before a doctor performs a medical procedure, the doctor and patient must first enter into an agreement that creates a legal commitment. This agreement or understanding between patient and doctor only exists in the medical industry for patients who need the doctor's expertise to cure their illness and of course the actions taken must be according to professional standards. In addition to patients who really need a doctor's skills and expertise to perform medical procedures, you should know that medical procedures are divided into 2 (two) parts, including:

1. *Inspanning verbintenis*
   Is an effort carried out by a doctor with all his might in accordance with the expertise and skills he has and in this case the actions carried out are in accordance with professional standards. In this case, it is only carried out by doctors whose fields usually handle critical or emergency conditions, such as specialist doctors or surgeons. So, it cannot guarantee that the patient will definitely recover.[5]
2. *Resultaats verbintenis*
   This is a medical procedure performed on the basis of promising results. Although doctors take an oath not to tell or promise anything to anyone, in reality there are still those who give real results.[6]

[4] Agus Gede Sutamaya, Dey Ravena, and Chepi Ali Firman Zakaria, "Informed Consent As A Therapeutic Agreement In Health Services: Persetujuan Tindakan Kedokteran Sebagai Wujud Perjanjian Terapeutik Dalam Upaya Pelayanan Kesehatan," *Interdental Jurnal Kedokteran Gigi (IJKG)* 18, no. 1 (June 25, 2022): 7–13, https://doi.org/10.46862/interdental.v18i1.4306.
[5] Fayuthika Alifia Kirana Sumeru and Hanafi Tanawijaya, "Inspanning Verbintenis Dalam Tindakan Medis Yang Dikategorikan Sebagai Tindakan Malpraktek," *Jurnal Hukum Adigama* 5, no. 2 (Desember 2022): 490–520.
[6] *Ibid*

Consent to medical procedures is the legal meaning of mutual agreement governed by Article 1320 BW. The conditions for the validity of an agreement specified in Article 1320 of the Civil Code, in the matter of therapeutic agreements, are: The agreement between the doctor and the patient, the agreement in the treatment agreement for certain medical actions must be called informed consent, specifically the patient's consent to the action Medical care is performed after it has been explained what and how the medical action will be performed.

The relationship between doctor and patient arises when the patient first comes with the intention of seeking help. From then on, what is meant by informed consent is the arrival of the patient, which means that the patient has given confidence to doctors and dentists, and automatically instills an attitude aimed at prioritizing the health of their patients. The relationship between doctor and patient is a special bond, but the patient has the right to decide whether the doctor may continue the relationship. It depends on the information the patient gets about the doctor's actions.[7] Consent given by the patient, or his family based on information and explanation regarding the medical action performed on the patient is called informed consent. Informed consent itself is very closely related to medical action, which means it is a transaction to determine or attempt to find the most appropriate therapy for the patient which is carried out by a doctor.[8] The definition of informed consent or medical approval can be seen in Regulation of the Minister of Health Number 290/MENKES/PER/III/2008 concerning Approval of Medical Treatment, Article 1 Number 1 which reads;

"*Consent to medical action/informed consent is consent given by the patient or his family on the basis of an explanation regarding the medical action to be performed on the patient*".

The essence of *informed consent* contains 2 (two) essential elements, namely: first, information provided by the doctor, and second, the consent given by the patient.[9] As for the opinion of Hendrojono regarding the meaning of informed consent, namely;

[7]Indra Setyadi Rahim, "Legal Protection of Patients in the Implementation of Informed Consent," *Lex et Societatis* 4, no. 4 (April 2016): 4.
[8] Vicia Sacharissa, "Legal Consequences of The Absense of Informed Consent in Therapeutic Transactions," *Mulawarman Law Review*, June 22, 2020, 1–17, https://doi.org/10.30872/mulrev.v5i1.296.
[9]Endang Kusuma Astuti, "Legal Relationship Between Doctors And Patients In Medical Service Efforts," *Diponegoro Law Review* 2, no. 1 (April 28, 2017): 123, https://doi.org/10.14710/dilrev.2.1.2017.123-140.

"What needs to be underlined from understanding informed consent is the consent of the new patient is given when the patient has received an explanation from the doctor. The consent is in the form of express consent, namely by being made in writing or secretly from the patient.[10]

In fact, the patient or the patient's family must get clear information about the medical actions performed by the doctor. Next doctors who wish to perform medical or surgical procedures must first provide information regarding the actions to be performed, what are the benefits, what are the risks, other alternatives (if any), and what might happen if the medical or surgical procedures are not performed. This information must be given clearly in simple language that the patient can understand and takes into account his educational and intellectual level.[11] In this case the doctor as the provider of health services must carry out all his duties and obligations for the benefit of the patient with all the competencies, responsibilities and existing codes of ethics, while the patient as the recipient of health services must comply with everything suggested by the doctor for the implementation of his recovery. The need to obtain this information makes *informed consent* as an absolute right for the patient and/or the patient's family. Furthermore, in terms of health, there are three patient rights that must be considered, namely the right to obtain health services *the right to health care*, the right to obtain information *the right to information*, and the right to participate in determining *the right to determination*.[12]

Based on Article 45 Paragraph (3) Law no. 29 of 2004 determines a complete explanation for patients that includes at least:

1. Diagnosis and procedures for medical action;
2. The purpose of the medical action performed;
3. Other alternative actions and risks;
4. Risks and compilations that may occur, and;
5. Prognosis of the actions taken.

[10]Iip Verra Selvia, Arief Suryono, and Sapto Hermawan, "The Legal Consequences of Informed Consent for Doctors and Patients in Theurapeutic Agreements," *Aloha International Journal of Health Advancement (AIJHA)* 3, no. 6 (June 29, 2020), https://doi.org/10.33846/aijha30601.

[11]Tri Setiawan, "Tri Setiawan, 2009, Thesis: 'Informed Consent Between Doctors and Patients in Performing Medical Actions at the Sragen Regional General Hospital' Surakarta: Muhammadiyah University Surakarta, p. 2." (Surakarta, Muhammadiyah University Surakarta, 2009).

[12]Dian Ety Mayasari, "Tinjauan Yuridis Tentang Informed Consent Sebagai Hak Pasien Dan Kewajiban Dokter," *Varia Justicia* 13, no. 2 (October 30, 2017): 93–102, https://doi.org/10.31603/variajusticia.v13i2.1883.

The requirement for patient consent for actions performed by doctors is contained in Law no. 29 of 2004 Article 45 which contains every action of medicine or dentistry to be performed by a doctor or dentist on a patient must obtain approval. Stating that the consent referred to in paragraph (1) is given after the patient has received a complete explanation.

Exceptions to this rule are contained in the Regulation of the Minister of Health Number 290/MENKES/PER/III/2008 concerning Approval of Medical Treatment (PERMENKES No. 290 of 2008), Article 4 Paragraph (1) reads:

"*In an emergency situation to save the patient's life and/or prevent disability, approval of medical action is not required.*"

As for the patient can cancel or withdraw the consent given before the start of the medical action as stipulated in Article 5 PERMENKENS No. 290 of 2008 namely:

Consent to medical action can be canceled or withdrawn by those who give consent before the start of the action. Cancellation of approval for medical treatment as referred to in Paragraph (1) must be made in writing by the person giving the approval. All consequences arising from the cancellation of the approval for medical treatment as referred to in Paragraphs (1) and (2) shall be the responsibility of the person who cancels the agreement.Furthermore, based on Article 15 PERMENKES No. 290 of 2008 contains regarding:

"*In the event that a medical action must be carried out in accordance with a government program where the medical action is for the benefit of the public at large, approval for medical action is not required.*"

Patients can also refuse or disagree with medical procedures as stipulated in Article 16 PERMENKES No. 290 of 2008 concerning:

(1) Rejection of medical action can be made by the patient and/or his/her closest family after receiving an explanation regarding the medical action to be performed.
(2) Rejection of medical action as meant in paragraph (1) must be made in writing.

This refusal is known as informed refusal. This can be justified based on the human rights of a patient to determine what to do with him. Furthermore, for informed refusal, the patient must understand all the consequences if it happens to him that might arise because of the refusal and of course the doctor

cannot be blamed for the consequences of the refusal. Refusal is done by signing by the patient on the Medical Action Refusal sheet.[13]

This study's originality is based on a number of earlier studies on related subjects, with an emphasis on there needs to be a review in terms of therapeutic agreements, there still needs to be a distinction in performance because engagements in plastic surgery with aesthetic goals are not guaranteed results, but in engagements the results are also a result of maximum effort. In this regard, author examines research conducted by Jannety entitled "Study of Verbintenis Inspanning and Verbintenis Results in the Field of Plastic Surgery for Aesthetic Purposes" In this article, it was concluded that Plastic surgery with aesthetic purposes, in a healthy patient condition, is a verbintenis result because it focuses on the final result in accordance with a special agreement at the beginning between the doctor and the patient, namely the existence of real results as expected. However, this engagement also includes inspanning verbintenis because plastic surgeons are required to give maximum effort according to their competency standards to patients and the final results may not be as predicted at the beginning due to unexpected factors that can occur and influence the results. Aesthetic plastic surgery falls into both types of engagement, namely, inspanning verbintenis and resultaat verbintenis. The plastic surgeon's responsibility for inspanning verbintenis and resultaat verbintenis is in the form of administrative, civil, and even criminal responsibility.

In addition to the research conducted by Jannety, there is another study that discusses informed consent, such as the research conducted by Khasna Fikriya, titled "Analysis of Medical Procedure Consent (Informed Consent) in Preparation for Hospital Accreditation at the Central Surgery Installation of Semarang City Public Hospital." This study examines the importance of informed consent in hospital accreditation preparation. It also found that existing organizational policies and procedures have not been sufficient to ensure doctors' compliance in implementing informed consent concerning accreditation preparation.

Based on the originality as outlined, this article will attempt to provide a legal analysis of two main points, which include: first, the deviation of informed consent practices, second, Inspanning Verbintenis and the legal aspects. From

[13]Adriana Pakendek Adriana Pakendek, "Informed Consent Dalam Pelayanan Kesehatan," *AL-IHKAM: Jurnal Hukum & Pranata Sosial* 5, no. 2 (July 21, 2012): 309–18, https://doi.org/10.19105/al-lhkam.v5i2.296.

the readings and understanding of previous research, there has not been an in-depth study that comprehensively analyzes about the legal protection. Which is a protection given to legal subjects in the form of legal instruments both preventive and repressive in nature, both written and unwritten. legal protection as an illustration of the function of law, namely the concept where law can provide justice, order, certainty, benefit, and peace. In essence, everyone has the right to protection from the law, one of which is the legal protection of patients on informed consent in health services. If one of the legal protections above applies effectively, the patient will get a sense of justice, order, certainty, benefit, and peace.

2. Research Method

This research will be structured using a normative law research type in which the subject matter of the study is law which is conceptualized as a norm or rule that applies in society and becomes a reference for everyone's behavior.[14]In an effort to obtain the data needed to compile legal writing, the specification of analytical prescriptive research will be used, namely studying the purpose of law, the values of justice, the validity of the rule of law, legal concepts, and legal norms.[15]

Data sources that will be used as a basis to support this research use secondary data. Secondary data in legal research can be divided into primary legal materials, secondary legal materials, and tertiary legal materials.[16] The data collection method was carried out by means of library research and documentary studies to obtain primary legal materials and secondary legal materials in the form of laws and regulations, books, articles and journals related to the object of research.

After obtaining the data using the data collection method, then the researcher performs data processing. Data processing is defined as the activity of tidying up the data collected so that it is ready to be used for analysis.[17] Presentation of data is done in the form of narrative text. The data obtained from the results of the research will be analyzed using qualitative normative analysis methods, namely in the form of regular, logical coherent, non-overlapping and effective sentences, then a discussion is carried out.

[14]Abdulkadir Muhammad, Law and Legal Research, Bandung: PT. Image Aditya Bakti. 2004, p. 52.
[15] Peter Mahmud Marzuki, *Legal Research* (Jakarta: Kencana Prenadana Media Group, 2010).
[16] Suratman and Philips, *Legal Research Methods* (Bandung: Alfabeta, 2012).
[17] Bambang Waluyo, *Legal Research in Practice* (Jakarta: Sinar Grafika, 2002).

3. Research Results and Discussion

3.1. The Deviation of Informed Consent Practices

Law is one of the means to regulate, discipline and resolve various problems in people's lives. The function of law in society is to act as a guide or rule for society to act, to provide order in social life. The word "protection" in the Big Indonesian Dictionary comes from the word "protect" which can be defined as guarding, maintaining, caring for, making something intact to avoid harm, while protection is defined as the process of protecting which is carried out by the protector.

The definition of Informed Consent (IC) is regulated in Article 1 point 1 of the Minister of Health Regulation No. 290/MENKES/PER/III/2008 (PERMENKES No. 290 of 2008) states that: "approval of medical action/Informed Consent is consent given by the patient or his family on the basis of an explanation regarding the medical action to be performed on the patient".

Based on research of Gillie Gabay in Israel there is deficiency in implementation of regulatory guidelines that more than half of the participants were asked to sign an IC form without any discussion before proceeding with surgery, violating the principles of informing patients of risks, implications, and identity of the surgeon. Participants described large gaps between the time they arrived and the time they received surgery.[18]

Meanwhile, in Indonesia, therapeutic transactions are developing into problems in several hospitals in the region due to allegations of medical malpractice. Doctors' actions in providing services that deviate from standard service procedures, for example in terms of carrying out operations that do not comply with procedures, negligence in using medical equipment, errors in analyzing diseases, and so on.[19]

Related to the above when these two subjects face each other, the doctor has the right to receive the identity, history and all complaints from the patient, the doctor will receive an identity and information about his health

[18]Indra Setyadi Rahim, "Legal Protection of Patients in the Implementation of Informed Consent," *Lex et Societatis* 4, no. 4 (April 2016): 4.
[19] Guwandi J, *Persetujuan Tindakan Medik : Informed Consent* (Jakarta: Balai Penerbit Fakultas Kedokteran Universitas Indonesia, 1990).

complaints to be used as a basis for determining further action in medical service efforts. After the doctor listens to various complaints from the patient then the doctor planning and analyzing diseases and planning treatment, medical care and procedures that must be given to patients. Doctors can sure to provide therapy and medication as a form of effort to patient recovery.

After the medical records are done properly, the doctor offers approval for medical action (informed consent). Consent to medical procedures. This is done after they received the information from the doctor about medical efforts that could be taken to help them, including obtaining information about all the risks that might occur. Even though in reality it is not necessary to provide information to obtain consent simply, but at least the issue has been legally regulated, so that there is power for both parties to take legal action.

Literally, informed can be interpreted as having been notified, delivered or informed, while consent is the approval given by someone to do something. Thus, informed consent can be interpreted as permission or a statement of agreement from the patient which is given freely, consciously, and rationally, after the patient has received information that is understood from the doctor about his illness.[20] Informed Consent refers to legal regulations that determine the obligations of medical personnel in interactions with patients. In addition to giving sanctions (under certain circumstances) if there is a deviation from what has been determined and the patient's human rights as a human being must still be respected. The patient has the right to refuse to have an action taken against him based on information that has been obtained from the medical personnel concerned.

Certainly, there are several common deviations from proper informed consent practices in medical and research settings. These deviations can compromise the ethical and legal standards surrounding informed consent. Here are some common examples:

1. Insufficient Information: Failing to provide patients or research participants with comprehensive and understandable information about the procedure, treatment, or study, including potential risks, benefits, alternatives, and the purpose of the intervention.

[20] Endang Sutrisno, "LEGAL ASPECT OF DOCTORS' RESPONSIBILITY IN PRESCRIPTION," *Jurnal Ilmu Hukum Sekolah Pascasarjana Universitas Swadaya Gunung Jati* 7, no. 2 (2023): 102, http://dx.doi.org/10.33603/hermeneutika.v7i2.8756.

2. Coercion or Undue Pressure: Pressuring or coercing individuals into providing consent, which may involve emotional manipulation, threats, or promises of benefits.
3. Lack of Capacity: Obtaining consent from individuals who do not have the capacity to understand the information presented due to factors such as cognitive impairment, mental illness, or intoxication.
4. Deception: Providing false or misleading information to individuals to gain their consent, such as misrepresenting the nature of a procedure, or the risks involved.
5. Failure to Obtain Voluntary Consent: Failing to ensure that consent is given voluntarily, without any form of force, pressure, or manipulation.
6. Proxy Consent Issues: In cases where individuals cannot provide consent themselves (e.g., minors or incapacitated adults), obtaining proxy consent without considering the best interests of the person in question.
7. Inadequate Documentation: Not properly documenting the informed consent process, including what information was provided, the individual's understanding, and their voluntary agreement.
8. Research Without Consent: Conducting research on human subjects without obtaining informed consent, particularly in situations involving vulnerable populations or emergencies.
9. Failure to Reconfirm Consent: For ongoing medical procedures or research studies, neglecting to periodically reconfirm consent, especially if there are changes in the procedure or study protocol.
10. Conflict of Interest: Failing to disclose conflicts of interest that may influence the recommendations made during the informed consent process, such as financial interests or personal biases.

Informed consent is a subjective requirement for the realization or implementation of therapeutic transactions that are based on 2 (two) kinds of human rights, namely the right of information to determine one's fate and is the authority of a person to do or not to do so, so that patients have the freedom to use or not use. Informed consent regulations, if carried out properly between doctors and patients, are equally protected by law. But if there is an act outside the regulations that have been made, it is certainly considered a violation of the law. The violation of informed consent has been regulated in Article 19 of PERMENKES No. 290 of 2008 states that doctors who take action without informed consent can be subject to

sanctions in the form of verbal warnings, written warnings up to revocation of practice permits.

Informed consent pursuant to Article 45 Paragraph (1) stipulates that, "Any medical action to be performed by a doctor on a patient must obtain approval". Furthermore, in Article 45 Paragraph (3) relating to the information provided at least includes:

a. Diagnosis and procedures for medical action;

b. The purpose of the medical action performed;

c. Other alternative actions and risks;

d. The risks and complications that may occur; and

e. Prognosis of the actions taken.

The purpose of Informed Consent according to J. Guwandi quoted by Hamim Tohari is:[21]

a. Protect the patient against all medical actions performed without the patient's knowledge; and

b. Providing legal protection to doctors against unexpected and negative consequences, for example against risks of treatment that cannot be avoided even though doctors have tried their best and acted very carefully and thoroughly.

The function of informed consent is divided into 6 (six) parts, namely:[22]

a) Promotion of the right to individual autonomy;
b) Protection of patients and subjects;

c) Prevent fraud or coercion;

d) Causing stimulation to the medical profession to conduct introspection on oneself;

e) Promotion of rational decisions; and

f) Community involvement (in advancing the principle of autonomy as a social value and providing oversight in biomedical investigations.

[21]Hamim Tohari and Akhmad Ismail, "Informed Consent Sirkumsisi Di Puskesmas Waru, Kabupaten Pamekasan, Provinsi Jawa Timur, PERIODE 1 JANUARI – 31 DESEMBER 2013" 5, no. 1 (2016).
[22]*Ibid*

According to Philipus M. Hadjon legal protection is the protection of dignity, dignity and recognition of human rights owned by legal subjects based on legal provisions of arbitrariness. Everyone has the same rights in the health sector. This is guaranteed by Law no. 17 of 2023 concerning Health in Article 4 states that everyone has the right to health and Article 5 paragraph (2) stipulates that everyone has the right to obtain safe, quality and affordable health services. To achieve this, it is necessary for health workers to carry out their obligations in the form of providing health services.

Law No. 17 of 2023 concerning Health implicitly stipulates informed consent in Article 56 paragraph (1) that "Everyone has the right to accept or refuse some or all of the measures of assistance that will be given to him after receiving and understanding complete information about these actions", while health services is one of the efforts to improve the degree of human health, so that in this case doctors and patients have the same important obligations and/or rights in a health service.

The value contained in legal protection is related to the fulfillment of the rights and/or obligations of both parties in health services, namely between recipients of health services and providers of health services or doctors and patients. This health service effort is healing and restoring patient health by way of the government establishing or organizing government hospitals and managing, guiding, assisting, and supervising hospitals established by private bodies.

As for Article 52 of Law no. 29 of 2004 concerning Medical Practice states that patients have the following rights:

1. Get a complete explanation of medical procedures.
2. Ask for the opinion of another doctor or dentist
3. Get services according to medical needs
4. Refuse medical action.
5. Get the contents of the medical record.

Doctors in carrying out the medical profession when they accept patients to cure their illnesses actually have an agreement between the two parties. The doctor's relationship with the patient is referred to as medical approval or informed consent. Article 1 point 1 Permenkes No.

290/Menkes/Per/III/2008 states that informed consent is an agreement given by a patient or family on the basis of an explanation regarding the medical action to be performed on the patient. Informed consent is an agreement/or consent of the patient for medical efforts to be made to help himself, which is accompanied by information about all the risks that may occur.

Informed consent on Permenkes No. 290/Menkes/Per/III/2008 concerning Approval of medical action determines the explanation that must be given by doctors to patients, namely:

1. Diagnosis and procedures for medical action;
2. Purpose of medical action performed;
3. Alternative actions and risks;
4. Risks and complications that may occur;
5. Prognosis of the actions taken; and
6. Estimated financing.

There are 4 known principles of informed consent, namely:

1. The principle of autonomy, which is to protect and enhance individual autonomy, a good relationship between doctors and patients will prevent ignorance that actually hinders the autonomy of patients and their families to decide. Ignorance can come from a lack of information or a lack of understanding.
2. The principle of beneficentia, namely protecting patients and research participants.
3. The principle of non maleficentia, namely preventing harm to patients, especially in patients who are unconscious, children, mentally retarded. In this case the parent or guardian or other person who is legally acceptable to represent the patient and can give consent.
4. The principle of utility, namely increasing the introspective nature of the medical team in carrying out actions that benefit everyone in society, including the health workers themselves.

5. The principle of informed consent that can be implemented will guarantee the running of medical service activities that have scientific value, benefits, justice, humanity, balance as well as protection and safety for patients. Therefore, the effectiveness of patient legal protection on informed consent in health services is reviewed from the implementation of the principles of autonomy, beneficentia, non maleficentia, and utility.

6. Arrangements regarding the principle of informed consent, of course, cannot just run after a rule has been established. There are a number of factors that can affect the effectiveness of patient legal protection on informed consent in health services.

3.2. Inspanning Verbintenis and the Legal Aspects

The presence of law in society aims to integrate and coordinate conflicting interests. In the context of banking law concerning the role of banks in protecting customers during bank liquidation, it is guided by the laws and regulations of the Indonesian government. The law provides customer protection in two ways:

Juridically, the validity of an agreement must be measured based on the criteria provided by law. The conditions for a therapeutic transaction to occur are determined by article 1338 Jo. 1320 of the Civil Code. There are three different kinds of work agreements recognised by the BW, including: a. an agreement to temporarily execute certain services; b. a labour agreement; and c. a work contract agreement. An engagement between the provider and the recipient of medical services emerges from the establishment of a therapeutic connection that has contractual value and is known as verbintenis in civil law. Depending on how an achievement is expressed, verbintenis can be divided into two categories: inspanning verbintenis and resultaat verbintenis. In this context, "inspanning" and "resultaat" are Dutch words that translate to "effort" and "consequence," respectively, while "verbintenis" denotes participation. Given that the outcomes of a medical effort are not something that is exact or can be calculated with certainty (uncertainty), doctors or healthcare facilities are

not required to provide or produce results in accordance with the wishes of patients or their families.[23]

If the conditions If this has been carried out well by both parties then something will happen agreement. In this agreement there are two types of engagement viewed from the agreed performance, namely engagements that must be carried out carefully and with great effort *(inspaning verbintenis)* and engagements that His achievements produce something of his nature it's certain *(resultat verbintenis).*

The Differences between *Inspanning Verbintenis* and *Resultaat Verbintenis*

Table 1

Aspect	*Inspanning Verbintenis*	*Resultaat verbintenis*
Differences	The efforts of a doctor or health facility are not required to provide or produce results that are in accordance with the wishes of the patient or his family, bearing in mind that the results of a medical effort are not exact or can be calculated with certainty (uncertainty).	If a specific result has been determined before the action is carried out (special agreement) then the doctor must provide the results of his performance in the form of a certain result as desired by the patient and his family, so that what applies is a resultaat verbintenis type agreement or agreement. Medical service providers can be sued legally if the results agreed upon before the agreement do not materialize

Inspanning Verbintenis and *Resultaat Verbintenis* in Therapeutic Agreement

Every medical procedure performed by a physician has an element of uncertainty regarding the outcome. Hariadi says the final outcome of a medical action or procedure depends on several factors, including:[24]

[23]Janetty, "Kajian Mengenai Inspanning Verbintenis Dan Resultaat Verbintenis Di Bidang Kedokteran Bedah Plastik Dengan Tujuan Estetika," *Jurnal Spektrum Hukum* 19, no. 2 (2021): 20–31, https://doi.org/10.35973/sh.vl6i2.1248.

1. progression of the disease and its complications (clinical course of the disease);
2. medical risks (medical risks);
3. risks of surgical action (surgical risks);
4. compared to side effects of treatment and medical procedures (adverse reactions);
5. due to limited resources (limited resources);
6. medical accident (medical accident);
7. inaccurate diagnosis (error of judgment);
8. medical malpractice (medical malpractice); And
9. medical error.

The aforementioned factors can result in death or disability. Medical procedures for *resultaat verbintenis*, where the patient in the engagement agreement aims for example in Indonesia plastic surgery action and the patient is typically in good health, are more risky than medical procedures for *inspanning verbintenis* or on patients with the aim of improving their health status.

A doctor who has received specialised training in plastic surgery is required to do plastic surgery. According to Law article 29 paragraph (1) of 2004 governing Medical Practise, doctors must obtain a Doctor's Registration Certificate (STR) that is valid at the time of performing the procedure in order to perform plastic surgery. The doctor must also obtain the patient's and the witness's signatures on a consent form before beginning any procedure. According to what is mentioned in Article 45 paragraph (1), the doctor is required to give a thorough explanation regarding the diagnosis, risks, and consequences that may arise as a result of the medical intervention. Doctors must create medical records as quickly as possible after treating a patient for a condition, according to Article 46, paragraphs (1), (2), and (3) governing Medical Practise. These documents must include crucial record information such the patient's name, the date, and the doctor's signature. service providers in the health profession.

Then, doctor who intentionally practises without a practise licence is subject to a maximum term of three years in prison and a fine of Rp. 100,000,000,- (one hundred million rupiah), according to Law Number 29 of

[24]Janetty, "Kajian Mengenai Inspanning Verbintenis Dan Resultaat Verbintenis Di Bidang Kedokteran Bedah Plastik Dengan Tujuan Estetika," *Jurnal Spektrum Hukum* 19, no. 2 (2021): 20–31, https://doi.org/10.35973/sh.vl6i2.1248.

2004's article 76. Specialists are a calling that gives therapeutic administrations to patients, are required to take after appropriate standard operational strategies and must pay consideration to their proficient rights and commitments in statutory directions. Patients have rights and commitments, the proper to get therapeutic administrations, get total data around their condition and the services they will get, but patients are moreover obliged to supply data and be fair around their wellbeing conditions and issues.

In understanding with Serve of Minister of Health Number 4 of 2018 concerning Clinic Commitments and Quiet Commitments, article 26 states that in getting administrations, patients are obliged to supply genuine and total data with respect to their wellbeing issues, as well as giving data with respect to their money related capabilities. Patients moreover have secondary rights such as: the correct to get restorative data, the proper to get data with respect to therapeutic strategies that will be carried out on them, the proper to grant educated assent for any medical procedures that will be carried out on them, the proper to end legally binding relations at any time, and the correct to get a certificate non-judicial specialists (such as passing certificates, certificates for protections purposes, and so on).

Civil liability of a plastic surgeon's hone on the premise of breach of contract may happen due to non-fulfillment of the comes about of the beginning concurred understanding. Be that as it may, non-compliance with execution does not continuously cruel disappointment to attain performance, as clarified over, disappointment to attain execution can be caused by a few components such as the course of the illness, complications of the illness, therapeutic dangers, dangers of agent strategies, side impacts of treatment, restricted assets, mischances, mistakes in conclusion, therapeutic carelessness, and misbehavior.

For offenders who are demonstrated to have committed restorative negligence, the sanctions forced can be within the frame of composed notices, repudiation of Taste, or re-education or re-schooling, to be specific the commitment to retake instruction at a therapeutic instruction institution. Article 360 sections (1) and (2), as well as article 361 of the Criminal Code states that specialists are obliged to be capable for their activities in the event that the therapeutic activity they have carried out comes about in genuine damage or passing due to their carelessness. Separated from that, in Law no. 29 of 2004 concerning Restorative Hone too contains criminal arrangements, specifically in article 75, article 76, and article 79. Article 75 section (1) states that each specialist without a enlistment certificate and purposely carrying out restorative hone will be sentenced to 3 (three) a long time in jail. and with a greatest of Rp. 100,000,000,- (one hundred million rupiah). Law Number 23 of 1992

concerning Wellbeing, criminal dangers for doctors/dentists are contained in articles 80 to 86.

The explanation above demonstrates that in Indonesia plastic surgery is an in-depth *verbintenis* where a plastic surgeon is obliged to exert all of his skill and ability on behalf of his patient. However, there is also a verbal result in plastic surgery, when the patient demands the best possible outcomes that match their initial expectations. However, both *inspanning verbintenis* and *resultaat verbintenis* may result in the failure to achieve the intended outcome of the medical action.

4. Conclusion

4.1. Summary

Every medical procedure performed by a physician has an element of uncertainty regarding the outcome. The conditions for a therapeutic transaction to occur are determined by article 1338 Jo. 1320 of the Civil Code. Both inspanning verbintenis and resultaat verbintenis may result in the failure to achieve the intended outcome of the medical action. Therefore, the purpose of informed consent to protect the patient against all medical actions performed without the patient's knowledge

4.2. Recommendations

Due to engagements in certain medical matters, like plastic surgery in Indonesia for example, are not guaranteed results (*inspanning verbintenis*), there still needs to be a distinction in performance. However, in these engagements, the results are also a maximum effort.

REFERENCES

Adriana Pakendek, Adriana Pakendek. "Informed Consent Dalam Pelayanan Kesehatan." *AL-IHKAM: Jurnal Hukum & Pranata Sosial* 5, no. 2 (July 21, 2012): 309–18. https://doi.org/10.19105/al-lhkam.v5i2.296.

Alifia Kirana Sumeru, Fayuthika, and Hanafi Tanawijaya. "Inspanning Verbintenis Dalam Tindakan Medis Yang Dikategorikan Sebagai Tindakan Malpraktek." *Jurnal Hukum Adigama* 5, no. 2 (Desember 2022): 490–520.

Arun, Bhatt. "Protocol Deviation and Violation. Perspectives in Clinical Research" 3 (2012): 117. https://doi.org/10.4103/2229-3485.100663.

Astuti, Endang Kusuma. "Legal Relationship Between Doctors And Patients In

Medical Service Efforts." *Diponegoro Law Review* 2, no. 1 (April 28, 2017): 123. https://doi.org/10.14710/dilrev.2.1.2017.123-140.

Gabay, Gillie, and Yaarit Bokek-Cohen. "Infringement of the Right to Surgical Informed Consent: Negligent Disclosure and Its Impact on Patient Trust in Surgeons at Public General Hospitals – the Voice of the Patient." *BMC Medical Ethics* 20, no. 1 (December 2019): 77. https://doi.org/10.1186/s12910-019-0407-5.

J, Guwandi. *Persetujuan Tindakan Medik : Informed Consent*. Jakarta: Balai Penerbit Fakultas Kedokteran Universitas Indonesia, 1990.

Janetty. "Kajian Mengenai Inspanning Verbintenis Dan Resultaat Verbintenis Di Bidang Kedokteran Bedah Plastik Dengan Tujuan Estetika." *Jurnal Spektrum Hukum* 19, no. 2 (2021): 20–31. https://doi.org/10.35973/sh.vl6i2.1248.

Marzuki, Peter Mahmud. *Legal Research*. Jakarta: Kencana Prenadana Media Group, 2010.

Mayasari, Dian Ety. "Tinjauan Yuridis Tentang Informed Consent Sebagai Hak Pasien Dan Kewajiban Dokter." *Varia Justicia* 13, no. 2 (October 30, 2017): 93–102. https://doi.org/10.31603/variajusticia.v13i2.1883.

Rizki Kartika Ilahi, Wahyu. "Resiko Medis Dan Kelalaian Medis Dalam Aspek Pertanggungjawaban Pidana." *Jurnal Hukum Volkgeist* 2, no. 2 (April 2018): 170–86.

Sacharissa, Vicia. "Legal Consequences of The Absense of Informed Consent in Therapeutic Transactions." *Mulawarman Law Review*, June 22, 2020, 1–17. https://doi.org/10.30872/mulrev.v5i1.296.

Selvia, Iip Verra, Arief Suryono, and Sapto Hermawan. "The Legal Consequences of Informed Consent for Doctors and Patients in Theurapeutic Agreements." *Aloha International Journal of Health Advancement (AIJHA)* 3, no. 6 (June 29, 2020). https://doi.org/10.33846/aijha30601.

Setiawan, Tri. "Tri Setiawan, 2009, Thesis: 'Informed Consent Between Doctors and Patients in Performing Medical Actions at the Sragen Regional General Hospital' Surakarta: Muhammadiyah University Surakarta, p. 2." Muhammadiyah University Surakarta, 2009.

Setyadi Rahim, Indra. "Legal Protection of Patients in the Implementation of Informed Consent." *Lex et Societatis* 4, no. 4 (April 2016): 4.

Suratman, and Philips. *Legal Research Methods*. Bandung: Alfabeta, 2012.

Sutamaya, Agus Gede, Dey Ravena, and Chepi Ali Firman Zakaria. "Informed

Consent As A Therapeutic Agreement In Health Services: Persetujuan Tindakan Kedokteran Sebagai Wujud Perjanjian Terapeutik Dalam Upaya Pelayanan Kesehatan." *Interdental Jurnal Kedokteran Gigi (IJKG)* 18, no. 1 (June 25, 2022): 7–13. https://doi.org/10.46862/interdental.v18i1.4306.

Sutrisno, Endang. "Legal Aspect Of Doctors' Responsibility In Prescription." *Jurnal Ilmu Hukum Sekolah Pascasarjana Universitas Swadaya Gunung Jati* 7, no. 2 (2023): 102. http://dx.doi.org/10.33603/hermeneutika.v7i2.8756.

Tohari, Hamim, and Akhmad Ismail. "Informed Consent Sirkumsisi Di Puskesmas Waru, Kabupaten Pamekasan, Provinsi Jawa Timur, PERIODE 1 JANUARI – 31 DESEMBER 2013" 5, no. 1 (2016).

Undang-undang Kesehatan, Pub. L. No. Undang-Undang Nomor 17 Tahun 2023, 17 (2023).

Waluyo, Bambang. *Legal Research in Practice*. Jakarta: Sinar Grafika, 2002.