

## Informed Consent in Hospitals: A Model for Implementing Bioethical Principles and Legal Protection for Patients

Siti Soekiswati<sup>1</sup>, Naeem Allahrakha<sup>2</sup>, Arief Budiono<sup>1\*</sup>, Mukhammad Ali Turdialiev Polatjon Ogli<sup>2</sup>, Nida Faradisa Fauziyah<sup>1</sup>, Asri Alfajri<sup>1</sup>, Lisanul Latifa<sup>1</sup>, Ahmad Reza Diagitama<sup>1</sup>, Alibek Matmurodov<sup>2</sup>

<sup>1</sup>Universitas Muhammadiyah Surakarta, Surakarta, Indonesia

<sup>2</sup>Tashkent University, Tashkent, Uzbekistan

### Abstract

*Informed consent is part of the health care process that health workers must carry out in treating patients with elective conditions. Hospitals must provide patients with complete, clear, and understandable information. However, in many cases, patients are not given adequate information before signing the informed consent form. This study aims to obtain empirical facts on the application of informed consent with invasive measures in X hospital. This research was conducted in a class-D private hospital in Central Java Province, Indonesia. This qualitative research with an analytical descriptive research type. The authors conducted direct observation, semi-structured interviews with informants consisting of health workers and hospital medical personnel, and undercover in-depth interviews with patients and health workers in the hospital. Medical record data and semi-structured interviews show that the hospital has properly implemented informed consent. The authors conducted triangulation of data obtained from interviews, medical records, direct observation without disclosing the researchers' identity, as well as undercover interviews with health workers and patients at the hospital. Data triangulation and observation results showed that X Hospital failed to correctly carry out informed consent. It was found that there were still many instances where the implementation of informed consent was not by the bioethical principles of autonomy and legal protection for patients in X hospital.*

**Keywords:** Indonesia, Informed Consent, Invasive Measures, Legal Dispute, Patient Protection.

### Introduction

The government of the Republic of Indonesia followed up with the Declaration of Human Rights by the United Nations on December 10, 1948, by promulgating the Law on Human Rights No. 39 of 1999. This law regulates that all public authorities are required to act according to the rights listed in the Human Rights Act [1]. Then, the courts must, as far as possible, interpret other laws following those rights. The main articles that may be relevant in medical case law are Article 4 and Article 9 (the right to life and the right to a healthy environment), Articles 5 and

58 (the right to legal protection and justice), as well as Article 62 (the right to adequate health care and social security) [2].

The implementation of human rights in health services is mainly in the form of the patient's autonomy rights in making decisions regarding the therapy they will undergo or receive [3]. Patients have the right to information related to the therapy they will receive. Then, they may approve or refuse treatment according to their autonomy rights. The approval of treatment actions is commonly referred to as informed consent [4].

Informed consent is an integral part of good medical practice [5].

The legal basis of informed consent, i.e., the provision of information related to actions to be taken by a doctor in health services, is contained in Article 293 Clause 5 of the Health Law Number 17 of 2023. Doctors must provide patients with adequate and understandable information, including the diagnosis; indications, health care actions taken and their objectives, risks and complications, other alternative actions and their risks, as well as the risks if one chooses to refrain from treatment. Apart from that, doctors must also explain the prognosis of the disease after the action is taken [6]. Then, patients also have the right to be informed about the cost of health services they receive, as stated in Article 294 of the Health Law [7]. The provisions and procedures for implementing informed consent in Indonesia are Health Law Number 17 of 2023. Before that, there was the Regulation of the Minister of Health Regulation Number 290 of 2008 [8].

The failure to effectively deliver information on such health treatment may break the doctor-patient relationship and may even lead to litigation. A series of high-profile litigations has redefined the way the consent process is conducted. Procedurally, the courts expect doctors to inform their patients of all risks that each patient considers important, regardless of how unlikely they may be [9].

Concerning the practice of surgery-related information provision in hospitals in Indonesia, a dark history of such medical practice has been recorded. There have been cases where doctors were sentenced to prison because they were said to have committed malpractice by failing to provide patients with clear information. For instance, there was a case where a final-year obstetrician-gynaecologist specialist resident was said to be negligent in conducting informed consent in conducting C-section surgery. As a consequence, the patient was declared dead

due to embolism [10]. Another doctor was also sued due to his negligence in providing informed consent to the patient when performing circumcision, resulting in the patient feeling harmed by the doctor's actions [11].

These two cases are the tip of the iceberg, as many more legal cases have happened due to the incorrect implementation of pre-operative informed consent in hospitals in Indonesia [12]. Health or medical personnel must be professional in carrying out their task and responsibilities [13]. Departing from the conditions of the empirical facts above, in this paper, the authors conducted an empirical study of the legal protection of patients in the implementation of informed consent for patients with invasive actions in hospitals.

## **Materials and Methods**

This was qualitative research. It employed a descriptive-analytical study, which was an analysis of empirical facts on the application of informed consent for patients who underwent invasive actions in hospitals [14]. This type of research allows researchers to directly collect data from empirical facts and identify data from interviews, documents (medical records), or observation results [15].

This research was conducted in a private hospital in a city in Central Java province, Indonesia, hereinafter named X Hospital. The research was conducted from November 2023 to January 2024. The authors obtained data by observing medical records that were selected and provided by the hospital's Head of the Education and Training Department.

Researchers made direct observations of the implementation of informed consent and recorded the semi-structured interviews with informants. Informants were given informed consent as proof of their willingness to have their interviews used as research data. The Head of Education and Training also determined the informants who were interviewed using informed consent. The

authors interviewed five informants representing each profession, namely one nurse, one midwife, one general practitioner in charge of the emergency room, one specialist in obstetrics and gynaecology, and one specialist in general surgery.

In addition to semi-structured interviews, researchers also conducted undercover interviews without informed consent from the interviewees [16, 17]. Undercover interviews were conducted with two patients, three families of patients, one Medical Records officer, and one nurse. The researchers conducted undercover interviews by blending in as patients undergoing treatment at the hospital [18, 19].

After obtaining data from observations of medical records, direct observations, and interviews, the authors categorized the data [20]. Then, the authors conducted data triangulation. After that, the authors analysed the data and concluded on the implementation of informed consent in the hospital.

## Results

The authors asked to observe the Medical Records in X hospital. The authors conveyed the purpose of the research on the implementation of informed consent in X hospital with Mrs. M, i.e., the hospital's Head of the Training Department. The hospital management was willing to help with the research. However, it could only provide Medical Record data selected by Mrs. M. Because Mrs. M had to find the data in the Medical Record data room, the researchers were asked to come again on Saturday, December 9<sup>th</sup>, 2023, at 2 p.m. Western

Indonesian Time. On the agreed day, the researchers arrived, and Mrs. M provided the medical record data of fifteen patients. To record patient data, X hospital did not fully implement electronic medical records, as the medical records of outpatient control are carried out electronically, while pre-operative and emergency patients still use paper medical records that can be directly signed or thumb-printed by the patient or/patient's family [21].

The researcher first informally obtained data, with preliminary interviews at X hospital. The researcher was scheduled by hospital management to meet with the Head of the Training Department of the hospital, Mrs. M, on November 25<sup>th</sup>, 2023. In the morning before meeting Mrs. M, the researcher took the time to visit X hospital, to be a patient's caregiver. Then, the researchers reveal their identity as researchers to the patients who would receive invasive treatment, so that the researcher (as a patient's caregiver) could follow the service activities at X hospital. After the examination, the doctor only briefly explained the invasive action that would be performed. Then, the nurse handed the form for the patient to sign. When the researcher (as a patient's caregiver) asked about the drugs that must be taken, the doctor's answer was, "The medicine is to cure the pain." Then, the doctor's assistant nurse asked the researcher (as a patient's family) to immediately take the medicine from the hospital's pharmacy department. The queue for medicine was quite long, about an hour. This fact became the initial data that the researcher noted.

**Table 1.** Hospital Informed Consent Data in Medical Records

No	Polyclinic	Patient	Patient's age (years)	Sex	Doctor	Approver
1	Obstetrician-gynecologist	Mrs. M	25	Female	C	Mrs. M's family
2	Obstetrician-gynecologist	Mrs. Dn	29	Female	C	Mrs. Dn's husband
3	Obstetrician-	Mrs. K	37	Female	C	Mrs. K

	gynecologist					
4	Obstetrician-gynecologist	Mrs. G	30	Female	C	Mrs. G
5	Obstetrician-gynecologist	Mrs. Nt	27	Female	C	Mrs. Nt's husband
6	Obstetrician-gynecologist	Mrs. S	39	Female	C	Mrs. S
7	Obstetrician-gynecologist	Mrs. D	26	Female	C	Mrs. D's family
8	Obstetrician-gynecologist	Mrs. A	39	Female	C	Mrs. A's husband
9	Obstetrician-gynecologist	Mrs. I	25	Female	C	Mrs. I's family
10	Obstetrician-gynecologist	Mrs. Dt	31	Female	C	Mrs. D's husband
11	Obstetrician-gynecologist	Mrs. Rn	25	Female	D	Mrs. Rn's family
12	General Surgery	Mrs. N	68	Female	D	The patient's son, Mr. K
13	General Surgery	Mrs. R	52	Female	D	Patient, Mrs. R
14	General Surgery	Mr. M	49	Male	D	The patient, Mr. M
15	Orthopedics	Child O	17	Male	H	The patient's mother, Mrs. S

Informed consent data in the medical records of X hospital are shown in Table 1. Data from the medical records that the authors analysed showed that all patients obtained information from the doctor who performed the invasive action. Most of the consent was not approved by the patient who received the treatment, but rather by the patient's guardian or family members. The researcher asked the reason for this fact to the hospital's Head of Education and Training Department, Mrs. M. She said that in the area, there is a very strong guardianship model over the patient by the family. Thus, to sign the informed consent, the

majority of preoperative patients give their signature of approval for surgery to the guardian/family.

The fact that the medical record data provided has been selected by the researcher made it easier for researchers to observe the data without having to search for such data in the medical record folder storage room by themselves. The fact that medical record data used in this research was selected by the research party (the hospital) allows the research party to find data from the medical record that was by the correct rules in the implementation of informed consent.

**Table 2.** Interview Results of Health Workers with Informed Consent to Become Research Informants

No	Polyclinic/Date/Informant	Question	Interview Results
1	Emergency Room/December 16, 2023/Duty	What does the informed consent comprise?	"In addition to the diagnosis, I should tell you about all the treatments or therapies I will conduct, their purposes, indications, benefits,

	doctor, J		side effects, and possible risks."
		Is the informed consent written or oral?	" In this hospital, some of the informed consents are delivered orally, while some are delivered in a written manner. Verbal ones usually include infusion and an agreement with the patient or his family, depending on the patient's situation and condition."
		When is informed consent given?	"If the emergency room patient needs immediate surgery, the informed consent is usually delivered in the emergency room before the surgery, specifically before the patient is taken to the operating room. But if the operation is elective and it requires prior treatment/condition stabilisation, information about the operation is usually delivered one day before the surgery."
		How does the doctor know if the patient or family has understood the information?	"Usually, I ask the patient whether the information is clear. Is there anything they need to ask about? Or, are they still confused? If the information is still unclear, I repeat the unclear part to increase their understanding. If there are no questions, it means that the patient has understood. Thus, I consider the patient has agreed."
		Is the cost of the action also conveyed to the patient or family?	"As for the cost, it is conveyed if the patient asks, but it is seldom carried out because, in this hospital, the majority of patients use BPJS (Social Security Administering Agency insurance), thus most of the services are paid by insurance. Once, there was an independent patient who did not use BPJS insurance. He asked about the cost. Thus, I asked him to ask the information office or hospital administration."
2	Emergency room clinic/December 16, 2023/Nurse on duty, Mrs. S	What is conveyed in the informed consent, and who delivers it?	"The informed consent that was submitted could include the diagnosis, the purpose of the action, the reason that the action is carried out, the risks and complications that might occur, the required follow-up actions, as well as the drugs that must be consumed. All of this is explained by the general practitioner on duty in the emergency room after reporting to the doctor in charge of service, including whether the surgery will be performed by the doctor in charge of service."

		To whom is the informed consent delivered?	"Informed consent is conveyed by the doctor in charge of the emergency room to the patient or his family."
		What do emergency room nurses do regarding surgery?	"The nurse records the patient's main complaint and reports it to the duty doctor. Then, the duty doctor who examines the patient explains the informed consent to the patient. We then ask the patient or his family to sign the written informed consent form."
		What is the flow of the emergency department patient examination?	"Usually, the patient comes to the emergency room. He is triaged, and then the nurse and/or the emergency room duty doctor records the patient's brief medical history. If there is an indication of ' <i>cito</i> ' surgery, it is reported to the surgeon/obstetrician/gynaecologist who will perform the operation and the operating room is prepared."
3	Emergency room clinic/ December 16, 2023/Emergency room midwife Mrs. M,	What is conveyed in the informed consent by the midwife, and to whom is the informed consent conveyed?	"What we usually tell the patient or family is the condition of the pregnant woman, voluntary termination of pregnancy, physical examination carried out to support the diagnosis, the purpose of the action, complications, as well as the prognosis. For example, during labour, the patient and her family are informed of her contractions, fetal heart rate, the stage of labour, and whether normal birth may be carried out or if a Cesarean section surgery must be carried out. Then, the obstetrician reports such information."
		In what ways do midwives usually treat patients?	"We usually take care of patients who go through normal labour and assist obstetricians in case of Cesarean section surgery before the operation, during the operation, and post-operation."
		Who is involved in obstetric or gynecologic care?	Those involved in handling obstetric or gynecologic care include midwives and obstetric doctors. Then, if there are cases where the Cesarean section surgery must be conducted, the surgery team, anaesthesia doctor, and baby room nurses are involved."
4	Obstetrics-Gynaecology Poly/January 2, 2024/ with Doctor (D)	What is conveyed in informed consent? Is it written or verbal?	"Yes, usually, the informed consent comprises the purpose of Cesarean section surgery, the indications, the complications and risks that may arise, as well as therapy/management. It is delivered orally

			and in writing, and the patient is asked for his signature of consent."
		Does the informed consent have to explain everything?	"Not everything is conveyed. For example, the things that may make the patient afraid or 'down' are not conveyed."
		When is informed consent given?	"It depends on the case or patient; mostly it is given long before the procedure is carried out."
		How does the doctor know that the patient or family has understood the information conveyed?	"I usually ask, 'Is there anything you would like to ask, Sir/Madam? What are you supposed to/will do?' So, the patient/family to whom I give information must repeat such information. If there are no questions, it means that they have understood the information given."
		Is the cost communicated to the patient or family?	"Because the majority of patients are BPJS insurance patients, patients rarely ask about the cost. If it is an independent surgery, patients who want to know the cost of these health treatments are asked to ask the administration office."
5	General doctor in charge of service/January 2, 2020/with doctor (D).	What is included in the informed consent, and is it in verbal or written form?	"I orally explain the diagnosis, then the course of action to be taken, what the aims and objectives of the action are, as well as what the risks, complications and side effects are. Also, I explain the future prognosis of the disease if surgery must be carried out."
		Should all contents of the informed consent be conveyed or not?	"If it is informed consent, of course, I explain everything, as nothing can be covered up."
		When is informed consent given?	"In some of my surgeries, I give information on elective surgery at the surgery clinic when the patient is examined and diagnosed. I explain these things, and then ask for the consent of patient. However, sometimes, I not only give information to the patient but also to the patient's family if the patient is in a weak condition on the operating bed. Then, I also ask for the family's signature of approval, especially for children or elderly patients. In the case of an emergency room patient, the informed consent is delivered in the emergency room by the emergency room duty doctor. During emergency conditions, the patient is treated first. Then, after the emergency has been overcome, the doctor

			explains and asks for a signature of informed consent."
		How does the doctor know that the patient or family has understood the conveyed information?	"If the patient is amenable to two-way communication, I confirm by asking the patient to repeat what I have said, especially the diagnosis, goals, and risks if surgery is not taken. If the patient or his/her family still does not seem to understand, I repeat the explanation. Then, I asked, 'Is there anything that you still do not understand?' If there is no feedback and no more questions, I consider them as having understood the information given."
		If the patient does not want surgery, what does the doctor do?	"If the patient does not want to have surgery, I will explain the risks if one fails to have surgery."
		Is the cost of the surgery also communicated to the patient or family?	"Rarely, because patients usually use BPJS financing and other private health insurance."

The results of interviews conducted by researchers with health workers with informed consent to become research informants are shown in Table 2.

## Discussion

Pre-operative patients are patients who will undergo surgery or medical operations. Such an action is part of therapy, treatment, or health diagnosis that is carried out using invasive procedures to save the patient's life or prevent further complications. The surgery process requires the involvement of patients and medical and health personnel before such procedures. In carrying out his obligations, a doctor must respect the dignity and rights of the patient, especially the right to self-determination and the right to think logically in making decisions by the wishes of the patient [22].

More broadly, a patient must give consent in a conscious and voluntary manner after having fully understood and accepted the medical action. Doctors must clearly provide information on medical actions in the form of treatment or therapeutic procedures that will be provided. The information given is related

to the risks, benefits, alternative therapies, and consequences of medical action. Approval (consent) to medical action is used as a form of guarantee or responsibility for the actions and consequences arising from the doctor's actions in providing health services. Informed consent is a tool to give patients the authority to make decisions, as well as a means of legal protection for the therapy that will be undertaken. In addition to providing legal protection for patients, doctors also need a legal basis for their actions and efforts to protect or minimize demands. Thus, it is crucial for informed consent to be implemented correctly [23].

Preoperative patients in hospitals have great expectations of hospital services. They want the hospital to be quick, responsive, and able to provide comfort in responding to their illnesses or complaints. In hospitals, surgery is performed by surgeons, anesthesiologists, and surgery team members who have been trained with advanced technology. The types of surgery in hospitals include general surgery, orthopaedic surgery, cardiovascular surgery, oncologic surgery, gastrointestinal surgery, neurosurgery surgery, and so on. These



procedures must meet established service quality standards as well as meet the patients' needs satisfaction [24].

Empirical facts show that there are many factors that become obstacles to implementing informed consent in preoperative actions on patients in hospitals. Among them are the patient's lack of understanding, as well as language barriers. Patients' level of education or lack of knowledge of health problems affects their ability to understand information conveyed by doctors or health workers. Other obstacles include the lack of opportunities to ask questions, the lack of availability of complete and clear information, and the lack of efforts to provide freedom to patients to agree or disagree to have health procedures conducted on them [25].

By the Minister of Health Regulation No. 3 of 2020 on Hospital Classification and Licensing, hospitals in Indonesia are divided into general hospitals and special hospitals. General hospitals are divided into four classes, namely class A, class B, class C, and class D. This research was conducted in a class D private general hospital with limited basic health services, namely general and dental health services. In terms of its facilities and capabilities for conducting medical services, it provides at least two basic medical services. It can serve some surgeries such as minor and emergency surgery services, general surgery, orthopaedic surgery, and Caesarian section surgery [26].

Through the researchers' undercover interviews with several informants, it was shown that there was still a gap in negligence where the explanation of informed consent was not given by the doctor who performed the action. The researchers confirmed this with some doctors, including obstetricians, general practitioners on duty in the emergency room, and managing doctors of X hospital. It was found that due to the doctors' limited time, sometimes obstetricians, surgeons, and general practitioners on duty in the emergency room

explain the outline of the surgery or treatment actions that will be performed. Meanwhile, in the surgery polyclinic, the obstetrician's polyclinic, or the emergency room, the nurse has the task of asking for the patient's signature. This result strengthens the analysis that in X hospital, the implementation of informed consent has not fulfilled the rules of autonomous bioethics and the patient protection law in this hospital.

The practice of health services in hospitals often faces patients' lack of understanding of information from doctors. This is usually due to language barriers, lack of education, and lack of health knowledge. Patients' understanding of informed consent is also hindered by the unavailability of clear, complete, and easily understandable information. Another factor that becomes an obstacle to this is the individual's lack of ability to understand the information or the lack of opportunity to ask questions in case the patient does not understand. There is freedom and no coercion in giving consent [27]. Available information needs to be communicated accurately to patients or family members so that they may understand the medical condition and fully understand their decision to accept or reject a health service. This is to minimize the occurrence of unwanted events [28].

Informed consent is the implementation of the autonomy bioethical rules in health services, with the principle of prioritizing respect for the rights and capacity of individuals (patients) to make decisions about medical actions by considering the mental capacity and complete information from medical personnel and/or health personnel. Bioethical rules consider and provide ethical guidance regarding decisions and actions in the fields of medicine, biomedical research, and health. It takes ethical values, human rights, and principles of justice into account [29].

Informed consent is a standard rule that must explain the actual information to the patient, respect the patient's privacy, maintain the confidentiality of information, and obtain consent from the patient or the patient's family to carry out invasive actions on the patient. The failure to fulfil informed consent in conducting health services with invasive actions poses health workers or hospital medical personnel with a risk of being subject to lawsuits [30].

Even so, not all information related to the invasive action is conveyed to the patient. For example, in cases where information may make the patient afraid or down, the doctor still provides honest information, but with motivating or positive language or sentences that may maintain the patient's confidence. About rights, every patient has the right to obtain information about the treatment procedures that will be undertaken. The treatment must not harm or endanger the patient. This is stated in the principle of the bioethical rule of non-maleficence, which demands that medical practitioners not cause damage or harm to patients [31]. By providing complete and understandable information about an invasive action that will be given to the patient, the patient is expected to avoid unwanted or adverse risks. This is where patient protection law lies [32].

The provision of informed consent in the X hospital is carried out at any time, depending on the action that will be taken. After the doctor explains the information to the patient or the patient's family, to minimize the occurrence of misunderstandings or missed information, the doctor will usually repeat the explanation again in detail. The doctor will also provide feedback, such as asking, "Is there still something you want to ask about? Or, are you still confused with the information that I explained?". By asking the patient or family, the doctor or health worker can find out whether or not the patient has understood the information provided. There needs to be

clear two-way communication between the doctor and patient, and ensure that no information is missed.

In X hospital, there are some cases where patients do not want to undergo invasive actions/surgery. Even in this condition, doctors must still apply the principles of autonomy bioethics, specifically the principle that the patient has the right to make decisions on therapeutic measures for their diseases/physical disorders. Meanwhile, the doctor cannot force the patient to follow the former's therapeutic decisions. In an interview that the authors conducted, the surgeon stated, "If the patient does not want to perform surgery, I explain first the risks if no surgery is performed. After explaining the risks of not undergoing surgery and the patient still chooses treatment other than surgery, they are asked to sign a refusal form and can be given an alternative to surgery."

At X Hospital, the majority of patients use BPJS insurance. So, it is rare for patients to ask about the amount of fees that must be paid. The amount of health service fees that must be paid is also part of the information that must be conveyed to the patient and/or their family. Patients have the right to receive explanations from doctors who perform medical procedures. After obtaining a comprehensive explanation, the patient has the right to agree or reject the medical action recommended by the doctor without any pressure or coercion from any party. In situations where the patient is unable to give consent, the family or authorized individuals can act as a substitute for the patient. They have the right to receive information and explanations, as well as give or refuse consent to the actions recommended by the doctor [33].

The main part of this research's findings is the data obtained from undercover interviews with rather detailed descriptions. This information was delivered without any particular motivation when the researcher first came to convey the purpose and objectives of

the research. This was supported by other undercover interviews. The application of informed consent in X hospital has not fully met the bioethical principles. Mrs. M stated, "Sometimes the doctor explains [the information regarding the procedures] after the emergency has been handled. It is often the emergency room nurse is the one who explains such information because the doctors must take care of other patients. For surgical operations, doctors can rarely give lengthy information. Yes, it is understandable because the surgeons have long working hours and they do not only work in this X hospital. This is to maintain time efficiency, and the important thing is that the patient can be helped. Usually, the one who explains is the surgery nurse or the emergency room duty doctor. As for the obstetrician's patients at X hospital, they always get enough explanation. It is only a few times in an urgent condition that the obstetrician has to perform a Cesarean section surgery. Thus, the patient received an explanation from the midwife. This is so that when the obstetrician came, the patient could immediately be operated on."

The action-taking method that health workers and medical personnel of the X hospital carry out related to informed consent illustrates the model of medical and legal thinking patterns. For a health worker, healthcare is conducted to provide help and bring benefits to the patient or the rule of beneficence in bioethics. Meanwhile, from the legal perspective, informed consent is part of the implementation of the bioethical rule of autonomy, which is respect for the patient's right to self-determination. Violation of autonomy rights is included in the violation of human rights, which means a violation of the patient protection law [34].

Undercover interview data show that the implementation of informed consent has not correctly fulfilled the bioethical principles of patient autonomy. This condition should be overcome by increasing the number of

surgeons practicing in the hospital so that they have more time to correctly explain informed consent for patient safety. Some undercover interview findings support this finding [35].

This research also shows that in qualitative research, formally-obtained interview data that fulfils research rules, namely the existence of informed consent, cannot be deemed valid and become research conclusions, without undercover interview data where informants freely convey information without knowing that their information will become research data. In addition, it is important to triangulate data with direct observation without knowing the researchers' identity, as in the observed activities [36].

## **Conclusion**

Qualitative research with interview data following research rules (using informed consent for informants) must be triangulated with undercover interview data and direct observation by researchers, without knowing their identity as researchers. The empirical conditions observed can be used to triangulate data. This is to obtain the correct conclusions about the implementation of a rule in an institution. In conclusion, it was found that the informed consent for patients with invasive surgery at the X hospital has not fully implemented the rules of autonomous bioethics and the hospital patient protection law. Medical record data and interviews with informed consent for informants do not match the empirical conditions witnessed by researchers through undercover interviews.

## **Conflict of Interest**

There is no conflict of interest.

## **Acknowledgements**

This research is funded by HIT (Hibah Integrasi Tridharma or Tridharma Integration Grant) by the Faculty of Medicine Universitas Muhammadiyah Surakarta.

## References

- [1]. Yuspin, W., Wardiono, K., Nurrahman, A., and Budiono, A., 2023, Personal Data Protection Law in Digital Banking Governance in Indonesia. *Stud Iurid Lublinensia*, 31(1), 99–130. <https://doi.org/10.17951/sil.2023.32.1.99-130>
- [2]. Absori, A., Nugroho, S. S., Haryani, A. T., Sarjiyati, Budiono, A., and Nugroho, H. S. W., 2020, The Prospect of Environmental Law to Achieve Healthy Environmental Development in Indonesia. *Medico-Legal Update*, 20(1), 204–208. <https://doi.org/10.37506/mlu.v20i1.356>
- [3]. Budiono, A., Absori, A., Ngestiningrum, A. H., and Nugroho, H. S. W., 2018, Pseudo National Security System of Health in Indonesia. *Indian J Public Heal Res Dev.*, 9(10), 556–560. <https://doi.org/10.5958/0976-5506.2018.01404.3>
- [4]. Page, K., 2012, The four principles: Can they be measured and do they predict ethical decision making? *BMC Medical Ethics*, 13(1), 10. <https://doi.org/10.1186/1472-6939-13-10>
- [5]. General Medical Council, 2013, *Good Medical Practice* (London: GMC). [http://www.gmc-uk.org/static/documents/content/GMP\\_.pdf](http://www.gmc-uk.org/static/documents/content/GMP_.pdf). Accessed March 12, 2024
- [6]. THE REPUBLIC OF INDONESIA'S GOVERNMENT, Health Law of the Republic of Indonesia Number 17 of 2023, Paragraph 5 Article 293 paragraph (3). <https://aksetlaw.com/?practicetag=indonesia-health-law>
- [7]. Hernanda, T., Absori, Wardiono, K., Azhari, A. F., Arlinwibowo, J., and Azizah, N., 2023, The Impact of Environmental Regulation Implementation: A Meta-Analysis. *Int J Sustain Dev Plan*, 18(10), 3235–3242. <https://doi.org/10.18280/ijstdp.18i1023>
- [8]. Budiono, A., Nurrizky, A. S., Fairuzzaman, F., Gulyamov, S. S., Prakoso, A. L., and Yuspin, W., et al., 2024, Lessons from Indonesian National Healthcare Security (BPJS Kesehatan): HIV/AIDS Patient Medical Data Protection Policies. *Malaysian J Med Heal Sci*, 20(9), 201–208. <https://doi.org/10.47836/mjmhs/20.s9.33>
- [9]. Chan, S. W., Tulloch, E., Cooper, S., Smith, A., Wojcik, W., and Norman, J. E., 2017, Montgomery and Informed Consent: where are we now? *BMJ*, 357, j2224.
- [10]. Syafruddin, and Rohman, A., 2019, Model of Protection and Fulfillment of Patient Rights towards the Implementation of Informed Consent in Indonesia, *Mimbar Hukum*, 3(2), 222-236. <https://doi.org/10.1136/bmj.j2224>
- [11]. Hartotok, H., Absori, A., Dimiyati, K., Santoso, H., and Budiono, A., 2021, Stunting prevention policy as a form of child health rights legal protection. *Open Access Maced J Med Sci*, 9, 1218–1223. <https://doi.org/10.3889/oamjms.2021.7254>
- [12]. Wardiono, K., 2019, Prophetic: An Epistemological Offer for Legal Studies. *J Law Justice*, 1(1), 17–41. <https://doi.org/10.23917/jtl.v1i1.8797>
- [13]. Hambodo, P. T., Arismar, F. R., Salasabila, T. V., Kusumo, D. F. A., Mufidah, F., and Sulistyani, S., 2021., Negligence of Medical Actions Resulting in Allegations of Malpractice at Kandai Hospital Manado. Proceeding Book Call for Papers Faculty of Medicine, Universitas Muhammadiyah Surakarta, *Surakarta, Indonesia*, pp. 153-159. <https://jsr.ums.ac.id/jkk/article/download/373/381/2809>
- [14]. Busetto, L., Wick, W., and Gumbinger, C., 2020, How to Use and Assess Qualitative Research Methods, *Neurological Research and Practice*, 2(14). <https://doi.org/10.1186/s42466-020-00059-z>
- [15]. Ichsan, B., 2022, Introduction to Medical and Public Health Research Methodology (Surakarta: Muhammadiyah University Press). [https://books.google.com/books/about/PENGANTAR\\_METODOLOGI\\_PENELITIAN\\_KEDOKTER.html?id=UTpIEAAAQBAJ](https://books.google.com/books/about/PENGANTAR_METODOLOGI_PENELITIAN_KEDOKTER.html?id=UTpIEAAAQBAJ)
- [16]. Haq, H. S., Achmadi, Hangabei, S. M., and Budiono, A. 2022, Community Mediation-Based Legal Culture in Resolving Social Conflicts of Communities Affected by the COVID-19 Pandemic in West Nusa Tenggara, Indonesia. *Stud Iurid Lublinensia*; 31(2), 11–32. <http://dx.doi.org/10.17951/sil.2022.31.2.11-32>
- [17]. Budiono, A., Absori, A., Harun, Nugroho, H. S. W., Dimiyati, K., Wardiono, K., 2020, The Ideal

Management of Health Insurance for Indonesia According Constitution. *Qual to Success*, 21(176), 48–50. <https://repo.poltekkesdepkes-sby.ac.id/2399/>

[18]. Walsh, K., 2006, You couldn't make it up. Or could you? *Med Teach*, 28, 81-82. <https://doi.org/10.1111/medu.13339>

[19]. Scholz, R., Hönning, A., Seifert, J., Spranger, N., and Stengel, D., 2019, Effectiveness of Architectural Separation of Septic and Aseptic Operating Theatres for Improving Process Quality and Patient Outcomes: A Systematic Review. *Systematic Reviews. BMJ Open*, 8(1), 1-5. <https://doi.org/10.1186/s13643-018-0937-9>

[20]. Hitaningtyas, R. D. P., Subhan, M. H., and Nurwahjuni, 2024, Deactivation of Health Security Participation as a Form of Unlawful Act (Legal Reasoning of the Judicial Decision in the Khalimah vs BPJS Case. *J Jurisprud*, 14(2), 277–295. <https://doi.org/10.23917/jurisprudence.v14i2.6460>

[21]. Varkey, B., 2021, Principles of clinical ethics and their application to practice. *Medical Principles and Practice*, 30(1), 17-28. <https://doi.org/10.1159/000509119>

[22]. Samino, S., 2014, Analysis of Informed consent implementation. *Journal of Health*, 5(1). <https://journal.unnes.ac.id/sju/jllr/article/download/39891/16777/>

[23]. Krismanto, H., and Irianto, S., 2020, Analysis of Outpatient Service Quality at the Regional General Hospital (Rsud) of Dumai City. *Journal of Public Service Management*, 3(1), 32. <https://doi.org/10.37036/jhmr.v4i1.568>

[24]. Glaser, J., Nouri, S., Fernandez, A., Sudore, R. L., Schillinger, D., Klein-Fedyshin, M., and Schenker, Y., 2020. Interventions to improve patient comprehension in informed consent for medical and surgical procedures: an updated systematic review. *Medical Decision Making*, 40(2), 119-143. <https://doi.org/10.1177/0272989X19896348>

[25]. Listiyono, R. A., 2015, Descriptive Study of Service Quality at Dr. Wahidin Sudiro Husodo General Hospital Mojokerto City After Becoming a Type B Hospital, *Journal of Public Policy and Management*, 1(1), 2-7.

<http://journal.unair.ac.id/download-fullpapers-kmp1ad01a2a56full.pdf>

[26]. Amalia, N., Azhri, M. Z., Anna, R. Wijayanti, D. R., and Riestiyowati, M. A., 2021, The Implementation of Electronic Medical Record (EMR) in the Development Health Care System in Indonesia: A Literature Review. *International Journal of Advancement in Life Sciences Research*, 4(3), 8-12. <https://doi.org/10.31632/ijalsr.2021.v04i03.002>

[27]. Denzin, N. K., and Lincoln, Y. S., 2005, *The Sage Handbook of Qualitative Research* (Thousand Oaks, CA: Sage Publications, Inc.) <https://us.sagepub.com/en-us/nam/node/52625/print>

[28]. Glaser, J., Nouri, S., Fernandez, A., Sudore, R. L., Schillinger, D., Klein-Fedyshin, M., and Schenker, Y., 2020, Interventions to improve patient comprehension in informed consent for medical and surgical procedures: an updated systematic review. *Medical Decision Making*, 40(2), 119-143. <https://doi.org/10.1177/0272989X19896348>

[29]. Yuda, B., 2021, Patient's level of understanding of informed consent. *Juristic journal*, 2(3), 230-235. <http://dx.doi.org/10.35973/jrs.v2i03.2530>

[30]. Rompegading, A. M., and Putra, B. P., 2023, Euthanasia: Medical, Bioethical, Humanities and Professionalism Review, *Ecosystem Scientific Journal*, 23(1), 120-134. <https://doi.org/10.35965/eco.v23i1.2506>

[31]. Dewanda, R. A., Hidayat, T., and Suchitra, A., 2021, Differences in the Level of Knowledge of Basic Bioethics Rules Among Students of the Faculty of Medicine, Andalas University. *Indonesian Journal of Health Sciences*, 2(2), 51-57. <https://doi.org/10.25077/jikesi.v2i2.362>

[32]. Beauchamp, T. L., and Childress, J. F., 1979, *Principles of Biomedical Ethics* (Oxford: Oxford University Press). <https://www.scirp.org/reference/referencespapers?referenceid=2219993>

[33]. Risdawati, I., 2024, Legal Aspects in Implementing an Informed Consent System in Patient Health Practices. *International Journal of*

*Society and Law*, 2(1).  
<https://doi.org/10.61306/ijsl.v2i1.85>

[34]. Ramadianto, A. R., 2023, The Deviation Of Informed Consent Practices: Understanding The Inspanning Verbintenis And Legal Aspects. *Jurnal Dunia Hukum*, 8(1).  
<https://doi.org/10.56444/jidh.v0i0.3462>

[35]. Rezler, A. G., Lambert, P., Obenshain, S. S., Schwartz, R. L., Gibson, J. M., and Bennahum, D. A., 1990, Professional decisions and ethical values

in medical and law students. *Acad Med*, 65(9, Suppl), 31-32. <https://doi.org/10.1097/00001888-199009000-00030>

[36]. van Zelm, R., Coeckelberghs, E., Aeyels, D., Sermeus, W., Wolthuis, A., Panella, M., and Vanhaechet, K., 2020, Qualitative Evaluation of the Implementation of a Care Pathway for Colorectal Cancer Surgery. *Sage Journals*, 31(2).  
<https://doi.org/10.1177/1049732320965188>