



Information of Medical Malpractice and Risks in The Informed Consent Process Before Surgery in Indonesia

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Abstract

This study examines Indonesian statutory regulation that requires doctors or hospitals to explain the medical malpractices or risks to surgery patients during the informed consent process. The study was triggered by the frequent medical disputes caused by the patient's misinformation regarding possible medical malpractices or risks related to surgery. In this case, patients need transparent and relevant information during the informed consent process. Therefore, this study examines the statutory regulation that requires doctors or hospitals to explain the medical malpractices or risks to surgery patients during the informed consent process. It used secondary data collected from literature studies of relevant materials and analyzed using normative and qualitative methods. The results indicated that no statutory regulation requires doctors to explain the medical malpractices and risks associated with surgery during the informed consent. This means that the required transparency principle is often not implemented. Therefore, these laws are urgently needed because the public is misinformed about medical malpractices and risks.

I. Introduction

There is a deep interrelation between patient safety and risk management ([di Luca et al., 2019](#)). However, conflict and misunderstanding emerge when the communication between surgeons and their patients is not transparent. In this case, the doctors using the surgical process to treat patients are known as surgeons, including their subspecialties. Examples include ear, nose, and throat doctors, ophthalmologists, and obstetricians-gynecologists. A surgery involving a major operation is highly risky due to the operation time and the patient's condition before and after the surgery.

Case in point: During the informed consent process, a person operable for appendicitis explained that the surgery only takes an hour at most for a wound, not more than 10 centimeters. In this case, the surgery had complications that required a larger operation involving a longer skin incision. Subsequently, this caused a disability in the patient after recovery, leading to legal proceedings. However, this could be avoided in case the patient had been informed sufficiently and transparently. Although this is a mild example, a severe case could result in death, equally undesirable.

The relationships between patients and doctors have changed with time. Previously, patients were considered objects because doctors were perceived to know what was best for patients. However, this has changed into an increasingly equal and balanced relationship in which doctors and patients have rights and obligations to be fulfilled. Furthermore, both parties participate in decision-making before the patient undergoes therapy, treatment, or surgery in the current doctor-patient relationship.

The doctor-patient relationship leads to equality based on the right to autonomy for everyone, though it cannot be realized absolutely. The main reason is that patients visit doctors for medical help. Therefore, doctors are in a superior position with better knowledge and expertise about disease compared to patients.

The doctors' profession is tough because patients and their families expect healing from them or the hospital. However, doctors are humans that apply their knowledge and limited expertise in treating patients. Moreover, many factors affect the treatment results, including the patients themselves, the type of disease, and the medical risk. Therefore, doctors should conduct a clear and transparent informed consent process for patients and their families.

Patients have the right to clear and transparent information about the disease and medical treatment. Specifically, they have the right to health care, which is inseparable from other rights, including the right to information about the disease, a second opinion, and to keep the illness confidential ([Supriadi, 2001](#)).

II. Research Methods

This study used a normative juridical method to analyze the rules or norms used in the positive law on *informed consent* ([Ibrahim, 2006](#)) using a qualitative approach. Data were collected by researching and logically describing the norms, rules, and legal theory on informed consent ([Waluyo, 2002](#)). The secondary data were obtained through literary research by collecting, compiling, and studying primary and secondary legal materials related to informed consent. Primary legal data on informed consent included Law Number 36 of 2009 concerning Health and Law Number 29 of 2004 concerning Medical Practices. Others were Law Number 36 of 2014 concerning Health Workers and the Regulation of the Minister of Health Number 290 / Menkes / PER / III / 2008 concerning Approval for Medical Action. Secondary legal materials comprised information not formalized as law, such as books, research papers, and articles related to informed consent.

III. Research Result and Discussion

A. Surgery by Doctor

In the surgery or medical fields with invasive procedures, doctors and patients encounter problems related to the actions. Some cases, including those that end in death, are often caused by unclear information about medical procedures and their risks to patients or their families. This is usually the lack of doctors' openness in providing explanations.

Data from the Indonesian General Surgeons Association showed 25 cases of medical disputes between 2002 and 2006 ([Bulletin of the Prabu PABI, 2006](#)). This number does not include cases not reported to PABI because those not resulting in death are resolved amicably before being reported to the authorities. The analysis shows that the main cause of a medical dispute is a mismatch in the doctor's explanation before surgery regarding the outcome of the process. Alternatively, they are caused by a mismatch between the results and the patient's expectations. This problem could arise due to the lack of information from the patient and the doctor providing the explanation.

Doctors want to do their best for the patient's recovery, while the patient often has several considerations in deciding the best medical course. Theoretically, informed consent is a process, not a one-time event occurring only when the patient signs the informed consent sheet ([Weinstein, Clay, and Morgan, 2007](#)). Furthermore, informed consent for invasive healthcare procedures is a fundamental ethical and legal obligation for clinicians ([Lee-2017](#)). Therefore, transparency plays an important role in informed consent. Transparency is openness or honesty in conveying information from patients and or doctors, also known as freedom of information or FOI ([Ala'I, Vaughn, 2016](#)). The principle of transparency is essential in the decision-making process of informed consent.

The existing laws and regulations do not address transparency in conveying information to patients. According to these statistics, openness must be provided by the hospital for patients' comprehensive consideration. For instance, this type of operation has a percentage success rate.

Paragraph 3d of article 45 of Law number 29 of 2004 concerning medical practice highlights the risks and complications in writing and orally. However, it does not explain the malpractices and medical risks at the hospital during a surgical procedure.

Regulation of the Minister of Health Number 290 / Menkes / PER / III / 2008 concerning Approval for Medical Action does not indicate this obligation.

1. Medical Malpractice and Risk

Patients and medical professionals experience tremendous burdens when a patient is harmed, leading to medical malpractice claims ([Myers at all, 2020](#)). One area in which malpractice could hold a distinctively absolute sway is in the consent to consultation and physical examination by the healthcare practitioner ([Oguno, P. and Anigbogu, I.E., 2020](#)). Moreover,

medical malpractice is often confused with medical risk and vice versa, though the two are different. Medical malpractice is the negligence to take action or acting carelessly. Therefore, many perceive medical malpractice and risk as negligence. Medical negligence is the breach of a legal duty to care, including damages and establishing causation ([P.K.Uma, 2020](#)).

When doctors commit medical malpractice, the patient incurs a material loss, disability, or death, resulting in a criminal case. Medical risks occur anytime regardless of the medical action's magnitude, which becomes an Unexpected Event. Also, medical risks known beforehand might occur, although not necessarily.

Veronica stated that malpractice is an error in the profession caused by doctors' obligations. Therefore, medical malpractice is errors not in line with the standards of carrying out the medical profession. Furthermore, Stephen J. Brown defined medical risk as to the physical risk to patients that medical treatment, therapy, surgery, or drugs would harm them or leave them in a worse position than before. Therefore, according to Guwandi, doctors must be careful because medical risks, such as anaphylactic shock, occur even when preventive measures have been taken and cannot be blamed on the doctor.

Malpractice is a loss, disability, or death caused by negligence and incautiousness in medical actions. An example is operating on the right ear instead of the left due to the patient's carelessness. In comparison, the medical risk is a loss, disability, death previously known to occur or not, though its occurrence is uncertain. An example is an operation to separate conjoined twins whose heads are fused with the brain. In this case, it is predicted that someone would die, despite being careful, the same as in anaphylactic shock.

Medical negligence litigation is a contentious area of law, with strong and passionate advocates on both sides, and may not disappear soon ([Duignan, K. and Bradbury, C., 2020](#)). Reducing medical malpractice lawsuits is an underappreciated opportunity to lower healthcare costs ([Boyll et al., 2018](#)). Doctors have to face lawsuits for medical malpractice whose various allegations were negligence in diagnosing and treating patients. Medical risks that become Unexpected Events include force conditions, which mean medical disasters. When the cause is proven to be a medical risk, the doctor cannot be sentenced because they are protected by existing legal regulations when they work following the standards. However, they must not intend to harm the patient. Moreover, in medical malpractice cases, a patient needs to request an explanation for any failure and claim for compensation ([Tarkiainen, T, 2021](#)).

Medical conflicts arise due to a lack of understanding of medical malpractice and risks. The two terms have different meanings with varied implications in the doctor-patient relationship. Malpractice means a

bad practice or out of order and occurs in all professions consciously or unconsciously. When associated with doctors or medical malpractice, it is interpreted as bad practice or deviating from what it should be. Unfortunately, the public opinion only perceives the outcome side as though the doctor was guilty. They hardly consider whether the action was intended or due to the doctor's negligent attitude. It is called medical malpractice when a doctor's legal obligations are violated ([Chazawi, 2015](#)) and contains the following elements:

- a. Involves certain actions (active or passive) in medical practice.
- b. Carried out by a doctor or person under their orders.
- c. Performed on the patient.
- d. Deliberately or negligently.
- e. What is contrary to professional standards, operating procedures, professional medical principles, violates the law, or is carried out without authority. It is performed without informed consent, Doctor's Registration Certificate, or Practice License, according to the patient's medical needs.
- f. Results in loss of physical or mental health or the patient's life.
- g. It establishes legal liability for doctors.

Medical malpractice is more appropriate when connected with negligence. According to Lord Wright, negligence is more than *careless conduct*, where a patient that filed a lawsuit for reasons of negligence by a doctor must prove ([Kassim, 2003](#)):

- a. The doctor is not obligated towards the patient (the doctor owed a duty of care).
- b. There is a breach of obligation (that duty has been breached).
- c. A violation causes damage (the breached damage).
- d. The damage incurred is predictable (the damage reasonably foreseeable).

Stephen J. Brown defined medical risk as to the physical risk to patients that medical treatment, therapy, surgery, or drugs would harm them or leave them in a worse position than before. This risk is referenced in the goal of any physician to cause no harm (Brown, 2008).

Medical risks may arise due to diagnostic and therapeutic actions that could be predicted. Also, doctors do their best for patients according to applicable standards and are guided by the principle of "*do no harm*." The doctor needs to be proven to have committed malpractice and caused civil harm to the patient due through a medical action. When proven, a violation of their legal obligations in their relationship with the patient based on the law of engagement may arise: *Wanprestasi* (broken promise, default) or Act against the law or *Zaakwaarneming* (representing voluntarily) ([Chazawi, 2015](#)).

The engagement between the doctor and the patient is classified as an effort engagement or *inspanning verbintenis*. The Law on Health Workers Article 61 explains this business engagement, stating that “*In carrying out the practice, Health Workers who provide direct services to Health Service Recipients must carry out their best efforts for the benefit of Health Service Recipients without promising results.*” A doctor commits medical malpractice when they do not follow professional, or service standards and the patient fails to recover, gets worse, or dies. In this case, informed consent is not free of the legal risk for the doctor. As stated in the Regulation of the Minister of Health Number 290 / Menkes / PER / III / 2008 concerning Approval for Medical Action article 6, “*granting approval of medical action does not eliminate liability law in the case of proven negligence in performing medical acts that resulted in the loss to the patient.*” The doctor-patient relationship remains a form of contract with legal rights and obligations of both parties. In this contract, the doctor is deemed to have made an offer and achieved the patient. Therefore, in the relationship, doctors are liable for default. *Wanprestasi* (broken promise) or default is defined as poor performance that violates the terms of the agreement. Therefore, a doctor defaults when they fail to provide medical services according to existing standards, causing harm to the patient. The default of doctor’s services must reflect true results through material losses measurable in money, such as medical expenses. In this case, immaterial losses cannot be prosecuted based on default but an illegal act (*onerchtmatige daad*). However, not all share the same opinion about default in the doctor-patient relationship. Some opinions consider that because the doctor-patient engagement is open, it cannot be classified as default.

Malaysia adheres to the common law system, where medical negligence is held under contract or tort law. However, tort charges were made more frequently, with judges considering them inappropriate for prosecution under contract law. This is because a surgeon or doctor never promises results, except for a non-therapeutic measure ([Kassim 2003](#)).

Article 1365 of the Indonesian Civil Code states, “*every act violating the law, which brings loss to others, obliges the person who because of his fault caused the loss, to compensate for the loss.*” Therefore, the doctor’s actions that deviate from the existing standards and harm the patient are considered illegal. It is often impossible to determine whether malpractice is a default or an act against the law. Therefore, it is determined based on whether the incident enters the realm of criminal law. When the incident is unproven to be a criminal act, it is not a default but an act against the law. The reason is that the essence of default is based on a violation of a legal obligation in an engagement. In comparison, acts against the law result in direct losses blamed on the maker or contain unlawful characteristics that are not always in an engagement. As a result, their determination depends on the reasons for the lawsuit filed. The four conditions to be met to sue for damages caused by illegal acts in medical malpractice are:

1. An act classified as against the law.
2. There is a fault of the maker.
3. There are losses.
4. There is a relationship between the actions and the loss consequences.
5. A doctor's legal liability due to malpractice is classified as an unlawful act. It may only be eliminated with a justification or an excuse, as stated in the criminal law, which does not specify the amount of compensation to be given. Therefore, the judge assesses the appropriate amount of material and immaterial compensation. Also, the loss and its amount must be proven, as stipulated within the plaintiff.

In connection with Article 1365 of the Indonesian Civil Code, the patient arguing that there was an act against the law must prove that the act occurred due to the doctor's negligence or wrongdoing. However, the average patient cannot prove the doctor's mistake or omission.

2. Informed Consent and Transparency Principles

a. Legal Arrangements

In Indonesia, legal regulations on informed consent are contained in Law Number 36 the Year 2009 concerning Health Article 56 regarding the Patient Protection, and Law Number 29 of 2004 concerning Medical Practices Article 45 of the Agreement actions of Medicine and Dentistry. Also, the regulations are included in Law Number 36 2014 concerning Health Workers Article 58 of the Rights and Duties of Health Workers, and Article 68 of the Regulation of the Minister of Health Number 290/Menkes / PER / III / 2008 concerning Approval for Medical Action.

These regulations have many shortcomings and elements that cause differences of opinion and ambiguity in their interpretation and application. Subsequently, they are potentially harmful to doctors as the weak party. For instance, paragraph 2 of Regulation of the Minister of Health Number 290 Menkes / PER / III / 2008 concerning Approval for Medical Action Article 2 states that medical treatment could be approved in writing or oral. Furthermore, Article 3 paragraph 4 states that the treatment could be approved verbally with words from the patient. Alternatively, it could be approved through patient movements, such as nodding, interpreted as agreeing. In communication science, non-verbal expressions cannot replace but only strengthen or clarify verbal expressions ([Daryanto, Rahardjo, 2015](#)). There is a risk of misunderstanding due to cultural differences, or nonverbal expressions may manifest in several actions simultaneously.

This non-verbal or unwritten agreement could have legal force in law. However, when a medical claim or dispute between a health worker and a patient often causes problems. For instance, the patient or

their family may deny having agreed to a medical action by a doctor. In this case, other evidence is needed to solve the problem, such as witnesses or records where possible.

Another example is in Regulation of the Minister of Health Number 290 / Menkes / PER / III / 2008 Article 3 paragraph 1, which states *"every medical action that carries a high risk must obtain written approval..."*. However, this statement has no rules in law or its derivatives with a distinct division in classifying the severity of the risk of an action. Therefore, it might provide an advantage for doctors that do not provide informed consent to patients. However, it could create a risk of prosecution from the patient when things happen beyond previous estimates. This is caused by the doctor providing unclear regarding the risk of a particular action on the patient.

The existing regulations do not specify the person to approve medical action when the patient is unconscious or incompetent. Therefore, the action is approved by the patient's introduction or their immediate family. However, the patient's introduction provides their consent only to a certain extent, especially related to the right to the confidentiality of the patient's illness. This also creates dilemmas for physicians in certain situations.

Article 6 of Decree No. 290 / Menkes / PER / III / 2008 concerning Approval of Medical Action states that informed consent cannot remove liability law for doctors when they are guilty of negligence. The same applies when the doctor does not work according to operational and professional standards. The informed consent should be clarified based on the existing legislation, not lead to a dualistic interpretation that harms doctors. In line with this, the communication between doctors and patients is based on two standards as references. First, the doctor or health service provider must openly describe the basic reasons for therapy or action. Second, the patient must be allowed to ask questions and receive satisfactory answers from the doctor ([Brody, 1989](#)).

The information provided by the doctor should facilitate the patient to ask useful questions related to their decisions. The doctor should always ask the patient every time they finish explaining, such as *"is there anything to ask?"*.

b. The Importance of Transparency

Doctors must exercise transparency to improve the health service system and the quality and safety of patient care (*patient safety*). There are four main reasons why transparency is necessary and must become a culture in the doctor-patient relationship, especially concerning informed consent, namely ([Shinning Light, 2015](#)):

i. Creating accountability.

- ii. Improving quality and safety.
- iii. Increasing trust and ethics.
- iv. Facilitating patient choice.

In connection with transparency, [Law Number 36 of 2009](#) concerning Health Article 56 concerning patient protection states "... after receiving and understanding the information regarding the action in full." However, there is no mention of the obligations of either a doctor or a patient to be transparent in providing information. Also, [Law Number 29 the Year 2004](#) Concerning Medical Practice, Article 45 concerning Approval of Medical Action and Dental Medicine includes only five main points the explanations to be provided by a doctor. Similarly, [Law Number 36 of 2014](#) concerning Health Workers Article 58 concerning the Rights and Obligations of Health Workers. [Regulation of the Minister of Health Number: 290 / Menkes / PER / III / 2008](#) concerning Approval of Medical Action Article 9 states that the explanation in Article 8 must be made easy to understand or in various other ways. Therefore, the Regulation of the Minister of Health emphasizes the principle of transparency in providing information.

More problems are arising in the medical world related to legal issues in relationships originally based on *trust*. Cases that often occur due to communication between the doctor and the patient or their family are not right. Not everything a doctor does, though it aims for the good based on medical science, is in line with the patient's wishes due to cultural, belief, psychological, financial, or religious considerations. This difference in perspective has led to conflict.

Effective communication between doctors and patients is vital in the trust-building process that eases the decision-making process. Furthermore, good communication between the surgeon and the patient leadsto patient safety, while poor communication failure causes adverse effects ([Manias, 2015](#)).

An effective informed consent process starts from good communication between doctors and patients. Communication based on trust leads to openness from both parties because the doctor-patient relationship is built on trust. However, the many problems in communication between doctors and patients or their families are a major obstacle in providing information, resulting in medical disputes.

As health service consumers, patients have expectations related to the services they receive, while doctors as service providers must also uphold openness or honesty. Therefore, the doctor-patient relationship is inseparable from Law Number 8 of 1999 concerning Consumer Protection. However, this still creates a conflict whether the Consumer Protection Act is a reference for resolving medical disputes. It is because

of the assumption that the relationship between doctors and patients is unique and not properly categorized as the relation between business actors and consumers.

Regarding the emergence of medical disputes, transparency is closely related to the theory of legal effectiveness, according to Lawrence M. Friedman, which consists of legal substance, structure, and culture. Based on legal substance, it is necessary to determine how the laws or regulations govern transparency in informed consent. Furthermore, the legal structure describes how law enforcers understand and handle a problem. Similarly, legal culture relates to how patients and health workers comply with the principle of transparency in *informed consent* in a doctor-patient relationship ([Ali, 2015](#)).

3. Human Rights of Patient and Analysis in The Informed Consent Process

a. Human Rights of Patient.

The two main human rights of patients are the right to self-determination and the right to information. These two rights refer to the Declaration of Lisbon (1981) and the Patient's Bill of Rights (American Health Association, 1972). The patient has the right to accept or reject treatment and receive information ([Hatta, 2013](#)).

The right of patients to make decisions about health care is enshrined in law and ethics worldwide. The WMA (*World Medical Association*) Declaration on the Rights of Patients states, "Patients have the right to self-determination and free to make decisions concerning themselves. Also, the doctor must tell the patient the consequences of the decisions made. Moreover, mentally healthy adult patients have the right to consent to diagnostic or therapeutic procedures and have the right to obtain the information necessary to make decisions. The patient must clearly understand the goal of a test or treatment, the expected results, and the impact in case a decision is delayed ([William JR, 2005](#)).

Surgery is closely related to ethics and the surgeon's morality. It differs from other fields of medicine where the doctor-patient interaction entails participation and involvement. In comparison, in the interaction between surgeons and patients in the operating room, the surgeon is always in a higher position. The patient is under general anesthesia, while the surgeon is in a superior position to control the situation and even make decisions for the patient ([McCullough, Jones, Prody, 1998](#)).

Another aspect of medical and surgical procedures related to ethics is the possibility of a conflict of interest, especially related to financial problems, also known as economic interest. The field of health financing related to doctor's medical services consists of the capitation and the fee for service systems. The capitation system encourages doctors not to

perform surgery, while the *fee* for service drives them to perform more operations. Economic interest is not based only on the doctors' ethics and morality but is related to the interests of the hospital.

The doctors' profession upholds and must work according to standards and ethics, meaning that they must be honest and open in providing information to patients and their families. Doctors must respect the human rights of patients, ensuring transparency explanations are provided without hiding anything for personal interests.

b. Characteristics of Medical Surgery

Medical action according to the general provisions in Regulation of the Minister of Health Number 290 / Menkes / PER / III / 2008 concerning Approval of Medical Action includes preventive, diagnostic, therapeutic, or rehabilitative actions performed by doctors on patients. Furthermore, medical treatment according to the Guardianship and Administration Act 1986, include (Victorian Law Reform Commission - Guardianship Final Report, 2013), involves:

- 1) a special procedure
- 2) a medical research procedure
- 3) non-intrusive examinations made for diagnostic purposes
- 4) first-aid treatment
- 5) administration of pharmaceutical drugs according to prescription or, when it is a drug for which a prescription is not required, according to the manufacturer's instructions

The Victorian Medical Treatment Act 1988 amended on May 17, 2012, states that medical treatment includes an operation, administering a drug or other related substance, or any other procedure but not including palliative care;

Medical measures include all examinations aimed at diagnostics, administering drugs or pharmaceutical preparations, research, first aid, and surgery, but not including palliative care. However, according to the Occupational Safety of Health Administration, there are other classifications issued by the United States Department of Labor. Consultation and diagnostic procedures, such as supporting examinations through X-rays and blood tests, are not included in medical procedures. Also, first aid measures of providing oxygen, suturing wounds, and surgical prostheses for immobilization are medical measures. However, 14 classes of first aid measures are not included in medical treatment, known as Medical Treatment Beyond First Aid. They include administering drugs without prescription, anti-tetanus, wound cleansing, simple wound closure, hot and cold therapy, and installing non-rigid supports. Other measures are the use of non-

permanent supports for patient transportation, removing fluid from the fingers to reduce pressure, use of eye patches, removing foreign objects from the eye using fluids or swabs, removing foreign objects from the body, using finger protectors, massage (except chiropractic treatment), and giving fluids to combat heat stress.

Surgery or a surgical process is making an incision using a tool to overcome damage or disease to a living body. Synonyms for surgery or surgical procedure are operation, surgery, or surgical process. A surgical procedure has its specifics and characteristics compared to other medical procedures. It is an invasive procedure of incision that causes injury to a living body, though the aim is to repair or treat the damage.

Surgery has specific characteristics compared to non-surgical medical procedures regarding the patient, doctor, disease, and situation. Surgery patients face a much different situation psychologically than non-surgical patients. They experience psychological stress due to their illness, anxiety about possible surgical procedures, including anesthesia, and being away from home and family ([Ayers, Baum, McManus, et al., 2007](#)).

This situation affects the process of receiving and understanding the information by the patient or their family. Consequently, it affects the decision-making process of the medical treatment offered by doctors in this surgery. Similarly, a surgeon has limited time to explain to patients or their families and hardly allows them to ask questions. A study found that very few patients discuss with surgeons during clinical visits, and only 38% of surgeons responded positively to the patient's desire to discuss the disease ([Jones, McCullough, Richard, 2008](#)).

Surgery has a different character from non-surgical medicine because it affects the relationship between the surgeon and the patient. The doctor-patient fiduciary relationship was originally paternalistic and built on equality, though it was not an equation because it was not the same. This is because surgeons must be more trustworthy, transparency during the informed consent process is essential.

- c. There are two competing analyses in the informed consent process,

According to Martin S. Pernick and psychologist Jay Katz. Pernick stated that based on sources in the 19th century, truth-telling is an original tradition in medical science, where the doctor's knowledge and the patient's autonomy affect the patient's health. Additionally, there is a difference between the content and purpose of informed consent in the 19th century and modern views. In the 19th century, informed consent was not based on patient rights but only a process to convey therapy benefits.

Legal writing that informed consent is an original tradition in medicine was first obtained in the early 20th century in the case of *Cantebury v. Spence*. Judge Spottswood Robinson wrote, "suits charging failure by a physician to adequately disclose the risks and alternatives of proposed treatment are not innovation in American law. They date back a good half century."

Contrary to the analysis that informed consent only aims to convey therapy benefits, Katz stated that doctors hardly consider patients' rights and desires to make decisions. According to Katz, the law has no power in the communication between doctors and patients. Alternatively, the lack of openness between doctors and patients was the cause for simple informed consent, or simple consent, regarding the patient's "yes" and "no" answers to an action. Regarding medical intervention, Judge Benjamin Cardozo stated that communication ([Faden, Beauchamp, 1986](#)).

In the USA, several court cases relating to informed consent began to be published in the second decade of the 20th century. It was assumed that physicians began conducting the informed consent process at that time, initiated by surgeons. In the 17th century, British surgeons began contracting with patients in managing their diseases. Subsequently, in the 18th century, a doctor concerned with ethical issues, John Gregory (1724-1773), stated that patients had the right to express their opinion about their life and health. In the 19th century, a Brooklyn obstetrician, Alexander Skene, developed a concept that would later underlie informed consent in gynecology. Alexander Skene offered patients the indications for surgery and negotiates an alternative procedure in case the patient refuses. This process demonstrated the origin of informed consent in the common law legal system.

In 1914, in the New York district court, in the case of *Schloendorff v. The Society of the New York Hospital* are still used in the bioethics literature are:

"Every human being of adult years and sound mind as the right to determine what shall be done with their body, and a surgeon performing an operation without their patient's consent commits an assault for which they are liable in damages, except in cases of emergency, where the patient is unconscious, and where it is necessary to operate before consent is obtained" ([Jones, McCullough, Richard., 2008](#)).

In 1908, Mrs. Schloendorff came to the surgeon complaining of abdominal pain and agreed to be examined under anesthesia without any surgery. When the surgeon identified a tumor in the patient's stomach during an examination, they removed it because it was potentially life-threatening. Furthermore, removing the tumor would reduce the

patient's risk of exposure to the second anesthesia. Unfortunately, the patient had complications after surgery, and the surgeon was sued because the patient had claimed not to consent to surgery. Therefore, even when beneficial to the patient, a doctor's clinical decision cannot be legalized due to respect for patient autonomy.

Informed consent is a process of exchanging information for patients to exercise their autonomous rights to decide medical treatment for themselves. Transparency is crucial in the informed consent process because it reduces the risk of prosecution due to unclear information received by patients.

- d. The basis of building trust and respect between doctors and patients is communication. According to the National Health Service, 2010, communication involves exchanging at least two people to convey facts, desires, opinions, thoughts, feelings, or other information in verbal or non-verbal forms, including face-to-face and in writing. Therefore, it could be face-to-face, non-verbal, or written. Communication in the doctor-patient relationship is the delivery of information, from "to inform," meaning to inform. Information is a noun form defined as fact told, heard or discovered about, or knowledge ([Crowther, 1995](#)). It is different from communication because it is more rational and contains elements of logic. Communication requires the involvement of humans emotionally and is based on perception. Therefore, information becomes more effective when kept away from emotions, while communication must be adjusted to a system of values and perceptions. Additionally, information influences patients in making decisions and affects medical action ([Komalawati, 2002](#)).

The main problem in doctor-patient communication is limited time. A survey by the Commonwealth Fund in the USA found that only 50% of respondents felt that doctors spent enough time interacting with patients. Conversely, data from the Bureau of Health Information (New South Wales) shows that 60% of medical staff in Australia spend enough time with their patients. Moreover, Robins, Fasih, & Schweitzer (2014) showed that communication is the main cause of patient complaints. Reader, Gillespie, & Roberts (2014) found that 88 069 cases of patient complaints were mainly due to communication and problems with the patient's handling ([Manias, 2015](#)). Therefore, the doctor must carefully tailor the information they provide to patients, depending on their treatment needs ([Dunn et al. 1, 2018](#)).

Problems related to communication in Indonesia as a Southeast Asian country have the following special characteristics ([Claramita et al., 2017](#)):

- 1) There is a hierarchical social divide between people.
- 2) Non-verbal, politeness communication is used more than oral or written communication.
- 3) Clinical decision-making is influenced by the patient's family or the surrounding community. Patient autonomy faces challenges because it is more oriented towards group decisions.
- 4) The use of alternative or traditional medicine is prominent in Southeast Asian society.
- 5) Patients and their relatives are more informed and even trust information obtained from social networks than health professionals.

Cultural communication between doctor and patient in Indonesia is mainly one-way, directive, and instructional. Patients are rarely asked for feedback in the communication process, and many leave the decision to their doctor. This is different from the context in Western countries characterized by trust, equality, and a two-way exchange of information. According to some doctors, one obstacle to partnership communication is an unstructured health care system with many patients and limited time. Also, there is a high culture of blaming, making doctors always try and protect themselves from patient claims. This causes the emphasis on informed consent only to obtain the patient's signature, not to ensure they have adequate information. Furthermore, Indonesia's medical faculty and specialist education do not specifically teach communication, and doctors are not ready for a participatory communication model. Similarly, the people's culture is not ready for a participatory communication model, especially in areas with low education levels.

Communication between surgeons and their patients has its characteristics. The process of sharing information and making joint decisions before surgery is very important. Moreover, effective communication ensures patient satisfaction. However, surgeons should avoid complex medical terms to enhance patients' understanding. Good communication between surgeon and patient begins on an outpatient basis. Studies show that claims of patient dissatisfaction in the surgical field are mainly related to doctor-patient communication. This is mainly due to failure to understand patient expectations and to explain the risks and surgical procedures. Therefore, it is necessary to have a clear information form accompanied by a written statement that the patient has understood the information received, though this is not a guarantee.

Relationships between surgeons and patients based on trust and good communication are the main keys to the informed consent process. Trust is inseparable from honesty, which is the doctor's duty

and the patient's obligation. The stumbling block in the doctor-patient relationship is time constraints, arising because doctors practice in three places, causing honoraria. It is possible for the hospital to determine the doctor's honorarium based on the consultation time, though this has changed with the covid 19 pandemics. The pandemic could repair the relationship of trust between medical staff and patients ([Bilotta, 2020](#)).

For instance, a doctor must serve a patient consultation for at least 20 minutes, and an additional fee is charged in case the next session lasts more than 20 minutes. Subsequently, it is hoped that doctors would spend more time interacting with patients. This pattern of limiting time for consultations with adjusted costs is common in other countries, such as Singapore.

- e. Transparency occurs spontaneously and naturally but still requires the rules and procedures. For instance, in doctor-patient relations, transparency should be relevant to the patient's confidentiality. Openness is not always the best option, in some circumstances, non-transparency is required, such as:
 - 1) To protect the lives of human beings, at the time, the state prioritizes keamanan nationwide.
 - 2) To support democracy.
 - 3) To protect weak social groups.
 - 4) To maintain social interaction, people should not always tell others about everything in their minds.
 - 5) To ensure the dignity of human beings, such as maintaining personal confidentiality or information privacy. Also, to maintain the privacy of information within a small group of people, such as family, close friends, or parties with authority (doctor, therapist, lawyer).

Transparency in the health sector is defined as the free, uninhibited flow of information that is open to the scrutiny of others. It is also known as disclosure, openness, or freedom of information. There are four types of transparency in the health sector, including between clinicians and patients, among clinicians, organizations, and the public.

Health sector transparency, according to the American College of Physicians, has the following nine domains ([Kirschner, 2010](#)):

- 1) Clinical quality and safety.
- 2) Resources use.
- 3) Efficiency.
- 4) Patient experience of care.
- 5) Professionalism.
- 6) Healthcare system or facility recognition accreditations for meeting national standards

- 7) The financial relationship between physicians and other healthcare professionals and industry
- 8) Health insurance company processes

Transparency between doctors and patients is closely related to their relationship. Patients seek information and have limited medical knowledge, meaning that doctors must exercise openness efficiently to create pemahaman in their actions ([Faden, 1986](#)). [4] Transparency comprises the doctor's professional, the patient's individual, and the subjective standards. Communication standards are needed in the informed consent process to invite active participation from patients in the information exchange. Specifically, doctors must create an atmosphere that encourages patients to ask questions, not just receive explanations. The main essence of openness is:

- 1) Patients realize that their right to accept or reject the medical actions offered by doctors.
- 2) Doctors should state reasons why patients should choose their recommendations.
- 3) The patient's desire to seek information and implications for the action to be taken.

Communication should be two-ways for patients to value the information provided and receive dissatisfying results. Also, explanations must be "extra subjective component" sometimes to provide information about important issues. The exchange of information involves the physician and patient. Therefore, both parties must provide clear and open information from the beginning of their relationship during diagnosis. However, patients are not honest or open about their health problems or conditions because they fear or shame or do not trust the doctor. Similarly, physicians could also not provide open information on certain issues, such as the risk of action, though this is usually done for the patient's benefit ([Fainzang, 2002](#)). The dishonesty in information exchange is caused by a difference in the doctors' and patients' perspectives. Disclosure of patient information includes picture *penyakit* being suffered, state agencies, a history of family health, and their residence. In connection with the complaint of patients and arising disturbances, information about the following seven things is important ([Komalawati, 2002](#)), namely:

- 1) The place that caused the complaint (localization)
- 2) Type of complaint (quality)
- 3) The overwhelming complaint (quantity)
- 4) Time of occurrence and progression of complaints (chronological)
- 5) The beginning of the emergence of complaints (onset)
- 6) Things that make it lighter or worse
- 7) Its symptoms

Information disclosure from the patient is their obligation, as stated in Health Minister Regulation number 69 the year 2014 about Hospital Obligation and Obligations of Patients Article 28. Patients must provide truthful, complete, and accurate information about their abilities and knowledge on health and financial issues. Furthermore, the physician's information disclosure according to Regulation of the Minister of Health Number 290 / Menkes / PER / III / 2008 concerning Approval of Medical Action Regulation of the Minister of Health Number 290 / Menkes / PER / III / 2008 concerning Approval of Medical Action article 7 includes:

- 1) Diagnosis and planning for medical action.
- 2) The purpose of the medical action.
- 3) Alternative measures and risks.
- 4) Possible risks and complications.
- 5) Prognosis of the action.
- 6) Estimated cost.

Transparency in Regulation of the Minister of Health Number 290 / menkes / PER / III / 2008 is not spelled out. It is unclear regarding the patient's confidentiality and the person to whom it could be conveyed transparently. Therefore, there are possibilities of patients claiming that doctors disclosed their secrets. What should be listed are instructions in number 4 regarding possible risks and complications. It could be explained in passing due to lack of time, but not aimed at frightening the patient, making them shun surgery. Instead, it should be explained in detail, accompanied by incident data at the hospital.

- f. The principle of legality set out in the Criminal Code is important in criminal law. According to Jonkers, Article 1 paragraph (1) of the Criminal Code states that no act is punishable except by the criminal law that existed before the act was committed. This legality principle is explicitly stated in law and is not a concrete rule ([Hiariej, 2014](#)).

There are three definitions contained in the legality principle ([Moeljanto, 2002](#)). First, no act is prohibited and is punishable by punishment when not stated in statutory regulation. Second, in determining the existence of a criminal act, the analogy should not be used. Third, criminal law rules are not retroactive.

Boot ([Machteld, 2001](#)) stated that several things are related to the principle of legality. First, the principle of *nullum crimen, noela sine lege praevia*, means that there is no criminal act or crime without the previous law. This suggests that the provisions of criminal law cannot be retroactive.

Second, the principle of *nullum crimen, noela poena sine lege scripta*, means that there is no criminal act or crime without a written law.

Therefore, all criminal provisions must be written, meaning that punishable crimes must be written in the law. It is wrong to impose a sentence based solely on unwritten or customary law.

Third, the principle of *nullum crimen, noela poena sine lege certa* means that there is no criminal act or crime without clear statutory rules. This means the criminal act formulation must be clear without multiple interpretations that endanger legal certainty, which applies to prosecution. With a clear formula, the public prosecutor easily determines which actions qualify as criminal acts.

Fourth, the principle of *nullum crimen, noela poena sine lege stricta*, means that there is no crime without a permanent law, indicating that analogy is not allowed. Therefore, criminal provisions must be interpreted strictly to avoid the emergence of new criminal acts. The principle of legality could be differentiated into material and formal criminal law. Therefore, this principle has protective and instrumentation functions. The criminal law protects the people against the unlimited power of the government and operates within limits stipulated by law. Furthermore, this principle is regulated in Article 6 paragraph (1) of Law Number 48 of 2009 concerning Judicial Power, stating that no one could be brought before a court unless the law stipulates otherwise.

Based on these reasons, the absence of data on malpractice and medical risks would not make a patient prosecute the hospital. Also, doctors conducting an informed consent process without providing data at the hospital concerned cannot be criminally charged. However, this information is useful for the patient in decision-making and transparency based on the legality principle.

IV. Conclusion

Surgeons must be professional and prudent, establish good relationships with patients, build trust, and respect the patient's autonomy during the informed consent process. This would reduce demands or lawsuits against surgeons or hospitals by their patients. However, transparency must be exercised for patients or their families to understand any medical risks. Furthermore, transparency should be exercised when explaining data on previous malpractice and medical risks in the hospital concerned.

Laws and regulations should be revised to encourage surgeons to conduct the informed consent process transparently. The revision requires hospitals to prepare data on previous medical malpractice and medical risks in the hospital concerned. Additionally, doctors should provide clear information to patients during the informed consent process as a form of transparency. For instance, Regulation of the Minister of Health Number 290 / Menkes / PER / III / 2008 concerning Approval for Medical Action No. 290 of 2008 needs revision. It would be strengthened in Law Number 29 of 2004 concerning Medical Practice and Law Number 44 of 2009 concerning Hospital.

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