

Autonomous informed consent in term of completeness of medical information disclosure

Ervin Dyah Ayu Masita Dewi¹, Sunarto Sastrowijoto², Retna Siwi Padmawati³

Abstract

Purpose: Many lawsuits filed by patients to doctors exist because patients don't receive adequate information concerning their illness which mainly resulted from non-exposure to medical treatment risks. The research was performed to identify the completeness of information disclosure by doctors for informed consent purposes from the perspective of respect for autonomy. **Method:** The research was conducted by a descriptive qualitative method. Researchers had interviewed five surgeons and five adult patients as subjects with high-risk elective surgical treatment in the hospital as case criteria. Surabaya is the location of the research. **Conclusion:** By non-exposure of complete medical information to patients, decisions made by patients are not autonomous since they have incomplete understanding, and proper disclosure technique for doctors is required.

Keywords: informed consent; respect for autonomy; information disclosure

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INTRODUCTION

Every medical treatment taken by a doctor on a patient, particularly those which impose high risk, should be commenced by patient consent [1]. As the possessor of his body, the patient has the autonomy to accept or refuse the treatment [2] through a process called informed consent. Based on its term, informed consent is defined as agreement/consent after an explanation is given. Therefore some preliminary explanation must be given before the patient's consent [3].

So far, differences exist related to the completeness of medical information, which doctors should inform patients. Indeed all components must be informed

starting from diagnosis, therapy option, risks of each therapy, doctor recommendation, possible complication, and even the budget calculation [4]. In Indonesia this issue has been regulated in Permenkes RI No 290/MENKES/PER/III/2008 [5]. However, the completeness and detail of information in practice depend on each doctor's consideration and patient condition. As a result, it is common that doctors reduce information related to medical treatment risks to hinder patients from excessive concern about the treatment; hence they are willing to give their consent [6] or even some doctors exceedingly provide information about disease diagnosis by the intention that patients feel the urgency of the medical treatment or surgery so they will agree to the treatment option.

Other doctors convey all information and even in detail since they are worried about lawsuits or medical claims. Patients file many lawsuits against doctors in Indonesia. Kompas newspaper documented that MKDKI (Indonesian Medical Discipline Honor Assembly) in Indonesia from 2006 to January 2013, MKDKI accepted 186 lawsuits related to medical treatment which 7% were related to inadequate communication between doctor and patient [7]. All cases are related to medical information given by doctors but accepted inadequately by patients; hence in most cases, patients believe that doctors lie to them. Patients believe that doctors don't inform them completely about the disease and medical treatments; hence they feel harmed. Patients can make a medical decision but don't understand their decision. It is as stated by Agustina [8]. Information considered incomplete involves treatment complications and disease prognosis. On the other hand, doctors think that information given to patients has been complete and adequate for patients [9]. Doctors consider they know most about a patient's condition, and occasionally, some details don't need to be informed to patients since doctors think it doesn't need to disclose. Medical suits occur when patients believe doctors commit a mistake. The actual situation is that they don't get adequate information about their condition, as in the case of patient Ms. N in Jakarta on July, 10th 2018 [10]. Her initial diagnosis was ovary cyst hence cyst removal was required. The doctor advanced to ovary removal surgery without informing and getting consent from the patient. Feeling harmed, the patient filed a lawsuit against the doctor. A doctor who considered himself knowing the best for a patient should consider patient autonomy to know all about his/her disease.

Previous research conducted by Oriza and Nuryati [11] in a Yogyakarta hospital found that almost 50% of informed consent documents didn't have a form of information disclosure, indicating it couldn't decide whether a patient had been given adequate information or not. Other research conducted by Saryoto [12] in Purwodadi hospital found that in the informed consent process, doctors said that they had informed patients and obtained their consent but patients didn't understand the information adequately. Both researches only discussed administrative side and patient right compliance but similar research that discuss bioethics aspects has not been conducted.

METHODS

This research was conducted in Surabaya between July to August 2020 using qualitative descriptive

research by depth interview on five surgeons and five patients as research subjects. This article is part of the thesis research result titled "Implementing Principle of Respecting Autonomy in Informed Consent for High Risk Medical Treatment in Hospital" Bioethics Magister Department, Post Graduate Program, Universitas Gadjah Mada. Due to Covid 19 pandemic, research cannot be performed in the hospital hence research subject/respondent selection both surgeon and patient used purposive sampling with the snowball method. Patient respondents were not necessarily becoming surgeon subject patients. Surgeon respondents eligible for inclusion criteria include surgeons who have performed high-risk elective surgery on adult patients in the hospital from July 2019 to June 2020. Patient respondents include adult patients who are competent to provide informed consent and have received high-risk elective surgery in the hospital from July 2019 to June 2020. The elective case opted, so patients have adequate time to consider before making a decision.

Table 1. List of operational definition

Terms	Definition
Informed Consent	Patient consent is made in his/her full freedom without any coercion by other parties after doctors provide adequate information about the significance of the treatment, benefit expected, risk contained within, possible complications, and available alternative treatments.
Autonomy	Individual capacity to determine what to do upon him/herself and making decisions about him/himself in full freedom without coercion or pressure from external parties.
Respecting Patient Autonomy Principle	The principle that puts doctor or health staff to respect patient autonomy/freedom in making decisions about what to do upon him/herself in relation with therapy or medical treatment required by him/her.
High risk elective surgery	Scheduled surgery treatment has consequences harming the patient's life but this effort can be accepted and minimized in relation to the importance or benefit gained by the patient.

Selected respondents were adults with a minimum age of 18 years old, psychologically healthy to meet competence criteria in informed consent. Doctor respondents consist of two general surgeons, two urologists, and one orthopedist while patient respondents were four women and one man with ages

ranging 37 to 65 years old. The surgery obtained by patient respondents were bile surgery, kidney tumor surgery, appendicitis surgery, fibula fracture surgery, and knee joint replacement.

Since this research couldn't be conducted in a hospital, researchers performed in Surabaya with subjects derived from several hospitals in this city. Surabaya is selected as a research location since it has more than fifty-eight hospitals both state and private-owned with more than fifty surgeons and with diverse high-risk elective surgery cases. Upon respondent request, the interview couldn't be performed face to face but by phone and be recorded. Interviews with surgeons were focused on their experience and opinion related to medical information completeness they must inform patients in an informed consent process. Interviews with patients were focused on all medical information received by the patient before surgery was performed and causing factors for patients to give consent on surgical treatment based on this information.

Further, the interview result was transcribed and collected in coding form before being specified in categories and themes. These themes were analyzed by supporting documents including the Indonesian Medical Ethics Code and Statute/Regulation in Indonesia and other research findings related to informed consent and finally conclusion was drawn and a solution was recommended by the author. Operational definitions in this research are in Table 1.

RESULTS

Complete medical information according to surgeon

All surgeons in this research stated that they have provided complete medical information to patients but in practice, every surgeon has specific and different criteria about it. Three surgeons stated that medical information must be complete and detailed starting from disease prognosis, therapy planning, surgery procedure, possible risk and complication of therapy, patient prognosis, and budget calculation. All therapy options were explained by surgeons despite patients having used insurance or BPJS as funding sources. According to respondents, receiving information as complete as possible is patient right. A respondent stated his reason to provide complete medical information:

“Providing medical information in obtaining informed consent is not directing patients to agree for surgery treatment but to enable patients and their family to determine the best decision for the patient. So information must be complete, even about death risk must be informed.” (orthopedist)

An interesting statement is found from one respondent that the purpose to convey medical information is not leading patients to consent for surgery options. Therefore the information must be conveyed completely including its risk, since whether surgery is taken or not the risk still exists and the patient has the right to make his own decision. Two other respondents stated that medical information doesn't necessarily need to be conveyed completely but is conditional. It is the doctor who knows what is necessary and not necessary for the patient to know. For patients without basic disease and in cases where the mortality rate is very low then the death risk doesn't need to be informed since it will raise excessive fear in patients and lead to refusal of medical treatment. Moreover, if the patient doesn't have a basic disease previously then it can be considered that the death risk is extremely low. Thus the doctor only informs the common risk of the medical treatment. Furthermore, according to both respondents, if patients had used insurance or BPJS as guarantor, then therapy options other than those covered by insurance/BPJS is not necessarily explained since it cannot change the treatment plan of the patient. In insurance or BPJS the budget has been determined for every disease and also therapeutic options and patients must comply with this budget. Explaining the other therapy options will only confuse patients and waste doctor's time. Following are interview quotes on five surgeon respondents:

Table 2. Medical information completeness according to surgeon

Research subject doctors	Statement quotes
Doctor HS, Orthopedist	“Whether surgery or not, both have risks. We are not leading them to take the surgery option.”
Doctor SS, General Surgeon	“Possible risk to arise for surgery treatment must be informed but in the way not putting impetus or overstate specific parts.”
Doctor AS, Urologist	“If surgery like for TUR prostate the death risk is not informed. If not, the patient will be excessively feared.”
Doctor HW, General Surgeon	“So from a surgery perspective, we must explain the disease, our plan, possible complications, all be explained.”

Based on this information, it is found that doctors inform all medical information before obtaining informed consent but the completeness of each information is comprehended differently by each doctor. Some respondents are informed completely and detailed since they consider that knowing complete medical information is patient right while others consider that medical information to be disclosed doesn't necessarily be complete but only what doctors believe is necessary for patients. This group of respondents selects medical information based on their personal consideration by putting the impetus on specific parts and lessening other parts.

Complete Medical information in Patient Perspective

According to two respondents, a doctor has conveyed complete and detailed medical information up to the way surgeons conduct surgery, as stated by one patient:

“If the lump grows attached to the kidney and becomes disturbing, the kidney must be removed. Later surgical procedure be taken, in the womb, we make 3 holes, that is what doctor said” (Patient with kidney tumor)

Three other respondents stated that the surgeon's explanation was not complete. One patient said that the surgeon who operated on him told that all to do is believing in the surgeon as an experienced expert so the patient shouldn't bother to worry about the surgical procedure. One respondent stated that the medical treatment information he received from the doctor is different from reality.

“Doctor said that he only removed the stone, after taking control he said that the gallbladder is also removed. I have no information about the operation details. I am very disappointed” (Patient with gallstones)

In this research, it is found that some respondents were disappointed since they received incomplete information and even different than the real surgery result.

DISCUSSIONS

Patient autonomy in informed consent

Informed consent is a procedure that must be passed before any medical treatment is taken for a patient. This process is done to respect the patient's autonomy as the possessor of his body. According to Kusmaryanto [2], autonomy is a person's freedom to regulate him/herself and to determine what he/she will receive for him/herself. A patient can give informed

consent based on his/her understanding of the decision and it is derived from the surgeon's explanation [13]. In this case, surgeon explanation plays a significant role in patient decision-making [14]. The patient is the possessor of his body but doesn't understand medical indication, medical risk, and other information related to his disease while he must make decisions about accepting or refusing medical treatment upon his body. On the other hand, a doctor is in a position to understand the patient's disease but not the possessor of the body. This discrepancy can be bridged by a doctor providing medical information through an informed consent process [15]. A patient can make autonomous medical decisions if she/he has adequate understanding while the understanding can be possible by an adequate explanation from the doctor. It is in accordance with Kadam [16] that there are four components in autonomous medical consent: patient competence, adequate explanation, comprehension of the explanation, and voluntariness in making decisions. But it often occurs that a patient gives consent on medical treatment without being knowledgeable about the treatment, its benefit, and effect for himself or forgetting the doctor's explanation [17]. If a patient doesn't really understand what he/she will decide but is still brave enough to make a decision, then the issue to question is the autonomy of the decision. A non-autonomous decision is open to patient complaints or claims upon a doctor in the future should the result of treatment doesn't satisfy him/her.

Information restraining in informed consent

Patient comprehension of medical information is affected by the completeness of information she/he receives. It is stated by Kadam [16] that some factors exist to determine whether one information has been adequate or not as follows: the way to communicate it must be good, the content of information must be right/not manipulated, and the content must be complete. In Indonesia, a regulation that regulates the completeness of informed consent has been existing as stipulated in Statute RI No 29 the Year 2004 about Medical Practice, Article 45 [18], that informed consent at least consists of diagnosis, medical treatment procedure, medical treatment purpose, alternative treatments and their risks, possible risk and complication and prognosis of the medical treatment. The problem exists within every part of this, to what extent doctors should inform the information?

From this research, each doctor/surgeon has a different understanding related to completeness in conveying informed consent. Of five surgeon respondents, Three respondents stated that medical information must be informed completely so the

patient has enough information to make a decision. One respondent confirmed that providing medical information is not to lead a patient to consent to the operation option but in order to help the patient make the best decision. Two other respondents stated that doctors must conform the information they give with patient conditions. For a patient who has a guarantor like insurance/BPJS then the doctor doesn't need to inform all therapeutic options since the guarantor has determined what treatment the patient will take. If doctors inform all therapeutic options, including those which aren't covered by insurance, it will waste time. Related to medical treatment risk, some respondents stated that severe medical risk or those that cause death is not necessary to inform since it will create excessive fear and refusal for surgery. From the patient's side, all respondents stated that they are more satisfied if the information is informed in detail and complete for their consideration before deciding whether to accept or refuse the operation. When a doctor hides one piece of information, patients feel disappointed despite knowing the doctor's intention to calm them.

Until recently, some problems still exist for doctors, particularly regarding the extent of information completeness and inadequate informed consent to make autonomous decisions. In general, the doctor understands that medical information must be informed completely but information for patients still needs to be selected. A concern exists on the doctor's part if complete information given to the patient will weaken the patient's mental state, raise excessive fear and refusal for surgery which in fact constitutes the best treatment for him [6]. A patient who will pass his best chance to treat his disease should refuse the surgery option due to getting complete information. Therefore, some doctors agree to select only positive medical information for patients and hide negative ones (for example, operation risk, complication, or bad prognosis). Doctors believe that selecting information will benefit patients and prevent excessive fear. Even according to them, a patient's mental state will worsen if the information is revealed too to complete and it leads to worsening his condition. Some doctors also view that not everyone can be given complete information depending on his culture and social background [19]. There is a culture believing that a specific disease or death risk is a taboo issue to discuss, hence the patient and his family ask the doctor to hide negative medical information. Ethically, the question arising is "Whether selected or manipulated information by intention to benefit patients can be considered as information which will result in autonomous informed consent?"

According to Kusmaryanto [2], some factors exist to determine whether one information is adequate or not as follows: the way to communicate information must be good, the content of information must be right/no manipulation and the content of information must be complete. Not only must the content be complete but also must be right, so there is no impetus or limitation on a specific part for a specific purpose. Theory to be the basis for informed consent is revealed by Faden and Beauchamp [13], stating that medical information disclosure by doctors affects the patient's understanding of the information. Should the information be incomplete, then patient comprehension will be incomplete either. Therefore, patient decisions will be built based on incomplete information; hence, in this case, patient decision autonomy is questionable.

According to Beauchamp [13], a decision can be influenced by many external factors. The less patient they understand about what to decide, the more external factors to control a decision, and the more non-autonomous the decision.

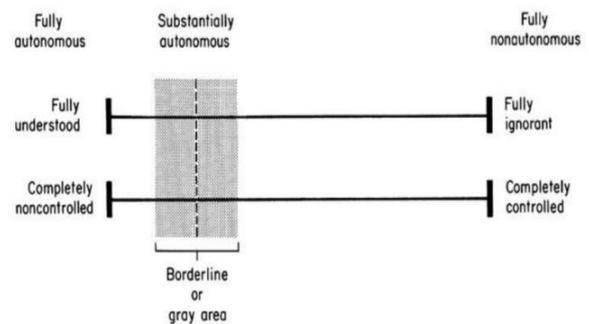


Figure 1. Autonomy level from intentional action

Faden and Beauchamp [13] also explains as follow:

“..that patients often fail to remember and perhaps fail to understand what they have been told—are interesting and important, but do not resolve the basic question of patients' capacity to exercise informed consent. People's failure to understand a particular disclosure may result from inadequacies in that disclosure rather than inadequacies in the patient....”

From this explanation, it is clear that inadequate information disclosure by a doctor can lead to a non-autonomous decision by a patient since it leads to improper comprehension by the patient. Patients will be led toward specific decisions from manipulative information decisions. The principle of respecting patient autonomy is violated despite the doctor's intent to protect the patient (beneficence) from excessive fear. It is prone to rise in conflict between doctor and patient since when unwanted results arise in the future, the

patient will blame the doctor who didn't give him the complete and right information.

Managing negative effect of information disclosure on patient

In Practical Guide of Medical Ethics Code Year 2012 Article 5 [1], it is clearly stated that explanations about conditions and medication for patients can be conformed with the patient's mental condition. It means that doctors must consider time and the proper and appropriate way to disclose medical information. It is true that sometimes one piece of information can weaken a patient's mind but it doesn't mean that information cannot be disclosed. Soeparto [20] stated that if one medical information can weaken a patient's mental state, then the information can be disclosed to the patient's family. In this way, it is expected that the family will keep informed about the patient's real condition and can help the doctor to inform the patient in the right and proper time and manner. Further notification to patients depends on the deal between doctor and patient family bearing in mind that the information will be kept disclosed directly by a doctor to a patient or via patient family. According to Kaibara [21], at the beginning of treatment, the doctor and patient/patient family must have been dealing with the person who will receive the first information about patient medical information, be it a patient directly or one of the patient family members. The deal at the beginning of therapy enables doctors to disclose all required information to the right person.

In addition, doctors' fear of possible medical risks can be minimized by risk management. Janicek [22] stated that risk management can simultaneously evaluate and predict possible medical risks. Thus, even if a doctor discloses possible medical risks to a patient, he also can inform that hospital has been taking the effort to minimize it and it will make the patient calm.

The explanation above can be traced to the principle of respecting patient autonomy and good communication between doctor and patient/patient family [23]. Despite bad information, he must respect patient autonomy by keeping patients informed. Information content to disclose must be confirmed with the patient's condition but not necessarily very detailed and lengthy – it must be complete and non-manipulative (overstating or understating a particular part). The right time and person to disclose information is also very important. Thus, four bioethics principles including respect for autonomy, beneficence, non-maleficence, and justice keep operating in balance for the patient's best interest.

CONCLUSION

Not all surgeons in this research have provided complete and adequate information to patients in an informed consent process. Some of them consider it is not necessary to disclose complete medical information in order to protect patients' mental health. Thus, they select medical information and emphasize the positive part only. Information about therapy has not been disclosed entirely since they consider whether the guarantor for covering therapy exists or not. If a patient has been using insurance/BPJS Kesehatan, then the therapy option given is one covered by insurance.

Surgeons must reconsider this matter since their goodwill given in such a way hiding medical information is violating the principle of respecting patient autonomy in the informed consent process. Patients should have adequate information both in its completeness and honesty. Should a patient receive inadequate information then his decision can be considered as non-autonomous and prone to rise medical claims among doctors and patients in the future [24]. Medical information can be disclosed in a complete and honest way through good and proper communication both from a time and information receiver perspective. Thus it is recommended that the deal between doctor and patient should be performed at the beginning of therapy related to information disclosure method, the person who will receive information, and information scope to be disclosed. Patient decision to accept or refuse medical treatment must be performed in an autonomous way to fulfill the principle of respecting human dignity. All these efforts are for fulfilling informed consent purposes as stated by Jackson [25] including clinical purpose (obtaining patient trust and cooperation), legal purpose (protecting doctors from lawsuit), and moral purpose (respecting patient autonomy).

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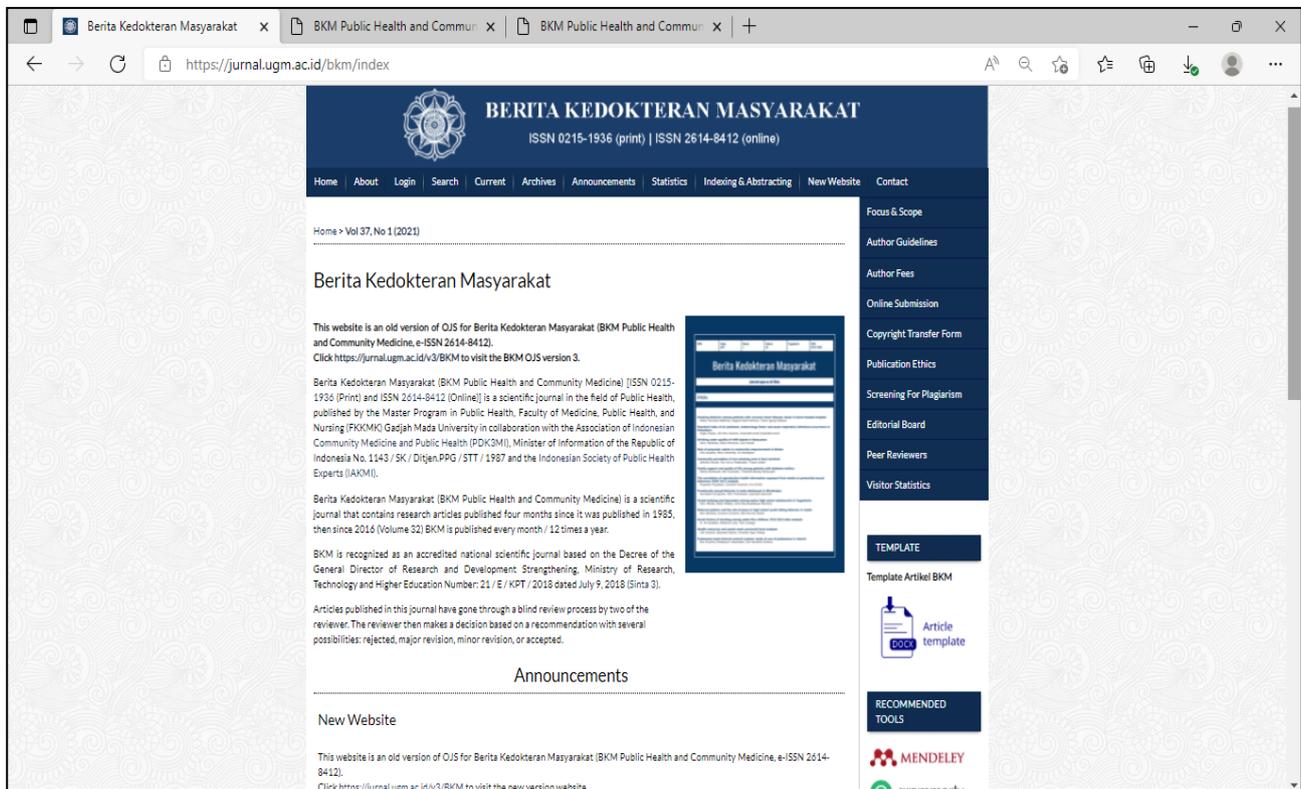
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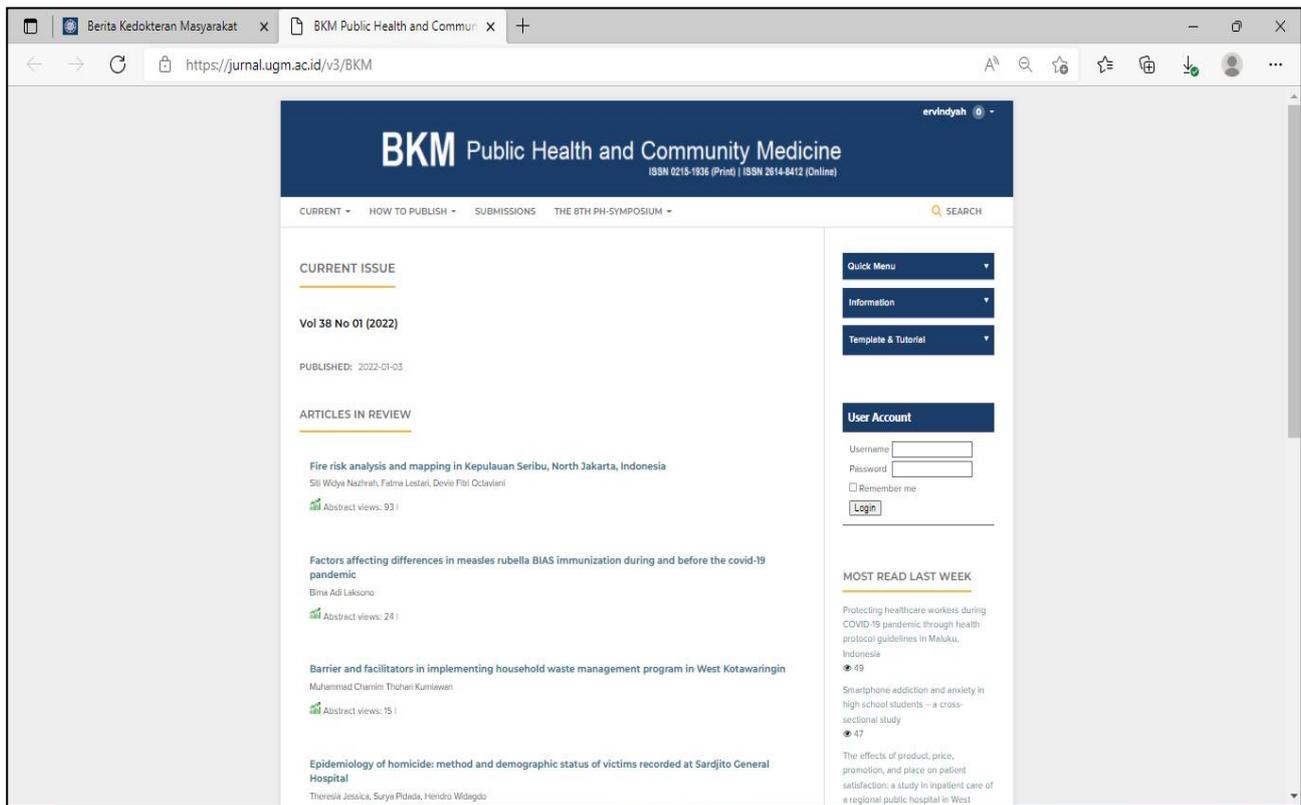
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The screenshot shows the top portion of a journal article page. The header includes the journal title "BKM Public Health and Community Medicine" with ISSN numbers. Below the header are navigation tabs: "CURRENT", "HOW TO PUBLISH", "SUBMISSIONS", and "THE 8TH PH-SYMPOSIUM". A search bar is located on the right. The main content area features the article title "Autonomous informed consent in term of completeness of medical information disclosure" and the author "Ervin Dyah Ayu Masita Dewi". Other authors listed are "Siswanto Sastrowijoto" and "Retna Siwi Padmawati". The article is published on "2021-03-27". A "PDF" button is visible. The abstract section begins with the text: "Purpose: Many lawsuits filed by patients to doctors exist because patients don't receive adequate information concerning their illness which mainly resulted from non-exposure to medical treatment risks. The research was performed to identify". On the right side, there is a "Quick Menu" with options for "Information" and "Template & Tutorial". Below that is a "User Account" section with fields for "Username" and "Password", a "Remember me" checkbox, and a "Login" button. At the bottom right, a "MOST READ LAST WEEK" section lists two articles: "Protecting healthcare workers during COVID-19 pandemic through health protocol guidelines in Maluku, Indonesia" (49 views) and "Smartphone addiction and anxiety in high school students – a cross-".

Tampak depan Artikel – Bagian 2

The screenshot shows the lower portion of the journal article page. The abstract continues: "non-exposure to medical treatment risks. The research was performed to identify the completeness of information disclosure by doctors for informed consent purposes from the perspective of respect for autonomy." The "Method" section states: "The research was conducted by a descriptive qualitative method. Researchers had interviewed five surgeons and five adult patients as subjects with high-risk elective surgical treatment in the hospital as case criteria. Surabaya is the location of the research." The "Conclusion" section states: "By non-exposure of complete medical information to patients, decisions made by patients are not autonomous since they have incomplete understanding, and proper disclosure technique for doctors is required." On the right side, there is an "ISSUE" section for "Vol. 37 No. 03 (2021)" and a "SECTION" section for "Articles". Below that is a "Statistics" section with a "Visitors" table showing the number of visitors from various countries: ID (8,491), MY (22), US (247), TW (19), JP (133), CA (18), PH (25), SG (17), IN (24), DE (17). The total pageviews are 29,419. At the bottom, there is an "Editorial Office" contact information and a Creative Commons Attribution-ShareAlike 4.0 International License logo. The page footer includes the text "Platform & workflow by OJS / PKP".

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Autonomous informed consent in term of completeness of medical information disclosure

Ervin Dyah Ayu Masita Dewi¹, Sunarto Sastrowijoto², Retna Siwi Padmawati³

Abstract

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Purpose: Many lawsuits filed by patients to doctors exist because patients don't receive adequate information concerning their illness which mainly resulted from non-exposure to medical treatment risks. The research was performed to identify the completeness of information disclosure by doctors for informed consent purposes from the perspective of respect for autonomy. **Method:** The research was conducted by a descriptive qualitative method. Researchers had interviewed five surgeons and five adult patients as subjects with high-risk elective surgical treatment in the hospital as case criteria. Surabaya is the location of the research. **Conclusion:** By non-exposure of complete medical information to patients, decisions made by patients are not autonomous since they have incomplete understanding, and proper disclosure technique for doctors is required.

Keywords: informed consent; respect for autonomy; information disclosure

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