

Research

## Analysis of Completeness Filling in the Informed Consent Formulir at Bhakti Husada General Hospital. Krikilan, Banyuwangi, East Java

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## ABSTRACT

**Background:** The quality and success of medical record unit services can be seen from the management of the units that have been carried out by professional staff. The minimum service standard for the medical record unit for completing informed consent is 100%. Completeness of filling out informed consent at the Bhakti Husada Krikilan Banyuwangi General Hospital from April to June is still not in accordance with the SPM, namely 79.33%. The aim of this research is to analyze the completeness of filling out informed consent at Bhakti Husada Krikilan Banyuwangi General Hospital.

Subjects and Method: This research is a qualitative research with a case study approach conducted at Bhakti Husada Krikilan General Hospital, Banyuwangi, East Java. The sampling technique used was purposive sampling. Data collection techniques using interviews, observation, documentation and questionnaires. Test the validity of the data using triangulation.

**Results:** The percentage of completeness of filling out the informed consent sheet at the Bhakti Husada Hospital from May to July 2022 is 15.28%. The lowest percentage lies in the content and authentication section. Management elements that affect the incomplete filling of informed consent include man factors (knowledge and years of service), machine (availability of office stationery, monitoring and evaluation), method (standard operating procedures) and money (rewards and salaries). In addition, it was also found that busy work schedules and emergency cases could affect the incomplete filling of informed consent.

Conclusion: The percentage of completeness of filling out informed consent at Bhakti Husada Krikilan Hospital is low. Elements of management that influence are man factors (knowledge and years of service), machine (availability of office stationery, monitoring and evaluation), method (standard operating procedures) and money (rewards and salaries).

**Keywords:** Medical Records, Completeness of Informed Consent, Quality of Medical Record Units

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## BACKGROUND

Medical record is one part of the unit in a hospital or health care facility that has an important role in the continuity of health services in that institution. The quality and success of medical record unit services can be seen from the management of the units that have been carried out by professional staff. In order to

e-ISSN: 2549-0281 66 be able to produce quality health information, in managing the medical record unit it is also necessary to be supported by using appropriate resources, such as human resources, facilities and infrastructure in order to achieve the goal. Medical Records and Health Information are human resources who have education relevant to qualifications and have competence in the field of medical records and health information. In the systems approach, the medical record unit consists of several subsystems that are interrelated and work together with each other in producing quality and quality output (Siswati, 2018).

Informed consent is consent given to a patient or patient's family who has received a complete and detailed explanation regarding the medical action to be performed on the patient. Informed consent is very important as legal protection for doctors and patients (Kepmenkes, 2008).

The completeness of the informed consent filling sheet at the Bhakti Husada Krikilan Banyuwangi General Hospital in the second quarter of 2021 to be precise from April to June is 79.33%, which based on the minimum service standard the medical record unit should complete filling out of informed consent by 100%. This will later have a negative impact when there are cases in the hospital and affect the assessment in the hospital accreditation process. If the consent form for action or informed consent is not filled in completely, then if at any time unwanted things occur such as complaints from the patient or the patient's family regarding the medical action services provided by the hospital, then the informed consent form can serve as evidence for the hospital, that the patient has received an explanation from the doctor concerned regarding the action to be taken and agrees to the action (Astutiningsih et al., 2018).

At Bhakti Husada Krikilan Banyuwangi General Hospital, the components used to see the completeness of filling out informed consent are still not in accordance with the standard which should consist of 3 components, but only contain complete and incomplete. The components in informed consent itself are divided into 3, including identification or identity, important reporting or content, and authentication or signature (Arimbi et al., 2021).

In accordance with the results of the description of the problems above, the authors are interested in conducting research with the title "Analysis of completeness of filling out informed consent at Bhakti Husada Krikilan General Hospital". This study aims to analyze the completeness of filling out informed consent at Bhakti Husada Krikilan Banyuwangi General Hospital.

### SUBJECTS AND METHOD

#### 1. Study Design

This research is a qualitative research with a case study approach. Case studies are research that focuses on a case and explores through data collection involving various reliable sources of information (Creswell, 2015). This method is very appropriate for analyzing certain events in a certain place and a certain time.

The case study in this study was related to the completeness of filling out the informed consent sheet at Bhakti Husada Krikilan Hospital, Banyuwangi.

## 2. Study Informant

The sampling technique in this study was purposive sampling. Purposive sampling is a sampling technique in selecting individuals who can be trusted to provide the best information about research problems based on the researcher's judgment (Creswell, 2015). The sampling method used is the key informant technique in which researchers take people who are considered key to be used as data sources that will help reveal the pro-

blems that have been formulated by researchers. The key informants in this study were specialist doctors, heads of operating rooms and medical record quality officers. The number of informants in this research is 7 informants.

### 3. Data Analysis

The data in this study were analyzed using qualitative data analysis starting from a process that involved organizing data (text data, transcripts, image data or photos), preliminary reading of databases, coding and organizing themes, presenting data and interpreting data during the research process (Creswell, 2015). It can be concluded that data analysis in qualitative research starts

from collecting data, compiling data systematically and interpreting data.

#### **RESULTS**

# Percentage of completeness of filling out informed consent

Informed consent is one of the most important sheets in the medical record as proof of approval from the patient or the patient's family for the medical actions performed by the doctor for the patient.

The actions that are often carried out are actions in the orthpedic poly, obstetric poly and general surgical poly. The total population of informed consent forms analyzed from May to July 2022 was 236 forms.

Table 1. Percentage of complete informed consent

Component	Complete	Incomplete	%
Identity	-	-	
Name	236	0	100
Birthday	235	1	99.58
No. Medical records	235	1	99.58
Address	234	2	99.15
Relations with Patients	179	57	75.85
Performing doctor	222	14	94.07
Information giver	221	15	93.64
Recipient of information or giver of			
consent	170	66	72.03
Content			
Diagnosis	208	28	88.14
Medical action	216	20	91.53
Procedures	221	14	93.64
Destination	212	24	89.83
Risk	216	20	91.53
Complications	211	25	89.41
Prognosis	82	154	34.75
Alternatives & other risks	67	169	28.39
Authentication			
Signature	177	59	75
Name	157	79	66.53
Completeness of informed consent	35	201	15.28

The highest percentage of completeness of filling out informed consent is in the identity section. These items include 236 complete patient names with a percentage of 100%. Date of birth and patient medical record number of 235 complete sheets with a

percentage of 99.58%. 234 complete patient addresses with a percentage of 99.15%.

While the lowest percentage is in the content and authentication section. In the content section for the lowest items, namely risk alternatives and others, there are 67

complete sheets with a percentage of 28.39%. Prognostic items as many as 82 complete sheets with a percentage of 34.75%. In the authentication section for signature items as many as 177 pieces complete with a percentage of 75%. Then for items with bright names as many as 157 complete sheets with a percentage of 66.53%.

Overall, the percentage of completeness of filling out informed consent forms at the Bhakti Husada Hospital from May to July 2022 was 15.28%, of which only 35 sheets of informed consent were completely filled out of the total.

## General description of management elements in incomplete filling of informed consent

The findings of the study on the man factor of knowledge items, where some informants did not know the standard percentage of complete informed consent due to the lack of socialization of information related to the standard percentage of complete informed consent for specialist doctors. Many items that were not carried out were left blank due to a lack of socialization of the importance of filling in items that were not carried out. There were informants who did not know the impact of incomplete filling in informed consent, these informants considered that some of the contents were unnecessary and too excessive.

From the tenure item, there were informants who stated that tenure could influence the filling of informed consent. In addition, other factors were also found that could affect the completeness of filling out informed consent, namely that busy or too busy schedules and emergency cases could affect performance in filling out informed consent.

The findings of a study on the machine factor of office stationery items, where there were informants who stated that they often lost pens in their room and the use of pens that were carried out alternately could hinder officers from filling out medical records, including informed consent sheets. In the monitoring and evaluation item, there were informants who stated that there had been no monitoring and evaluation of the completeness of informed consent for a long time. There was no further action from the medical record unit after monitoring and evaluating the informed consent form. Lack of socialization of monitoring and evaluation results from the medical record unit. There are obstacles in evaluating the completeness due to the large amount of work to be done.

The findings of the study on the machine factor of SOP items, where the absence of SOPs makes officers less familiar with the standard percentage of informed consent and how to correct writing on medical record files and informed consent sheets.

The findings of the study on the material factors of the form format items, where there were informants who stated that the content formats overlapped and were reluctant to rewrite the same items.

### **DISCUSSION**

The informed consent form is one of the most important forms in the medical record file and must be considered for its completeness. Based on the Regulation of the Minister of Health of the Republic of Indonesia Number: 129/Menkes/SK/II/2008 concerning hospital service standards that the minimum service standard in the medical record unit is related to the completeness of the contents on the informed consent sheet, which is 100%. This shows that it is important for all contents of the informed consent sheet to be filled in completely.

The results of observing medical record documents at the Bhakti Husada Krillilan Hospital show that the percentage of completeness of filling out informed consent sheets from May to July 2022 was 15.28%, of which only 35 filled out informed consent sheets out

of the total. This shows that the low quality of the medical record unit at Bhakti Husada Hospital is mainly related to filling out the informed consent sheet. The lowest percentage lies in the content and authentication section. In the content section for risk alternative items and others, 28.39% are completely filled. The completeness of the prognosis item is 34.75%.

Based on the man factor, the results of the study showed that knowledge had an effect on the incomplete filling of the informed consent sheet. Where some doctors do not know the standard percentage of complete informed consent. The results of the questionnaire also showed that the majority of the answers for the standard percentage of completeness of informed consent were 80% -100%. Where the answer should be 100%. This illustrates that doctors feel they are not obligated to fill in all the items on the informed consent sheet.

This percentage makes the completeness at the Bhakti Husada Krikilan Hospital relatively low. This also relates to filling in items that are not done. Many risk alternative items are not filled in or not marked (-) if there are no other risk alternatives. From the medical record unit, there is also showed a lack of socialization regarding the standard percentage of completeness of informed consent, so doctors assume that there is no problem with the completeness of filling out the informed consent sheet.

There are doctors who do not know the impact of incomplete filling in the informed consent form. He considered some of its contents unnecessary and excessive. This is supported by the research of Tahun and Ananda which states that the lack of filling out informed consent in the medical record file is caused by doctors' lack of understanding of the importance of informed consent, doctors' limited time, doctors' busyness, doctor's

dependence on nurses, doctor's lack of attention to filling out informed consent. Year and Ananda, 2022). As for education itself, it does not affect the incomplete filling of informed consent. Where the officer stated that when studying, they were required to fill out a complete medical record file, including an informed consent sheet in it.

Based on the results of the study showed that the length of service also affects the incompleteness of filling out the informed consent sheet. There is a doctor who states that "For example, in the first year the doctor may have a few patients, he tries to complete it because in proportion he is more flexible. As time goes on, there are more and more patients, there are many actions, working in several hospitals, I think it is irrational to do all of that." According to Gibson, a person's tenure will determine individual achievement which is the basis for achievement and organizational performance. The longer a person works in an organization, the level of individual achievement will increase as evidenced by the high number of completeness of medical records (Saptanty et al., 2022). The results of research (Prihandini et al., 2020) show that the variable of working period has the most dominant relationship with the completeness of filling out medical record files. It can be concluded that the human factor can affect the incomplete filling of informed consent.

In addition, it was also found that a busy work schedule can affect the incomplete filling of the informed consent sheet. Where the doctor stated that "Related to the tight schedule of operations. From the room to the busy all so sometimes there is a filling missed ". This was also seen at the time of document observation, there were doctors who carried out 4 major medical actions within the same day, and the results of the informed consent sheet were incomplete.

Then emergency cases also affect the incomplete filling of the informed consent sheet. Where the doctor stated that "In obstetrics it was situational, yes and at that time it played a very important role in the safety of mothers and children. Usually because of an emergency there are several things that are not complete." In the code of medical ethics, in an emergency, when a decision must be made immediately, the patient cannot participate in decision making, and a substitute for the patient is not available, the doctor can start treatment without prior approval (Halpern, 2002). This can lead to missing items in the informed consent form.

Based on the machine factor, this study show that the availability of office stationery can affect the incomplete filling of the informed consent sheet. The doctor stated that "This pen is often lost. Often do not know also where the loss. Because we often look for it, it's quite a hindrance to me." The results of the observation also stated that in some rooms it was often unavailable and lost pens. In Wijayanti's research, it was stated that the limitations of office stationery, especially pens, affect the filling of inpatient medical record files, causing incomplete medical record files for inpatients (Wijayanti, 2019).

Then monitoring and evaluation also affect the incomplete filling of the informed consent sheet. The doctor stated that there had been no monitoring and evaluation of the completeness of informed consent for a long time. From the medical record side, they also stated that they had never returned medical record files that filled out incomplete informed consent. The observation results stated that monitoring and evaluation were only carried out at the end of each month by the medical record unit and information related to the percentage of completeness of filling out informed consent was not conveyed or socialized to the doctor concerned. This is in

line with the results of Nurhaidah et al's research that the monitoring and evaluation system for filling out medical records can affect the completeness of filling out medical records (Nurhaidah, Harijanto and Djauhari, 2016).

Based on the method factor, the results showed that there was no SOP related to filling out medical record files or informed consent sheets at the Bhakti Husada Krikilan Hospital. This makes the officers do not understand the standard percentage of informed consent, so that the quality of the medical record unit for completeness of filling out informed consent is low. The absence of SOPs also made officers less aware of how to correct writing on medical files, including informed consent in them. Where when there is a writing error, the officer just crosses it out and immediately adds the correct writing without any signature and date of correction. Research from Ulfa states that there must be policies and SOPs within an organization and without SOPs, completeness will be difficult (Ulfa, 2018).

Based on material factors, the research results show that the content format on the informed consent form is clear, easy to understand and in accordance with the standards. This was conveyed by the medical record quality officer that the informed consent form used was in accordance with the provisions. It's just that there are doctors who are reluctant to rewrite the same items on the informed consent sheet and consider the contents overlapping. Doctors object to writing diagnoses repeatedly in the medical record file. This is related to the discipline of doctors in filling out medical record files, including the width of informed consent. So that material factors do not affect the incomplete filling of informed consent.

Based on the money factor, the results of the study show that money can affect the

incompleteness of filling out informed consent. Where at the time of conducting interviews many informants were doubtful regarding the eligibility of the salary that had been given. One of the doctors emphatically explained that the salary given was not appropriate, especially related to medical fees received from BPJS patients. Then regarding rewards, the majority answered that they had never received a reward when their performance was good, especially regarding filling out informed consent. The officer also agreed to hold a reward in order to motivate the officer to complete the medical record file, including the informed consent sheet. Based on the results of observations, there are rewards given to officers if their performance is very good, such as a promotion. However, this assessment is related to the performance of officers as a whole. This made the majority of officers never received a reward when their performance was good, especially regarding filling out the informed consent form. Filling out complete informed consent is an obligation, but giving awards is also needed to motivate officers to fill in complete informed consent (Pratiwi et al., 2022).

#### **AUTHORS CONTRIBUTION**

Muhammad Dudayev Caesar Putra is the main researcher who selects topics, searches for, and collects research data. Bhisma Murti and Hanung Prasetya analyzed and reviewed research documents.

### **CONFLICT OF INTEREST**

There is no conflict of interest in this study.

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