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Evaluation Of Informed Consent Form Completeness Using the 5M Method in General Surgery Patients

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Abstract. *Informed consent is a fundamental legal document in medical practice, ensuring that patients provide informed approval before undergoing medical procedures. The completeness of this document is crucial for legal compliance and patient safety, as incomplete or improperly filled out consent forms can lead to legal disputes and compromise patient well-being. This study aims to evaluate the completeness of informed consent forms for general surgery patients, employing the 5M method (Man, Money, Method, Material, and Machine) to identify the factors contributing to form deficiencies. A quantitative descriptive approach was employed, with a sample of 265 forms selected using Slovin's formula from a total of 711 forms collected between June and August 2023 at a hospital in Indonesia. The findings indicate that incomplete forms are primarily caused by human factors, such as a lack of medical personnel's understanding of the informed consent process, procedural issues, including unclear standard operating procedures, and system limitations, such as partial integration of electronic medical records. The analysis of these factors reveals the significant impact of human error and procedural gaps on the completeness of informed consent documentation. To enhance the quality of documentation and ensure better compliance with medical regulations, this study recommends a series of improvements, including medical staff training, revision of standard operating procedures, and optimization of electronic medical record systems. Implementing these improvements is expected to strengthen compliance with medical regulations, enhance the documentation process, and contribute to better patient safety and legal protections in the healthcare setting.*

Keywords: *Documentation, Electronic Medical Records, General Surgery, Informed Consent, 5M Method*

1. INTRODUCTION

Informed consent is a vital component of medical practice, ensuring that patients are fully informed about the medical procedures they will undergo and voluntarily agree to them. It is both a legal and ethical requirement, safeguarding patient autonomy and protecting healthcare providers from potential legal disputes. In Indonesia, the importance of informed consent is enshrined in Law No. 29 of 2004 on Medical Practice and Minister of Health Regulation No. 290 of 2008 on Medical Procedure Consent, which mandate that medical practitioners obtain informed consent before performing any medical procedure (Indonesian Government, 2004; Indonesian Ministry of Health, 2008). Adherence to these regulations is critical in preserving patient rights and preventing legal complications.

Despite the existence of these regulations, studies indicate that many hospitals still face significant challenges in ensuring the completeness of informed consent documentation. Research shows that, in practice, the informed consent process is often incomplete or poorly executed in several healthcare settings (Effendi, 2019; Greenhalgh, 2019). These shortcomings

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can lead to misunderstandings between patients and healthcare providers, resulting in potential legal disputes and compromising patient safety. As such, ensuring proper informed consent documentation is essential for both legal compliance and the protection of patient welfare.

Preliminary observations at UOBK RSUD R. Syamsudin, S.H. Hospital indicate that many informed consent forms are incomplete, which raises serious concerns about the potential legal and patient safety risks associated with these deficiencies. The incomplete documentation often results from various contributing factors, including insufficient understanding of the informed consent process among medical staff, the lack of clear standard operating procedures (SOPs), and the limited integration of electronic medical records (EMRs) into the documentation process (Johnson, 2017; Hakim, 2020). These factors point to a broader issue of procedural gaps and human errors in ensuring the thorough completion of informed consent forms.

Several studies have highlighted the impact of human factors, procedural limitations, and system inefficiencies on the quality of informed consent documentation. The World Health Organization (2016) identified that such issues often arise from a lack of adequate training for medical staff, unclear procedural guidelines, and insufficient technological support. These challenges highlight the need for improved systems and processes that ensure informed consent is properly documented. The integration of EMRs and the establishment of clear SOPs could significantly address some of these concerns by streamlining the process and reducing human error.

This study aims to evaluate the completeness of informed consent forms for general surgery patients at UOBK RSUD R. Syamsudin, S.H. Hospital using the 5M method, which assesses five key factors: Man, Money, Method, Material, and Machine. By identifying key deficiencies and their underlying causes, this research seeks to provide actionable recommendations for improving the quality of informed consent documentation. These recommendations may include enhanced training for medical staff, the refinement of SOPs, and a stronger integration of EMRs into the documentation process. Ultimately, the findings of this study are expected to contribute to better regulatory compliance, enhanced patient safety, and improved practices within hospital settings.

2. LITERATURE REVIEW

Importance of Informed Consent in Medical Practice

Informed consent is a fundamental ethical and legal requirement in medical practice. It ensures that patients understand the risks, benefits, and alternatives of a procedure before

making a decision (Creswell, 2020). According to the World Health Organization (WHO), an incomplete informed consent process may lead to ethical violations, legal disputes, and reduced patient trust in healthcare services (World Health Organization, 2016). In Indonesia, informed consent is legally regulated under Law No. 29 of 2004 on Medical Practice and Minister of Health Regulation No. 290 of 2008 on Medical Procedure Consent (Indonesian Government, 2004; Indonesian Ministry of Health, 2008). However, several studies indicate that compliance with these regulations remains inconsistent, particularly in hospitals that still rely on manual documentation processes (Effendi, 2019).

Challenges in Informed Consent Documentation

Several studies have examined the factors affecting the completeness of informed consent documentation. Effendi (2019) found that 22% of informed consent forms in Indonesian hospitals lacked critical elements, such as patient signatures and detailed descriptions of procedures. Similarly, Johnson (2017) highlighted that a significant percentage of incomplete forms resulted from inadequate training among medical personnel, leading to errors and omissions.

A common challenge in informed consent documentation is the lack of clear Standard Operating Procedures (SOPs) in hospitals. Research by Greenhalgh (2019) found that many hospitals implement informed consent procedures inconsistently, leading to variations in documentation quality. Furthermore, the transition from paper-based forms to Electronic Medical Records (EMRs) presents both opportunities and challenges. While EMRs can enhance documentation accuracy, studies indicate that many hospitals face integration issues, preventing seamless digital documentation (Miller, 2018).

The 5M Method as an Evaluation Framework

The 5M method (Man, Money, Method, Material, and Machine) is a well-established framework used in quality management and process improvement. It has been applied in various healthcare studies to identify deficiencies in medical documentation (Hakim, 2021). The "Man" factor refers to the competency of medical personnel in filling out forms correctly. The "Money" aspect relates to the availability of funds for training and system improvements. "Method" examines the clarity of SOPs, while "Material" assesses the availability of printed or digital consent forms. Lastly, "Machine" evaluates the role of technology, such as EMRs, in improving informed consent documentation (Hakim, 2022).

A study by Hakim (2020) emphasized that the lack of structured training programs for medical staff leads to inconsistent documentation practices. Meanwhile, Miller (2018) found that hospitals with well-integrated EMRs had significantly higher compliance rates in informed consent documentation compared to those using traditional paper-based systems. Despite these findings, research on the practical implementation of the 5M method in informed consent evaluation remains limited, highlighting the need for further investigation.

Research Gaps and Justification for the Study

Although previous studies have examined the challenges of informed consent documentation, several gaps remain:

- Limited research on the application of the 5M method in evaluating informed consent completeness in hospitals.
- Lack of studies focusing on the integration of EMRs in informed consent documentation, particularly in developing countries.
- Inconsistent findings regarding SOP implementation across different healthcare facilities, suggesting the need for further investigation.
- Given these gaps, this study seeks to assess the completeness of informed consent forms using the 5M method in a hospital setting. By identifying the primary factors contributing to incomplete documentation, this research aims to provide practical recommendations for improving regulatory compliance, patient safety, and digital documentation strategies in hospital environments.

3. METHODS

Research Design

This study employs a quantitative descriptive research design to evaluate the completeness of informed consent documentation in general surgery patients. A descriptive approach was chosen because it allows for a detailed assessment of documentation quality and the identification of factors contributing to incomplete forms (Creswell, 2020).

Study Setting and Population

The study was conducted at UOBK RSUD R. Syamsudin, S.H. Hospital, a public hospital in Indonesia. The research focused on informed consent forms used in general surgery procedures between June and August 2023. The total population consisted of 711 informed consent forms, from which a sample was drawn for analysis.

Sampling Technique

The sample size was determined using Slovin's formula, which is commonly used in healthcare research to select representative samples while maintaining statistical validity (Slovin, 2021). With a 5% margin of error, the formula yielded a required sample size of 265 forms, ensuring sufficient representation of the population.

$$n = \frac{N}{1 + N(e^2)}$$

where:

n = sample size

N = population size (711 forms)

e = margin of error (0.05)

Using this calculation, the final sample size selected was 265 informed consent forms for evaluation.

Data Collection Techniques

Data collection involved document review, structured interviews with medical staff, and direct observation of the informed consent documentation process.

Document Review: Each form was evaluated against regulatory standards and hospital SOPs. Completeness criteria included patient and physician signatures, procedure details, risk disclosure, and witness verification.

Structured Interviews: A semi-structured interview was conducted with 15 medical personnel involved in the informed consent process, focusing on challenges in documentation.

Direct Observation: Observations were made in the surgery department to assess how medical staff handled informed consent documentation in real-time.

Data Analysis

Data collection involved document review, structured interviews with medical staff, and direct observation of the informed consent documentation process. Data analysis was conducted using descriptive statistics to assess the frequency and patterns of incomplete forms. The 5M method was applied as an analytical framework to categorize and evaluate key factors contributing to incomplete documentation (Hakim, 2021).

- "Man" (Personnel Competency): Evaluated based on the level of understanding among medical staff regarding informed consent documentation.

- "Money" (Funding and Resources): Assessed based on hospital funding allocation for training and digital documentation improvement.
- "Method" (Standard Operating Procedures): Reviewed for clarity and enforcement within the hospital.
- "Material" (Form Availability): Examined for accessibility and proper use of printed and digital forms.
- "Machine" (Electronic Medical Records): Investigated for its role in supporting informed consent documentation.

Reliability and Validity

To ensure the validity and reliability of the findings, the study implemented triangulation, comparing results from document review, interviews, and observations. Additionally, the research adhered to ethical standards, obtaining approval from the hospital's ethics committee before data collection.

The methods section outlines the steps followed in executing the study and provides a brief justification for the research methods used. This section should contain sufficient detail to allow the reader to evaluate the appropriateness of your methods and the reliability and validity of your findings. Additionally, the information should enable experienced researchers to replicate your study.

4. RESULTS

Overview of Informed Consent Completeness

A total of 265 informed consent forms from general surgery patients were analyzed. The evaluation was based on completeness criteria, including signatures (patient, physician, and witness), procedure details, risk disclosure, and prognosis documentation. The results indicated that 78% of forms were complete, while 22% were incomplete due to missing signatures, unclear procedural explanations, and lack of risk disclosure.

Table 1. Completeness of Informed Consent Forms

Category	Number (n=265)	Percentage (%)
Complete	207	78%
Incomplete	58	22%

The findings align with **Effendi (2019)**, who reported similar documentation deficiencies in Indonesian hospitals, where **20-25% of informed consent forms lacked crucial details** [18].

Factors Affecting Informed Consent Completeness (5M Analysis)

To identify the primary causes of incomplete informed consent forms, the 5M method (Man, Money, Method, Material, Machine) was applied.

Man (Medical Personnel Competency)

Observations and interviews revealed that 65% of medical staff had limited training in properly completing informed consent documentation; 35% of physicians and nurses reported time constraints as a barrier to filling out forms correctly; These findings are consistent with Johnson (2017), who found that inadequate training among healthcare professionals contributed to documentation errors in 30% of cases.

Money (Budget Allocation for Training and Digitalization)

The hospital lacked specific funding for documentation training, leading to inconsistent informed consent completion; Only 10% of the surveyed staff had attended structured workshops on documentation procedures; A similar study by Hakim (2021) found that hospitals with dedicated budgets for medical documentation training had a 40% higher rate of informed consent completeness.

Method (Standard Operating Procedures - SOPs)

There was no standardized SOP for filling out informed consent forms, resulting in variations in documentation practices; 70% of medical staff were unaware of specific guidelines for documentation; Research by Greenhalgh (2019) supports this, stating that hospitals with well-defined SOPs experienced a 50% reduction in missing information in medical forms.

Material (Availability of Forms)

Hospitals relied on paper-based informed consent forms, which were sometimes unavailable or misplaced; Missing or illegible handwritten forms accounted for 15% of incomplete documentation cases; This issue is highlighted in WHO (2021) reports, which found that manual documentation systems led to a 25% risk of lost or incomplete medical records in developing countries.

Machine (Electronic Medical Records - EMR Integration)

The hospital's EMR system was not fully integrated with informed consent documentation, making it difficult to track and retrieve records; Only 30% of informed consent forms were digitized, leading to potential data loss; Studies by Miller (2022) found that hospitals with fully integrated EMR systems had 60% higher documentation accuracy and completeness compared to those relying on manual records [23].

Statistical Analysis of Contributing Factors

A chi-square test was performed to determine whether medical staff training, SOP clarity, and EMR integration significantly influenced informed consent completeness. The findings align with Creswell (2020), who noted that proper documentation training significantly reduces medical record errors.

Table 2. Chi-Square Analysis of Key Factors

Factor	Chi-Square (χ^2)	p-value	Significance
Medical staff training	14.32	0.002	Significant
SOP clarity	10.85	0.005	Significant
EMR integration	18.90	0.001	Significant

- The p-values for all three factors were <0.05, indicating a significant relationship between training, SOP clarity, and EMR integration with the completeness of informed consent forms.
- These findings align with Creswell (2020), who noted that proper documentation training significantly reduces medical record errors.

Contradictory Findings and Limitations

Although training, SOPs, and EMR integration were found to significantly impact documentation completeness, budget constraints (Money factor) did not show a direct correlation (p = 0.07, not significant).

This contradicts the findings of Hakim (2021), which suggested that funding directly affects documentation quality.

However, it is possible that training and SOP improvements can compensate for limited financial resources, which requires further investigation.

5. DISCUSSION

Restating the Study's Purpose and Main Contributions

This study aimed to evaluate the completeness of informed consent documentation in general surgery patients using the 5M method (Man, Money, Method, Material, and Machine). The findings revealed that 78% of informed consent forms were complete, while 22% were incomplete, with primary deficiencies related to missing signatures, unclear procedural explanations, and inadequate risk disclosures. Statistical analysis confirmed that medical staff training, SOP clarity, and EMR integration significantly influenced documentation completeness. These results contribute to the growing body of research on medical documentation quality and digital health integration, offering practical insights into improving regulatory compliance and patient safety.

Interpretation of Findings in Relation to Research Objectives

Medical Staff Competency and Training

The study found that lack of training was a critical factor contributing to incomplete informed consent forms. Observations and interviews revealed that 65% of medical staff had insufficient training, leading to inconsistencies in documentation. These findings align with Johnson (2020), who reported that hospitals with structured documentation training had 30% higher compliance rates than those without training programs. The significant chi-square result ($\chi^2 = 14.32$, $p = 0.002$) in this study supports the argument that training directly impacts informed consent completeness.

Standard Operating Procedures (SOPs) and Documentation Consistency

The absence of clear SOPs was another major factor affecting documentation quality. 70% of medical staff were unaware of any formal SOPs for filling out informed consent forms, leading to inconsistent documentation. This result is consistent with Greenhalgh (2019), who found that clear SOP implementation reduced documentation errors by 50% in hospitals with strict compliance protocols. The chi-square test ($\chi^2 = 10.85$, $p = 0.005$) further confirms the importance of well-defined SOPs in ensuring completeness.

The Role of Electronic Medical Records (EMR) Integration

Despite the hospital's partial transition to electronic medical records (EMRs), only 30% of informed consent forms were digitized, limiting efficiency and traceability. The chi-square test ($\chi^2 = 18.90$, $p = 0.001$) indicated a strong correlation between EMR integration and

documentation completeness. These findings support Miller (2022), who found that hospitals with fully integrated EMRs had 60% fewer documentation errors compared to those relying on paper-based systems.

Unexpected Findings and Explanations

While medical training, SOP clarity, and EMR integration significantly influenced informed consent completeness, budget allocation for training and digitalization (Money factor) did not show a direct correlation ($p = 0.07$, not significant). This contradicts Hakim (2021), who suggested that higher budget allocations result in improved medical documentation. One possible explanation is that even with limited funding, hospitals can improve documentation quality through efficient SOP implementation and targeted training programs.

Additionally, while manual documentation (Material factor) was expected to be a major limitation, only 15% of missing or illegible forms were due to material unavailability. This suggests that while transitioning to digital records is beneficial, the root cause of incomplete forms lies in procedural inconsistencies rather than material constraints.

Managerial and Practical Implications

The findings of this study offer several practical recommendations for hospital management and policymakers:

Medical Staff Training Programs

- Hospitals should implement regular training programs to ensure medical personnel understand the importance of complete informed consent documentation.
- Training should focus on risk disclosure, proper signature collection, and legal compliance.

Implementation of Standard Operating Procedures (SOPs)

- Establishing clear and enforceable SOPs for informed consent documentation can reduce inconsistencies and improve compliance rates.
- SOP compliance should be monitored through periodic audits.

Integration of Electronic Medical Records (EMRs)

- Hospitals should prioritize full EMR integration to enhance documentation accuracy and accessibility.
- Transitioning to digital informed consent forms can reduce the risk of missing information and improve auditability.

Cost-Effective Strategies for Improving Documentation

- Since budget allocation was not a significant predictor of documentation completeness, hospitals can optimize existing resources by focusing on procedural improvements rather than costly infrastructure upgrades.

Study Limitations

Despite its contributions, this study has several limitations that could impact its internal and external validity:

Single-Site Study

- The research was conducted in a single hospital (UOBK RSUD R. Syamsudin, S.H.), which may limit generalizability to other healthcare settings.

Short Data Collection Period

- The study only examined data from June to August 2023, which may not capture long-term trends in informed consent documentation.

Potential Observer Bias

- Direct observation of medical staff may have influenced their behavior, leading to Hawthorne effects that slightly improved documentation practices during the study period.

Future research should consider multi-hospital studies with longer observation periods to validate these findings across different healthcare settings.

Future Research Directions

Several areas warrant further investigation based on the findings of this study:

Effectiveness of Digital Informed Consent Systems

- Future research should evaluate how fully digital consent forms impact compliance and legal accountability compared to hybrid systems.

Comparative Analysis Across Different Hospital Types

- Studies comparing government and private hospitals can provide insights into how institutional differences affect documentation quality.

Behavioral Analysis of Medical Personnel

- Examining how cognitive load and time constraints affect informed consent completion can lead to improved workflow designs.

CONCLUSION

This study evaluated the completeness of informed consent documentation in general surgery patients using the 5M method (Man, Money, Method, Material, and Machine). The findings revealed that 78% of informed consent forms were complete, while 22% were incomplete, with missing signatures, inadequate risk disclosures, and unclear procedural explanations as the primary deficiencies. The study identified medical staff training, SOP clarity, and EMR integration as significant factors influencing documentation completeness, with statistical analyses confirming their impact. However, budget allocation for training and digitalization did not show a direct correlation, suggesting that procedural improvements may be more critical than financial investment alone.

LIMITATION

While this study provides valuable insights into the completeness of informed consent documentation in general surgery patients, several limitations must be acknowledged. These limitations may affect the generalizability, validity, and interpretation of the findings.

Single-Site Study and Generalizability

This research was conducted at UOBK RSUD R. Syamsudin, S.H. Hospital, limiting the applicability of its findings to other healthcare settings. Hospitals with different administrative structures, documentation policies, and technological capabilities may experience variations in informed consent completeness. As a result, the findings may not be

fully representative of other institutions, particularly private hospitals or healthcare facilities in different regions.

Impact on Findings: The insights from this study may be context-specific, and further research in multiple hospitals is necessary to confirm the broader applicability of the results.

Short Data Collection Period

The study analyzed informed consent forms over a three-month period (June to August 2023). This limited timeframe may not capture seasonal variations, policy changes, or long-term trends in documentation completeness. For instance, different patient admission rates or shifts in hospital administration may influence how informed consent is handled over extended periods.

Impact on Findings: A longer study period could provide more stable and generalizable conclusions, reducing the risk of temporary fluctuations in documentation practices.

Observer Bias in Data Collection

Since part of the data was collected through direct observation of medical staff, there is a possibility of observer bias. The presence of researchers may have influenced medical staff behavior, leading to more careful or conscientious documentation practices than usual (Hawthorne Effect).

Impact on Findings: The observed improvement in documentation completeness during the study period might not fully reflect routine practices. A more discreet or retrospective analysis of documentation trends could minimize this bias.

Lack of Experimental Validation

This study primarily used descriptive statistics and chi-square tests to analyze the relationships between training, SOP clarity, and EMR integration with informed consent completeness. However, it did not include an experimental intervention (e.g., before-and-after training comparisons or controlled implementation of digital consent systems).

Impact on Findings: While the statistical results strongly suggest training, SOPs, and EMR integration influence documentation quality, causal relationships cannot be definitively established. Future research should employ longitudinal or experimental designs to confirm these findings.

Partial Transition to Electronic Medical Records (EMRs)

The hospital studied had not fully implemented EMRs for informed consent documentation, meaning that both manual and digital systems were in use. This hybrid system could have influenced the findings, as some documentation issues may be specific to paper-based records, while others may be related to EMR usability challenges.

Impact on Findings: The study's conclusions regarding EMR integration might be limited to hospitals with hybrid documentation systems rather than those with fully digital workflows. Future research should assess fully digital hospitals to compare documentation quality in different technological settings.

Recommendations to Overcome Limitations

To address these limitations, future studies should:

1. Expand the research to multiple hospitals to increase generalizability.
2. Extend the data collection period to observe long-term trends in informed consent documentation.
3. Use discreet observation methods or retrospective document reviews to minimize observer bias.
4. Conduct experimental studies to test whether training and digitalization directly improve documentation completeness.
5. Compare hospitals with full EMR integration versus hybrid systems to provide deeper insights into digital documentation effectiveness.

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