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Physician Knowledge and Training as Determinants of Informed Consent Implementation: A Cross-Sectional Study in Two Indonesian Hospitals

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ABSTRACT

This study aims to analyze the relationship between physicians' knowledge of informed consent and the completeness of its implementation in medical procedures. The research employed an observational analytic approach with a cross-sectional design and quantitative methods. The study population consisted of general practitioners, specialists, dentists, and dental specialists working at Banten Provincial General Hospital and Dr. Drajat Prawiranegara Regional General Hospital. A total of 94 physicians were included as respondents. The variables examined included physicians' knowledge of informed consent, the completeness of its implementation, and respondent characteristics such as age, years of service, and training history. Data were analyzed using the chi-square test with a significance level of $p < 0.05$. The results indicated a significant association between physicians' knowledge, years of service, and prior training with the completeness of informed consent implementation. Physicians with good knowledge demonstrated a higher likelihood of complete implementation (OR 10.6; 95% CI 3.7–30.4) compared to those with poorer knowledge. Similarly, physicians with less than five years of service had a higher rate of complete informed consent implementation (78%) compared to those with five or more years of service (57.1%). Moreover, those who had received training were significantly more likely to implement informed consent completely (OR 6.95; 95% CI 1.51-31.94) than those without training experience. In contrast, physician age was not significantly associated with informed consent completeness. In conclusion, enhancing physician knowledge and promoting ongoing training are essential to improving the quality of informed consent practices in clinical settings.

Key Messages:

- Physician knowledge and training on informed consent are the primary determinants of its complete implementation; doctors with good knowledge and a history of training are proven to be significantly more compliant in thoroughly applying the procedure.

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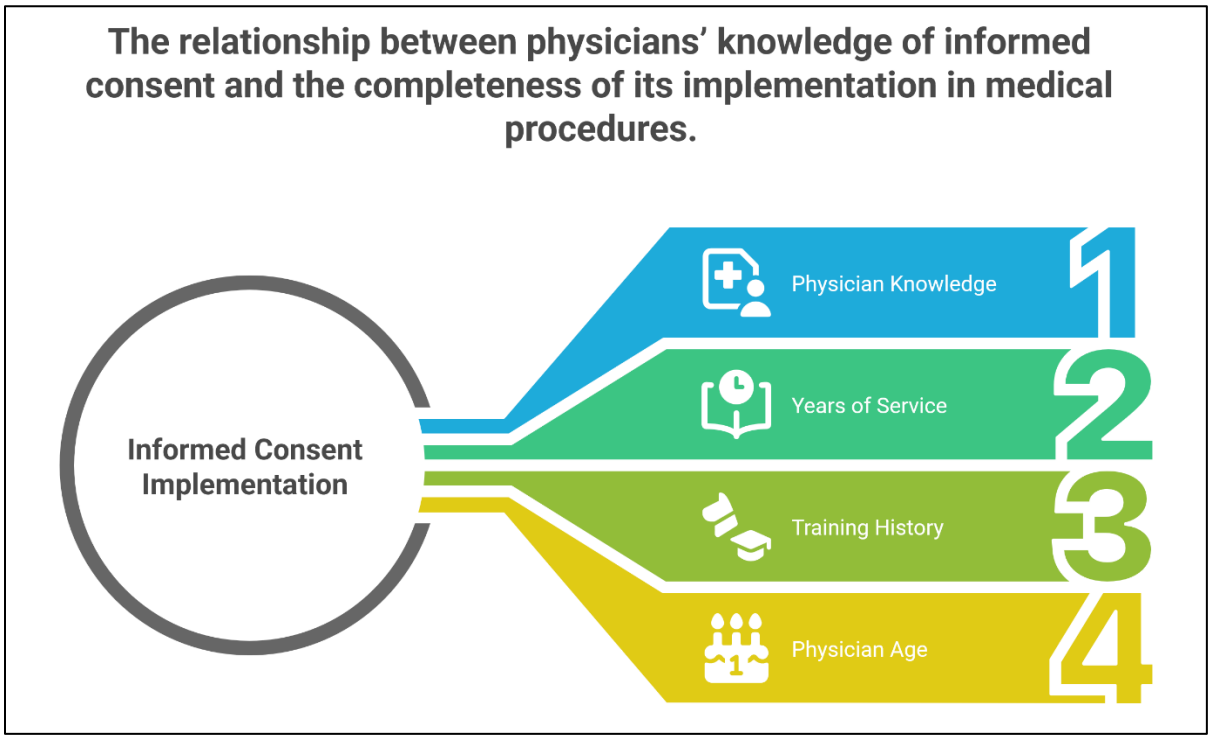
GRAPHICAL ABSTRACT



INTRODUCTION

Medical action consent, or informed consent, is a crucial aspect of modern medical practice (1). It is not only an ethical and legal obligation for physicians but also a fundamental right of patients in making decisions regarding their healthcare. Properly implemented informed consent serves as a safeguard for both patients and physicians, protecting them from potential legal and ethical risks throughout the course of medical care.

The development of informed consent regulations in Indonesia has shown significant progress, culminating in the enactment of Law No. 17 of 2023 on Health. This law reinforces informed consent as both a fundamental patient right and an ethical-legal duty of healthcare professionals, emphasizing the importance of information quality, patient understanding, and comprehensive documentation. Its implementation holds the potential to improve doctor-patient communication, standardize informed consent procedures, and enhance public health literacy (2).

Obtaining informed consent prior to any medical procedure is a critical responsibility for physicians and must be conducted in accordance with established standards and regulations (3). When carried out appropriately, informed consent can protect patients from malpractice and physicians from unreasonable legal claims. Conversely, incomplete implementation may constitute a disciplinary violation and result in sanctions against the physician (4). A physician's level of knowledge about informed consent is therefore a key factor in securing adequate consent from patients and ensuring that the process aligns with professional standards.

Moreover, several hospitals in Indonesia have observed that although many healthcare providers are aware of the importance of informed consent, there is still considerable variation in its practical application. Contributing factors include time constraints, high workloads, and patients' limited understanding of medical terminology (2). International studies have similarly highlighted a persistent gap between healthcare professionals' knowledge of informed consent principles and their consistent application in practice, indicating this is a widespread challenge not unique to Indonesia. However, the correlation between physicians' knowledge of informed consent and the completeness of its implementation remains unclear at Banten Provincial General Hospital (RSUD Provinsi Banten) and Dr. Drajat Prawiranegara Regional General Hospital (RSUD Dr. Drajat Prawiranegara).

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In light of this, the present study aims to analyze the relationship between physicians' knowledge of informed consent and the completeness of its implementation in medical practice. This study hypothesizes that factors such as knowledge, training history, and years of service are key determinants influencing the thoroughness of informed consent implementation, aiming to provide a clearer theoretical premise for investigation.

METHODS

This study employed an observational analytic design with a cross-sectional approach and quantitative methods. The research was conducted at Banten Provincial General Hospital (RSUD Provinsi Banten) and Dr. Drajat Prawiranegara Regional General Hospital (RSUD Dr. Drajat Prawiranegara). Data collection took place between February and May 2024.

The study population consisted of medical professionals, including general practitioners, medical specialists, dentists, and dental specialists working at both Banten Provincial General Hospital and Dr. Drajat Prawiranegara Regional General Hospital. A minimum sample size of 94 participants was determined and selected using a consecutive sampling method from both hospital sites.

Physicians' Knowledge of Informed Consent

Physicians' knowledge of informed consent was defined as their understanding of several key aspects: the definition, purpose, and function of informed consent; the components it must include; the individuals authorized to give consent; who is entitled to receive information and provide consent; the processes for refusal or withdrawal of consent; and exceptions or special situations regarding informed consent. Knowledge was categorized based on a scoring system, where a score of ≥73 indicated good knowledge, and a score below 73 indicated insufficient knowledge. This cutoff was established based on Bloom's taxonomy, where a score of 73% or higher is considered to represent a level of mastery sufficient for competent practice.

Completeness of Informed Consent Implementation

To assess the completeness of informed consent implementation, the researchers examined informed consent forms and written consent sheets completed by the subjects. Each component of the informed consent was reviewed. If any required element was missing, the consent process was considered incomplete. The essential components evaluated via the checklist included: (1) patient identification, (2) a clear diagnosis, (3) the proposed medical procedure, (4) explanation of risks, (5) potential benefits, (6) alternative treatments, and (7) valid signatures from the patient (or proxy) and the physician, along with the date.

Respondent Characteristics

Age was defined as the length of time an individual had lived, calculated from the date of birth listed on an official identity document (such as a national ID or driver's license) to the date the questionnaire was completed. Respondents were grouped into two categories: <33.5 years and ≥33.5 years. Years of service referred to the duration of a physician's professional practice, calculated from the year they began working up to the date of data collection. This variable was categorized into <5 years and ≥5 years of service. Training was defined as whether or not the physician had previously attended a formal training session specifically focused on the implementation of informed consent in medical procedures.

The appropriateness of the signatory on the informed consent form was assessed by evaluating whether the person who signed the form matched the patient's capacity to provide consent. A patient was considered competent if they met all of the following criteria: aged over 18 years or legally married, fully conscious (GCS score of 15), and without any mental health disorders. In cases where the patient was deemed competent, the patient themselves should have signed the informed consent form. If the patient was not competent, a representative was required to sign on their behalf.

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Instruments

The questionnaire used in this study consisted of questions assessing physicians' knowledge of informed consent, based on the legal frameworks governing its implementation. A checklist was employed to evaluate the completeness of informed consent documentation, based on components found in the informed consent forms and approval sheets used at Banten Provincial General Hospital and Dr. Drajat Prawiranegara Regional General Hospital. These components included: patient identification, provision of information, types of information given, and signatures.

In addition, a separate checklist was used to assess the appropriateness of the signatory and recipient of information. This was done using data extracted from the patient's medical records and the informed consent form. The items assessed included the patient's age, marital status, GCS score, and the presence or absence of mental disorders.

Data Analysis

Data analysis was conducted using the chi-square test with a 95% confidence interval. Results were presented in the form of odds ratios (OR), with a p-value of <0.05 considered statistically significant.

This study received ethical clearance from the Health Research Ethics Committee of Universitas Sultan Ageng Tirtayasa under reference number 12/UN43.20/KEPK/2024. Permissions for data collection were also granted by Banten Provincial General Hospital (Letter No. 900/PEP-0103/III/2024) and Dr. Drajat Prawiranegara Regional General Hospital (Letter No. 800/Tim Kordik 117/III/2024)

RESULTS

Table 1 presents the characteristics of the respondents. The distribution of age among the physicians was balanced, with 47 respondents (50%) categorized as older (≥34 years) and 47 (50%) as younger (<34 years). The majority of respondents were female, totaling 64 individuals (68.1%). In terms of length of service, most physicians (59 respondents or 62.8%) had worked for less than five years. A significant proportion, about 69 physicians (73.4%), had never participated in training related to medical record completion or informed consent documentation. Regarding workplace distribution, 54 doctors (57.4%) were employed at Banten Provincial General Hospital, while 40 (42.6%) worked at Dr. Drajat Prawiranegara Regional General Hospital. As for the professional categories, 51.06% of respondents were general practitioners, 20.2% were dentists, 26.5% were medical specialists, and 2.24% were dental specialists.

Table 1. Respondent Characteristics

Characteristics	n	%
Age		
≥ 34 y.o	47	50.0
< 34 y.o	47	50.0
Gender		
Female	64	68.1
Male	30	31.9
Years of services		
≥ 5 years	35	37.2
< 5 years	59	62.8
Training history		
Attended	25	26.6
Never attended	69	73.4
Place of work		
Banten Provincial General Hospital	54	57.4
Dr. Drajat Prawiranegara Regional General Hospital	40	42.6

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Table 2. Association Between Physicians' Knowledge, Age, Years of Service, and Training History on Informed Consent and the Completeness of Its Implementation

Variable	Completeness				P *value**	OR (95% CI)
	Complete		Incomplete			
	n	%	n	%		
Knowledge						
Good	49	89.1	6	10.9	<0.001	10.6 (3.7- 30.4)
Poor	17	43.6	22	56.4		
Age						
≥34 y.o	32	68.1	15	31.9	0.652	0.81 (0.33-1.97)
<34 y.o	34	72.3	13	27.7		
Years of service						
≥5 years	20	57.1	15	35.0	0.03	0.37 (0.15-0.93)
<5 years	46	78.0	13	59.0		
Training history						
Attended	23	92.0	2	8.0	0.005	6.95 (1.51-31.94)
Never attended	43	62.3	26	37.7		

Table 2 presents the association between physicians' knowledge, age, length of professional service, and prior training on informed consent with the completeness of its implementation. The data show a marked difference in completeness based on knowledge levels. Physicians who demonstrated a good level of knowledge regarding informed consent procedures were significantly more likely to perform complete informed consent documentation, with 89.1% achieving completeness. In contrast, only 43.6% of physicians with poorer knowledge achieved the same. This difference was statistically significant, as indicated by a p-value of less than 0.001. Furthermore, the odds ratio (OR) was calculated at 10.6 with a 95% confidence interval (CI) of 3.7 to 30.4, suggesting that physicians with a good understanding of informed consent were more than ten times as likely to complete the informed consent process properly compared to those with inadequate knowledge.

With regard to age, the results suggest that it is not a significant determinant of informed consent completeness. Among physicians aged 34 years or older, 68.1% achieved complete implementation, compared to 72.3% among those under 34. The difference was not statistically significant (p = 0.652), and the odds ratio of 0.81 (95% CI: 0.33–1.97) further confirms that age was not a meaningful predictor in this context.

Interestingly, the length of professional experience was shown to influence performance. Physicians with less than five years of experience had a higher rate of completeness (78%) compared to those with five or more years of service (57.1%). This relationship was statistically significant, as evidenced by a p-value of 0.030. The calculated odds ratio was 0.37 (95% CI: 0.15–0.93), indicating that physicians with longer professional tenure were approximately 63% less likely to complete the informed consent process adequately compared to their less experienced colleagues. This counterintuitive result may point to possible complacency or outdated procedural habits among more senior physicians.

Finally, training emerged as a critical factor influencing performance. Physicians who had previously participated in training related to informed consent procedures were found to have a much higher rate of completeness (92%) compared to those who had never received such training (62.3%). This association was highly statistically significant (p = 0.005), with an odds ratio of 6.95 (95% CI: 1.51–31.94). These findings suggest that participation in relevant training programs increases the likelihood of implementing informed consent thoroughly by nearly seven times. Thus, training interventions appear to be a highly effective strategy for improving compliance with ethical and legal standards in clinical practice.

DISCUSSION

Our analysis demonstrates a statistically significant association between physicians' knowledge and the completeness of informed consent implementation. Physicians with a strong understanding of informed consent were substantially more likely to document and execute the process comprehensively. Specifically, 89.1% of physicians with good knowledge achieved complete informed consent, compared to

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only 43.6% among those with poorer knowledge. The p-value of <0.001 confirms a highly significant relationship, while the odds ratio (OR) of 10.6 (95% CI: 3.7–30.4) indicates that physicians with good knowledge were over ten times more likely to ensure complete informed consent than their less-informed counterparts.

This finding highlights the central role of knowledge in facilitating effective and comprehensive informed consent practices. As Wahyuni, Laskarwati, & Al Qulub, 2020 (5) emphasize, physicians who understand the legal frameworks and procedural provisions governing informed consent are more likely to implement it conscientiously and consistently in clinical settings. Similarly, a study conducted at Dr. Moewardi Regional General Hospital and Kasih Ibu Hospital in Surakarta in 2014 reported that physicians generally possessed a high level of knowledge concerning the components of information delivery within the informed consent process (6). However, knowledge alone does not always translate into practice. Research by Fikriya, Sriatmi, & Jati, 2016 (7) indicates that while physicians may exhibit strong cognitive understanding of informed consent, the actual implementation in clinical practice is often suboptimal. Healthcare providers with adequate knowledge of surgical consent were found to be 2.5 times more likely to adhere to proper informed consent practices compared to their counterparts with insufficient knowledge (8,9). Comprehensive knowledge includes an understanding of the elements of consent, the applicable legal framework, and the patient's capacity for decision-making (10). Without a strong foundation of knowledge, informed consent risks becoming just another form-filling process, rather than a process of communication and shared decision-making between doctor and patient(11). Therefore, increasing knowledge should be a primary target in any intervention to improve informed consent practices.

In contrast, the variable of physician age was not found to significantly influence the completeness of informed consent procedures. The statistical analysis yielded a p-value of 0.652, and the odds ratio of 0.81 (95% CI: 0.33–1.97) suggests that age does not meaningfully affect informed consent performance. This indicates that other factors, particularly knowledge and formal training may have a greater impact on physicians' ability to conduct thorough informed consent procedures than chronological age.

Interestingly, the study also revealed that physicians with less than five years of professional experience had higher rates of complete informed consent (78%) compared to those with five or more years of experience (57.1%). This association was statistically significant, with a p-value of 0.03 and an odds ratio of 0.37 (95% CI: 0.15–0.93). These findings imply that early-career physicians may exhibit greater diligence or attentiveness to procedural requirements, potentially due to more recent training or heightened awareness of legal and ethical responsibilities associated with informed consent. This counters the common assumption that longer professional experience correlates with improved performance in documentation and communication. This trend may also reflect systemic factors, such as recent changes in medical school curricula that place a greater emphasis on medico-legal ethics and patient communication, potentially equipping newer graduates with a more robust framework for informed consent from the outset of their careers.

While it is generally assumed that longer work experience is positively associated with greater competency and adaptation to job demands, existing research suggests that this may not always be the case. A previous study found that regardless of whether physicians had short, moderate, or long durations of experience, over 50% failed to complete medical records adequately (12). This suggests that length of service may not be a reliable predictor of adherence to documentation standards, and underscores the importance of continuous professional development and refresher training for all physicians, regardless of tenure.

Additional findings indicate that differences in the completeness of medical record documentation based on years of professional experience may be attributed to increased familiarity and improved efficiency over time. As individuals spend more years working in the same environment, they are more likely to develop time management skills, professional discipline, and task organization capabilities, which in turn enhance the quality of their work output (13). In the context of physicians, longer service in the medical profession is expected to foster a deeper understanding of the significance of thorough medical

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record documentation, especially when physicians begin to recognize the functional and legal benefits that comprehensive records provide.

Moreover, recent shifts in the professional landscape of medicine may partly explain variations in performance. Junior doctors are often more adept with digital systems and technological tools, which support faster and more efficient documentation practices, including the execution of informed consent procedures. This generational familiarity with digital platforms may contribute to the higher documentation accuracy and completeness observed among younger physicians.

Training on informed consent has also been shown to significantly enhance the quality and completeness of its implementation. Physicians who had previously participated in informed consent training programs demonstrated a considerably higher rate of completeness in executing informed consent (92%) compared to those without such training (62.3%). This association was statistically significant ($p = 0.005$), with an odds ratio (OR) of 6.95 (95% CI: 1.51–31.94), indicating that physicians who have undergone training are nearly seven times more likely to carry out complete informed consent procedures than those who have not. Medical students and new interns lack confidence and competence in conducting informed consent discussions (14). Another study found that effective surgical informed consent practice is influenced by four key factors among healthcare providers (8): a minimum of 5 years of work experience, adequate knowledge, a positive attitude, and the absence of communication barriers. Therefore, improvement efforts should be focused on enhancing the knowledge, attitude, and communication skills of healthcare providers regarding the informed consent process(8). Therefore, the research recommends the creation of a specialized, practical, and needs-based training program to teach this skill, as well as the necessity of continuous evaluation to measure the program's success (14).

These findings underscore the critical role of structured and continuous training programs in reinforcing the principles and practices of informed consent. Incorporating periodic, formal training as part of institutional policies may serve as an effective strategy to improve compliance and elevate the quality of informed consent practices among healthcare professionals.

Nonetheless, several challenges continue to hinder the optimal implementation of informed consent procedures. According to a previous finding, common issues include insufficient training opportunities for healthcare staff, limited awareness regarding the importance of informed consent, time constraints, personnel shortages, inadequate supervision during documentation, the absence of digital backup systems, and the lack of integrated electronic platforms (15). Addressing these systemic barriers requires a multifaceted approach, in which continuous education plays a pivotal role. Ongoing professional development programs can help mitigate these challenges by enhancing awareness, improving time efficiency, and fostering accountability in the documentation process.

Based on these findings, several practical and policy implications emerge. Hospitals and national medical bodies should consider implementing mandatory, periodic training on informed consent for all physicians, irrespective of their tenure, to ensure standards are consistently met. Furthermore, developing standardized digital informed consent templates integrated into the electronic health record system could significantly improve compliance, reduce variability, and provide a reliable safeguard for both patients and practitioners. These actions would translate the study's findings into concrete strategies for improving medico-legal practice.

Despite the valuable insights gained from this study, several limitations must be acknowledged. First, the scope of this research was restricted to specific variables—namely physician knowledge, age, years of service, and participation in training programs. Other potentially influential factors, such as physician motivation, institutional support, or the presence of electronic health systems, were not thoroughly examined. Second, the cross-sectional design employed in this study limits the ability to infer causality between the independent and dependent variables. Finally, the generalizability of the findings may be limited, as the sample was drawn from a specific set of institutions and may not fully represent the broader population of physicians in different healthcare settings.

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CONCLUSION

This study demonstrates that physician knowledge, length of professional service, and participation in training related to informed consent are significantly associated with the completeness of informed consent implementation. Physicians with a good level of knowledge were found to be 10.6 times more likely to carry out the informed consent process completely compared to those with insufficient knowledge. Similarly, physicians with less than five years of experience reported a higher rate of completeness in performing informed consent (78%) than those with five or more years of experience (57.1%). Furthermore, doctors who had attended training on informed consent were 6.95 times more likely to execute the process in a complete manner compared to those who had never received such training. In contrast, the physician's age did not show a statistically significant influence on the completeness of informed consent implementation.

These findings highlight the crucial role of improving physician knowledge and providing ongoing training in efforts to enhance the quality of informed consent practices. Regular educational interventions may strengthen physicians' understanding of ethical and legal standards and improve documentation practices across healthcare settings.

Further research is recommended to explore other factors that may influence the completeness of informed consent implementation, including physician motivation, workload, and the level of institutional support, particularly in terms of resource allocation and the provision of electronic systems. Additionally, the development and evaluation of more structured and periodic training programs are essential to assess their long-term impact on informed consent practices. Future intervention studies involving the integration of digital tools or supervision systems during the informed consent process could also serve as a relevant direction for improving compliance and operational efficiency in clinical settings

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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