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RESEARCH ARTICLE

APPLICATION OF INFORMED CONSENT IN SURGERY AND WOMB ROOM IN SIBUHUAN GENERAL HOSPITAL NORTH SUMATERA INDONESIA: A QUALITATIVE STUDY

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ABSTRACT

Background: A doctor in conducting medical examinations and treatment must respect the rights of patients and work according to the standards of the medical profession. This can be done by implementing the provisions according to the procedure in giving informed consent, so that doctors are deemed to have carried out their obligations to provide information to patients or families of patients and get their approval. **Aims:** to explore informants about the application of informed consent in the surgical and womb room in Sibuhuan General Hospital. **Methods:** A qualitative study with analytic description was used. Four informants were selected using purposive sampling in this study. The data were gathered in-depth interview. Analysis and interpretation used verbatim descriptions in Bahasa Indonesia and subsequently translated into English language. **Results:** 1) Explanation of Diagnosis of Diseases of Patients, 2) Giving Informed Consent in Detailed, 3) Executors Explained Informed Consent and Signed Informed Consent, 4) Explanation of Disease and the Need for Medical Action, 5) Explanation of the steps when the risk arises, 6) Explanation of Risks and Possible Effects of Not Performing Medical Measures, and 7) Explanation of Informed Consents Done Honestly. **Conclusion:** As health provider must be attention with informed consent to avoid the negligence.

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INTRODUCTION

A doctor in conducting medical examinations and treatment must respect the rights of patients and work according to the standards of the medical profession. This can be done by implementing the provisions according to the procedure in giving informed consent, so that doctors are deemed to have carried out their obligations to provide information to patients or families of patients and get their approval. The occurrence of negligence which is a form of error that is not in the form of intentions, but also is not something that happened by accident. negligence causes harm to patients (Erdiansyah, 2011). Conflict often occurs in post-surgery because it is unsatisfactory according to the patient's view and because they feel aggrieved the patient will seek justice through parties who are considered competent in their resolution. Things like this are often highlighted by the public lately in electronic media that preach the existence of malpractice. Health services are always viewed from the negative side and failures, if things happen that are not desirable then immediately considered malpractice regardless of the cause of the failure. A doctor is said to have done a bad practice when he did not meet the requirements specified in the medical code of ethics, professional standards, and medical service standards (Yunapto, 2009). In August-October 2017 that was currently running, there were 89 general surgery, bone surgery, and

womb surgeries. From the data obtained, there were 9 operating licenses that were not signed by a specialist who performed the operation, there were 7 names of doctors who were not included in the signature of a specialist, there were 8 names of types of surgery not mentioned, there were 47 signed by family witnesses, and there were no 89 operating licenses signed by the nurse as a witness from the hospital. Most patients do not understand the explanation given by the doctor and the causes are very varied, partly because the doctor who operates gives an explanation of the actions to be taken only at a glance even seems rushed. Patients who are anxious about their health condition when asked whether they agree with the action to be taken, just respond to agree and continue with the signing of the letter of approval for medical action. From the above problems the researchers wanted to examine the application of informed consent in surgery and womb room in sibuhuan general hospital north sumatera Indonesia.

MATERIALS AND METHODS

Study design: This was a qualitative study with analytic description. This study was conducted from August 2017 to September 2018.

Research subject: Four informants who volunteered to participate in this study were selected using purposive. Inclusion criteria included: general and obstetric surgeon.

Data collection: Primary data in this study was obtained by conducting in-depth interviews (in-depth interviews) to all informants. The purpose of the in-depth interview is to explore more information about the implementation or application of informed consent. Secondary data was obtained through an informed consent file that had been carried out which was obtained from the surgical installation and obstetric surgery at Sibuhuan Regional Hospital. Data collection is done in four ways, namely: 1) observation of informed consent implementation activities in the surgical installation and obstetric surgery room, 2) interviews are conducted using in-depth interview guidelines, 3) documentation, in the form of an informed consent file in the surgical room of Sibuhuan Regional Hospital, 4) triangulation, which is data collection by combining the three data collection techniques above to obtain data from the same source.

Data analysis: Data analysis is the process of organizing and sorting data into patterns, categories, and a basic description so that certain themes can be found. The steps taken in analyzing the data are: 1) collecting is data collected from observations. After all data is collected in the form of records of interview results and observations, 2) classification which is similar data collection. The researcher will formulate and write it in the form of a narrative to then set the findings into categories and provide a complex picture of the phenomenon that is happening, 3) editing is to correct data collected from research, and 4) presentation of data is to decipher the data that has been collected into sentences so that it is easy to understand. From the results, conclusions are drawn which are the answers to the problems raised in this study.

RESULTS

Do You Explain the Diagnosis of Diseases to Patients?:

Table 1. all 4 specialists, general surgeons and obstetricians (100%) interviewed said that they always explained the diagnosis of the disease experienced by patients. Because each patient has the right to know about the diagnosis of the disease, both the understanding of the disease, the symptoms experienced, and the course of the disease experienced by the patient. This is done so that the patient knows what disease is being faced by the patient and understands the extent to which the patient's disease is disrupting the physical stability of the patient, and how the patient's condition if medical treatment is not carried out can interfere with the patient's physical condition.

Table 1. Distribution of Giving Explanation of Diseases by Doctors

No	Answer	Amount	%
1	Yes	4	100
2	No	0	0
	Amount	4	100

If Your Patient Needs Medical Action, For example Operation, Do You Informed Consent in Detail? When do you do it? (For example Is At Time Will Operation Or One Or Two Days Before? Give Reason For Each: Table 2, it was found that Informed consent was given in detail by 3 specialist doctors (75%) to patients who were to undergo surgery, namely 2 general surgeons and 1 obstetrician. While 1 person (25%) other obstetricians, said that they also provide an explanation to the patient about the plan of action to be taken, but not in detail, arguing that the level of ability of each patient

or family must vary in how to understand medical explanations, so that if a lot is given an explanation, it will become confusing and will cause many questions and take not a little time if each patient is given an explanation for each operation.

Table 2. Distribution of Giving Informed Consent for Medical Measures

No	Answer	Amount	%
1	Yes, with detail	3	75
2	Yes, but just explain	1	25
	Amount	4	100

Informed Consent That You Are the One Who Carried Out or the Nurse and Do You Always Sign Agreements That Have Been Given by Patients or Families?:

Table 3, Informed consent was carried out by 4 people (100%) specialists, both general surgeons and obstetricians who handled patients and planned surgery and were never done by nurses, arguing that the obligation of specialists to explain about the patient's illness and the plan of action to be carried out by the specialist doctor, and the specialist said that the nurse did not have the obligation to explain the condition of the disease and the plan of action of the doctor. Information about the disease and the actions to be taken may not be represented by the nurse because it can lead to bias, both the addition and reduction of actual information, so that it will cause doubt to the patient or family. Specialists also said that they signed a medical action agreement, where they signed it either before the operation or at the time after the operation.

Table 3. Distribution of Implemented Informed Consent to Patients

No	Answer	Amount	%
1	Doctor	4	100
2	Nurse	0	0
	Amount	4	100

Do you explain the disease in giving informed consent and why do you need medical action? (This includes how prognosis is not done):

Table 3, 2 specialists (50%), namely 1 general surgeon, and 1 obstetrician said that when giving informed consent, the explanation given by the doctor is often only limited to understanding the disease and the reasons for its importance. medical action is carried out if it has a poor prognosis, but if the prognosis of the disease is not bad, the specialist provides an opportunity for the patient to make a decision whether or not the operation is carried out. But from interviews with 2 specialists namely general and obstetric surgeons (50%), they said all information must be given so that patients are satisfied with the explanation given, whether it is a bad prognosis or a bad prognosis.

Table 4. Distribution of Disease Descriptions and the Need for Medical Actions when Informed Consent

No	Answer	Amount	%
1	Yes, with detail	2	50
2	Yes, just explain	2	50
	Amount	4	100

Are You Explaining the Steps You Might Do When There Are Risks?:

Table 5, there is 1 specialist doctor (25%),

namely an obstetrician who does not explain in detail about the disease to the risks that will occur if surgery is carried out, so that the steps that will be taken when the risk arises is never explained by a specialist, on the grounds that if explained in detail to the risk of good or bad surgery to be performed, it is likely that the patient and family will refuse. While 3 other specialists (75%) said that this was done up to the plan of action in the event of a risk, so that patients or families can make decisions before the operation is carried out and avoid future lawsuits.

Table 5. Distribution Explanation of Steps If There Is a Risk

No	Answer	Amount	%
1	Yes, with detail	3	75
2	Without explanation	1	25
	Amount	4	100

Are You Explaining the Risk and Possible Effects of No Medical Measures?: Table 6, all specialist doctors both general surgeons and obstetricians (100%) said that they provide detailed explanations if surgical procedures were not performed by looking at the diagnosis of the patient's disease, which should be performed surgically, but if the disease diagnosis and condition the patient does not have to take action immediately and the patient refuses surgery, the specialist does not impose an action plan and submit his decision to the family. However, if medical action is felt to be done, but the family rejects the doctor's action, the specialist advises the patient or family of patients to sign a statement rejecting medical action, so that the hospital will be strengthened, especially specialists if there is a risk of rejection of medical action.

Table 6. Distribution Explanation of Risks and Possible Effects of Not Performing Medical Measures

No	Answer	Amount	(%)
1	Yes, with detail	4	100
2	Without explanation	0	0
	Amount	4	100

Do You Explain the Above Honestly (There Is No Coercion) So That the Agreement Given by Patients Is Really Pure Approval?: Table 7, like the answers given by the informants above, 4 specialists (100%) said that all information given to patients was as honest as possible, but the informants limited the information given due to the possibility of rejection to be carried out by patients and patients' families if all information that should be provided by a specialist is delivered.

Table 7. Explanatory Distribution Is Done Honestly

No	Answer	Amount	(%)
1	Yes	4	100
2	No	0	0
	Amount	4	100

DISCUSSION

Explanation of Diagnosis of Diseases of Patients: Based on the research carried out, all specialists both general surgeons and obstetricians said that they did explain the diagnosis of the disease, because they understood that receiving information about the disease was the right of every patient who came to the doctor with his confidence in the doctor's knowledge to

cure the disease. Ameln (1991), said that the doctor's professional obligations include always paying attention to and respecting the rights of patients, including the right to obtain information, where patients have the right to know everything related to the condition of the disease, namely about diagnosis, medical treatment will be done, the risk of doing or not doing the medical action, including the identity of the treating doctor, the rules that apply in the hospital where the patient is treated. A doctor must provide information about the patient's disease. The information must be given by the doctor to the patient or his family in an easily understood language. Likewise doctors also do not provide a more detailed explanation of the disease because patients and families have knowledge as limited as their own thinking that appendicitis must be operated on immediately. Likewise, for example, with sectio caesarean surgery, where the operation has been a trend for this era, even though there is no indication for surgery, the doctor who recommends surgery rarely explains when surgery is needed or not and the patient does not ask too much about it because it has become commonplace today to be done from normal or spontaneous labor. This incident is very common in the community, thanks to the rapid development of information, operations that are common in the daily lives of people such as the example above make people become "smarter" and give more approval than receiving more detailed information from doctors. This pattern needs to be changed so that it does not become a habit for doctors and patients themselves. Because even though the operation is very common, the doctor should still provide a detailed explanation of the patient's illness and the patient must listen to an explanation from the doctor so that there is a consistent understanding of the disease.

Giving Informed Consent in Detailed: Field observations that often occur, specialist doctors do make informed consent, but the explanation given is very limited, because the different levels of understanding of patients make it not done in accordance with the applicable rules. The limited understanding of patients or families in understanding medical explanations that must be given is directly proportional to the time that is not small, if each patient must be given information as complete as possible. While in giving informed consent, there are a number of things that must be explained, namely: 1) diagnosis and procedures for medical treatment, 2) the purpose of medical actions taken, 3) alternative other actions and risks, 4) risks and complications that may occur, and 5) prognosis of actions taken (Hanafiah & Amir, 2012). Doctors who want to do surgery often forget some of the most basic things mentioned above. The sudden arrival of visit patients and the desire of patients to get immediate action, are considered by the doctor as an agreed statement only without the need for explanation as a consideration for patients to make decisions. In fact, it is not uncommon for communication between nurses and doctors to report patient consuls, doctors recommend nurses to prepare patients for surgery even though doctors have not seen firsthand the condition of the patient himself. Events like this often occur in the field. Beginning with the nurse's report on the initial examination of the guard doctor who examined the patient, the counselor doctor considered the report correct, so that doctors often advised the patient to be operated immediately only through means of communication.

Executors Explained Informed Consent and Signed Informed Consent: Doctors as implementers of health service delivery must carry out all their duties and obligations in the interests of patients with all existing competencies,

responsibilities and codes of ethics. One of the obligations of the doctor is to provide information about medical actions to be performed on the patient. This obligation is based on the patient's right to know all medical information he understands, so the patient can decide whether or not to take medical action on him. Doctors have legal responsibility for patients. Doctors as professionals are responsible for every medical action performed on patients. In carrying out his professional duties based on good intentions, he strives earnestly based on his knowledge based on the doctor's oath, medical ethics code (Erdiansyah, 2011). In the research conducted, every explanation of informed consent has been carried out by specialists who will plan medical actions for patients, but for the signing of the statement of informed consent, there are still statements that are not signed or filled in completely by the doctor who performed the surgery, whether it was the type of action taken, the name of the doctor who did it, even there was an informed consent that was not signed by the doctor who performed the surgery. The reason, said the doctor, was an unintentional factor or because of forgetfulness because of the many operations, or because there was no other officer who reminded the doctor. The signing of the informed consent must be taken into account, whether the patient or family signature, witness signature, and the signature of the nurse and the doctor who performed the operation must be written in full. This is useful to protect the parties who provide medical action, if something unexpected happens later, this written informed consent statement becomes strong evidence that will help strengthen the defense of the problems that occur. For doctors who perform medical actions without the consent of patients or their families, they may be subject to administrative sanctions in the form of revocation of practice licenses, as well as criminal sanctions, or civil sanctions.

Explanation of Disease and the Need for Medical Action:

Based on interviews conducted, specialists more often convey information that is important to patients and families to avoid confusion between doctors and patients who in the end will only take time. For this reason doctors sometimes provide detailed explanations for cases where the prognosis is poor. However, for cases where the prognosis is not bad and the information provided does not affect the patient's desire for immediate surgery, the doctor hands it to the patient until the patient decides on the decision to be ready for surgery. In the implementation of informed consent, it is expected that patients get good information, so that patients are satisfied and without burden or doubt giving consent (Susanto, Al-Rasyid, & Hakim, 2017).

Explanation of the steps when the risk arises: Based on the results of the interview, it was found that most doctors rarely explain to the steps that will arise if there is a risk, with the reason that if explained to the risk, what often happens is the cancellation or rejection of surgery from patients or families. Because each surgical procedure has risks, both those that can be overcome and unexpected, the doctor should explain all the possibilities that occur, but due to differences in understanding, it becomes a reason for doctors to rarely provide explanations. According to Wiradharma and Danny (2003) three components in the approval of medical actions are: 1) information, 2) understanding, and 3) willingness.

Explanation of Risks and Possible Effects of Not Performing Medical Measures: Doctors who want to take medical action or surgery, must first provide information about what actions

will be taken, what are the benefits, what are the risks, other alternatives (if any), and what might happen if no medical action or surgery is carried out. This information must be given clearly in a language that is simple and understandable to patients and takes into account their educational and intellectual level. Medical action by a doctor without legal approval because the patient does not obtain complete and correct information can result in a doctor being sued in court. From the results of the study, the doctor has provided an explanation of the progress of the patient's disease if no surgical action is taken. But doctors still give decisions to patients or families. If the patient or family continues to refuse surgery after the doctor gives an explanation, the patient or family is encouraged to sign a statement rejecting medical action in the patient's medical record status to avoid demands if a problem occurs because the patient is not operated on. Patients who have the capacity as legal subjects in therapeutic agreements with doctors, should be given the opportunity to determine their choices rationally, as a form of respect for their human rights to determine their own destiny. Although the patient's choice is wrong, the doctor must respect it and try to explain it according to the professional knowledge and skills of the doctor so that the patient really understands the consequences that will arise if the choice is not in accordance with the doctor's recommendations. In providing information to patients, doctors should realize that a patient's lack of knowledge about health and fear of his illness and the background of his beliefs, customs, socio-economic conditions, will greatly influence the agreement he will give.

Explanation of Informed Consents Done Honestly: In therapeutic transactions, the legal relationship between doctors and patients has several legal principles. According to Komalawati and Veronika (1999) one of them is the principle of honesty. This principle is the basis of the implementation of the correct delivery of information, both by patients and doctors in communication. Honesty in conveying information will be very helpful in the process of healing patients. The truth of this information is closely related to the right of every human being to know the truth. In this study, all doctors said the information provided was information that was as honest as the doctor's understanding. Doctors explain honestly about the main things that need to be known by patients or families, to avoid misunderstanding of the patient if the doctor is too detailed to give an explanation. This is the problem, while an obligation of the doctor to honestly inform the results of the examination, the disease, and the treatment steps that he will do is certainly in wise ways.

Conclusion

Surgery condition must be known by patient, family or family member with using informed consent, explain by health provider like doctor before doing surgery. Informed consent is explained with detail, clearly, and honestly to avoid the negligence.

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