THE IMPLEMENTATION OF MEDICAL INFORMED CONSENT IN SLEMAN REGENCY

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ABSTRACT

Background: 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. Those obligation become legal responsibilities that lies in informed consent. Those responsibilities are reflected in the implementation of the hospital’s obligations to fulfil patient rights carried out by doctors, nurses, midwives, and other health workers based on their authority and competence in accordance with professional ethics, as well as standard operating procedures that apply in the hospital by Minister of Health Regulation number 290 of 2008.

Purpose: This research to understand the legal analysis of informed consent in health services as well as to evaluate and enhance the implementation of medical informed consent in Sleman Regency, especially in the Ananda Maternity Clinic.

Methods: The type of this research is a normative-empirical legal research method which in this case combines elements of normative law.

Results and conclusion: This normative-empirical research shows that the informed consent has to be imply.

Implications of research: 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.

Originality/value: the work produced by the person concerned. Self-made, distinctive and personal and the work created is self-produced without quoting, copying, or plagiarism of other people’s work.

Keywords: implementation, Informed consent.

Received: 28/09/2023
Accepted: 29/12/2023
DOI: https://doi.org/10.55908/sdgs.v12i1.2777

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A IMPLEMENTAÇÃO DO CONSENTIMENTO MÉDICO INFORMADO NA REGÊNCIA DE SLEMAN

RESUMO

Histórico: Yogyakarta tem um alto número de taxa de morbidade que equivale a alta possibilidade de usar serviços médicos. Na transação terapêutica surge a obrigação entre paciente, pessoal de saúde e instituição de saúde. Essas obrigações se tornam responsabilidades legais que residem no consentimento informado. Essas responsabilidades refletem-se no cumprimento das obrigações do hospital de cumprir os direitos dos pacientes realizadas por médicos, enfermeiros, parteiras e outros profissionais de saúde com base em sua autoridade e competência de acordo com a ética profissional, bem como procedimentos operacionais padrão que se aplicam no hospital pelo número 290 do Regulamento do Ministro da Saúde de 2008.

Finalidade: Esta pesquisa visa compreender a análise jurídica do consentimento informado em serviços de saúde, bem como avaliar e aprimorar a implementação do consentimento informado médico na Regência de Sleman, especialmente na Clínica Maternal Ananda.

Métodos: O tipo desta pesquisa é um método de pesquisa legal normativo-empírico que, neste caso, combina elementos da lei normativa.

Resultados e conclusão: Esta pesquisa normativo-empírica mostra que o consentimento informado tem de ser implícito.

Implicações da pesquisa: É expressamente regulamentado que a concessão de aprovação para ação médica não elimina a responsabilidade legal no caso de se provar que há negligência na realização de ações médicas que resultaram em danos para o paciente.

Originalidade/valor: o trabalho produzido pela pessoa em causa. Auto-feito, distinto e pessoal e o trabalho criado é autoproduzido sem citar, copiar ou plágio do trabalho de outras pessoas.

Palavras-chave: implementação, consentimento informado.

1 INTRODUCTION

The survey released by the Central Statistics Agency (BPS) Yogyakarta showed the morbidity rate of the Yogyakarta population was 14.13 percent. By the details that the morbidity rate for women is 16.89 percent and for men is 11.24 percent. Indirectly, those figures show the possibility of using medical services that is relatively high. The possibility worsen by the current global pandemic, which hardly impacting Yogyakarta. This global pandemic has made everyone concern about their health, in such events, everyone wanting the best medical services they could afford. 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 health facilities is quite long and far. Moreover, the Special Region of Yogyakarta (DIY) has only 44 private Hospitals.

Development enhance the critical thinking of Indonesians, especially their right...
and duties in medical services provided by the hospital\textsuperscript{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\textsuperscript{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)\textsuperscript{9}. One of the parameters to determine the quality of health services in hospitals is a complete medical record which can be obtained from correct, complete and updated data of the patient. All of it was obtained from the informed consent.

The research Haryati, et al was to develop KIA E-Health, as a novelty, in maternal health services based on the Android application to improve the quality of Indonesian health services\textsuperscript{10}.

It was evident that the medical clinic of the investigated hospital has the recommended documentation, as well as human and material resources. However, inconsistencies were identified in the process, which emphasizes the need for educational actions, replacement of damaged equipment, identification of dumpsters, transport cars and shelters, adequacy of the temporary shelter environment, and restriction of the external shelter to access only for those involved in waste management\textsuperscript{11}.

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\textsuperscript{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 required¹¹.

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.

2 RESULTS AND DISCUSSION

a. 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 umber 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 2005³⁴.

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, Istri 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:

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

b. 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. 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. Regarding SPTM (Informed Consent) Ananda Clinic always provides Informed Consent to patients who have previously made an informed choice. 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. The 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.

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. 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.

3 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 implementing 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.
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(2) Ibid.


(8) See Law Number 44 of 2009 on Hospital.

(9) See Article 1 point 1 of Health Minister Regulation number 269/Menkes/Per/III/2008 on Medical Record

(10) Haryati, dkk. Developing E-Health Kia as an Innovation on Maternal and Child HEALTH Services Based on Android Application for Quality Improvement on Health Services in Indonesia.


(13) See Minister of Health of the Republic of Indonesia Number 290 / MENKES / PER / III / 2000


(17) See Article 1 point 7 of Law Number 36 of 2009 on Health

(18) See Article 29 Paragraph (1) of Law Number 44 on Hospitals.


(20) Law Number 36 of 2004 on Health (Undang-Undang nomor 36 Tahun 2009 tentang Kesehatan)

(21) Anny Isfandyarie, 2006, Tanggung Jawab Hukum dan Sanksi Bagi Dokter (Buku Satu), Jakarta: Prestasi Pustaka, p. 69

(22) Article 45 paragraph (1) of Law No. 29 of 2004 on Medical Practice.


(34) See Article 7 Point 7 of the Minister of Health Regulation Number Number 290/MENKES/PER/III/2008 on Approval of Medical Actions

(35) Ibid.

(36) Interviewed with Mrs. Istri Utami, the Ananda Maternity Clinic Owner, on May 2021

(37) Interviewed with Mrs. Utami, Wives of the Ananda Maternity Clinic Owner, on May 2021.


(39) Interviews with Mrs. Utami, Wives of the Ananda Maternity Clinic Owner, on May 2021.

(40) Interviews with nurses of Ananda Maternity Clinic.

(41) Ibid.

(42) Ibid.

(43) Interviewed with the Doctor of the Ananda Maternity Clinic, on May 2021.

(44) Interviewed with midwives of the Ananda Maternity Clinic, on May 2021.

(45) Ibid.

(46) See Article 45 of Law Number 29 of 2004 on Medical Practice and Regulation of the Minister of Health Number 290/Menkes/Per/III/2008 on Approval for Medical Action.

(47) Ibid.