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Informed Consent in Pringsewu Regional General Hospital: Legal Evidence Perspective

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A B S T R A C T

Quality health care is the right of every patient and his family. One of the indicators of quality services is the fulfillment of informed consent in accordance with the laws and regulations. Preliminary studies of several informed consent documents at Pringsewu Hospital found that all of them were not filled out completely. This study aims to analyze informed consent documents from the perspective of legal evidence. The study was conducted at Pringsewu Hospital in July 2021. The research method used a qualitative descriptive analysis approach, with 75 informed consent documents and two informants. How to collect data by reviewing the informed consent document that has been filled in at the hospital medical record installation, by checking the completeness of filling out the informed consent document for the five most types of actions, and in-depth interviews with the responsible leadership. The results showed that 75 informed consent documents were reviewed, none of which were filled out completely. The five most important indicators were not filled in completely, consecutively: name and signature of witness II, name and signature of witness I, gender of the patient, and gender of the giver of consent. To improve the completeness of filling out documents, the hospital will provide education to doctors, nurses, and administrative staff, as well as strict supervision. It was concluded that incomplete informed consent documents, as legal evidence, were low quality. The hospital leaders should conduct socialization to doctors, nurses and administrative staff regarding the importance of filling out the medical treatment approval form properly and completely.

Kata kunci:

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A B S T R A K

Pelayanan kesehatan bermutu merupakan hak setiap pasien dan keluarganya. Salah satu indikator pelayanan bermutu terpenuhinya pelaksanaan *informed consent* sesuai peraturan perundang-undangan. Studi pendahuluan terhadap beberapa dokumen *informed consent* di RSUD Pringsewu ditemukan semuanya tidak terisi dengan lengkap. Penelitian bertujuan untuk menganalisis dokumen *informed consent* perspektif alat bukti hukum. Penelitian dilakukan di RSUD Pringsewu Juli 2021. Metode penelitian menggunakan pendekatan analisis deskriptif kualitatif, dengan 75 dokumen *informed consent* dan dua informan. Cara pengambilan data dengan mengkaji dokumen *informed consent* yang telah isi di instalasi rekam medik RS, dengan melakukan checklist kelengkapan pengisian dokumen *informed consent* pada lima jenis tindakan terbanyak, dan wawancara mendalam pihak pimpinan yang bertanggung jawab. Hasil penelitian menunjukkan 75 dokumen *informed consent* yang dikaji tidak ada satupun dokumen yang terisi dengan lengkap. Lima indikator terbanyak tidak diisi dengan lengkap berturut-turut: nama dan tanda tangan saksi II, nama dan tanda tangan saksi I, jenis kelamin pasien, dan jenis kelamin

pemberi persetujuan. Untuk meningkatkan kelengkapan pengisisan dokumen RS akan melakukan edukasi terhadap para dokter, perawat, dan tenaga administrasi, serta pengawasan secara ketat. Disimpulkan dokumen *informed consent* yang tidak terisi dengan lengkap, sebagai alat bukti hukum kualitasnya rendah. Pimpinan RS melakukan sosialisasi pada para dokter, perawat dan tenaga administrasi mengenai pentingnya pengisian formulir persetujuan tindakan kedokteran dengan baik dan lengkap.

INTRODUCTION

Health services carried out by the government and the community must meet quality standards, as well as become the rights of patients (customers). In the process of providing health services in a normal situation (not an emergency), health workers (doctors) must obtain approval from the patient and the closest family. Everyone has the right to accept or reject part or all of the assistance that will be given to him after receiving and fully understanding the information regarding the action (Article 56(1) of Act No. 36/2009). Explanation of medical action at least includes: a. Diagnosis and procedures for medical action; b. The purpose of the medical action taken; c. Alternative courses of action, and their risks; d. Risks and complications that may occur; e. Prognosis of the actions taken, and f. Estimated financing (Article 7 (3) Minister of Health regulations No. 290/2008). Approval for medical action is an agreement given by the patient or his closest family after receiving a complete explanation regarding the medical or dental action to be performed on the patient (Article 1(3) Minister of Health regulations No. 290/2008). Consent for medical treatment can be given in writing or orally. Every medical procedure that contains a high risk must obtain written approval signed by the person entitled to give the consent (Article 2 (3) of Minister of Health regulations No. 290/2008). The consent document is evidence that the doctor has given a complete explanation and the patient or his family has understood and both agree to be bound in health services. Documents of approval/rejection can be used as one of the written evidence in court. Medical records are important documents as valid evidence in the future. One of the legal evidence is a letter (document/writing) (Article 184 (1) letter c of the Criminal Procedure Code).

Pringsewu Hospital is a Type C Hospital belonging to the local government of Pringsewu Regency in carrying out health services, especially medical procedures, requires approval from the patient or his closest family. Based on a preliminary study of several informed consent documents, it was found that the form was incomplete in filling out the form. Indicators (columns) were not filled in, such as: the patient's gender, the type of doctor's action to be carried out, the gender making the consent, the name and signature of witness I and the name and signature of witness II, none of the informed consent documents were stamped by the hospital. According to Samino (2013), several indicators were not filled in completely, such as the gender of the consenting party (37.5%), doctor's name (22%), signature and name of witness I (16.8%), signature and name of witness II (64.9). Incompletely filling out the informed consent form can cause the document to become legally flawed. The aim is to find out the completeness of filling out the informed consent document from a legal perspective.

METHOD

The study used a make method approach, with a sample of 75 informed consent documents, selected purposively from the 5 most common types of disease (gangrene, hernia, cataract, mammary tumor, and coli tumor), 15 each. Data collection was done by means of a checklist. To complete the descriptive results, 2 (two) informants were deepened through in-depth interviews. Analysis of the data from the document review is descriptive (%) while the results of in-depth interviews are content analysis.

RESULT AND DISCUSSION

Completeness of filling out the informed consent document.

An assessment of 75 informed consent documents in the Class III inpatient room at Pringsewu Hospital, covering 25 indicators for filling out, namely: a. Patient identity (9 indicators 1-9), including: patient's name, patient's age, patient's gender, medical record number, patient's address, hospitalized room, date of treatment, hour, type of action; b. The contents of the information submitted (5 indicators 10-14), include: providing information (diagnosis (working diagnosis/WD and Differential Diagnosis (DD)), basic diagnosis, medical action, indications for action, procedure for action, purpose of action, risk of action, complications of action, prognosis, alternatives and risks), name of information provider/doctor in charge, signature, name of recipient of information, signature; c. Identity of the giver of consent (4 indicators 15-18), including: name, age, gender, and address; d. Closing (7 indicators 19-25), includes: the city where agreement made, date of the statement made, name of statement giver, signature of statement giver, name and signature of witness I, name and signature of witness II. The results of the full assessment are in the table. 1.

From twenty-five indicators in table 1, there were 17 (68%) completely filled in: patient's name, date of birth, medical record number, address, treatment room, date of treatment, time of providing medical information, occupation information , signature of informant, signature of informant, full name Information provider, full name of information recipient , date of birth of the approval giver, address of the approval giver, city where statement made, date when statement made, written name of informant, signature of informant. The indicators were not filled in completely (8 indicators (32%)), namely: gender, type of treatment, complete name of the information provider/doctor in charge, complete name of the information recipient, gender of approval giver, time of approval, name and signature of witness I , name and signature of witness II.

The incomplete indicators from the highest consecutively: the name and signature of witness II were 75 (100%), the name and signature of witness I were 59 (79%), the type of action to be carried out was 43 (57%), the type of the gender of the patient was 32 (44%), the gender of the approver was 18 (24%), the complete name of the information provider/doctor in charge was 6 (8%), the complete name of the recipient of the information was 2 (3%), the time of making the statement was 1 (1%).

Table.1
Distribution of Completeness of Informed Consent Document Filling at the Class III Inpatient Wards

Document Fill Indicator	Jumlah	
	C (%)	IC (%)
Patient ID:		
Patient's name	75 (100)	0 (0)
Date of birth	75 (100)	0 (0)
Gender	43 (56)	32 (44)
Medical Record No	75 (100)	0 (0)
Address	75 (100)	0 (0)
Ward	75 (100)	0 (0)
Treatment date	75 (100)	0 (0)
Time	75 (100)	0 (0)
Treatment type	32 (43)	43 (57)
Information provided		
Occupation of Information provider	75 (100)	0 (0)
Full name of information provider/ doctor in charge	69 (92)	6 (8)
Information giver's signature	75 (100)	0 (0)
Full name of information recipient	73 (97)	2 (3)
Information Recipient's signature	75 (100)	0 (0)
Approver Identity		
Full name of approver	75 (100)	0 (0)
date birth of approver	75 (100)	0 (0)
Gender of approver	57 (76)	18 (24)
Approver address	75 (100)	0 (0)
Closing:		
City where statement made	75 (100)	0 (0)
Date when statement made	75 (100)	0 (0)
Time when statement made	74 (99)	1 (1)
Full name of approver	75 (100)	0 (0)
Signature of approver	75 (100)	0 (0)
Name and signature of witness I	16 (21)	59 (79)
Name and signature of witness II	0 (0)	75 (100)

The results showed that the management of informed consent at the hospital was not completed. Every document made by the hospital as evidence that the service had been carried out as stated inthere. If this was left unchecked, it would reduce the quality of medical records, and make it difficult to evaluate the service process, including the low quality of evidence if legal problems arise in the future, especially in the court.

In contrast to Anggraini (2017), it was stated that the incompleteness of filling out the informed consent document was due to the busyness of doctors. In addition, they argued that they were in a hurry, but some were too lazy to fill it out.

The cause of the incomplete filling of the informed consent document was caused by the involved human resources (HR), such as doctors, nurses and administrative staff on duty at that time. According to the informants, they did not understand the importance of filling out informed consent completely and correctly according to the SOP that has been made. Apart from this, according to the informant, there was still a shortage of administrative staff on duty, so there was no opportunity to re-check the document, whether it has been filled out completely or not. The following are some of the informants' statements:

"The HR does not understand the importance of filling out informed consent documents correctly, the HR is not obedient/orderly in carrying out existing SOPs, administrative staff is still lacking so that the number of HR is not proportional to the existing workload, less 1, does not have time to re-check whether the informed consent document has been filled in completely" (AY) (Head of Medical Information Section). Meanwhile, the factors causing incomplete informed consent According to Helena Meyyluniar (2019): (a). Doctor's understanding of informed consent and the importance of informed consent, (b). Doctors' limited time to practice, (c). Doctor's busyness, (d). Dependence of doctors on nurses, (e). Lack of doctor's attention to filling out informed consent, (f). Hospital organizational policies related to informed consent, (g). There is no Punishment and Reward implementation yet.

The reasons of doctors and nurses are various and difficult to identify specifically because the situation in each hospital and the practitioner is different, but according to researchers, whatever the reason, this cannot be justified, because this is an important part of the service process, as a tool evidence that the officer has taken the action as explained in the description.

The content of informed consent document

The legal basis for informed consent "Everyone has the right to accept or reject part or all of the assistance that will be given to him after receiving and fully understanding the information regarding the action" (Article 56 (1) of Law No. 36/2009). The implementation of informed consent in health services/hospitals has been carried out according to their ability. The results of the study obtained information on the informed consent document used in the Class III Inpatient Ward at Pringsewu Hospital consisting 25 indicators. The informed consent form used by the hospital was not fully adopted as stated in the medical action approval manual. The form contains 32 indicators that must be filled out in full. The informant explained that the use of the form was the result of the work of the hospital ethic committee. The Regulation of the Minister of Health does not stipulate the form in question, but stipulates information that must be explained to the patient or his family, at least including: a. Diagnosis and procedures for medical treatment; b. The purpose of the medical treatment performed; c. Alternative courses of action, and their risks; d. Risks and complications that may occur; and e. Prognosis of the treatment taken; f. Estimated financing (Article 7 (3) Permenkes No. 290/2008).

Samino (2013) argues that the contents of the informed consent document, include giver of consent: name, age/gender, address, and proof of ID/KTP. Approval of actions to be taken (in the form of certain actions). The patient's identity consists of: name, age/gender, address, proof of ID/KTP, ward (care room), and medical record number. The final part: the city where approval given, the name and signature of the person giving the consent, the name and signature of the treating doctor, the name and signature of the first witness (nurse) and the name and signature of the second witness (from the patient's family).

The informed document form must contain the data of the patient and accompanying family, the doctor's identity, the information provided by the doctor to the patient/family, as well as the names and signatures of the witnesses who witnessed the process of providing information and approval or refusal. If these indicators are met, even though there are

differences in the form, it does not reduce the meaning and content of the document.

Strategies for achieving complete informed consent

The strategy that will be implemented by the hospital to increase the completeness of filling out informed consent documents comprises to educate doctors, nurses, and administrative staff, to disseminate information about the importance of filling informed consent, to increase supervision by carrying out sudden inspection to see an example of an informed consent document. In addition, the informant explained that he would give rewards and punishments for officers thorough form filling. The following are some of the informants' statements:

"*Educating nurses, doctors and administrative staff, socializing the importance of filling out informed consent, increasing supervision by unannounced inspections… "* (AY).

Supervision of the implementation of the informed consent document was carried out by the head of the ward, while the responsibility for the completeness of filling out the informed consent document is a doctor assisted by a nurse.

Efforts to overcome incompleteness in filling out the Informed Consent are as follows: (a). During the admission process, when the patient is still accompanied by the family, the officer immediately provides an explanation of the contents of the information and fills out the informed consent form to the patient's family because the inpatients cannot be accompanied by the patient's family; (b). As much as possible the doctor explains the patient's family in an understandble language, because most of the patient's family does not understand the medical jargon used by doctors when explaining the contents of the informed consent information.

Legal aspects of informed consent

The indicators for the legal aspect in the document are based on five elements: completeness of document filling, clarity of writing, scribbles, deletion, and presence of a hospital stamp. The results of the assessment were as in table 2.

Table.2
Indicators of Legal Aspects of Informed Consent Documents at the Class III Inpatient Ward

Indicators	Total	
	Yes (%)	No (%)
Completeness of filling out documents	0 (0)	75 (100)
Clear writing/no multiple interpretations	75 (100)	0 (0)
No scribbles	73 (97)	2 (3)
No deletion	74 (99)	1 (1)
Stamped by hospital	0 (0)	75 (100)

Source: Processed from the results of the informed consent document review; n= 75

Five indicators of legal aspects, showing that only one indicator met the legal aspect, "Writing is clear/not multiple interpretations", the rest do not meet, even the indicator "Stamped by Hospital" was not given.

The informed consent document is one of the written evidences, both in normal situations and in the occurrence of legal problems. One of the legal evidence is a letter (document/writing) (Rosadi, (2016), Article 184 (1) letter c of the Criminal Procedure Code), and Article 1866 of the Civil Code). Abdulkadir (2000), letter or written evidence is written evidence that contains writing to state one's thoughts as evidence. According to the form of written evidence, there are two types of written evidence, namely deed and non-deed. A deed is a dated and signed letter, which contains the events that form the basis of a right or an engagement used for proof. Deeds are further classified into two types, namely authentic deed and non-authentic (under the counter) deeds.

Letter or written evidence is anything that contains reading signs intended to convey one's thoughts and is used as evidence. Everything that does not contain reading signs, or even though it contains reading signs but does not contain ideas, does not belong to written evidence or letters.

Samino (2013) states that informed consent documents that are not filled out completely, do not meet legal aspects and are weak as evidence. Completeness of filling out the informed consent document must be in accordance with what is requested. Wulandari and Sugiarsi (2014) medical records contained in the medical record file are said to have legal validity when the health worker who treats the patient or the letter of approval given by the patient or guardian in the medical record ends by affixing or validating the signature accompanied by a complete name.

Informed consent documents that meet legal aspects must meet the following criteria: (a). The column is completely filled, (b). The contents are clear (the information is written in full, including those approved), (c). The writing is clear and legible, (d). Written in ballpoint, (e). There is no deletion, if repairs are made it must remain real and dated and initialed. If the document is in the form of a soft file, it should be in the form of pdf/jpg, don't change it, because the storage date is very difficult to change. "*It is better if the document is filled in completely and there should be no scribbles or nothing should be deleted, or if it is necessary to delete it, provided that the old writing is still visible*" (ES)

CONCLUSION AND RECOMMENDATIONS

None of the informed consent documents that were reviewed were filled out completely. The five most important indicators were not filled in completely consecutively: name and signature of witness II (100%), name and signature of witness I (79%), gender of patient (44%), and gender of the consent giver (24%). The indicators set forth in the informed consent document used by the hospital did not meet the guidlines for approval of medical treatment, but the core information explained to the patient fit the guidlines. To improve the completeness of filling out documents, the hospital will apply education to doctors, nurses, and administrative staff, as well as strict supervision. The informed consent document is valid evidence, which must be filled out completely, the writing is clearly legible and does not have multiple interpretations, there are no scribbles and deletions, and stamped by hospital. If These aspects are not met, the quality of the evidence will be low.

The hospital leaders conduct socialization to doctors, nurses and administrative staff regarding the importance of filling out the medical action approval form properly and completely, as well as conducting regular supervision.

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Conflict of Interest Statement

The author declares that there is no conflict of interest associated with the authorship and publication of this research article.

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