Vol. 02, No. 1, March 2026, Page 1-10 E-ISSN 3123-6952

JOURNAL REKAM MEDIS

Research and Evidence on Knowledge in Administration and Management — Medical Electronic Data and Information Systems

Factors Associated with Incomplete Informed Consent in Inpatient Medical Records

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Article Information

Received: May 04, 2026

Revised: May 13, 2026

Online: May 16, 2026

Keywords

Informed Conset, Medical Records, Knowledge, Workload, SOP Compliance

ABSTRACT

Informed consent is a crucial component of medical records that serves as legal evidence and a means of protecting patient rights; however, incomplete documentation remains a common issue that may compromise healthcare quality. This study aimed to analyze factors associated with incomplete informed consent documentation in inpatient medical records. A quantitative study with a cross-sectional design was conducted on 120 medical records selected using systematic random sampling. The dependent variable was the completeness of informed consent, while the independent variables included staff knowledge, years of experience, workload, and compliance with standard operating procedures (SOPs). Data were collected using a checklist based on Ministry of Health Regulation No. 290 of 2008 and analyzed using univariate and bivariate methods with the Chi-square test at a significance level of 0.05. The results showed that incomplete informed consent documentation was relatively high (62.5%). Bivariate analysis indicated that knowledge (p=0.002; OR=5.5), workload (p=0.004; OR=5.0), and SOP compliance (p=0.001; OR=7.55) were significantly associated with incomplete documentation, while years of experience was not significantly associated (p=0.087). In conclusion, the incompleteness of informed consent is influenced by both individual and system-related factors, with SOP compliance identified as the most dominant factor.

Keywords: *Informed Conset, Medical Records, Knowledge, Workload, SOP Compliance*

DOI: https://doi.org/10.69855/rekammedis.v2i1.636

Available online at website: https://gpijournal.com/index.php/rekammedis

PUBLISHED BY : GPress Indonesia

INTRODUCTION

Medical records are important documents in healthcare that serve as a means of communication among healthcare professionals, a form of legal evidence, and a basis for evaluating the quality of care (Indonesian Ministry of Health, 2008). Additionally, medical records play a role in ensuring continuity of care and serve as a data source for educational and research purposes (Ministry of Health of the Republic of Indonesia, 2008). One of the key components of medical records is informed consent, which is the patient's or family's approval of a medical procedure following a comprehensive explanation regarding the diagnosis, purpose of the procedure, risks, alternative treatments, and prognosis (World Medical Association, 2022).

From an ethical and legal perspective, informed consent is a manifestation of the principle of patient autonomy in healthcare. This principle affirms that every individual has the right to make decisions regarding the medical procedures they will undergo after receiving adequate information (World Health Organization, 2021). Therefore, the presence of a complete and clear informed consent serves as a crucial indicator in ensuring the protection of patients' rights as well as legal protection for healthcare providers.

In Indonesia, the implementation of informed consent is regulated through several healthcare regulations, including Ministry of Health Regulation No. 290 of 2008 concerning Consent for Medical Procedures, which outlines the procedures for obtaining patient consent prior to medical actions, and Ministry of Health Regulation No. 24 of 2022 concerning Medical Records, which emphasizes the importance of complete, accurate, and accountable medical record documentation as part of healthcare quality and legal protect. Furthermore, Ministry of Health Regulation No. 269 of 2008 on Medical Records stipulates that every healthcare service must be fully documented in medical records, including the informed consent form. This provision indicates that the completeness of informed consent is not merely an administrative matter but an integral part of healthcare quality standards.

Various studies indicate that inadequate informed consent remains a significant problem in hospitals (Putri et al., 2022; Kusumawati et al., 2022). Factors influencing this situation include individual factors among healthcare workers, such as knowledge and attitudes, as well as organizational factors, such as workload and supervision systems (Sari & Handayani 2022; Rizkika & Sugiarti, 2022). Additionally, a lack of adherence to standard operating procedures (SOPs) is also a major cause of suboptimal completion of medical records. The high workload of healthcare workers often results in incomplete medical record documentation. This aligns with findings that work-related stress contributes to the quality of clinical documentation (World Health Organization, 2021). On the other hand, a lack of understanding regarding the importance of informed consent also leads healthcare workers to not fully realize the legal and ethical consequences of such incomplete documentation.

Although previous studies have discussed the completeness of informed consent documentation, most studies have only focused on single determinants, such as knowledge,

workload, or administrative compliance separately (Putri et al., 2022; Rizkika & Sugiarti, 2022). Limited studies have comprehensively examined the interaction between individual factors and organizational system factors simultaneously in influencing incomplete informed consent documentation, particularly in inpatient healthcare services. In addition, previous studies generally emphasized descriptive findings without identifying the dominant factor contributing to incomplete informed consent. Therefore, this study offers a different perspective by simultaneously analyzing staff knowledge, years of experience, workload, and compliance with standard operating procedures (SOPs) within one analytical framework to identify the most influential factor associated with incomplete informed consent documentation. This approach strengthens the theoretical understanding that the quality of informed consent documentation is influenced not only by individual competence but also by organizational and system-related factors within healthcare services. Thus, this study contributes to the development of medical record quality improvement strategies that are more comprehensive and evidence-based in inpatient healthcare settings. Furthermore, identifying the dominant factor associated with incomplete informed consent is important to support the formulation of targeted interventions for improving medical record quality and patient safety.

METHODS

This study employs a quantitative design with a cross-sectional approach, which involves examining the relationship between independent and dependent variables at a specific point in time. The study was conducted using the medical records of inpatients at a hospital. The study population consisted of all medical records of inpatients during the study period. The sample size was determined using the proportion formula for cross-sectional designs because the variables under study are categorical, namely:

$$n = \frac{Z^2 \cdot p \cdot (1-p)}{d^2} \quad (1)$$

Where n is the sample size, Z is the value at the 95% confidence level (1.96), p is the assumed event proportion of 0.5 (since it is not yet known with certainty), and d is the precision of 0.1. Based on the calculation, the minimum sample size is 96, to which 20% is added to account for incomplete data, resulting in a final sample size of 120 medical records. The sampling technique used was systematic random sampling, which involves systematically selecting samples from the population at specific intervals. The sampling interval (k) was determined using the formula k = N/n, where N is the population size and n is the sample size. As an illustration, if the population consists of 600 medical records, the interval value is 5, so sampling is performed by selecting every 5th record from the population list. The starting point is determined randomly between 1 and the interval value, then the process continues systematically until the required sample size is reached. Prior to data collection, permission to conduct the study was obtained from the hospital management. This study

used secondary data from medical records and maintained the confidentiality of patient information by anonymizing all patient identities. The research process was conducted in accordance with research ethics principles, including confidentiality, privacy, and data protection.

To ensure data quality, inclusion and exclusion criteria were established. Inclusion criteria include: (1) medical records of inpatients with informed consent forms, (2) records involving medical procedures requiring consent, and (3) records that are available and accessible at the time of the study. Meanwhile, the exclusion criteria include: (1) medical records that are missing or cannot be found, (2) records with damaged or illegible informed consent forms, and (3) records of patients without identification that do not allow for an objective assessment of completeness.

The variables in this study consist of dependent and independent variables. The dependent variable is incomplete informed consent, while the independent variables include staff knowledge, length of service, workload, and compliance with standard operating procedures (SOPs). Data collection was conducted using an instrument in the form of an informed consent completeness checklist developed based on the provisions of Ministry of Health Regulation No. 290 of 2008 on Consent for Medical Procedures. Data analysis was performed in stages, namely univariate and bivariate analysis. Univariate analysis was used to describe the frequency distribution of each study variable. Subsequently, bivariate analysis was performed using the Chi-square test to determine the relationship between independent and dependent variables with a significance level (α) of 0.05. Statistical test results were considered significant if the p-value was < 0.05.

RESULTS

1. Univariate Analysis

Table 1. Frequency Distribution of Research Variable Characteristics in Inpatients

Variable	Category	Frequency	Presentation (%)
IC Qualifications	Complete	45	37,5
	Incomplete	75	62,5
Knowledge	Good	50	41,7
	Lack of knowledge	70	58,3
Years of Experience	≥ 5 years	55	45,8
	< 5 years	65	54,2
Workload	Light	40	33,3
	Heavy	80	66,7
SOP Compliance	Compliant	48	40
	Non-Compliant	72	60

Based on the results of a univariate analysis of 120 medical records of inpatients, it was found that the majority of informed consent documents fell into the incomplete category, totaling 75 records (62.5%), while only 45 records (37.5%) were complete. This indicates that the rate of incomplete informed consent remains relatively high and does not yet meet the expected standards

for medical record completeness. Regarding staff knowledge, the majority of respondents had insufficient knowledge, totaling 70 individuals (58.3%), while only 50 individuals (41.7%) demonstrated adequate knowledge. This situation indicates that there remains a lack of understanding among staff regarding the importance of completing informed consent forms in full accordance with applicable standards. Based on length of service, the majority of staff had less than 5 years of service, totaling 65 people (54.2%), while those with ≥5 years of service numbered 55 people (45.8%). This distribution indicates that most staff still fall into the category of relatively lower work experience.

Regarding the workload variable, the majority of respondents fell into the heavy workload category, totaling 80 people (66.7%), while those with a light workload numbered 40 people (33.3%). This high proportion of heavy workloads may be one of the factors influencing the quality of medical record documentation, including informed consent forms. Meanwhile, regarding compliance with standard operating procedures (SOPs), the majority of respondents were non-compliant, totaling 72 individuals (60%), while only 48 individuals (40%) were compliant. This indicates that the level of compliance with established procedures remains low, which could potentially lead to incomplete completion of informed consent forms. Overall, the results of the univariate analysis show that the incompleteness of informed consent remains high and is accompanied by a significant proportion of risk factors such as insufficient knowledge, heavy workload, and low compliance with SOPs. This situation indicates a potential association between these factors and the incompleteness of informed consent, which will be further analyzed in the bivariate analysis.

2. Bivariate Analysis

Table 2. Relationship Between Knowledge, Length of Service, Workload, and Compliance with Standard Operating Procedures and Incomplete Informed Consent in the Medical Records of Inpatients

Variable	Category	Incomplete	Complete	p-value	OR	CI 95 %
Knowledge	Good	55	15	0,002	5,5	2,39 – 12,64
	Lack of knowledge	20	30			
Years of Experience	≥ 5 years	45	20	0,087	1,88	0,89 – 3,98
	< 5 years	30	25			
Workload	Light	60	20	0,004	5,0	2,19 – 11,42
	Heavy	15	25			
SOP Compliance	Compliant	58	14	0,001	7,55	3,19 – 17,85
	Non-Compliant	17	31			

The results of the bivariate analysis indicate an association between several factors and the incompleteness of informed consent in the medical records of inpatients. For the variable of staff knowledge, a p-value of 0.002 ($p < 0.05$) was obtained, indicating a significant association between staff knowledge and the completeness of informed consent. The proportion of incompleteness was

higher among staff with lower knowledge (55 out of 70 individuals) compared to those with good knowledge (20 out of 50 individuals). This indicates that the lower the staff's knowledge level, the greater the likelihood of incompleteness in the completion of informed consent forms. For the length of service variable, a p-value of 0.087 ($p > 0.05$) was obtained, indicating that there is no significant relationship between length of service and the completeness of informed consent. Although proportionally, more staff with <5 years of service had incomplete forms (45 people) compared to those with ≥5 years (30 people), statistically this difference is not significant. This indicates that length of service does not directly influence the completeness of informed consent forms.

For the workload variable, a p-value of 0.004 ($p < 0.05$) was obtained, indicating a significant association between workload and the completeness of informed consent forms. Staff with a heavy workload had a higher proportion of incomplete forms (60 out of 80 individuals) compared to staff with a light workload (15 out of 40 individuals). This indicates that the higher the workload, the greater the likelihood of incompleteness in document completion. Furthermore, for the variable of compliance with SOPs, a p-value of 0.001 ($p < 0.05$) was obtained, indicating a significant association between SOP compliance and the completeness of informed consent. Staff who did not adhere to SOPs had a significantly higher proportion of incompleteness (58 out of 72 people) compared to those who did adhere (17 out of 48 people). This indicates that adherence to standard operating procedures plays a crucial role in ensuring the completeness of informed consent forms.

Overall, the results of the bivariate analysis indicate that knowledge, workload, and adherence to standard operating procedures (SOPs) are significantly associated with incomplete informed consent forms, whereas length of service is not significantly associated. These findings suggest that both individual factors and factors within the healthcare system play a role in determining the quality of medical record documentation.

DISCUSSION

The study results indicate that the rate of incomplete informed consent remains high, at 62.5%. These findings suggest that the quality of medical record documentation, particularly regarding informed consent, is still suboptimal. This situation aligns with studies showing that the completeness of informed consent in hospitals has not yet met expected standards, and various deficiencies in form completion are still observed (Putri et al., 2022; Kusumawati et al., 2022). This finding indicates that informed consent documentation has not yet become an optimal component of quality assurance in healthcare services. Incomplete informed consent may not only affect administrative quality but may also weaken legal protection and patient safety implementation within hospital services. This condition reflects that documentation compliance remains a systemic challenge in healthcare management. Regulatory-wise, this situation does not comply with the provisions of Ministry of Health Regulation No. 269 of 2008, which requires that every healthcare service be documented completely, clearly, and accurately

The results of the analysis indicate that staff knowledge has a significant association with the completeness of informed consent. Staff with low levels of knowledge tend to have a higher proportion of incomplete informed consent forms. This finding aligns with the research by Rizkika & Sugiarti (2022), which states that knowledge is one of the main causes of incomplete informed consent documents. Theoretically, knowledge is a predisposing factor that influences an individual's behavior at work (Sari & Handayani 2022). A lack of understanding regarding the importance of informed consent both from legal and patient safety perspectives can lead staff to neglect the completeness of document completion. In practice, healthcare workers who have limited understanding regarding the legal and ethical implications of informed consent tend to perceive documentation merely as an administrative task rather than an essential patient protection mechanism. This situation may reduce awareness regarding the importance of complete documentation as part of healthcare accountability and professional standards. This contradicts Ministry of Health Regulation No. 290 of 2008, which stipulates that every medical procedure must be accompanied by complete and legally valid consent.

The workload variable also showed a significant association with incomplete informed consent. Healthcare workers with heavy workloads are more likely to fail to complete documents optimally. These findings align with research showing that high workloads negatively impact the quality of medical record documentation (Rizkika & Sugiarti, 2022). High workloads cause healthcare workers to prioritize clinical actions over administrative tasks, resulting in incomplete informed consent forms. Heavy workload conditions may also contribute to work fatigue, decreased concentration, and time limitations among healthcare workers, thereby affecting documentation accuracy and completeness. This finding suggests that incomplete informed consent should not only be viewed as individual negligence but also as a consequence of organizational workload management within healthcare facilities.

Compliance with standard operating procedures (SOPs) was the most dominant factor in this study and was significantly associated with the completeness of informed consent. Staff who did not comply with SOPs had significantly higher rates of incompleteness. This finding is supported by the study by Pont & Enggar (2022), which shows that the implementation of healthcare procedures, including informed consent, is greatly influenced by the level of healthcare workers' compliance with applicable regulations. SOPs are work guidelines designed to ensure that every procedure is performed consistently and in accordance with standards. Low compliance indicates that regulatory implementation is not yet optimal, even though Ministry of Health Regulation No. 269 of 2008 stipulates that medical records must be completed fully and in a timely manner.

Meanwhile, the length of service variable did not show a significant relationship with the completeness of informed consent. This indicates that work experience does not always correlate directly with compliance in document completion. These findings align with the research by Lakhmudien et al. (2022), which showed that understanding and compliance with the medical record system are more influenced by training and work systems than by length of work experience.

Thus, even though healthcare workers have longer tenure, this does not guarantee compliance if it is not supported by a good monitoring system. Furthermore, from a legal perspective, incomplete informed consent can lead to serious consequences. Informed consent is a key piece of evidence in medical disputes; therefore, its completeness is crucial to the legal validity of the healthcare services provided (Sinaga, 2021). Consequently, incomplete informed consent forms can increase legal risks for healthcare providers and healthcare institutions.

Overall, the results of this study indicate that the incompleteness of informed consent is influenced by a combination of individual and systemic factors. Individual factors include healthcare providers' knowledge, while systemic factors include workload and adherence to standard operating procedures (SOPs). These findings are further supported by the study by Bachri et al. (2022), which states that legal aspects, the healthcare system, and healthcare providers' behavior collectively influence the quality of informed consent. Therefore, comprehensive efforts are needed through enhancing healthcare providers' competencies, strengthening oversight, and optimizing the implementation of regulations to improve the quality of medical records and patient safety.

In addition to the factors already identified, the quality of informed consent is also influenced by patient safety and the safety culture within healthcare facilities. A global study by the World Health Organization confirms that complete clinical documentation, including informed consent, is a critical component of patient safety systems for preventing adverse events (WHO, 2021). Incomplete documentation can lead to miscommunication among healthcare providers and increase the risk of medical errors. Another international study by the Agency for Healthcare Research and Quality indicates that the quality of medical documentation is significantly influenced by teamwork systems and communication among healthcare professionals (AHRQ, 2022). In this context, incomplete informed consent is not only an individual's responsibility but also reflects weak team coordination in healthcare services. This aligns with the findings of this study that systemic factors, such as workload and adherence to standard operating procedures (SOPs), play a significant role.

In Indonesia, the advancement of digital transformation in healthcare also presents opportunities to improve the completeness of informed consent. The implementation of electronic medical records, as regulated by Ministry of Health Regulation No. 24 of 2022 on Medical Records, enables automated control systems, such as mandatory fields and data validation. Research by Lakhmudien et al. (2022) indicates that the use of electronic systems can improve healthcare providers' compliance in completing medical records, including informed consent. Thus, digitization serves as a strategic solution to address issues of incomplete documentation.

Additionally, patients' health literacy also influences the quality of informed consent. International research by the National Academies of Sciences emphasizes that patients' limited understanding of medical information can hinder the optimal process of consenting to medical procedures (National Academies, 2020). In practice, healthcare providers' time constraints and the complexity of medical information often result in the patient education process not being fully

effective, thereby impacting the completeness and quality of informed consent. From a quality management perspective, the continuous quality improvement (CQI) approach is highly relevant for improving the completeness of medical records. Internal medical record audits, periodic training, and providing feedback to healthcare workers have proven effective in improving documentation compliance (Indonesian Ministry of Health, 2022). This indicates that system-based interventions are more effective than relying solely on individual factors.

Furthermore, from a risk management perspective, incomplete informed consent can increase the potential for malpractice claims. A study by The Joint Commission confirms that incomplete documentation is one of the primary factors in medical litigation cases (The Joint Commission, 2021). Therefore, the completeness of informed consent must be a priority in hospital risk management systems. Considering these various findings, it can be affirmed that improving the completeness of informed consent requires a multidimensional approach that includes strengthening healthcare workers' competencies, improving work systems, utilizing information technology, and enhancing patient literacy. The integration of policies, clinical practices, and management systems is key to achieving optimal healthcare quality that is patient-safety oriented.

CONCLUSIONS

Based on the results of the study, it can be concluded that the rate of incomplete informed consent in inpatient medical records remains relatively high at 62.5%, indicating that the quality of medical record documentation has not yet reached optimal standards. The results of the bivariate analysis showed significant associations between staff knowledge, workload, and compliance with standard operating procedures (SOPs) and the incompleteness of informed consent documentation. Staff with poor knowledge, heavy workloads, and non-compliant with SOPs were more likely to produce incomplete informed consent forms. Among these variables, compliance with SOPs was identified as the most dominant factor (OR = 7.55), followed by knowledge (OR = 5.5) and workload (OR = 5.0). Meanwhile, years of experience did not show a significant association with incomplete informed consent, suggesting that work duration alone does not directly influence documentation quality. Overall, the findings indicate that incomplete informed consent is influenced by both individual and organizational factors, highlighting the importance of strengthening staff compliance, improving supervision systems, and enhancing documentation practices to support healthcare quality and patient safety.

REFERENCES

Agency for Healthcare Research and Quality. (2022). *Patient safety and medical documentation*. Agency for Healthcare Research and Quality. https://www.ahrq.gov

Bachri, S., Nurnaeni, & Nabila. (2022). Legal aspects of the completeness of the medical action consent form (informed consent). *Jurnal Berita Kesehatan, 15*(1), 77–89. https://doi.org/10.58294/jbk.v15i1.96

Kementerian Kesehatan Republik Indonesia. (2008). *Regulation of the Minister of Health of the Republic of Indonesia Number 269/MENKES/PER/III/2008 concerning medical records*. Kementerian Kesehatan Republik Indonesia.

Kementerian Kesehatan Republik Indonesia. (2008). *Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning approval of medical procedures*. Kementerian Kesehatan Republik Indonesia.

Kementerian Kesehatan Republik Indonesia. (2022). *Regulation of the Minister of Health of the Republic of Indonesia Number 24 of 2022 concerning medical records*. Kementerian Kesehatan Republik Indonesia.

Kusumawati, P. D., Widiyanto, W. W., & Sukmaningsih, W. R. (2022). Analysis of the completeness of filling out the informed consent form for inpatient surgical cases. *Journal Health Information Management Indonesian, 3*(1). https://doi.org/10.46808/jhimi.v3i1.103

Lakhmudien, L., et al. (2022). Medical recorders' understanding of electronic medical records based on Minister of Health Regulation No. 24 of 2022. *Jurnal Cakrawala Ilmiah, 2*(9). https://doi.org/10.53625/jcijurnalcakrawalailmiah.v2i9.5803

National Academies of Sciences. (2020). *Health literacy and patient communication*. National Academies of Sciences. https://www.nationalacademies.org

Pont, A. V., & Enggar. (2022). Application of informed consent in medical services at hospitals. *Poltekita: Jurnal Ilmu Kesehatan, 17*(1). https://doi.org/10.33860/jik.v17i1.2022

Putri, R. S. E., Kusumo, R., & Larasati, A. H. (2022). Analysis of the completeness of filling out informed consent in the inpatient ward. *Jurnal Rekam Medis, 2*(3), 370–380. https://doi.org/10.25311/jrm.Vol2.Iss3.993

Rizkika, S. N., & Sugiarti, I. (2022). Factors for completeness of informed consent using the fishbone method. *Jurnal Manajemen Informasi Kesehatan Indonesia, 10*(2), 142–150. https://doi.org/10.33560/jmiki.v10i2.445

Sari, D. P., & Handayani, L. (2022). Factors affecting healthcare workers' compliance in medical record documentation. *Jurnal Administrasi Kesehatan Indonesia, 10*(2), 115–123.

Sinaga, N. A. (2021). The legal force of informed consent and medical records as evidence in medical disputes. *Jurnal Ilmiah Hukum Dirgantara, 12*(2). https://doi.org/10.35968/jihd.v12i2.955

The Joint Commission. (2021). *Documentation standards in healthcare*. The Joint Commission. https://www.jointcommission.org

World Health Organization. (2021). *Patient safety and quality of care*. World Health Organization. https://www.who.int

World Medical Association. (2022). *WMA Declaration of Lisbon on the Rights of the Patient*. World Medical Association. https://www.wma.net