



# The Implementation of Medical Informed Consent in Sleman Regency

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**Abstract.** Yogyakarta has a high number of morbidity rate which equal high possibility of using medical services. In therapeutic transaction arise obligation between patient, health personnel and health institution. This research to understand the legal analysis of informed consent in health services as well as to to evaluate and enhance the implementation of medical informed consent in Sleman Regency, especially in the Ananda Maternity Clinic. This normative-empirical research shows that the informed consent has to be imply. It is expressly regulated that the granting of approval for medical action does not eliminate legal liability in the event that it is proven that there is negligence in carrying out medical actions that resulting harm for the patient.

**Keywords:** implementation · informed consent

## 1 Introduction

### 1.1 Background

The survey released by the Central Statistics Agency (BPS) Yogyakarta showed the morbidity rate of the Yogyakarta population was 14.13 percent [1]. By the details that the morbidity rate for women is 16.89 percent and for men is 11.24 percent [2]. Indirectly, those figure shows the possibility of using medical services that is relatively high. The possibility worsen by the current global pandemic, which hardly impacting Yogyakarta [3]. This global pandemic has made everyone concern about their health, in such events, everyone wanting the best medical services they could afford [4]. Every District in the Special Region of Yogyakarta (DIY) has Public Health Centre, however, the spatial distribution and considering the time and distance that must be travelled to helath facilities is quite long and far [5]. Moreover, the Special Region of Yogyakarta (DIY) has only 44 private Hospital [6].

Development enhance the critical thinking of Indonesians, especially their right and duties in medical services provided by the hospital [7]. History has shown that there are rising number of issues between patients and hospitals. Mostly, caused by the aggrieved patient of health services. Health care is one of the human rights guaranteed by the 1945 Constitution which must be realized through several efforts. As a health institution, the

hospital is obliged to provide its best services as stated in Law Number 44 of 2009 on Hospital [8].

Notably, the Ministry of Health Regulation Number 129/Menkes/SK/II/2008 explained that the quality is seen by hospital compliance with predetermined standards or in accordance with the requirements of Minimum Service Standards (SPM) [9]. One of the parameters to determine the quality of health services in hospitals is a complete medical records which can be obtained from correct, complete and updated data of the patient. All of it was obtained from the informed consent.

The Special Region of Yogyakarta (DIY) is known as the city of students, because of almost 20 percent of its productive population is students but only 17.81 percent of its productive population has higher level of education than preliminary school [10]. The data equally explain that not everyone aware of the hospital compliance with the predetermined standard made by the Ministry of Health. In fact, the Sleman District Health Office has published a guide book containing an attachment to the SOP for all health services in the district that can be used as a reference. As one of the SOP, informed consent play a significant role in overall medical services outcome.

Informed consent should not be an obstacle as stated in the Regulation of the Minister of Health of the Republic of Indonesia Number 290 / MENKES / PER / III / 2008 CHAPTER II approval and explanation of article 4 (1) which reads “In an emergency situation, to save patient’s life and / or prevent medical treatment approval is not required [11].

The Penal Code Articles 351, 359, and 360 involve actions that cause injury, disability, death due to negligence. Therefore, there are many things that make the author interested in conducting research on the implementation of this Informed Consent.

## **1.2 Statement of Problems**

Considering the research background above, the author formulated two questions to be researched, namely:

- What is the legal analysis of informed consent in health care services especially for medical service?
- How the implementation of medical informed consent in Sleman Regency?

## **1.3 Objectives of Research**

Based on the research questions above, there are three objectives to be achieved, namely:

- To understand the analysis of informed consent in health services in Sleman Regency.
- To evaluate and enhance the implementation of medical informed consent in Sleman Regency

## **1.4 Research Method**

### **1.4.1 Type of Research**

The type of this research is a normative empirical legal research method. The research used is juridical normative and juridical empirical[12]. This research was conducted

on secondary data such as legislation, scientific journals, legal books related to the law of cooperation and agreements. This type of research has chosen to fulfill the problem formulation and achieve the main research objective as evaluate and enhance the implementation of informed consent in Sleman Regency.

#### **1.4.2 Type of Data**

This research is a normative-empirical legal research. This research is a normative-empirical research with juridical approach, hence it uses primary and secondary data.

- Primary Data
- Secondary Data
- Tertiary material:

#### **1.4.3 Method of Collecting Data**

Data were collected through both Field Work and library-based study.

- Field Work
- Library-based Study
- Analysis

## **2 Overview of Health Care Service**

### **2.1 Health Service Definition**

Based on the Decree of the Minister of Health of the Republic of Indonesia No. 75 of 2014 Health service facilities are a place used to carry out health service efforts both in terms of promotive, preventive, curative and rehabilitative carried out by the government, local government and the community.

To provide a good service to people who want to get basic health services and consultation in the health sector, all supporting elements at the Puskesmas must strive to improve the quality of service if the Puskesmas does not want to be abandoned by the community because in essence the more perfect the services provided to patients, the better. The higher the level of satisfaction for the patient [13].

### **2.2 Type of Health Care System**

Health services are services either carried out by individuals or jointly with the aim of recovering and curing disease, improving the health of a person and/or society. In its implementation, health services have basic requirements that must be met so that health services can be said to be good. The requirements are available and sustainable, acceptable and reasonable, easy to achieve, easily accessible and of good quality.

Health care service is the right of every person guaranteed in the 1945 Constitution to make efforts to improve the health status of both individuals, groups or society as a whole [14]. Health care service can also be defined as any effort carried out alone or

jointly within an organization to maintain and improve health, prevent and cure disease and health, for individuals, families, groups or communities [15].

The Health Law of 2009 has broadened ways of services, as for Curative and rehabilitative health services<sup>16</sup>. Health services provided at public health centres, clinics and hospitals are generally regulated in the Health Law, Article 54 paragraph (1) of the Health Law.

Specifically in Article 29 paragraph (1) letter (b) of the Hospital Law, hospitals have the obligation to provide safe, quality, anti-discriminatory, and effective health services by prioritizing the interests of patients in accordance with hospital service standards [16]. The implementation of health in hospitals includes all aspects related to health care as stipulated in Health Law of 2009 [17]. Parties related to any health service activities, whether in hospitals, health centers, clinics, or private practice, are midwives.

### **3 Overview of Informed Consent**

#### **3.1 Informed Consent**

Informed consent is the consent given by the patient on the basis of an explanation of the medical action to be taken against the patient or in other words, the approval of medical action. The definition is regulated in the Regulation of the Minister of Health Number 290/Menkes/Per/III/2008 concerning Medical Informed Consent. Informed consent in a therapeutic transaction is the fulfillment of the principle of consensualism that obtain the law of the agreement where based on article 1320 of the Civil Code it is stated that an agreement will occur when both parties reach an agreement.

Informed consent has a dual function for doctors and/or medical institutions. The consent of the patient, in this case, has a very broad meaning because once the patient puts their signature on the informed consent form [17]. Every medical action must obtain consent, this is regulated in Article 45 of Law Number 29 of 2004 on Medical Practice. On the patient side, informed consent is an embodiment of the patient's right to [18].

- Everyone has the same rights in obtaining access to resources in the health sector.
- Everyone has the right to obtain safe, quality, and affordable health services.
- Everyone has the right to independently and responsibly determine the health services needed for themselves.

#### **3.2 Therapeutic Transaction**

Therapeutic transaction, included the relationship in performing service as has been regulated under Article 1601 Indonesian Civil Code (KUHPPerdata), performs a medical action to the patients as the recipient of such medical care service [19].

The informed consent and therapeutic transaction become a unity that cannot be separated. This is because the therapeutic transaction only then occurs after there is consent from the patient or the patient's family based on the medical action information [20].

The object of this agreement is in the form of efforts or therapy for healing the patient [21]. This kind of agreement has differences with agreements in general, which are

located on the object of the agreement [22]. Therapeutic transactions are a major part of health efforts, serves as providing medical services based on their expertise and skills, as well as thoroughness. This is based on the understanding that health workers need certain authority to carry out health efforts [23]. in therapeutic transactions rests on two kinds of human rights which are basic human rights, namely the right to self-determination and the right to obtain information [24].

Law Number 36 of 2009 concerning Health states that the parties in a therapeutic contract are patients and health workers, while Law Number 29 of 2004 concerning Medical Practice states [25].

### 3.3 The Legal Analysis of Informed Consent in Health Care Services

- Legal aspects of Informed Consent in Indonesia

In Indonesian positive law, informed consent is very clearly mandated in Law no. 36 of 2009 concerning Health Workers, Law on Medical Practice No. 29 of 2004.

Law No. 36 of 2009 concerning Health Worker, Article 56 clearly states the main rights of patients, namely, that everyone has the right to accept or reject part or all of the relief measures that will be given to him after receiving and understanding the information.

In the event that the patient is a child or an unconscious person, an explanation is given to the family or the accompanying person. If there is no escort and there is no family while medical action must be taken, an explanation is given to the child concerned or at the first opportunity the patient is conscious. Government Regulation No. 32 of 1996 concerning Health Workers, provides an explanation of the rights of patients contained in Article 22, where there is a right to information and informed consent For certain types of health workers in carrying out their professional duties are obliged to: respecting patient rights; maintain the confidentiality of the patient's identity and personal health data; provide information relating to the conditions and actions to be taken; request approval of the action to be taken; Create and maintain medical records

The relationship between health workers and patients is included in the area of civil law, namely an agreement to perform services (Article 1601 of the Civil Code) which is based on a relationship of mutual trust. The civil aspect of informed consent when related to the law of engagement is contained in book III, article 1230 of the Civil Code. If associated with informed consent, then: The agreement of those who bind themselves, is the first condition; The skills of the parties, in this case health workers and patients, must be mature so that they can carry out legal actions; A certain thing that is agreed upon must be clear, not a general thing; The existence of a lawful cause in the relationship between health workers and patients, meaning that they must not violate the law, decency or public order.

The cancellation of the agreement can only be carried out by the agreement of both parties as stated in Article 1338 of the Civil Code, but for Informed Consent in Medical Law there are exceptions, because Informed Consent concerns human rights and involves human life. If you take medical action without the patient's consent or consent, it is considered a violation of Article 351 of the Criminal Code regarding persecution. Even though there is no formal juridical justification.

The absence of Informed Consent can also be categorized as "Action against the law" (Onrechtmatige daad), which is regulated in Article 1365 of the Civil Code.

- The legal relationship among patient, medical personnel and health institution

Positioning the relationship between medical personnel and patients that has a legal basis, can be started with Article 1313 of the Civil Code. Thus the position of patients and medical personnel in health services should be equal. Each party, in this case medical personnel in the position of service providers (medical providers) and patients as service recipients (medical receivers), have rights and obligations that must be respected [26]. Before giving medical treatment to the patient, Law Number 36 of 2009 on Health Law number 29 of 2004 on Medical Practice and Minister of Health Regulation Number 290/Menkes/Per/III/2008 on Approval of Medical Action, the doctor must obtain medical approval from the patient or informed consent [27].

Just like an agreement in general, a Therapeutic Transaction must have a consensual in terms of consent to conduct a Therapeutic Transaction at the first place and informed consent [28].

The failure of one party to fulfill the rights of the other party, whether due to default or negligence, will result in a lawsuit or civil claim in the form of compensation for the losses suffered by the patient [29]. Legal problems that arise can be caused by errors or omissions by health workers or due to errors in implementing policies on regulations and also due to lack of knowledge of officers about Health Law or legislation in the health sector [30].

The development of the community is increasingly aware of their rights which automatically demands the transparency of health services, this is where the role of informed consent becomes important. The basic things in health services that are always questioned by the community or patients are related to openness, transparency, quality of service, application of rules, the discipline of time, so it is often suspected of medical negligence or clinical disaster [31].

The Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 on Approval of Medical Actions in Article 1 point (7) explains that competent patients to make informed consent are adult patients or non-children according to laws and regulations or have/have been married, not disturbed by their physical awareness, able to communicate naturally, do not experience mental retardation and do not suffer from mental illness so that they are able to make decisions freely [32]. The next condition is the existence of a certain thing (object). In the explanation of Article 1333 of the Civil Code, what is meant by a certain thing is that the object of the agreement must be certain, at least it must be determined.

The absence of informed consent can lead to medical malpractice, especially if there is harm or intervention to the patient's body [33].

In the violation of Informed Consent as regulated in Article 19 of the Minister of Health Number 290 of 2008 concerning Approval for Medical Action, it is stated that

doctors who take actions without Informed Consent may be subject to sanctions in the form of verbal warnings, written warnings to the revocation of the Practice License.

- **Informed Consent as a Protection of Patient Rights**

Informed consent that has been standardized is called a standard agreement, while the consent form for high-risk medical procedures such as surgery or other invasive procedures must be made in written form.

## **4 Implementation of Medical Informed Consent in Sleman Regency**

### **4.1 Overview of Ananda Maternity Clinic**

Ananda Maternity Clinic can be defined as a clinic that provides delivery, pregnancy consultation and services, immunization, baby massage, family planning, ultrasound, laboratory examination, as well as baby piercing. As one of the clinics in Yogyakarta, Ananda Clinic is located at damai street number 19, Wonorejo, Sariharjo, Ngaglik District, Sleman Regency. Ananda Clinic was started in 2005 by Istri Utami, a midwife. Istri Utami as the founder of the clinic explained that the initial pioneering of this clinic was based on her desire to have a Midwife Independent Practice (PMB) place in 2005 [33].

Before becoming Ananda Clinic, initially, this clinic was a Midwife Independent Practice (PMB) which was established on Jl. Student Soldiers. Istri Utami explained that the PMB has a capacity according to the minimum standards used by midwives, such as 1 delivery room, 1 obstetrical examination room, and 2 post-delivery rooms. In addition, the services available are not only the delivery process, but also cover all needs in maternal and child health services, such as examinations for pregnant women and postpartum, maternal and infant examinations, immunizations, and family planning. In the process, patients who come to the PMB place belonging to Istri Utami are increasingly crowded and become one of the health care places of choice for the community, especially in Sleman Regency.

Therefore, in 2012, we moved positions to Jl. Damai which is not far from Tentara Pelajar street.” said Istri Utami in the interview. He also emphasized that the move was accompanied by the addition of each room which previously only had 1 on Tentara Pelajar street, now Damai Street has grown to 2 delivery rooms and 5 postpartum rooms. In addition, Isti Utami also proposed a name change from the Midwife’s Independent Practice (PMB) to a maternity clinic. This clinic, which he later named the Ananda Clinic. In addition, the medical personnel at Ananda Clinic, such as midwives and assistant midwives, have been carefully selected, starting from the file selection and interview tests. As for other professionals, such as general practitioners and obstetricians, they entered into a separate MoU or cooperation agreement with Ananda Clinic. So, it is certain that Ananda Clinic has safe professionals.

In addition, Istri Utami also explained that Ananda Clinic has a brand, namely ‘Bidan Delima. The brand becomes legality carried out by professional organizations. It can be seen that the Bidan Delima is a system of standardizing the quality of practice midwives with an emphasis on monitoring and evaluation activities, as well as routine and continuous coaching and training activities. The Bidan Delima symbolizes quality services

in Reproductive Health and Family Planning that are based on compassion, courtesy, hospitality, a human touch, affordable, and midwifery actions according to professional standards and codes of ethics.

This then shaped the mission of the clinic to become an independent clinic of the community's choice. With that mission, the team owner then formed the Ananda maternity clinic mission to:

- Provide professional and quality services for mothers and children.
- Provide quality services according to standards and affordable to all levels of society.
- Improve the quality and coverage of maternal and child health services.
- Meet the needs and expectations of the community
- Establish partnership relationships with the government, educational institutions and IBI professional organizations.
- Improving human resources through education.
- friendly and caring about health services

#### **4.2 Analysis of Informed Consent in Ananda Maternity Clinic**

Ananda maternity clinic have the standard operational procedure for making and implying the informed consent for its patient. The SOP referred to the manual book by the Public Health Office of Sleman Regency [34]. The manual book later combined with the rights and obligation of midwives because it's a maternity clinic and adopting *bidan delima*. *Bidan delima* can be defined as a system to standardizing the services of private midwives [35]. Regarding SPTM (Informed Consent) Ananda Clinic always provides Informed Consent to patients who have previously made an informed choice [36]. Informed choice is conveyed to the condition of the patient who wants to use contraception and then informed consent is submitted only after the patient determines the choice of the type of contraception then informed consent is conveyed. The informed consent format was adopted by the *Delima* and IBI Midwives with clear rules.

The informant explained that since Ananda's clinic was established in 2005, there have been no incidents of actions that endanger patients. This happens because if there are new employees, they must explain again about the SOP that applies at the clinic and how it is applied in treating patients as well as possible. Later the informant stated that there must be informed consent that is delivered verbally or in written. There is no action will be taken if the patient does not know or refuses the action to be taken and a rejection of the action is conveyed if it is an emergency. Hence it can be conclude that Ananda maternity clinic does not adhere the usage of verbal consent in emergency situation and indicating its commitment on the safety both of its patient and medical personnel.

Ananda's maternity clinic, in its informed consent, provides an explanation of the diagnosis and procedures for medical treatment to patients, the majority of whom are pregnant women or about to give birth [38]. Midwife also explains the purpose of the action to be taken and the alternatives. In this phase, the patient will usually ask about the risks that may occur, so that the medical personnel who handle it at that time explain about the risks and complications that may occur along with the prognosis. The explanation is given in full in language that is easy for the patient to understand and then a written file will be included which essentially contains the date, time, name and signature of the patient as proof of his consent. In conditions where the explanation that will be given



is likely to be detrimental to the patient, the doctor and or midwife will ask the closest family or relatives to accompany as witnesses [37].

Through interviews with midwives, it is known that the midwife at Ananda's clinic also plays a role in obtaining informed consent from the patient. The midwife will explain the history and current health condition of the patient and the diagnosis [38]. Then provide an explanation of the choice of actions that can be taken along with each success rate of side effects. Then leave completely to the patient the choice to be taken. After the patient makes a choice, asks for approval for the action by asking for a signature and explaining the contents of the approval for the medical action, before the action is carried out. Thus, it can be concluded that the informed consent applied to Ananda's maternity clinic is in accordance with Article 45 of the Law on Medical Practice and the Regulation of the Minister of Health Number 290/Menkes/Per/III/2008 on Approval for Medical Action.

According to the interviews conducted with Mrs. Utami stated that since its establishment, there have been no significant obstacles in obtaining informed consent from patients. It's just that in an emergency sometimes informed consent is followed up by medical officers which can be done while taking the necessary medical actions. In such a condition, the head of Ananda's maternity clinic will reprimand the medical staff, whether nurses, midwives or doctors so that this does not happen again. The head of the clinic always emphasizes that informed consent is very important and will be fatal if the care or medical action is carried out before the informed consent of the patient or his relatives. As the head of Ananda's Clinic, they make sure the Standard operational procedure were correctly and fully implemented by all levels of its day-to-day operational staff. There are also a regular meeting to discuss and evaluate the implementation of SOP.

## **5 Closing**

### **5.1 Conclusion**

Based on research conducted at Ananda Maternity Clinic, it was found that these institutions were doing their best to apply informed consent to their organizations. But what is still lacking is an explanation of the cost of the medical action taken. Because medical actions are fundamentally different and require immediate action. This reduces the possibility of the two health institutions fully implement the regulation of the minister of health number 290. In terms of disclosure of information on the condition and possibilities and opportunities of patients to determine their fate, both institutions have given them well.

### **5.2 Recommendation**

Researcher suggest that the Ministry of Health issues regulations that clearly state the degree of relationship of all parties in therapeutic transactions so that they can also clearly interpret and raise the rights and responsibilities of each party. The local health office can provide periodic supervision of the application of informed consent and the form of its storage in medical records in both public and private hospitals.

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