

The Informed Consent in Indonesian Medical Practice Law (*Lex Specialis Derogat Lege Generali* and Freedom of Contract Principles in Therapeutic Field Implemented by Civil Judges)

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Abstract: Informed consent in medical effort obligation is an essential instrument. Regarding the patient-doctor legal relationship, the patient's right determines the choice of medical action and the doctor/dentist seeks a professional standard of medical action. The study was conducted to measure, analyze and provide "legal certainty" to patients, doctors, and parties involved in a "medical effort obligation". This is a normative juridical research using the secondary data collection (study documents) method, obtained from primary, secondary and tertiary legal materials; the data were also combined with field data sources collected through conducting interviews as well as observing patients, doctors, and related parties as informants to support the secondary data. The qualitative method is employed in data analysis. The patient-doctor relation in the informed consent is not optimal despite having been regulated in Law No. 29 of 2004 concerning Medical Practice. The *Lex Generali Derogat Legi Generali* and the Freedom of Contract principles should be implemented in the therapeutic field. In reality, however, the medical effort obligation in the informed consent disregarded the positive legal dogma and it is not perceived as strong evidence even if desired by the patient. The principle of informed consent desired unilaterally by the patient carries an obligation for the doctor/dentist to perform the professional standard of medical action, which is based on S.O.P and the patient's medical needs (one party agrees, the other party has an obligation). According to the results of the study, the relation of rights and obligations in the medical effort obligation needs to be applied consistently and with legal certainty as specified by the Medical Effort Theory.

Key Words: Informed Consent, Medical Effort Theory, Legal Certainty.

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I. BACKGROUND

The doctor-patient relationship in the informed consent conceptualized as a medical effort obligation in civil law of medical practices should be applied in accordance with the *Lex Specialis Derogat Lege Generali* and the Freedom of Contract Principles in the therapeutic field. This is because the informed consent used as evidence and the application of legal principles in the medical effort obligation requires legal consistency and certainty. In many cases, the patient-doctor relationship is often inharmonious; it is often triggered by miscommunication or even suspicion; if the patient deceases or the treatment does not work as expected by the patient/his family, the doctor is the one to blame for medical malpractice. In some pieces of literature, this disharmony occurred in two eras: the first era was before the commencement of Law No. 29 of 2004 concerning Medical Practice; it was described as an unbalanced era, with no legal certainty in protecting the rights and obligations of patients and doctors so that the practice of law enforcement is left to the provisions stipulated in the Criminal Code, the General Civil Code and the Minister of Health Regulations.

The second era was after the commencement of the Medical Practice Law; the public hoped for the legal certainty and guaranteed protection of the rights and obligations of patients and doctors in the relationship of medical efforts conceptualized in the informed consent. With this background, this research was conducted to examine the problem of the regulation and application of the informed consent's legal provisions as regulated in article 39, and article 45 of Law No. 29 of 2004 concerning Medical Practices¹, and which was based on the *Lex Specialis Derogat Lege Generali* and the Freedom of Contract Principles in the therapeutic field.

¹ Law No. 29 of 2004 concerning Medical Practice, 31 August 2004, (Jakarta: CV Eko Jaya, 2004), p. 19 and 21.

II. RESEARCH PROBLEMS

Based on the background, the research was focused on the following problems:

1. How is informed consent applied in the *Lex Specialis Derogat Lege Generali* and the freedom of contract principles in the therapeutic field according to the real of certainty or the legal certainty principles?
2. How is the legal strength of informed consent as evidence related to the *Lex Specialis Derogat Lege Generali* and the freedom of contract principles in the therapeutic field?
3. How is the evidence system of civil cases (positive wetelijk stelsel) ideally applied in the Indonesian civil justice system which has no specialized judicial institution for deviations of medical practice law (malpractice in medical law)?

III. DISCUSSION

Referring to the history of the commencement of the Civil Law system, Indonesia adopted the legal system commenced in the Netherlands along with some reforms. Consequently, the civil law system and the codification of the law imposed in Indonesia is the same as that applied in the Netherlands, which is based on the principle of concordance². This limits Indonesian civil judge's authority to only applying the law still in force before the special law is made and applied; this special law was subject to the Civil Code announced by the Government on 30 April 1847 through Government Gazette 1847 No. 23, based on the influence of *Algemene Bepalingen van Wetgeving (AB)*³ and applied in Indonesia since January 1, 1948. This institution of Dutch civil law codification was influenced by the Roman law⁴ and strongly affected the doctor-patient relationship in the medical effort obligation before and after the commencement of Law No. 29 of 2004 concerning Medical Practices. Based on this background, the patient-doctor legal relationship conceptualized in the informed consent is influenced by several meanings of the provisions concerning the agreement, contract, or obligation in Book III of the Civil Code and through several practices of a general civil judge decision. Before the commencement of Law No. 29 of 2004 concerning Medical Practice, the legal basis for informed consent is included in the Minister of Health Regulation and is seen as a "contractual relationship (agreement) between the patient and the doctor". The provisions applied in the Civil Code do not regulate the meaning of an agreement letter for medical action, informed consent, contract, or the meaning of obligation itself. The Civil Code only regulates and defines the term "agreement", while the terms "contract", "consent", and "obligation" are not defined. The definition in a medical effort obligation is clarified by the legal practice of the general civil judge decision. The commencement of the Special Law and Jurisprudence encourages the concept of understanding the terms 'obligation', 'contract', or 'consent' and other forms of 'agreement' in the therapeutic field. Initially, these were not clearly stated in the Civil Code; nevertheless, they have gradually been explained clearly, particularly related to their definition and how to apply their legal provisions.

Informed consents that are made and signed unilaterally by the patient, as stipulated in the provisions of article 45 of Law No. 29 of 2004 concerning Medical Practice, is a clear example of showing the meaning of 'consent' in 'informed consent' and 'forms of consent'; it is different from the meaning of 'agreement', 'contract' or 'public obligation' regarding material and assets (public services) as stated in Book III of Civil Code on Obligations. In the Civil Code, the form of the agreement is only known as a written one even though the law of obligations involves a written and oral agreement, which are only intended for material and property / public services agreement.

Ideally, after the commencement of the Medical Practice Law, the Indonesian Civil Judge will examine, consider and adjudicate the doctor-patient relationship disputes in the informed consent by not referring to and applying other sources or making their discretions; instead, they should make judgments based on the Law specified for Medical Practices and specific civil law principles related to the Civil Law system because medical practice law is not a general one; it is a special law and has a privilege based on the judgment and decree of the Constitutional Court No.14 / PUU-XII / 2014, 20 April 2015⁵.

3.1. The Concept of Informed Consent in Therapeutic Effort Contracts

The specialness of the definition of informed consent also lies in the different forms of consent manifestation, which are written consent, oral or physical body gestures (nodding or other gestures, not only by written words

² R. Subekti and R. Tjitrosudibio, "*Kitab Undang-Undang Hukum Perdata*" (Jakarta; PT. Pradya Paramit, 34th printing, 2004), p. 7.

³ Titik Triwulan Tutik, "*Hukum Perdata dalam Sistem Hukum Nasional*" (Jakarta; Intermasa, 1st printing, 2008), p. 15-19.

⁴ Peter de Cruz, *Perbandingan Sistem Hukum Common Law, Civil Law and Socialist Law* (Bandung: Nusa Media kerjasama Diadit Media: Jakarta, 5th printing, 2014), p. 61-62.

⁵ Decision of the Constitutional Court No.14 / PUU-XII / 2014, on 20 April 2015, p. 60.

or spoken utterances).⁶ Another uniqueness, according to the law of medical practice, is when a patient has an emergency condition and brought to the doctor's office, the doctor has a moral and legal obligation to perform emergency medical actions without having to wait for any forms of formal approval from the patient/or the person delivering the patient.⁷ This also broadens the meaning of "informed consent" in the legal domain of medical practice. In order to fulfill formal juridical reasons, it is possible for the person delivering the patient, who is not related to the family, to sign on an informed consent so that a competent doctor can attend to the patient needing immediate help.

In the world of medical practice, informed consent in an emergency can be done by the person who delivered the patient instead of the patient himself and it is treated the same as an informed consent signed by the patient. Although it is confirmed in the provisions of Article 4 of Minister of Health Regulation No. 290 / MENKES / PER / III / 2008 of March 26, 2008, the condition (emergency) does not require the informed consent⁸. In the civil field, such practice is not safe and can lead to legal consequences that are difficult to prove, including medical dispute/accusation from the patient/the patient's family that the doctor has done medical malpractice.

According to studies in the field of moral and disciplinary obligations, a doctor will still be easily accused if his medical actions result in medical malpractice, regardless people delivering the patient has ethically given approval for an emergency medical action, because the doctor is perceived to be in a hurry and does not conform to the patient's family in performing the medical action. The only evidence to dismiss this assumption is to be proven by doctors through clinical trials or autopsies and to present witnesses/experts. Emergency action in the practice of medical law is a necessity/obligation that must be performed by doctors to save the patient's life and to treat his disease.

The rights and obligations of patients and doctors in terms of moral, ethics, or medical discipline are not the same as the rights and obligations in terms of medical action, whether they imply s medical malpractice or not. It is because the philosophy of medical practice always starts from a doctor's good intention in trying to save and not to harm the patient's live. This is in contrast to a state that adopts the Common Law system; according to this legal system, although it is the Special Law, it is not perceived as the only basic norms used by Civil Judges in considering and applying medical-legal practices; instead, the judges use the doctrine of law and jurisprudence as the only source of reference for medical practice law.

3.2. The Concept of Medical Effort Obligation in Informed consent as a Limitation on the Legal Relationship of Doctors and Patients

In brief, medical effort obligation is similarly defined as medical effort agreement. Likewise, a therapeutic effort obligation is often put on a par with a therapeutic effort agreement/therapeutic effort transaction, whereas in the practice of medical action, a therapeutic effort obligation is different from a therapeutic effort agreement, from a therapeutic effort transaction, or a therapeutic effort contract. The therapeutic agreement, contract, or transaction has a broader scope than the therapeutic effort obligation or a special obligation in a doctor's medical treatment to patients. The therapeutic effort agreement has clearly illustrated the agreements in every effort in the therapeutic field, including an agreement in the facilities provision and use which is not an effort of medical-action service. The concept of an effort agreement in the therapeutic field implies an agreement or obligation in an effort made on all fields concerning the therapeutics due to an agreement made by both parties in the therapeutic services and non-services. The concept of medical effort obligation is conceptualized only in the area of medical action efforts approved by the patient and performed by the doctor based on professional standards, SOPs, and the patient's medical needs.

The concept of medical effort obligation in the informed consent means a special effort obligation ties to medical action that requires the will and consent of only one party (patient). Consequently, this form of agreement binds the doctor/dentist to legal, moral and disciplinary obligations to take medical action on their patients in accordance with Professional Standards, SOPs, and the patient's medical needs. Accordingly, medical effort obligation performed by doctors to their patients remains to refer to and be based on the

⁶ The Republic of Indonesia, Minister of Health Regulation No.290 / MENKES / PER / III / 2008) concerning Approval of Medical Measures, http://www.academia.edu/11179925/PERMENKES_290_2008_TENTANG_PERSETUJUAN_TINDAKAN_MEDIS_INFORMED_CONSENT accessed on 20th December 2016.

⁷*Ibid.*, Republic of Indonesia, Minister of Health Regulation No.290 / MENKES / PER / III / 2008) concerning Approval of Medical Measures, http://www.academia.edu/11179925/PERMENKES_290_2008_TENTANG_PERSETUJUAN_TINDAKAN_MEDIS_INFORMED_CONSENT accessed on 20th December 2016.

⁸*Ibid.*, (Article 4 paragraph (1) In an emergency, to save the patient's life and/or prevent disability, approval for medical action is not required)

obligations set in the ethical/moral guidelines (*KODEKI/Indonesian Medical Ethics Code*) and remains to refer to and be based on 28 disciplinary guidelines set in the *Peraturan Konsil Kedokteran Indonesia* (Indonesian Medical Council Regulation); the doctor is also bound by the legal basis for the obligation of special efforts in medical practice based on the Medical Practice Law, as well as the *Lex Specialist Derogat Legi Generali* and the Freedom of Contract principles in the therapeutic field.

One of the limitations and measures regarding the effort obligation in the informed consent is that doctors perform medical action efforts on their patients according to the Professional Standards, SOPs, and the patient's medical needs. To compare the agreement/contract for therapeutic field efforts with the effort obligation in the informed consent, the former's concept is made and required to obtain both parties' approval (the patient and the doctor), while the latter's can be made unilaterally by the patient; however, if the patient has agreed, the doctor is obliged to perform medical action according to the Professional Standards, SOPs, and the patient's medical needs. The second difference is that the therapeutic agreement/contract concept has a broader scope of obligation/ agreement compared to that of the medical obligation effort. In essence, the obligation of therapeutic efforts on informed consent is more specific and the scope of the obligation is narrower than the concept of agreement/contract of therapeutic field effort.

The Medical Practice Act⁹ explains that "Service Standards" are guidelines that must be followed by a doctor or dentist in performing a medical action (article 44 paragraph (1)). "Professional Standards" are the minimum ability limit (knowledge, skills, and professional attitude) that must be mastered by an individual to be able to independently carry out his professional activities to the community made by professional organizations (article 50). "Standard Operating Procedure" is a set of instructions/procedures standardized to complete a particular work routine. It provides the correct and the best steps based on mutual professional consensus to carry out various activities and service functions created by health service facilities according to the Professional Standards (article 50).

The articles of competence in the field of medical action constitute a guideline and limit the doctors' obligations in providing medical treatment services to their patients according to "Professional Standards". The patient-doctor legal relation in the medical effort obligation conceptualized in the informed consent is clearly stated in the provisions of article 39, article 45, article 51 of the Medical Practice Law¹⁰. Zahir Rusyad¹¹ further discussed the informed consent in the therapeutic effort obligation, especially in relation to the practice of medical law (quoting J.H. King Jr., in Veronica Komalawati's book entitled "The Role of Informed Consent in Therapeutic Transactions"), and he explained the two main legal theories supporting the doctor-patient relation, which is the "Contract Theory" and the "Undertaking Theory". According to the Contract Theory, if a doctor agrees to treat a person in return for a certain honorarium, then a contractual arrangement can be made which is accompanied by his rights and accountability. If the parties have reached an agreement on the requirements or treatment, a real contract can be made. Based on the Undertaking Theory, if a doctor volunteers to provide a person with treatment, a professional relationship is created and accompanied by the obligation to care for the recipient.¹²

According to King, as Zahir Rusyad¹³ wrote, the Undertaking Theory provides the basis for creating a relationship between doctors and patients in situations involving medical services, including those that are not covered by a contract. In addition, there is also an incidental relationship, in which the doctor's services are paid for by people who are not recipients of services. However, because the main purpose of medical services and therapeutic service is to provide care (not only medical treatment), the legal relationship between doctors and patients is generally found under the theory of Third-Party Benefits or the Undertaking Theory. This is considered appropriate by some experts, regardless of whether the service is free or paid for by someone who is not the service recipient. R. Abdoel Djamali and Lenawati Tedjapermana asserted that medical science is getting more extensive and complicated; no one knows all of them so it is necessary to maintain good relationships among members of the medical profession. Doing a consultation with colleagues or specialist doctors is increasingly needed. A medical doctor should seek consultation with a specialist if it is considered useful or if the patient wants it.¹⁴ Further said, a general practitioner or specialist must be truly aware of the limits of his knowledge and abilities. If he is at his limit, he must have a discussion with other doctors who are experts in the

⁹Law No. 29 of 2004 concerning Medical Practice, August 31, 2004, Op.Cit., p. 48-50.

¹⁰Law No. 29 of 2004 concerning Medical Practice, August 31, 2004, Op.Cit., p. 21.

¹¹Zahir Rusyad, *Hukum Perlindungan Konsumen, Konsep Perlindungan Hukum terhadap Pasien dalam Pemuahan Hak Kesehatan oleh Dokter dan Rumah Sakit* (Malang: Setara Press, 2018), p. 38.

¹²*Ibid.*, p. 38.

¹³*Ibid.*, p. 38.

¹⁴R. Abdoel Djamali dan Lenawati Tedjapermana, *Tanggung Jawab Hukum seorang Dokter dalam Menangani pasien* (Jakarta: ABARDIN, 1st printing, 1988), p. 98-99.

disease. In big cities, in which specialist doctors perform their practice, a general practitioner must not only be an intermediary between the patient and the specialist doctor.¹⁵

Referring to the previous discussion, the law of the therapeutic effort obligation on the informed consent is the legal basis of the relation between the doctor and the patient in a medical action according to the principle of *Lex Specialist Derogat Legi Generali* in positive law of medical practice and not based on the law of agreement or contract as regulated in the Civil Code. The legal principle of the therapeutic effort obligation conceptualized in the informed consent requires doctors to provide medical treatment for patients who visit and wish to seek treatment according to SP, SOP and the patient's medical needs. A doctor providing help does not necessarily mean that the doctor must assure to perform an action to cure the patient's disease (some sort of demand to fulfill the obligation of curing the disease/*Resultaat Verbentenis* in the therapeutic field) or demands in fulfilling therapeutic contracts with patients. A doctor providing help is more precisely interpreted that the patient utilizes all efforts of the doctor/team of doctors to carry out medical treatment on patients according to their competence and limit of knowledge as determined by provisions of article 51 of the Medical Practice Law.

The Medical Practice Act limits doctors only to the efforts of medical treatment according to SOP, SP and medical needs of patients. Based on the limitations of the regulation in the Medical Practice Law, the two main legal theories (Contract Theory and Undertaking Theory) explained by J.H. King, Jr¹⁶ are more precisely linked as a relationship between patients and doctors in terms of agreement/obligation in the therapeutic field in capitalist/individualist countries; it is inaccurate to link the theories to the therapeutic effort obligation in the informed consent in Indonesia that adhere to the philosophy of Pancasila. It is inappropriate to link the Contract Theory and Undertaking Theory¹⁷ to the profession of physician in conducting medical action efforts to patients according to the Medical Practice Law even though it is based on a therapeutic agreement/contract in exchange for certain fee; it is because the doctor-patient relationship, according to the Medical Effort Theory, is not related to contract transactions/transactions in the public service agreement in the type of medical treatment.

Likewise, the Undertaking Theory mentioned by J.H. King, JR is also not appropriate if applied to the doctor-patient relationship in terms of informed consent because the doctor/dentist is not doing business with the patient, even though the relation involves compensation services from one party or a third party. To be more precise, the patient-doctor relation is seen as an act/relationship between the doctor's medical efforts and the patients, utilizing all the efforts or abilities of the doctor/team of doctors to treat the patient based on the competence and professionalism of medical science according to SOP, SP, and medical needs of the patient. Therefore, according to the provisions of the Medical Practice Law, the legal theory that can be built and applied in the patient-doctor relation regarding the therapeutic effort obligation in informed consent is the Medical Effort Theory, not the Medical Contract Theory.

Based on the results of the study, the Medical Effort Theory can be explained as a new theory about doctors' medical action effort for patients based on the competence or professionalism of their medical knowledge in accordance with SP, SOP and medical needs of patients. The medical effort theory is more precisely labeled as a doctor-patient relationship theory in the obligation of medical action efforts according to the Medical Practice Act since the relationship is bound to the maximum utilization of the doctor's efforts for the patient to fulfill the humanitarian obligations based on medical philosophy. The Medical Practice Act is relatively new in force, so, naturally, an increase in medical practice cases is not in line with the expectations of patients, doctors and related parties. This also contributes to the high number of complaints or disputes in medical practice reported to MKDKI (*Majelis Kehormatan Disiplin Kedokteran Indonesia*-Indonesian Medical Disciplinary Honorary Council), to the MKEK (*Majelis Kehormatan Etik Kedokteran*- Medical Ethics Honorary Council), or resolved through the process of civil and criminal justice institutions so as to bring influence and raise patient awareness, doctors and related parties to continue to seek alternative solutions. Based on the investigation, there were recorded cases of complaints from the public/patients and related parties, of which the figures can be seen in Figure 1 and Figure 2.

NUMBER OF COMPLAINTS TO MKDKI = 381
Year 2006-2016
Complaints

¹⁵*Ibid.*, p. 99.

¹⁶Zahir Rusyad, Loc.Cit., p. 38.

¹⁷*Ibid.*, p. 38.

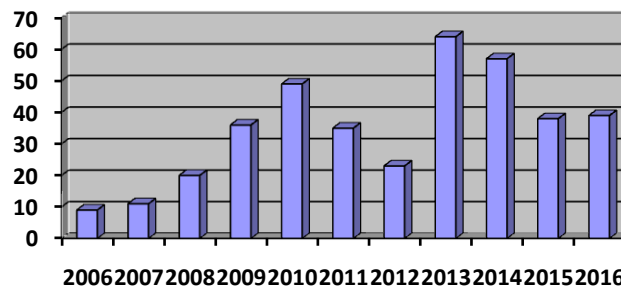


Figure 1
Source: MKDKI

Notes:

2006 = 9 ; 2007 = 11 ; 2008 = 20 ; 2009 = 46 ; 2010 = 49 ; 2011 = 35 ; 2012 = 23 ; 2013 = 64 ; 2014 = 57 ; 2015 = 38 ; 2016 = 39.

SOURCE OF COMPLAINTS

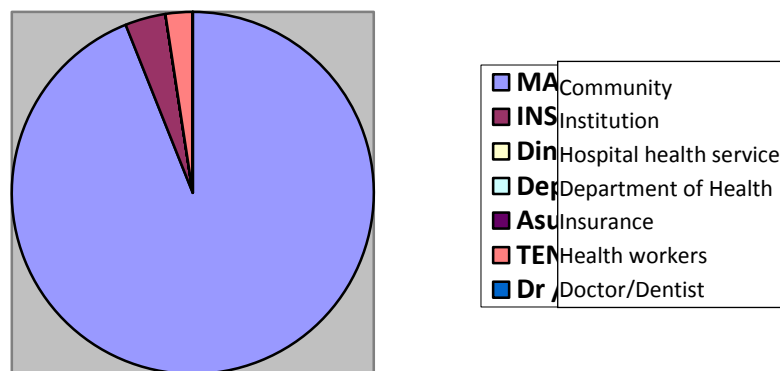


Figure 2
Source: MKDKI

Notes:

Community = 233; Institution = 9; Health workers= 6

3.3. Informed Consent in a Positive Legal Perspective

As the patients unilaterally give the therapeutic effort obligation in the informed consent under the Medical Practice Act, the doctors are obliged to perform medical action according to the medical effort theory, SP, SOP, and the patient's medical needs. This type of therapeutic obligation engages the patient-doctor relationship to the principle of the relationship in which one party agrees and the other party has an obligation. Implementing the medical effort theory in relation to the doctor-patient relationship is the doctor's obligation to perform medical action in accordance with the SP, SOP, and patient's medical needs. The legal obligations of the medical action efforts are clearly explained in Article 39 Jo., article 45 Jo., and article 51 of Law No. 29 of 2004 concerning Medical Practice on 6 October 2004.

To link the special provisions of these 3 articles with the provisions of article 30 of Law no. 38 of 2014 concerning Nursing, and with the provisions of article 1 number 11, article 46, article 47, article 48, article 49, article 50, article 51 of Law No. 36 of 2009 concerning Health, as well as with article 1 paragraph (1), article 4 paragraph (4), article 60e, and with article 61 of Law no. 36 of 2014 concerning Health Workers, they clearly indicate the meaning of a set of integrated and continuous activities within the framework of improving public health, preventing patient/community diseases, improving health status and restoring public health in general, not only specifically used and applied to individual patients. The relationship of the articles is related to the relationship between the patient and the doctor/health worker but is not directly related to the professional obligations of the doctor to an individual patient in a medical action. The interconnectedness of the Act's basic

provisions makes it likely and easy for patients to complain to the authorities; thus, disputes on medical action are addressed according to the legal basis.

Officials enforcing the law of medical practice implies that law enforcement pays more attention to legal certainty than other legal values because the European Continental legal system (Civil Law System) is applied. The substance of the medical practice regulation is the main point of the regulation regarding the patients' and doctors' rights and obligations based on the Medical Practice Law. Furthermore, in medical practice law cases especially in legal relationship disputes of informed consent, the civil judge generally may qualify the case based on formal positive law. It is essential to study and develop the civil law system for those who care about the legal certainty of a medical action obligation. Effective methods in medical action need to be standardized to create definitive rules of Professional Standards for the sake of law and justice. According to positive law in the field of medicine in Indonesia, informed consent is only known and regulated in the provisions of Article 39, Article 45 of Law no. 29 of 2004 concerning Medical Practices, while the detailed explanation is regulated in technical regulations under the Medical Practice Law in Minister of Health Regulation No.290 / MENKES / PER / III / 2008.

Civil judges often interpreted other positive laws related to informed consent differently; thereby, this frequently leads to inharmonious, unspecific, and unsynchronous application of medical practice laws. This encourages misinterpretation of the informed consent in the therapeutic effort law and enforcement which is not in accordance with the Medical Effort Theory, whose legal basis is regulated in Article 39, Article 45 and Article 51 of the Medical Practice Law and enforced not based on the *Lex Specialist Derogat Legi Generali* and the Freedom of Contract principles in the therapeutic field.

The comparison of studies of positive legal aspects in the civil and criminal fields of medical practice, regarding the application or non-application of informed consent as evidence, is presented in table 1.

Table 1. The Positive Law
Law of The Republic of Indonesia No. 29 Year 2004 regarding the Medical Practice

<p>Civil aspects: The emphasis of enforcement is applying the basis of article 39, article 45, article 51 of the Medical Practice Law Jo., article 1352, article 1365 Civil Code through the application of Wettelijk Stelsel's Positive Proof System, and positive law article 154, article 162, article 163, article 164 HIR / Rbg Jo., article 1865, article 1866, article 1867 Civil Code, based on the <i>Lex Specialist Derogat Legi Generali</i> and the Freedom of Contract principles in the therapeutic field.</p>	<p>Criminal aspects: The emphasis of enforcement is, applying the basis of article 39, article 45, article 51 relating to articles 75 to article 80 of the Medical Practice Law, Jo., article 359 of the Criminal Code (elements of violations of the criminal code of medical practice) through the application of the Wettelijk Stelsel's Negative Proof system, and positive law article 184, article 185, article 186, article 187, article 188 KUHAP, based on the Principle of Legality (Nullum delictum noella poena sine praevia lege poenali): There is no criminal offense if there is no criminal law previously governing it.</p>
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E. Some Facts of the Authority's Decision Regarding Disputes in Using Informed Consent as Evidence

The data of several decisions of the District Court, MKDKI, State Administrative Court related to the informed consent used as evidence are described and analyzed in table 2:

Table 2

No.	The Decisions of Civil Court Cases	Problem	Analysis
1.	No.577/Pdt/G/2011/P N.JKT.BAR, on May 16, 2012 ¹⁸ , Jo. No.08/PDT/2013/PT. DKI, on 11 June 2013 ¹⁹ , Jo. No.779	Is the evidence considered by the Civil Judge?	In the aforementioned 5 court decisions, the civil judge did not consider informed consent as strong and valid evidence based on the provisions of article 39, article 45 and article 51 of Law No. 29 of 2004 concerning Jo's Medical Practice, article 1352, article 1865,

¹⁸West Jakarta District Court Decision Civil Case No.577 / Pdt / G / 2011 / PN.JKT.BAR, May 16, 2012, p. 48-62.

¹⁹Jakarta High Court Decision No.08 / PDT / 2013 / PT.DKI, 11 June 2013, p. 4-5.

2.	K/Pdt/2014, on July 16, 2014 ²⁰ . No.484/Pdt.G/2013/P N.Jkt.Sel, on July 23, 2014 ²¹ , Jo. No.1001 K/Pdt/2017, on August 30, 2017 ²² .		article 1866, article 1867 of the Civil Code Jo., article 162, article 163, article 154, article 164 HIR / Rbg; however the civil judge immediately considers article 1365, article 1367 of the Civil Code as the basis for determining doctors and related parties to violate the law. The worse thing in the case decision No. 484 / Pdt.G / 2013 / PN.Jkt.Sel, on July 23, 2014, is that the civil judge did not consider the statements of expert witnesses and evidence of informed consent.
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Patient's lawsuit in case No.484 / Pdt.G / 2013 / PN.Jkt.Sel, on July 23, 2014, Jo. No.1001 K / Pdt / 2017, on 30 August 2017, was granted by the civil judge in different ways and levels of decision because the informed consent and the expert witness statement were not considered. The civil judge approved the patient's claim by considering the application of the civil law principles in a general obligation, which was the principle of ill will, whereas the principle of ill will/ goodwill had nothing to do with the obligation of Professional Standards in medical actions.

The next case is No.577 / Pdt / G / 2011 / PN.JKT.BAR, May 16, 2012, Jo. No.08 / PDT / 2013 / PT.DKI, 11 June 2013, Jo. No.779 K / Pdt / 2014, July 16, 2014, in which the civil judge considered the expert witness' statement about the commencement of the International SOP as a study and consideration in measuring limit of the doctor's mistake so that violations of general civil law principles and International SOPs were considered as the causes of the patient's death; the doctor was charged guilty.

Civil judges do not properly consider the legal basis for the provisions of article 39, article 45, article 51 of the Medical Practice Law as a measurement limit or basis for consideration in examining and assessing whether or not there are mistakes of civil law in medical practice. In the consideration and decision of Civil Judge No.577 / Pdt / G / 2011 / PN. JKT. BAR, on May 16, 2012, the doctors' mistake in medical practice was considered and assessed from an expert witness statement explaining that the obligation to examine blood of patients with Dengue indication must be done 2 (two) times according to International SOP, even though there is no factual decision on ethical violations from MKEK / disciplinary violations from MKDKI.

Table 3

No.	Decree of MKDKI	Problem	Analysis
1.	No.129/Kep/MKDKI/V/ 2010, on 26 May 2010 ²³ and 30 March 2011 ²⁴ .	Is the informed consent as the evidence of the relationship between the patient and the doctor considered by the MPD	From the MKDKI decrees, it is indicated that the MPD at MKDKI does not specifically consider the evidence of informed consent, even though the patient had given his consent to the doctor to perform the medical action.
2.	No.09/P/MKDKI/V/201 1, on 4 April 2013 ²⁵ and 5 June 2013 ²⁶ .	<i>(Majelis Pemeriksaan Disiplin-Disciplinary Panel)</i> in MKDKI?	

Moreover, the consideration and decision of the MPD on Decree (SK MKDKI) No.129 / Kep / MKDKI / V / 2010, May 26, 2010 and March 30, 2011, the panel impose disciplinary sanction the two doctors (as a team) despite having the evidence of informed consent and having been decided that they did not violate the law by a civil judge based on case No.237 / PDT.G / 2009 / PN.JKT.UT, on March 11, 2010.

²⁰Decision of the Supreme Court of the Republic of Indonesia No.779 K / Pdt / 2014, on 16 July 2014, p. 19-25.

²¹Decision of the South Jakarta District Court, Civil Case No.484 / Pdt.G / 2013 / PN.Jkt.Sel, on July 23, 2014, p. 67-90.

²²Decision of the Supreme Court of the Republic of Indonesia No.1001 K / Pdt / 2017, on 30 August 2017, p. 48-52.

²³MKDKI Decree No.129 / Kep / MKDKI / V / 2010, on May 26, 2010, p. 1-31.

²⁴MKDKI Decree No.129 / Kep / MKDKI / V / 2010, on 30 March 2011, p. 1-6.

²⁵MKDKI Decree No.09 / P / MKDKI / V / 2011 on April 4, 2013, p. 1-14.

²⁶MKDKI Decree No.09 / P / MKDKI / V / 2011 on June 5, 2013, p. 1-5.

Aside from that, the decision of the MPD in the MKDKI Decree No.09 / P / MKDKI / V / 2011 on April 4, 2013, and June 5, 2013, considered the technical violation of the blood provision mistake in preparing medical action for the patient; according to the provisions of article 3 paragraph 2 (f) Perkonsil No. 4 of 2011²⁷, the supply of blood in hospitals did not belong the doctors' authority as it is the obligation and responsibility of UTD (*Unit Transfusi Darah* - Blood Transfusion Unit) and the Government according to article 1 number 8, article 3, article 4, article 5, article 6, article 7 Government Regulation no. 7 February 4, 2011²⁸. The MPD also considers whether there is a mistake in the doctor's medical action based on article 3 paragraph 2 (h) Perkonsil No. 4 of 2011²⁹ in consideration of the presence or absence of the patient's family to hear the explanation from the doctor before signing the informed consent, whereas this lies in the fact indicating the patient's repeated visits to the doctor and the patient's signature on the informed consent letter ". To point out, the two studies did not consider the evidence of informed consent as a basis for deciding whether the doctor violated the discipline of medical practice.

The 2 (two) MKDKI Decrees (No. 129 / Kep / MKDKI / V / 2010 and No. 09 / P / MKDKI / V / 2011) about violations of medical discipline in Indonesia are different from the GMC (General Medical Counseling) decisions in London³⁰. In London, England, there was a case where a senior doctor (Prof. SC) delegated his duty to another doctor (Dr. CL) who had the same competence to perform medical action on a patient (MC woman); and the doctor had previously received the informed consent from the patient. In several court sessions, the GMC in London eventually decided that Dr. CL and Prof. SC were not guilty of violating the discipline of medical practice for the cause of the patient's death was continuous bleeding since the patient agreed to do a hysterectomy medical treatment in uterine surgery, according to evidence of informed consent.

The comparison between GMC decisions in London as written by J. Guwandi and 2 MKDKI Decrees in Indonesia brings an impact on several decisions of the State Administrative Court and the Civil Court. There are a few of them that consistently consider the informed consent and expert witness statements for the basis of their consideration and decision, while some are inconsistent in doing so, which is related to the provisions and procedures for issuing SK MKDKI (Object of Dispute) based on *PERKONSIL* (council regulation) or laws applied as a consideration and decision against a doctor deemed proven / not proven to violate the discipline of medical practice in the issuance of the Dispute Object.

Table 4 and Table 5 present the comparison between the decision of the State Administrative Court, which considers the evidence of informed consent and does not consider the evidence of informed consent as the basis in the viewing of medical discipline violation:

Table 4

No.	The Decision of the State Administrative Court	Problem	Analysis
7.	No.84/G/2011/PTUN.JKT, on 25 August 2011 ³¹ Jo. No.242/B/2011/PT.TUN.JKT, decision on 10 January 2012 ³² Jo. No.298/K/TUN/2012, decision on 29 August 2012 ³³ .	Was the informed consent as the evidence of the relationship between the patient and the doctor considered by the State Administrative judge?	4 levels of the State Administrative Court's Decision were consistent in considering the evidence of informed consent based on PERKONSIL.
8.	No.121/G/2013/PTUN.JKT, on 12 December 2013 ³⁴ .		

²⁷PERKONSIL No. 4 of 2011 concerning Professional Discipline of Doctors and Dentists, p. 3rd sheet.

²⁸Republic of Indonesia Government Regulation No. 7 of 2011 concerning Blood Services, p. 2-5.

²⁹PERKONSIL No. 4 of 2011 concerning Professional Discipline of Doctors and Dentists, Loc. Cit., p. 3rd sheet.

³⁰J. Guwandi, *Konsili Medik & "Serious professional Misconduct"*, (Jakarta: Balai Penerbit Fakultas Kedokteran Universitas Indonesia, 2004), p. 62-63.

³¹Decision of PTUN.JKT No.84 / G / 2011 / PTUN.JKT, on August 25, 2011, p. 1-94.

³²Decision of PTTUN.JKT No.242 / B / 2011 / PT. TUN. JKT, on January 10, 2012, p. 1-10.

³³Decision on Cassation TUN No.298 / K / TUN / 2012, on August 29, 2012, p. 1-28.

³⁴Decision of PTUN.JKT No.121 / G / 2013 / PTUN.JKT, on 12 December 2013, p. 1-126.

The decision of the State Administrative Judge in case No.84 / G / 2011 / PTUN.JKT, on August 25, 2011 and No.121 / G / 2013 / PTUN.JKT, on December 12, 2013, clearly considered the evidence of informed consent as a basis for deciding whether there is a violation of the discipline of medical practice; additionally, the State Administration judge considered the substance of the doctor's medical actions to patients based on SP, SOP and patient's medical needs related to the procedure for issuing Dispute Objects (SK MKDKI) according to the PERKONSIL as manifestation of Good Governance implementation.

The results of consideration of 2 State Administrative Dispute Objects related to the issuance of MKDKI Decree No.129 / Kep / MKDKI / V / 2010, May 26, 2010 and March 30, 2011 and MKDKI Decree No.09 / P / MKDKI / V / 2011 Date 4 April 2013 and 5 June 2013 implied that there were State Administrative Dispute Objects canceled by the State Administrative Judge because the issuance of the Disputed Object was seen as violating the PERKONSIL provisions and not in accordance with Good Governance, also there were Administrative Dispute Objects State Enterprises not canceled by PTUN (State Administrative Court) because they were seen to be in accordance with PERKONSIL.

The different data of civil judge decisions (State Administrative Court and Civil Court Decisions) proved that there were some civil judges who consider and some who did not consider informed consent as an assessment and strong evidence of the relationship between patients and doctors in the medical effort obligation. From the perspective of civil law, the consideration of the existence of an alleged mistake made by a doctor, according to the provisions of article 1365 of the Civil Code, is assessed and linked to the provisions of article 39, article 45, article 51 of Law No. 29 of 2004 concerning Medical Practice, article 1352, article 1865, article 1866, article 1867 of the Civil Code based on legal processes and procedures as well as proof systems according to the provisions of article 162, article 163, article 164 HIR / Rbg.

The consideration of the civil judge in applying the positive law previously mentioned must rely on and refer to the enactment of the *Lex Specialist Derogat Legi Generali* and the Freedom of Contract principles of the therapeutic field in the Wettelijk Stelsel Positive proof system. The practice of civil law enforcement that does not consider informed consent and expert testimony as strong evidence as well as ignores the provisions of positive law and the principles of law in civil disputes is a law enforcement practice that has no legal certainty and is not in accordance with the Civil Law legal system.

Effort obligation in the therapeutic field conceptualized in the informed consent letter, although regulated in positive law and has a strong philosophical foundation in the field of medical practice, were considered differently by the Indonesian Civil Judge and the MKDKI. The philosophy of informed consent is a medical practice philosophy that emphasizes on respecting the basic rights of patients to get assistance from doctors and requiring doctors to perform medical action based on medical effort theory as outlined in SP, SOP and patient's medical needs based on positive law. If we perceive the sociological aspects, informed consent is also a form of legal relation respecting the patient's final choice in social relations in the field of medical practice.

The principle of the patient-doctor obligation relationship in informed consent is a legal relationship between obligations that do not demand results (Inspection Verbentenis in the field of medical civil law). Based on the results of the study, civil judges in several cases of medical practice pointed out the fact that there were civil judges who considered elements of acts violating doctor's law article 1365, article 1367 of the Civil Code linked to violations of informed consent based on the theory of medical effort, SP, SOP and medical needs of patients Article 51 of the Law on Medical³⁵. Nonetheless, there are also civil judges who do not consider the element of unlawful conduct associated with informed consent but instead are associated with the ethical mistake/element of disciplinary mistake of an operator doctor as mentioned in several MKDKI's decisions. The legal consequences of such considerations of civil judges that directly determine and punish by asking compensation to the doctor operator or the Hospital / Hospital Legal Entity Owner because the doctor is personally considered guilty / violate ethics / violate medical discipline; it is a logical consequence of the civil judge's mistakes and lack of ability in making legal consideration and decision.

To determine whether there is a violation of civil law (Onrechtmatigedaad) in the Civil Law system, the legal basis should be based on the provisions of Article 1352, Article 1365 of the Civil Code Jo. article 51, article 45, article 39 of Law No. 29 of 2004 concerning Medical Practices and pay attention to the basic principles of the *Lex Specialist Derogat Lali Generali* and the Freedom of Contract the therapeutic field, in the positive evidence of Wettelijk Stelsel principles. Legal doctrines related to medical practice in the Common Law system, such as the doctrine of "Volenti nonfit Injuria", are sometimes also used by Indonesian civil judges as a source of reference even though Indonesia is a country that adheres to the Civil Law system. In law enforcement of medical practice, elements of acts violating the law article 1365 of the Civil Code should be responded to and considered according to the presence/absence of legal mistakes in patient-doctor relations

³⁵practice law No. 29 of 2004 concerning Medical Practice, August 31, 2004, Op.Cit., p. 23.

conceptualized in informed consent. The elements of acts violating civil law will be considered completed if the civil judge has considered the results of evidence derived from the proof of medical practice law based on the results of the Criminal Court's decision and/ or based on the results of the medical practice's legal mistake decision on according to the Positive proof legal system of *Wettelijk Stelsel*.

Tangible assessment of unlawful acts related to Article 1365 of the Civil Code so as to cause harm to others should be taken, determined and considered there are elements of positive acts violating medical practice, mainly violating the informed consent according to the basic assessment of the provisions of article 39, article 45 and article 51, done by a doctor / team of doctors according to the principles of *Lex Specialis Derogat Lege Generali* and the Freedom of Contract in the therapeutic field, not by the presence/absence of acts that violate ethics / violate the discipline of medical practice. Furthermore, the application of these principles in the positive evidence of *Wettelijk Stelsel*, or legal doctrines related to "*Volenti non fit Injuria*", should also be used as a reference source for civil judges in their consideration to maintain consistency and legal certainty, given that the limits of the doctor-patient "medical action" relationship is limited to SP, SOP, patient's medical needs and "Medical Effort Theory". Civil judges' decision disregarding the informed consent as evidence and ignoring the study of medical science based on the theory of medical efforts would be sufficient to encourage the world of medical practice to think of establishing a special judicial institution for medical malpractice, because civil judges are no longer independent and are unprofessional in prosecuting civil cases of medical practice.

IV. CONCLUSION

Based on the previous description, the conclusion is as follows:

1. Informed consent is not a form of agreement as regulated in the Civil Code. It is a legal relationship of medical effort obligation which first requires the doctor to explain the diagnosis, procedures for medical action, the purpose of medical action, alternative other actions, risks, and complications of the actions to be taken before the patient gives consent. Informed consent is a legal relationship that generated based on the Act as referred to in article 1233, and article 1352 of the Civil Code. In some cases of medical practice, informed consent was implemented in violation of Law No. 29 of 2004 concerning Medical Practices and the principles of *Lex Specialis Derogat Legi Generali* and the of Freedom of Contract in the therapeutic field. As a result, law enforcement against the commitment of medical action has no legal certainty.
2. In some cases of civil medical practice, evidence of the informed consent in the doctor-patient legal relationship is not seen as strong and valid according to the provisions of article 39, article 45 of Law no. 29 of 2004 concerning Medical Practice, even though the enactment of the provisions of this article is based on the principles of the *Lex Specialist Derogat Legi Generali* and the Freedom of Contract in the therapeutic field. In a number of decisions made by civil judges, the letter of informed consent is considered inaccurate. The proof system of "positive wetelijk stelsel", which is the standard proof system in the Civil Procedure Code, is also applied in violation, and even considered contrary to the enactment of the provisions of article 162, article 163, article 154, and article 164 HIR / Rbg Jo., article 1865, article 1866, article 1867 of the Civil Code, and are considered not in line with the medical effort theory.
3. Ideally, the evidence of informed consent is considered consistent by civil judges based on the principle of "positive wetelijk stelsel" and applied according to the Medical Effort Theory, so that the rule of law and law enforcement of medical practice in the field of special civil law has legal certainty, although Indonesia has no specialized judicial body of medical law malpractice yet.

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