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Review of the Completeness of Filling Out the Medical Procedure Consent Form (Informed Consent) for Inpatient Surgical Patients at Dr. Soedirman Regional General Hospital Kebumen

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Abstract: The informed consent form is a mandatory legal document that must be completed before any medical procedure, especially surgical interventions. The completeness of informed consent is essential to ensure patient safety, fulfill ethical standards in healthcare services, and provide legal protection for both medical personnel and hospitals. In practice, however, incomplete informed consent documentation is still frequently found, which may reduce the quality of medical records and increase the risk of medico-legal disputes. To determine the completeness of informed consent documentation for inpatient surgical patients at RSUD Dr. Soedirman Kebumen and to identify the components most frequently left incomplete. This study employed a quantitative descriptive design with a sample of 118 inpatient surgical medical records. Data were collected using an observation checklist based on key informed consent components, including patient identity, attending physician's signature, clarity of procedure information, and date and time of consent. The data were analyzed descriptively by calculating the frequency and percentage of completeness for each component. Of the 118 records analyzed, 90 records (76.3%) were categorized as complete, while 28 records (23.7%) were incomplete. The highest rate of incompleteness was found in the clarity of procedure information component, with 24 incomplete records (20.3%). The attending physician's signature was incomplete in 12 records (10.2%). Meanwhile, patient identity and date and time components each showed 3 incomplete records (2.5%). The completeness of informed consent documentation for inpatient surgical patients at RSUD Dr. Soedirman Kebumen is categorized as adequate but does not yet meet the ideal standard (≥90%). The components most frequently incomplete were clarity of procedure information and attending physician's signature. Improvements in healthcare personnel compliance, document format refinement, and strengthened verification systems are necessary to enhance the quality of informed consent documentation.

Keyword: Informed Consent, Documentation Completeness, Medical Records, and Surgical Patients

INTRODUCTION

Medical records constitute essential documents containing comprehensive notes regarding a patient's identity, examinations, treatments, medical procedures, and other services received. One of the mandatory documents in the medical records of surgical patients is the Informed Consent form, which is the consent for medical procedures provided by the patient after receiving a thorough explanation from the physician regarding the procedure to be performed (Ministry of Health of the Republic of Indonesia Regulation No. 24 of 2022).

Law No. 17 of 2023 on Health reinforces the obligation to obtain consent for medical procedures: Article 293 stipulates that every individual health service intervention must obtain consent. In surgical services, Informed Consent holds a highly critical position due to the high risks and complexity associated with surgical procedures. Incomplete documentation of the consent form may lead to various consequences, including reduced quality of medical records, noncompliance with accreditation standards, decreased patient trust, and potential legal issues should medical disputes arise (Simamora, 2020). Minister of Health Regulation No. 31 of 2022 concerning Hospitals states that hospitals, as healthcare service institutions, are required to provide services that are of high quality, safe, and in accordance with professional standards and statutory regulations. One of the key indicators in assessing hospital service quality is the completeness of medical records, particularly for patients undergoing invasive procedures such as surgery. Medical records serve administrative, clinical, educational, research, legal, and financial functions. Among all components of the medical record, the informed consent form is a document with significant legal value and serves as evidence that the patient has received complete medical information prior to the procedure being performed.

Informed consent is an approval given by the patient or their family after receiving adequate explanations regarding the diagnosis, procedure, risks, complications, benefits, and available alternatives. The fundamental concept of informed consent emphasizes that every medical intervention must be carried out based on voluntary, informed, and competent consent. Accordingly, physicians are obliged to provide explanations that are honest, comprehensive, and understandable to the patient, while patients hold the full right to accept or refuse the proposed procedure (Setiadi, 2019; Notoatmojo, 2018). The above findings are consistent with previous studies by Putri & Pratama (2020) and Yuliana & Ratnawati (2021), which indicate that the completeness of informed consent forms in Indonesia remains highly variable. Some hospitals demonstrate high levels of completeness, while others face serious issues such as incomplete patient identity information, absence of the physician’s signature, insufficient explanation of risks, and forms being signed after the procedure has already been performed. Such incompleteness not only has the potential to reduce the quality of healthcare services but also poses legal risks for healthcare providers should a medical dispute occur.

In the context of surgical services, the completion of informed consent becomes increasingly important because surgical procedures carry higher risks compared to other medical interventions. Surgical procedures involve the possibility of complications that may endanger patient safety. Therefore, patients must receive complete and clear information in order to provide consent based on adequate understanding (informed decision-making). Incomplete forms not only indicate weak documentation practices but may also reflect suboptimal educational processes provided by healthcare professionals to patients (World Health Organization, 2016). RSUD Dr. Soedirman Kebumen, as a regional referral hospital, plays a crucial role in providing high-quality surgical services. The high volume of inpatient surgical cases requires well-organized administrative processes and complete medical records. However, based on internal reports from the medical records unit, incomplete medical procedure consent forms are still being found. This issue has become a serious concern for hospital management, considering that the completeness of informed consent is an essential component in hospital accreditation assessments, legal considerations, and a key indicator of clinical service quality (Simamora, 2020).

Given these conditions, it is important to conduct a study on the completeness of informed consent form documentation for inpatient surgical patients at RSUD Dr. Soedirman Kebumen. This research aims to provide a clear overview of the actual condition of form completion, identify which components are most frequently incomplete, and offer a basis for the hospital to implement quality improvement measures in its services. These findings indicate the need for further analysis regarding the completeness of Informed Consent form documentation in the inpatient surgical unit of RSUD Dr. Soedirman Kebumen. The results of this assessment are expected to serve as a basis for the hospital to evaluate andimprove the quality of medical record documentation and patient safety.

METHOD

This study employs a quantitative descriptive method aimed at illustrating the level of completeness in filling out the Informed Consent forms for inpatient surgical patients at RSUD Dr. Soedirman Kebumen. This method was chosen because the research focuses on presenting an objective description of the completeness of medical record documents without administering any treatment or intervention (Notoatmodjo, 2018).

The research was conducted in the Medical Records Unit of RSUD Dr. Soedirman Kebumen, specifically using the medical record files of inpatient surgical patients. The study was carried out from August to October 2025.

The population in this study consists of all inpatient medical record files of patients who underwent surgical procedures during the research period, totaling 167 records. The sample was selected using purposive sampling, which involves selecting samples based on specific criteria relevant to the objectives of the study, resulting in 118 samples.

The Slovin formula was used to calculate a representative sample size from the population. The Slovin formula is as follows:

n = N / (1 + N(e^2))

Calculating the Sample Size:
n = 167 / (1 + 167(0,05^2))
= 167 / (1 + 167(0,0025))
= 167 / (1 + 0,4175)
= 167 / 1,4175
= 117,83

Thus, the required sample size is approximately 118 records.

RESULTS AND DISCUSSION

The sample selection followed the Slovin formula, ensuring that the number of records analyzed proportionally represented the population. These medical records were then reviewed based on four main components of the informed consent form, namely: patient identity, the attending physician’s signature, clarity of information, and the date and time of the procedure. From all the samples examined, it was found that most records were completed adequately; however, several records still did not meet the completeness standards as stipulated in the Ministry of Health Regulation No. 290 of 2008.

The following table presents the completeness of the informed consent:

Table 1. Completeness of Informed Consent in Surgical Patients

No	Indicator	Complete	Incomplete	Per(100%)
1.	Patient Identity	115	3	97,5%
2.	DPJP	106	12	89,8%
3.	Clarity of Information	94	24	79,6%
4.	Date and Time	115	3	97,5%

Based on the table above, Patient Identity (97.5%) shows the highest level of completeness, indicating that staff members understand the importance of patient identity in legal documentation. The Attending Physician (DPJP) component (89.8%) shows 12 cases of incompleteness, suggesting the need to improve physician discipline in providing initials or signatures. Clarity of Information (79.6%) is the weakest component. The high number of incomplete entries indicates that the patient education process is not yet optimal. For the Date and Time component (97.5%), most records are complete, although three records still contain blank fields.

Table 2. Completeness and Clarity of Information in the Informed Consent of Surgical Patients

No	Indicator	Complete	Incomplete	Per(100%)
1.	Diagnosis	116	2	98.31%
2.	Indication for the Medical Procedure	112	6	94.92%
3.	Risks and Potential Complications	112	6	94.92%
4.	Alternative Treatment Options	108	10	91.53%

The completeness of the diagnostic component reached 116 out of 118 documents, or 98.31%. This indicates that most healthcare professionals have consistently documented the diagnosis in the informed consent forms. Diagnosis serves as the primary basis for patients to understand their medical condition prior to the procedure; therefore, this high level of completeness represents a positive indicator of effective information delivery. The indication for the procedure was documented in 112 forms, or 94.92%. This component explains the rationale for performing the medical procedure. Although the percentage is high, some cases still lacked documentation of the indication. Strengthening adherence in completing this section is essential, as patients are entitled to understand the justification for the medical intervention.

Similar to the procedural indication, the component on risks and complications also demonstrated a completeness rate of 112 out of 118 documents, or 94.92%. Information on risks is a mandatory element in informed consent to ensure that patients understand potential complications that may arise. Despite the high completeness rate, continuous education for staff is still needed to ensure that risks are consistently documented in a comprehensive and clear manner. The alternative treatment component had the lowest completeness, with 108 out of 118 documents, or 91.53%. Alternative treatments provide patients with options beyond the recommended procedure. The lower completeness in this section indicates a need for further

guidance and reinforcement for staff in communicating and documenting available medical alternatives.

Overall, the completeness of informed consent documentation falls within the excellent category, as all components exceed a 90% completion rate. Nevertheless, there remain several documents that were not fully completed, particularly in the alternative treatment section, which holds significant legal and ethical importance in the medical decision-making process. This discussion provides an in-depth explanation of the research findings regarding the completeness of filling out the medical procedure consent (informed consent) forms for inpatient surgical patients, based on data from 118 medical record samples. The analysis was conducted on four main components of the form, namely: patient identity, the attending physician's signature (DPJP), clarity of information, and the date and time of consent.

The patient identity component shows the highest level of completeness, with only 3 records (2.5%) found to be incomplete. This result indicates that staff members possess a strong awareness of the importance of identity as a fundamental element in medical documentation. Patient identity is a crucial point to ensure accuracy of services, prevent procedural errors, and maintain the legal validity of the document. The observed incompleteness is likely attributed to administrative factors such as negligence during data entry or situations in which the patient is unable to provide complete identity information. The incompleteness in the Attending Physician (DPJP) component reached 12 records (10.2%). The DPJP's signature is required as evidence that the physician has provided information regarding the procedure, its benefits, risks, and available therapeutic alternatives. The absence of the DPJP's signature may have legal implications, as consent without physician validation is considered invalid both ethically and legally. Several factors may contribute to this incompleteness, including:

1. High physician workload, causing the documentation process to be completed hastily. Lack of coordination between the attending physician and nurses regarding document review prior to surgery.
2. Insufficient internal supervision from the medical records unit and the quality committee. Clarity of Information is the component with the lowest level of completeness, with 24 records (20.3%) left unfilled. This section includes information regarding:
   1) Diagnosis
   2) Indication for the procedure
   3) Risks and complications
   4) Alternative procedures

The incompleteness of this component is highly critical because clarity of information is the core of the informed consent concept. A patient is considered not to have provided valid consent if they do not receive complete information regarding the medical procedure.
Several possible contributing factors include:

1. Insufficient time for physicians to provide adequate explanations.
2. Inaccurate or inconsistent documentation practices within the surgical service unit.

The incompleteness of this section has a significant impact on patient safety, as patients may not be fully aware of the risks associated with the procedure.

The date and time of consent show a high level of completeness, with only 3 records (2.5%) found to be incomplete. The date and time serve as evidence that the consent was provided prior to the procedure. Incompleteness in this section may pose legal risks if there are claims suggesting that consent was given after the procedure was performed.

CONCLUSION

Based on the results of the study involving 118 medical record files of inpatient surgical patients at RSUD Dr. Soedirman Kebumen regarding the review of the completeness of medical

procedure consent (informed consent) forms, it can be concluded that the level of document completeness has not yet reached the ideal standard.

1. The overall completeness rate reached 76.3%, with 90 records categorized as complete and 28 records (23.7%) categorized as incomplete. This indicates that the completion of informed consent falls within the "adequate" category, yet it does not meet the recommended quality standard (≥ 90%).
2. Ketidaklengkapan terdapat pada empat komponen utama, yaitu: Incompleteness was found in four main components, namely:
   a. Patient identity: 3 incomplete records
   b. Attending physician's signature: 12 incomplete records
   c. Clarity of procedure information: 24 incomplete records (the lowest-scoring component)
   d. and time of consent: three records were found to be incomplete.
3. The component with the highest rate of incompleteness was the clarity of procedural information, which includes explanations of the procedure, risks, complications, and alternative interventions. This finding indicates that the patient education process provided by medical personnel has not been fully optimized.
4. The incompleteness of the attending physician's signature also represents a significant issue, as it serves as legal evidence that the physician has provided an explanation to the patient.
5. Overall, improvements are still required in administrative procedures, patient education, and healthcare personnel compliance to ensure that the informed consent forms are completed thoroughly, validly, and in accordance with legal and ethical medical standards.

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