

Implementation of Informed Consent at Bandung Hospital, Medan City

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Abstract. *This study aims to analyze the implementation of informed consent as a legal protection mechanism in medical practice at Bandung General Hospital, Medan City. The method used is normative legal research with a normative legal approach, utilizing secondary data from primary, secondary, and tertiary legal materials, as well as field data through interviews and surveys. The results of the study indicate that the implementation of informed consent at the hospital has followed the standard operating procedures regulated by the Minister of Health Regulation No. 290/MENKES/PER/III/2008. The informed consent process involves providing comprehensive information, consideration time for patients, and documentation of written consent. However, there are several challenges, including time constraints, ineffective communication, and low levels of patient health literacy. This study suggests improving communication training for medical personnel, providing patient education tools, and improving the documentation system to ensure legal compliance and quality of health services. Effective implementation of the informed consent procedure has the potential to improve legal protection for medical personnel and patient rights in medical decision-making.*

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INTRODUCTION

The implementation of informed consent in general hospitals is one of the important elements in health services that are oriented towards human rights, especially the patient's right to make informed decisions regarding medical actions that will be performed on him/her (Frunză & Sandu, 2017; Davoudi et al., 2017; Raposo, 2019). Informed consent not only functions as legal protection for medical personnel and hospitals, but also as a form of respect for patient autonomy (Bernat, 2006; Hall et al., 2012; Cocanour, 2017). Therefore, the implementation of good informed consent procedures in general hospitals is very important to maintain good relations between medical personnel and patients, and to ensure that patient rights are respected.

Informed consent is one of the important aspects of medical practice that aims to respect the patient's right to make informed decisions about medical actions that will be undergone (Whitney, McGuire, & McCullough, 2004; King & Moulton, 2006; Reid, 2017). This process ensures that patients understand the risks, benefits, alternatives, and possible consequences of a medical procedure, and allows patients to make decisions that are in accordance with their personal preferences and values. Although the implementation of informed consent has been regulated in medical regulations and guidelines in Indonesia, its implementation in general hospitals still faces certain challenges that affect the quality and success of its implementation (Handayani et al., 2015; Handayani et al., 2016; Khan et al., 2022).

The implementation of informed consent not only has ethical but also legal implications, where hospitals and medical personnel must ensure that they have followed legally valid procedures to protect patient rights. Therefore, informed consent serves as a protection mechanism for patients and medical personnel from the risk of legal claims that may arise from medical actions taken without the patient's consent.

Informed consent is a fundamental aspect of medical ethics and law that requires patient involvement in decision-making related to the medical actions to be undertaken (Paterick et al., 2008; Hall et al., 2012; Katz et al., 2016). Therefore, a good understanding of the importance of informed consent by doctors, paramedics, and patients is essential to ensure that this procedure is effective and in accordance with its main objectives: to respect patient rights, provide informed decisions, and protect medical personnel from potential lawsuits. This chapter will review the perceptions of doctors, paramedics, and patients regarding informed consent, and explore the various factors that influence the quality of implementation of this procedure.

A proper understanding of the importance of informed consent by doctors and paramedics greatly influences the success of implementing this procedure in hospitals (Pepe et al., 2009; Lin et al., 2019; Bijani, Abedi, Karimi, & Tehranineshat, 2021). Doctors and paramedics have a key role in educating patients and providing the information needed for patients to make informed decisions. A good understanding can also reduce the risk of ethical violations or legal problems that could potentially arise from providing medical treatment without valid consent from the patient.

As a medical professional who is directly responsible for patient care, the doctor has the primary obligation to explain all aspects related to the medical treatment to be performed. In many cases, the doctor is the first to interact with the patient to provide an explanation regarding the diagnosis, prognosis, procedure, and available treatment alternatives.

According to Brown (2004), the doctor must ensure that the information provided includes the benefits and risks associated with the medical procedure to be performed, and ensure that the patient fully understands the information before giving consent. A deep understanding of medical ethics and law is essential to providing accurate and clear information to the patient. In addition, the doctor's communication skills play a major role in the smooth running of the informed consent process. Grol (2013), stated that good communication skills allow doctors to explain medical information in a way that is easy for patients to understand, thereby minimizing the potential for miscommunication that can lead to patient misunderstanding.

However, even though it is clearly regulated in the operational standards, many doctors find it difficult to carry out this procedure due to various factors, such as time constraints, high workload pressure, and lack of training in medical communication ethics. Gigerenzer (2007), emphasized that doctors are often trapped in a busy medical routine, which reduces the opportunity to spend enough time explaining information to patients carefully.

Based on the results of an interview with Dr. Margaretha Damanik regarding paramedics' perceptions of Informed Consent, she stated that. In addition to doctors, paramedics including nurses, medical assistants, and other health workers also have an important role in the process of providing informed consent. In many cases, paramedics support doctors in providing additional explanations or answering questions asked by patients after consulting with doctors".

This is confirmed by Perona (2019), paramedics' understanding of the importance of informed consent contributes to improving the quality of interactions with patients and can improve the patient's experience in the decision-making process. However, paramedics' perceptions of the importance of informed consent often vary. Some paramedics feel that their duties are limited to carrying out medical procedures, and have no obligation to be involved in providing information to patients. This can happen if paramedics are not given enough training or direction regarding their role in supporting the informed consent process. According to Brown (2018), it is important for paramedics to receive training on medical ethics and communication

with patients so that they can contribute better in providing the explanations that patients need (Holmberg et al., 2023).

Meanwhile, the results of an interview with Anto regarding patient perceptions of the Quality of Explanations Given stated that "In addition to the understanding of doctors and paramedics, patient perceptions of the quality of the explanations given are also very important in determining whether they feel involved in the medical decision-making process. This perception is not only influenced by how clear and detailed the information is given, but also by the attitude and approach taken by medical personnel in conveying the information".

Meanwhile, the results of an interview with the Manager of Bandung General Hospital regarding patient understanding of Informed Consent stated that "In implementing informed consent, success lies not only in how much information is given, but also in the extent to which patients can understand the information". This is also confirmed by Grol et al., (2013) who stated that patients who have better health literacy tend to find it easier to understand the information conveyed by doctors or paramedics. However, in reality, many patients do not have a medical background and may have difficulty understanding medical terms or the consequences of the procedure to be performed.

Furthermore, de Moissac & Bowen (2019) confirmed that patients who come from lower educational backgrounds or who are not fluent in the medical language often feel confused or unsure about the information provided. Therefore, it is very important for medical personnel to convey information in a simple way, using language that is easy to understand, and ensuring that patients can ask questions if there is something they do not understand. The use of visual aids or other media can also help patients understand the information better.

Patients' trust in medical personnel also greatly influences their perception of the quality of the explanation given. Mechanic & Meyer (2000) explained that patients who have a good relationship and trust in their doctors tend to be more open in accepting explanations and giving consent for medical procedures. Conversely, if patients feel that the doctor does not pay enough attention or is not transparent in explaining the procedure, they may hesitate to give consent or even choose to refuse the recommended procedure.

It is important for doctors and paramedics to build a trusting relationship with patients, which can be achieved through open communication, empathy, and transparency in explaining treatment options. Berman & Chutka (2016) suggests that effective communication includes not only conveying medical information, but also listening attentively to the patient's concerns and needs. Patients' previous experiences with medical processes and treatments also influence their perception of informed consent. Patients who have previously undergone medical procedures may be more familiar with the process and feel more comfortable receiving explanations about medical procedures.

Larkin (2009), showed that patients who are experienced tend to have a better understanding of their rights to give consent and what is expected of them during the treatment process. However, patients who are experiencing a particular medical procedure for the first time may feel anxious and require more time and explanation to fully understand the procedure to be performed. This shows the importance of giving sufficient time to explain medical procedures, especially to new patients who may not be familiar with the concept of informed consent.

A good understanding of the importance of informed consent by doctors, paramedics, and patients is essential to ensure that these procedures can be carried out effectively. Doctors' and paramedics' perceptions of informed consent are greatly influenced by their training, workload, and understanding of medical ethics. Meanwhile, patients' perceptions of the quality of the explanation given are highly dependent on the communication skills of medical personnel, the patient's health literacy level, and social and cultural factors that influence the decision-making process.

To improve the quality of informed consent, hospitals need to pay attention to these factors and provide adequate training to medical personnel on effective communication, as well as develop inclusive strategies to accommodate the social and cultural diversity of patients. With a holistic approach, where doctors and paramedics act as good health educators, and patients feel heard and appreciated, the implementation of informed consent can run better and provide greater benefits for patients and medical personnel. Therefore, this study aims to analyze the implementation of informed consent as a legal protection mechanism in medical practice at Bandung General Hospital, Medan City.

METHODS

This research was conducted with normative legal research. Where normative legal research is research that focuses on studying the application of rules or norms in applicable positive law (Kingsbury, 2002). The type of normative legal research is carried out by studying various formal legal rules such as laws (Negara, 2023), regulations and literature containing theoretical concepts which are then connected to the problems that will be discussed in this thesis research. This research aims to reveal the truth systematically, methodologically and consistently. Through the research process, an analysis was carried out. This research was conducted at Bandung General Hospital, a public health facility located in Medan City, North Sumatra, Indonesia. Bandung General Hospital is one of the largest and leading hospitals in the area, which provides various medical services and health services to the surrounding community. As a research location, Bandung General Hospital was chosen because it is representative as an example of the health service system in Indonesia, where the implementation of Informed Consent is an integral part of medical practice and legal protection for doctors and paramedics. Through a case study in this hospital, researchers can analyze in depth the practice of Informed Consent, the challenges faced, and efforts that can be made to improve its effectiveness in the context of medical practice in Indonesia. Thus, Bandung General Hospital is a relevant and useful place to explore this research topic further. Respondents or informants in the thesis on Informed Consent as legal protection in the implementation and actions of doctors and paramedics at Bandung General Hospital can include several parties involved in the process, respondents or informants can include several groups as follows: (1) Patients who have undergone the Informed Consent process for medical procedures at Bandung General Hospital are one of the important respondent groups. Interviews with patients can provide insight into their experiences in receiving information, understanding medical procedures, and their experiences in giving consent; (2) Doctors and paramedics who are responsible for providing information to patients and obtaining consent from them are also important respondents. Interviews with doctors and paramedics can provide insight into their perspectives on the Informed Consent process, the challenges they face, and the efforts they have made to ensure the process runs smoothly; (3) Administrative staff at Bandung General Hospital who are involved in the Informed Consent administration and documentation process can also be relevant respondents. They can provide insight into how the Informed Consent administration process is carried out, the challenges they face, and suggestions for improving its efficiency and effectiveness; (4) Lawyers or medical ethicists involved in cases involving Informed Consent at Bandung General Hospital can also be valuable respondents.

Interviews with them can provide in-depth legal and ethical perspectives on the Informed Consent process and legal protection for all parties involved. In accordance with the type of normative legal research, the data sources used in this study are secondary data in the form of primary legal materials, secondary legal materials and tertiary legal materials. Data processing and analysis in this study involved several systematic stages. Data were collected through qualitative and quantitative methods, including in-depth interviews with doctors, paramedics, and patients (O'Hara et al., 2015), as well as surveys and studies of relevant documents at Bandung General Hospital. Qualitative data from interviews were analyzed using thematic analysis techniques to identify key patterns and themes related to informed consent implementation and legal protection. Quantitative data from surveys were processed using

statistical software to produce descriptive statistics that illustrate the level of understanding and compliance with informed consent procedures. Document studies involved analysis of medical records and hospital policies related to informed consent. All of this data was then integrated to provide a comprehensive picture of how informed consent is implemented and applied in everyday medical practice, as well as identifying factors that support or hinder its effectiveness as a legal protection tool.

RESULTS AND DISCUSSION

Procedure for Implementing Informed Consent at Bandung General Hospital, Medan City

The implementation of informed consent in general hospitals generally follows the procedures set out in the hospital's standard operating procedures (SOP), which aim to ensure that this process is carried out transparently and in accordance with the principles of medical ethics. Based on the guidelines issued by the Ministry of Health of the Republic of Indonesia (2020), the procedure for providing informed consent involves several main steps as follows:

Providing Adequate Information to Patients

The first step in the informed consent process is providing sufficient information to patients regarding the medical procedure to be performed. Medical personnel, in this case doctors, are required to provide a clear explanation of the purpose of the procedure, the expected benefits, the possible risks, and the available alternatives. Morony (2017), emphasized that the information provided must be adjusted to the patient's level of understanding, using simple and easy-to-understand language, and avoiding the use of complex medical terminology. Patients must be given the opportunity to ask questions and get adequate answers from medical personnel (Priolo & Tartaglia, 2023). For example, in major surgical procedures, patients should be given information regarding the type of surgery to be performed, the duration of recovery, possible complications, and whether there are safer or more effective alternative treatments. This aims to allow patients to make decisions that are truly based on a good understanding of their circumstances.

Providing Time for Consideration

After receiving the information, patients should be given sufficient time to consider their decisions. In some urgent cases, such as emergency medical procedures, time to think can be very limited. However, in more planned or non-emergency procedures, patients should be given time to discuss with family or trusted parties, or consider the information that has been provided. Bucknall (2003) stated that adequate consideration time allows patients to feel calmer in making decisions and reduces the possibility of pressure from the hospital or medical staff.

Signing the Informed Consent Form

After the patient understands the information provided, the next step is to sign the informed consent document. This form is proof that the patient has received and understood the information related to the medical procedure to be undergone. This signing not only serves as a formal agreement, but also as evidence that the communication process between medical personnel and patients has been carried out properly. However, Nijhawan et al. (2013) stated that signing the document is only one part of the overall informed consent process. What is more important is whether the patient really understands what they have agreed to.

Informed Consent Implementation Procedure at Bandung General Hospital, the informed consent procedure involves several stages that must be passed by the patient before medical action is carried out. This process begins with the provision of complete information by medical personnel to the patient about the type of medical action to be carried out, including the risks, benefits, and alternatives available. This information is conveyed in a language that is easily understood by the patient or the patient's family, with the aim of ensuring that they really understand the actions to be taken. In emergency situations, where it is not possible to obtain written consent directly, verbal consent is recorded in the medical record and must be followed

by written consent after the patient's condition improves. Based on the results of the interview with Dr. Evita Sri Ulina Ginting stated that:

"The implementation of medical action consent (Informed Consent) at Bandung General Hospital follows the procedures stipulated in the Regulation of the Minister of Health Number 290/MENKES/PER/III/2008. Every medical action taken must be accompanied by a comprehensive explanation to the patient or his/her family regarding the diagnosis, the procedure to be performed, the possible risks, and other available alternative actions. The consent document must then be signed by the patient or family as an emergency situation, where it is impossible to obtain written consent directly, verbal consent is recorded in the medical record and must be followed by written consent after the patient's condition improves."

In the initial stage, the doctor or other medical personnel must explain in detail about the medical procedure to be performed. This explanation includes information about the patient's diagnosis, the purpose of the medical procedure, the procedure to be performed, and the risks and benefits associated with the procedure. Information about alternative medical procedures and their possible outcomes must also be provided to ensure that the patient understands all available options. This is in accordance with the provisions stipulated in Article 7 of the Minister of Health Regulation No. 290/MENKES/PER/III/2008 concerning Consent for Medical Procedures, which emphasizes the importance of providing a comprehensive explanation to the patient or the patient's family (Hatta et al., 2024).

Furthermore, the information must be provided in a language that is easily understood by the patient or the patient's family. If necessary, the use of communication aids such as translators or information materials in the appropriate language can be done to ensure proper understanding. Effective communication skills of medical personnel are very important at this stage to avoid miscommunication and ensure that the patient truly understands what will happen. After the explanation is given, consent must be documented in an appropriate manner. At Bandung General Hospital, a consent form that must be signed by the patient or the patient's family is provided for this purpose.

This form includes details about the medical procedure, possible risks, and the patient's statement of consent. This document is then stored in the patient's medical record as evidence that consent has been given legally. In an interview conducted by the researcher with a doctor practicing at Bandung General Hospital, it was revealed that the implementation of informed consent at the hospital was carried out with strict procedures and in accordance with applicable regulations. A general practitioner (Dr. Evita Sri Ulina Ginting) said:

"That they have an obligation to provide detailed explanations to patients regarding the medical procedures to be carried out. This explanation includes the diagnosis, purpose of the procedure, the procedures to be carried out, and the risks and benefits that may arise. This information is conveyed verbally and stated in a consent form that must be signed by the patient or their family. The doctor also emphasized the importance of effective communication in the informed consent process. They realized that the use of overly technical medical language could confuse patients, so they tried to simplify the explanation without reducing the substance of the information. In addition, they mentioned the use of additional information materials and language translators if necessary, to ensure that patients fully understand the information provided."

Next, the researcher conducted an interview with Dr. Margaretha Damanik, SpA. She said:

"In emergency situations, doctors at Bandung General Hospital implement an oral informed consent procedure, following legal provisions that allow oral consent in urgent circumstances. However, they always try to document the explanation and written consent process as soon as possible after the emergency action is taken. This aims to meet legal requirements and ensure transparency and accountability in the medical decision-making"

process. Several doctors also mentioned challenges in implementing informed consent, such as limited time and the pressure of urgent medical situations. They admitted that sometimes there were difficulties in providing adequate explanations in a short time, but they tried hard to overcome these obstacles by ensuring that patients and families were always given the opportunity to ask questions and understand the information clearly. Overall, interviews with doctors at Bandung General Hospital showed their commitment to implementing informed consent and emphasized the need for clear communication and proper documentation to protect patient rights and comply with applicable legal regulations."

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SURAT PERSETUJUAN TINDAKAN () MEDIK / () PERAWATAN / () ANESTESI

Yang bertanda-tangan di bawah ini :

Nama _____
Tanggal Lahir / Umur _____
Alamat _____
No. KTP-SIM _____

Atas tanggung jawab dan resiko sendiri Menyetujui tindakan Operasi / Pengobatan / Prosedur / Perawatan*) yang telah dokter sarankan terhadap Saya Sendiri / Istri / Anak / Ayah / Ibu* Saya :

Nama _____
Alamat _____
No. MR _____
Diagnosis _____
Tanggal Lahir / Umur _____
Dirawat Di _____

Saya juga menyatakan dengan sesungguhnya dengan tanpa paksaan bahwa saya :

a. Telah diberikan informasi dan penjelasan serta peringatan akan bahaya, resiko, serta kemungkinan-kemungkinan yang timbul apabila dilakukan tindakan medis berupa **) :

b. Telah memahami sepenuhnya informasi dan penjelasan yang diberikan dokter.

Disetujui Oleh,

Tempat, Tanggal _____

Tanda Tangan dan Nama jelas (huruf bolak) _____

Tanda Tangan saksi keluarga dan Nama jelas _____

Tanda Tangan Dokter dan Nama jelas (huruf bolak) _____

Tanda Tangan saksi Pihak RS dan Nama jelas _____

() Tanda tindakan yang disetujui
(*) Coret yang tidak perlu
(**) Isi dengan jenis tindakan medis yang akan dilakukan

Figure 1. Informed Consent of Bandung General Hospital, Medan City

In situations where medical action must be taken immediately, such as in emergency cases, the informed consent process can be done verbally. However, even though consent is given verbally, written documentation of the explanation and consent must be made immediately after the action is taken, in accordance with the provisions stipulated in Article 4 of the Regulation of the Minister of Health No. 290/MENKES/PER/III/2008 concerning Consent to Medical Actions. Researchers also conducted interviews with paramedics at Bandung General Hospital, including nurses and midwives, revealing that they play an important role in the implementation of informed consent. Nurse Wanda Winata said: That they are involved in the informed consent process, especially in supporting doctors by providing additional information to patients and families regarding the medical actions to be taken.

They often act as a bridge of communication between doctors and patients, helping to explain medical information that may not have been fully understood by patients after being explained by the doctor. They routinely check the consent form before the medical action is carried out, ensuring that the patient has signed the document after receiving adequate explanation from the doctor. In addition, they provide additional explanations about the procedures to be performed, possible side effects, and steps that need to be taken after the medical action. This is critical in maintaining transparency and ensuring that patients have a good understanding of what to expect. Midwife Nelly Sinaga on the other hand, said:

"They are involved in informed consent especially in the context of childbirth and maternal and infant care. They provide explanations to pregnant women about the procedures that will be carried out during childbirth, the risks that may arise, and the treatment options available."

In addition, midwives also ensure that patient consent is obtained and properly documented, and provide information regarding postpartum care."

Both groups of paramedics revealed that although they tried to follow the informed consent procedure carefully, they sometimes faced challenges in terms of communication, especially when the patient was in an unstable emotional state or in an emergency situation. However, they always tried to provide clear explanations and ensure that all necessary information was conveyed to the patient. Paramedics at Bandung General Hospital indicated that they had a significant role in supporting the implementation of informed consent and ensuring that the consent process was carried out in an appropriate and effective manner.

In interviews conducted with patients or families of patients who had undergone medical procedures at Bandung General Hospital, various perspectives were revealed regarding the implementation of informed consent. Mr. Anto said: The process of consent for medical procedures at this hospital varies, depending on the type of procedure performed and the medical personnel involved. They received an explanation of the medical procedure from the doctor who would perform the procedure. This explanation usually included information about the procedure, possible risks, and available alternatives. However, they felt that the information provided was sometimes too technical and difficult to understand, especially for those without a medical background. The patient's family said:

"They often participated in the informed consent process when the patient was unconscious or when the patient needed help understanding the information being provided. They appreciated the efforts of the medical staff to provide adequate explanations and answer questions that arose. However, some families felt that the time available to discuss all the details was often limited, especially in urgent situations. They were simply given a consent form to sign without adequate explanation. This raised concerns about whether they fully understood the medical procedure being performed and the potential risks. Some patients also expressed concerns about being pressured to give consent, especially when they felt they did not have enough time to consider the information provided."

In general, although most patients and families felt that the informed consent process was carried out well, there were still areas that needed improvement, especially in terms of clearer communication and sufficient time to understand and consider the information provided. It is important to note that consent to medical procedures is not absolute and can be withdrawn before the procedure begins. If the patient or family changes their mind after giving consent, they have the right to withdraw the consent, and this withdrawal must be made in writing. The doctor or medical staff must respect this decision and not continue the medical procedure if the consent has been withdrawn. However, the implementation of informed consent faces several challenges. There are cases where doctors or other medical staff delegate the task of explaining to nurses or other medical staff, which sometimes causes patients or families to not receive adequate explanations about the procedures to be carried out.

This can potentially lead to medical disputes if patients feel they do not receive sufficient information and feel disadvantaged. To overcome this problem, Bandung General Hospital routinely conducts training and evaluations to improve the communication skills of medical staff, as well as ensure compliance with the informed consent procedure. Regular monitoring is also implemented to ensure that all procedures are carried out in accordance with established operational standards, and dispute resolution is carried out through mediation involving the hospital's legal team and medical committee. In an interview with a lawyer specializing in health law, several important insights were revealed regarding the implementation of informed consent at Bandung General Hospital. The lawyer, experienced in handling medical cases, outlined several key aspects of informed consent and the legal challenges often faced. He said:

"The implementation of informed consent at Bandung General Hospital generally follows the procedures stipulated by laws and regulations. However, there are still some shortcomings that can affect patient rights. One of the main issues is the frequent lack of

clarity in communication between medical personnel and patients. Although doctors and medical personnel are required to provide a complete explanation of medical procedures, risks, and alternatives, in practice, some patients may not receive adequate information. This can result in a lack of adequate understanding of the medical actions to be performed. The importance of proper documentation in the informed consent process. There are cases where consent forms are not filled out properly or do not reflect the explanations given, which then become a source of legal disputes. Inadequate documentation can lead to legal problems if complications or disputes arise later. Hospitals must ensure that all consent forms are filled out completely and documented accurately to protect all parties involved."

In the context of legal disputes, cases involving informed consent often focus on whether the patient truly understood and gave informed consent. If it is proven that the patient did not receive sufficient information or if the consent process was not carried out according to the correct procedure, this can be the basis for a lawsuit. Hospitals and medical personnel must pay attention to key aspects of informed consent, including clear communication, accurate documentation, and adequate understanding from the patient. These efforts will help minimize the risk of legal disputes and ensure the protection of patient rights in carrying out medical procedures. By following the procedures in accordance with the Regulation of the Minister of Health No. 290 / MENKES / PER / III / 2008 concerning Medical Action Consent (Pont & Enggar, 2023), Bandung General Hospital strives to meet ethical and legal standards related to informed consent, as well as protect patient rights in the medical decision-making process.

Effective implementation of these procedures not only ensures compliance with regulations, but also increases patient trust and satisfaction with the health services provided. The implementation of informed consent in general hospitals is an important element in providing ethical and legal medical services. However, existing challenges such as time constraints, patients' ignorance of their rights, and communication and health literacy barriers require more attention from hospitals and medical personnel. Hospitals must improve communication training for medical personnel, provide educational materials that are easy for patients to understand, and pay attention to socio-cultural factors that can influence the decision-making process. Thus, the implementation of informed consent can be more effective, ethical, and in accordance with the standards set by regulations.

CONCLUSION

The implementation of informed consent in Bandung Medan General Hospital is an important process in ensuring that patients provide informed consent regarding the medical procedures to be performed. This not only involves providing clear information about the procedure, risks, and benefits, but also involves respecting the patient's autonomy in making decisions regarding their health. However, the implementation of informed consent in general hospitals often faces challenges, such as time constraints, ineffective communication, and lack of patient understanding of the medical procedures they will undergo. Informed consent is not only a patient's right, but also provides legal protection for doctors and paramedics. By obtaining valid consent from patients, medical personnel can protect themselves from potential lawsuits related to malpractice or medical actions carried out without the patient's permission. This legal protection occurs because the informed consent process records that the patient has been given sufficient information about the procedure to be performed, including its risks and benefits. Thus, this process is evidence that medical actions are carried out with the patient's valid consent. Although informed consent is an important process in providing ethical and legitimate health services, its implementation in general hospitals is often hampered by several factors. The main obstacles faced include time constraints, ineffective communication, lack of patient understanding of medical procedures, and cultural and social differences that affect how patients receive medical information. In addition, administrative obstacles in terms of proper documentation can also hinder this process.

SUGGESTION

Improving education and training of medical personnel regarding effective communication and ethics in informed consent. The use of technology to assist the patient education process, such as educational videos or applications that explain medical procedures in a simpler way. and Further counseling and education for patients, especially for those with low levels of medical literacy, so that they can make informed decisions. Legal protection of the existence of Standardization of informed consent procedures in hospitals with clear guidelines so that all medical actions carried out by medical personnel are recorded legally and transparently. Improving stricter and more detailed documentation regarding the informed consent process, by ensuring that all information submitted and consent given is recorded completely and accurately. Legal education for medical personnel so that they understand the importance of this process in the context of legal protection and avoiding potential malpractice claims. Improved communication between medical personnel and patients through more in-depth training in clear and easy-to-understand communication techniques. Increased time allocated for consultation and explanation to patients, so that patients can fully understand the information provided before giving consent. And Improved documentation systems that are more integrated and standardized, ensuring that all informed consent processes are properly recorded and can be accounted for in legal cases.

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