

Relationship between the Quality of Informed Consent at Surgical Procedure in Terms of Ethics and Medicolegal with Satisfaction of Patient Health Service in dr. Zainoel Abidin Hospital

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Abstract

Objective: To determine the relationship between the quality of informed consent in terms of ethics and medicolegal with patient health service satisfaction at the dr. Zainoel Abidin Hospital (ZAH) Banda Aceh.

Methods: This study is an observational analytic with a cross-sectional method. Subject selection through a total sampling method. This study involved patients who were treated at dr. Zainoel Abidin Hospital (ZAH) Banda Aceh and a total of patients were 100 (52 men and 48 women) who met the inclusion criteria carried out on 16 December 2019 to 31 December 2019.

Results: As many as 90% of respondents rated informed consent made at ZAH as good quality and 85% expressed the satisfaction with health services at ZAH. An ethical and medicolegal review of informed consent emphasizes the basic principles of bioethics. As many as 84% of respondents stated that their autonomy rights had been fulfilled, 92.50% thought that the doctor had done beneficence, nonmaleficence, and justice well in the process of informed consent and 92.33% of respondents rated the three elements of informed consent as being well implemented. Based on the results of the chi-square statistical test showed a significant relationship between the quality of informed consent in terms of ethics and medicolegal with patient health service satisfaction under the value of $p=0.001$ ($p \leq 0.05$).

Conclusion: Good quality of informed consent in terms of ethics and medicolegal has an important role in increasing patient satisfaction with health services at the dr. Zainoel Abidin Hospital of Banda Aceh.

Keywords: Ethics, informed consent, medicolegal, satisfaction

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Introduction

Informed consent (IC) consists of two words, namely informed which means that it has received an explanation or information, and consent means approval or giving permission.¹ IC is an embodiment of the patient-doctor relationship based on trust

and good communication aimed at to get the best treatment results for patients. IC can be defined as the consent given by the patient and or his family to the doctor based on an explanation of the medical actions to be taken against the doctor and the risks associated by it.² IC is a method for sharing information between the doctor and the patient so it must occur collaboratively (cooperation) that both between doctors and patients and their families to get the best choice for the patient treatment.³

The patient-doctor relationship will be well established if each part understands the role itself and functions concerning IC. A

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doctor understands how to provide adequate information that can be accepted by patients. The doctor should provide information using language that is understood easily by patients. The doctor must also understand the sociocultural and emotional aspects of the patient.⁴ The IC process does not only to get the patient's signature but rather respects the patient's right to autonomy.⁵ IC while viewing through ethical principles is included in the basic rules of bioethics autonomy and when it views in the context of patient rights, IC is included in the right to self-determination.⁶

The quality of informed consent in terms of ethics can be assessed from the fulfillment of four basic principles of bioethics, that are beneficence, nonmaleficence, justice, and autonomy. Beneficence contains how the doctor will make informed consent which gives attention, friendliness, compassion, and empathy to patients. Nonmaleficence means that doctors try to minimize harm to patients with not to force it to frighten, and do not lie to patients in making decisions. Justice is genuinely done by doctors in conveying information and every patient is given an informed consent process before medical treatment. Autonomy is a right that is owned by the patient, namely how the patient gets information, giving choices, privacy, confidentiality and the right to give consent.^{6,7,8}

Based on medicolegal, IC is a legal concept that guarantees the patients have the right to know about the risks, benefits and alternative therapies to be taken,⁷ also if included in the approval of civil medical actions which if not implemented can be categorized as violating the law.^{2,8} Quality of informed consent in terms of medicolegal can be assessed from fulfillment based on three aspects, namely, the approver must be competent that is aged 21 years or more (threshold element), the giver of explanation and the contents of the explanation (information element), and approval (consent element). This concentration element consists of two parts, namely, voluntariness (freedom) and authorization (authority).⁸ The fundamental problem is that there are still many findings in the field about the informed consent process that have not been implemented properly so that it has the potential to be a problem of ethical and medicolegal violations. The ethical aspects related to IC focus on autonomy, trust, self-determination, personal integrity, and non-dominance. While the medicolegal aspect is protection, prevention of deviant behavior

and procedures that are not essential. IC is still often become a cause of conflicts between doctors and patients.^{6,7,8}

From previous study reported that poor communication is the highest cause of patient complaints with prevalence in Jakarta 66,3%.³ In Indonesia, obstacles in conducting ICs, including explanation problems which the patient does not understand. The results of the study of patient safety management team for hospital services obtained information that giving of informed consent in various health service institutions only asks patients to sign an informed consent sheet so that it affects the knowledge of patients and families.^{9,10} The main of purpose this study was to determine the relationship between the quality of informed consent in terms of ethics and medicolegal at surgical procedures with the satisfaction of patient health services in Dr. Zainoel Abidin hospital (ZAH) of Banda Aceh.

Methods

This research is an observational analytic with a cross-sectional method. Subject selection through a total sampling method. This study involved patients who were treated at the Dr. Zainoel Abidin hospital of Banda Aceh numbered 100 people (52 men and 48 women) who met the inclusion criteria carried out on December 16, 2019, to December 31, 2019. This study has conducted ethical clearance and has been approved by the ethics committee of the health research, the Faculty of Medicine, Syiah Kula University / Zainoel Abidin Hospital No. 333/EA/FK-RSUDZA / 2019.

Inclusion criteria in this study include (1) male and female patients over the age of 21 years, (2) patients who have had surgery, (3) patients who have given informed consent before the treatment, (4) patients who can read and write and communicate well. Exclusion criteria: (1) patients suffering from mental disorders.

The data taken is the primary data. Primary data were obtained from the results of filling out the informed consent quality questionnaire to determine the quality of the informed consent in terms of ethical and medicolegal aspects, and also the satisfaction of patient to health services obtained from the results of filling out the questionnaire that had been tested for validity. The questionnaire used in this study was made by the research team and has been validated with a validity value > 0.361 and reliability 0.871.

Results

The study was conducted on patients treated in Raudhah rooms of ZAH as many as 100 respondents, with characteristics based on age and gender presented in table 1. The average value of participant age was 51.52 (SD 15.51), 50.50 median, 47 modus, 21 minimum, and 83 maximum.

Table 1 shows that based on gender, most respondents are male with 52 respondents (52%) and based on age group, most respondents aged between 56 to 65 years are 26 respondents (26%), although the mode of age of respondents is not from these group but from the age group of 46–55 years that is 47 years old respondents are 7 respondents (7%). In terms of age, all respondents have the right to give consent which is 21 years or older so that the threshold element is fulfilled 100%. All participants stated that the doctor who explained was the doctor who took the surgery, from this statement it could be concluded that there was fairness in treating respondents in the IC process (justice fulfilled 100%). The description of the quality of informed consent in terms of ethics and medicolegal is shown in table 2:

Table 2 shows that the basic rules of bioethics have been implemented well. As many as 84% of respondents stated that their autonomy rights had been fulfilled and on average 92.50% thought that the doctor had done beneficence, nonmaleficence, and justice well in the informed consent process. Medicolegal obtained an average of 92.33%

Table 1 Characteristics of Respondents

Characteristics	Frequency of Respondents	
	(n=100)	%
Age		
21–25 years	8	8
26–35 years	14	14
36–45 years	12	12
46–55 years	20	20
56–65 years	26	26
>65 years	20	20
Gender		
Man	52	52
Women	48	48

of respondents rated the three elements of informed consent as fulfilling the medicolegal rules. Accumulatively, the assessment of ethical and medicolegal aspects is carried out simultaneously, the fulfillment of the basic ethical principles of beneficence and nonmaleficence is assessed when the doctor provides information (information element), while the autonomy rules are assessed together with the consent element. From the tabulation obtained data about the quality of informed consent in the hospital room ZAH cumulatively percent shows that of 100 respondents regarding the quality of informed consent, 90 respondents rated good (met the ethical and medicolegal rules) and 10 respondents rated not good.

The level of patient satisfaction with health services in ZAH was assessed based on 5 aspects, there are tangibles, reliability, responsiveness, assurance, and empathy. Obtained an overview of the level of satisfaction of health services from each respondent as listed in Table 3.

Table 2 The Description of the Quality of Informed Consent in Terms of Ethics and Medicolegal

Rated Aspect	Assessment	
	Fulfill (%)	(%)
Ethics		
Beneficence	93 (93)	7 (7)
Non maleficence	93 (93)	7 (7)
Justice	100 (100)	0
Autonomy	84 (84)	16 (16)
Average	92,50 (92,50)	7,50 (7,50)
Medicolegal		
Threshold element	100 (100)	0
Information element	93(93)	7 (7)
Consent element	84 (84)	16 (16)
Average	92,33 (92,33)	7,67 (7,67)
IC Quality		
Ethics and medicolegal	90 (90)	10 (10)

Relationship between the Quality of Informed Consent at Surgical Procedure in Terms of Ethics and Medicolegal with Satisfaction of Patient Health Service in dr. Zainoel Abidin Hospital

Table 3 Overview of Patient Satisfaction with Service Quality based on the Five Dimensions of Service Quality

Service Satisfaction	Satisfied	%	Not Satisfied	%
Tangibles	96	96	4	4
Reliability	81	81	19	19
Responsiveness	86	86	14	14
Assurance	92	92	8	8
Emphaty	95	95	5	5
Over all of service satisfaction	85	85	15	15

Table 3 shows that from 100 respondents, most respondents expressed satisfaction with the reality (tangibles) and empathy in providing health services as much as 96 and 95 percent. From the tabulation obtained data about patient satisfaction with health services in the hospital room of ZAH cumulatively based on statistical calculations showed that out of 100 respondents, 85 respondents rated satisfaction with services in ZAH and 15 respondents rated dissatisfaction in service at ZAH. In this study to assess the relationship between the quality of informed consent in terms of ethical and medicolegal aspects with the satisfaction of health services, the Chi-Square statistical test is used in Table 4.

In this study, the Chi square test was used to determine the relationship or effect of two nominal variables and to measure the strength of the relationship between these variables. Based on Table 4 it can be explained that the results of the chi-square statistical test showed a significant relationship between the quality of informed consent in terms of ethics and medicolegal with patient health service satisfaction with a value of $p=0.001$ ($p \leq 0.05$).

Discussion

IC must make the patient understand in the

context of receiving information before the patient gives consent for medical treatment against them, this can be achieved if there is effective doctor-patient communication.³ Patient satisfaction is also related to the quality of IC. Patient satisfaction is always the main target of health services. Quality treatment results are indicators of the quality of health services.⁵ Discussing patient satisfaction with health care, especially in surgical procedures and its relation to IC quality is not easy, because it is difficult to determine how the patient's understanding of surgical procedures.¹ Determination of patient satisfaction with health services is also not easy to achieve because of many factors that influence it, including socioeconomic, knowledge, culture, health status, doctor-patient relationship, staff performance, number of facilities, and medical records system.⁵

Regarding surgery, two principles of medical ethics are related closely, namely the principle of autonomy and non-maleficence. A patient must get full information before getting surgery and enough data must be submitted by the doctor to the patient so that ethical and medicolegal aspects can be accomplished.² The principle of autonomy means the doctor's moral principle to always respect the patient's rights, especially in this case is the right to

Table 4 The Relationship between the Quality of Informed Consent in Terms of Ethical and Medicolegal Aspects with the Satisfaction of Health Services

	Health Service Satisfaction			p-value
	Satisfied	Not Satisfied	(n=100)	
The Quality of Informed Consent				
Good	81	9	90	0,001*
Not Good	4	6	10	

determine what can be done to him (the right to self-determination), which is then developed in the doctrine of informed consent. The principle of non-maleficence is the moral principle of the doctor not to take actions that will worsen the patient's condition (primum non nocere, above all, do no harm).⁸

The results of this study conducted at the Raudhah ward (surgery ward) of ZAH in 100 respondents found a relationship between the quality of informed consent in terms of ethics and medicolegal with patient health service satisfaction. This is in line with a study conducted by Jhonson et al, in which result there was a significance relationship between giving informed consent and the level of satisfaction on the day of surgical procedure ($p=0,02$).¹¹ The results of this study were also supported by Sari's study showed that there was a relationship between giving informed consent before surgery and patient satisfaction.¹² When viewed specifically, the quality of Informed consent at ZAH most of the respondents rated good for both the giver of explanation, the contents of the explanation, and the giver of approval. Judging from the results of this study it was found that the doctors at ZAH had given good informed consent judged from ethical and medicolegal aspects.

During the interview with the respondent, the respondent also stated that the doctor who gave the IC was patient enough to wait for the patient's answer, allow to asking questions, and when giving consent there was no pressure and force. Thus the nonmaleficence code of ethics has also been implemented well which means that the doctor has tried to minimize losses to the patient due to decision making without coercion, fear or deception from the doctor. However, there are 7% of respondents who stated that there was a compulsion but not from a doctor but from a patient's family who wanted an immediate operation even though the patient himself did not want to. This research is different from research conducted by Aldossari et al.,⁵ who found that 8.3% of respondents felt pressured by medical staff in decision making.

From an ethical perspective, in this study, there were still 16% of respondents who had not been accommodated in their autonomy rights. This shows that respondents and the Indonesian people, in general, are still not strong in autonomy because it is common knowledge that Indonesia is still communal, that is, everything is left to the family and not yet entirely dependent on independent

decisions. The right of autonomy that has not yet been fulfilled is privacy (freedom of choice) because it still depends on the family of 14% and the right to give consent of 2%. From the aspect of Justice, doctors have done well both when giving information and when getting patient approval, all done fairly.

IC is a process that shows effective communication between doctors and patients and the meeting of thoughts about what will and what will not be done to patients. IC viewed from the legal aspect is not as an agreement between two parties, but rather towards unilateral agreement on services offered by other parties. Viewed from civil law, the relationship between health care providers and health service recipients is a contractual relationship. From this relationship, a bind of agreement between the two parties arises and rights and obligations emerge from each side. What is the right of the first side will become an obligation for the other side, and vice versa.^{7,8,13}

In medicolegal, IC has 3 elements, namely threshold elements, information elements, and consent elements. The threshold element, ie the consent giver must be competent. By law a person is considered competent (competent) is when an adult, conscious and in a mental state that is not under control. An adult is defined as an age that has reached 21 years or has ever been married.^{13,14} Information elements, consisting of two parts, namely disclosure and understanding. In this study, doctors have provided adequate information (93%), but there are also 7% inadequate that is related not given information about the benefits of the actions taken (5%) and doctors do not introduce themselves when giving IC (2%). Understanding based on adequate understanding brings consequences to medical personnel to provide information (disclosure) in such a way that the patient can reach an adequate understanding. Many experts say that if this element is not done then the doctor is considered to have neglected to carry out his duty to provide adequate information.^{7,8,13} Consent elements also consist of two parts, namely, voluntariness (freedom, freedom) and authorization (approval). Volunteering requires no deception, misrepresentation or coercion. Patients must also be free from "pressure" by medical personnel who behave as if to be "left" if they do not agree to the offer. Many experts still argue that carrying out "not excessive" persuasion can still be morally justified.^{8,13}

The description of patient health service

Relationship between the Quality of Informed Consent at Surgical Procedure in Terms of Ethics and Medicolegal with Satisfaction of Patient Health Service in dr. Zainoel Abidin Hospital

satisfaction shows that of 100 respondents, 85 respondents rated satisfaction with the service and 15 respondents rated dissatisfaction. Following the research objective of knowing the level of satisfaction of Raudhah inpatients with services, the following discussion will be carried out the results of research on patient satisfaction in evaluating the quality of health services by applying the concept of "RATER" that is reliability, assurance (guarantee), reality (tangibles), empathy and responsibility.¹⁴ According to Muninjaya¹⁴ which states that satisfaction is defined as the recipient's service response to the suitability of the customer's interest level with real performance can be felt after the service user receives the service.

The suitability of IC quality with patient satisfaction with health services is reflected in what is delivered to the patient at the time of providing information following what the patient feels after the surgical procedure is performed.^{6,7,8} This conformity is described: reliability criteria reflected by attitude the hospital staff who able to handles patient care issues precisely and professionally and who arrive on time to the room when the patient needs it, this is in accordance with the ethical principles of beneficence and non-maleficence. Hospital staff informs clearly them of the things that must be followed in treatment (autonomy and beneficence). Hospital staff notifies clearly about matters that are prohibited in treatment (autonomy and nonmaleficence).^{7,8} Assurance criteria reflected by attitude the hospital staff who pays attention to complaints the patient feel, who can answer questions about the treatment actions given, who honest in providing information about the situation and who always gives greetings and smiles when meeting to the patient, this is in accordance with beneficence and autonomy. Tangibles criteria reflected by attitude the hospital staff who always maintains neatness and appearance (beneficence). Emphaty criteria reflected by attitude the hospital staff who gives information about all treatments that will be carried out (autonomy-beneficence), who attentives and provides moral support for the patients (beneficence), services

provided by hospital staff do not look at rank / status but are based on patients conditions (justice-autonomy), Responsiveness criteria reflected by attitude the hospital staff who are are willing to offer assistance to the patient when patient experience difficulties even without being asked (beneficence and non-maleficence).^{6,7,8,13}

The results of the study on the level of patient satisfaction with health services in the Raudhah Room of ZAH showed that expressed satisfaction generally with the health services. Chi-Square statistical test results obtained p-value 0.001 in this study showed that there was a significant relationship between the quality of informed consent of surgical procedures in terms of ethics and medicolegal with patient health service satisfaction in ZAH ($p < 0.05$). This shows that the quality of informed consent at ZAH which has been good also contributed to the level of patient satisfaction. The results of the study are supported by Hallock et al.¹ study which states there was a significant association between satisfaction and knowledge of informed consent. According to Sari's study, that the patient's health condition includes the diagnosis of the course of the disease, the process of medical treatment, and the results of services. Indicators of health services chosen by patients are priority measures of the quality of health services, tend to be the main source of the formation of patient satisfaction.¹²

This study shows that there is a relationship between the basic rules of bioethics applied to the IC process with patient satisfaction criteria. Good quality IC in terms of ethics and medicolegal have an important role in increasing patient satisfaction with health services at the Dr. Zainoel Abidin Hospital of Banda Aceh. A limitation of this study is that data collection is limited to respondents in the operating theater at the time of the study, so the results of the study may not reflect all patients who had undergone previous operations. It might also not be relevant to the experience of patients in other rooms. But in general, this study is very useful for the development of hospital service systems in the future.

References

1. Hallock JL, Rios R, Handa VL. Patient satisfaction and informed consent for surgery. *Am J Obstet Gynecol.* 2017;217(2): 181.e1-181.e7.

2. Akasha RA, Beshi L, El-Fadul M. Mapping the quality of informed consent for major surgical procedures in public dental hospital in Khartoum state, Sudan, 2017: a cross sectional study. *Dentistry.* 2018;8 (11):1-7.

3. Afandi D. Aspek medikolegal dan tata laksana persetujuan tindakan kedokteran. *Jurnal Kesehatan Melayu*. 2018;1(2):99–105.
4. Sukendar S, Rahim AH, Hutabarat S. Tanggung jawab rumah sakit atas kelengkapan informed consent pada saat operasi di RS Premier Jatinegara Jakarta. *Soepra Jurnal Hukum Kesehatan*. 2016;2 (2):229–40.
5. Aldossari SH, Alfayed SS, Al Mutlaq RI, AlTurki DI, Aljaser AK, Nouh TA. The relationship between quality of informed consent and perioperative care, and patient satisfaction: a tertiary-care hospital's experience. *International Journal of Medical and Health Research*. 2017;3(9):107–12.
6. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 7th ed. New York: Oxford University Press. 2013. p. 190-317.
7. Shaha KK, Patra AP, Das S. The importance of informed consent in medicine. *Sch J App Med Sci*; 2013;1(5):455–63.
8. Sharma R. Informed consent in clinical practice and research: ethical and legal perspective. *Int J Healthcare Biomed Res*. 2014;3(1):144–151.
9. Realita F. Implementasi persetujuan tindakan medis (informed consent) pada kegiatan bakti sosial kesehatan di Rumah Sakit Islam Sultan Agung Semarang. *Jurnal Involusi Kebidanan*. 2014;4(7):25–39.
10. Kustiawan R, Lesharini E. Pengalaman pemberian informed consent tindakan pembedahan pada pasien pre operatif elektif di Ruang IIIA RSUD Kota Tasikmalaya. *Jurnal Kesehatan Bakti Tunas Husada*. 2014;(11)1:68–77.
11. Johnson MR, Singh JH, Steaward T, Gioe TJ. Patient understanding and satisfaction in informed consent for total knee arthroplasty: a randomized study. *Arthritis Care Res*. 2011;63(7):1048–54.
12. Sari PD. Hubungan antara pemberian informed consent sebelum tindakan operasi dengan kepuasan pasien. *Jurnal INFOKES*. 2016;6(2):1–4.
13. Patil AM, Anchinmane VT. Medicolegal aspects of consent in clinical practice. *Bombay Hospital Journal*. 2011;53(2)203–8.
14. Muninjaya G. *Manajemen kesehatan*. 3rd ed. Jakarta: Penerbit EGC; 2011.