



The Accuracy of Information Recipients and Consent Givers for Informed Consent in Hospitals

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ABSTRACT

This study aimed to assess the accuracy of the party receiving information and giving consent in the hospital. This type of research is observational and was conducted at Public Hospital of Banten Province (RSUD Banten) and Dr. Dradjat Prawiranegara Public Hospital in 2024. The minimum sample size used was 94 samples taken using consecutive sampling methods. This study used a checklist as a record to check the completeness of the informed consent form and approval sheet by the SOP and applicable legal basis. Data analysis is descriptive of the accuracy of the party receiving information and giving consent. The study observed 28 pieces of information and consent being received and given by the right party, while the wrong party signed 66 (70.2%) consents for medical procedures. The study's focus on the accuracy of the party receiving information and giving consent in the hospital is a contribution to a monitor process of informed consent in hospital according to principles of patient's competency.

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Key Messages:

- The results of this study indicate the urgency to improve oversight of the informed consent process in hospitals. Hospitals need to develop clearer and more detailed procedures regarding who is authorized to give consent and ensure that patients or families fully understand the information provided.

Introduction

The complexity of the healthcare system necessitates a more holistic approach to patient care. Collaborative interdisciplinary models involving psychiatrists, other clinicians, and integrated case managers can improve care coordination, patient safety, and health outcomes while reducing costs (1). Additionally, understanding healthcare as a complex system and applying principles of complexity science may help guide future policies and avoid unintended consequences of regulation (2). This approach is intended to improve the process of informed consent of medical procedure in the hospital system.

Healthcare providers and patients often have differing perceptions about the sufficiency of information exchanged during informed consent processes. While patients and nurses may feel they have shared adequate information due to ongoing communication, therapeutic relationships, and use of lay terms (3), observational data suggests insufficient information exchange due to lost opportunities, paternalistic practices, and withholding of information (3). This discrepancy highlights the complexity of achieving truly informed consent. Interestingly, studies have found that patient recall and comprehension of risk information is generally poor, especially when conveyed only verbally (4). Providing written or video information in addition to verbal explanations can improve risk recall, comprehension, and patient satisfaction (4). However, in resource-constrained settings, challenges persist in effectively communicating risk information and addressing linguistic and cultural barriers (5).

In Indonesia, the doctrine of informed consent is articulated in several laws, including Law No. 36 of 2009 on Health, Law No. 29 of 2004 on Medical Practice, and Law No. 8 of 1999 on Consumer Protection. The recently enacted Law Number 17 of 2023 concerning Health further strengthens the foundation for implementing informed consent, emphasizing it as both a medical duty and a patient's right (6). This legal framework requires physicians to share comprehensive informations with patients and ensure of patient competency to give approval before obtaining their consent for medical procedure.

Interestingly, despite the robust legal framework, studies have revealed that implementing informed consent in various healthcare institutions in Indonesia is not always optimal. Many health workers merely ask patients and families to sign consent forms without providing detailed explanations, which can lead to potential issues if undesirable outcomes occur (7). This contradiction between legal requirements and actual practice highlights the need for improved awareness and implementation of informed consent procedures. This study aims to determine the description of the accuracy of the recipient of the information and the consent giver of medical actions at the Public Hospital of Banten Province and dr. Drajat Prawiranegara Public Hospital.

Methods

This type of research is observational which was conducted at Public Hospital of Banten Province and dr. Drajat Prawiranegara Public Hospital in 2024. The time taken for this study was February-May 2024. The population was general practitioners, specialists, dentists, and dental specialists who worked at Public Hospital of Banten Province or dr. Drajat Prawiranegara Public Hospital. The minimum sample size used was 94 samples taken using consecutive sampling methods from these hospitals. This study used a checklist as a record to check the completeness of the informed consent form and approval sheet by the SOP and applicable legal basis. The checklist assessed the completeness of informed consent from the items on the consent form and informed consent form Public Hospital of RSUD Banten and RSUD Dr Drajat Prawiranegara, including patient identity, information provision, type of information, and signature. In addition, a checklist of items on the medical record and consent form was used to assess the accuracy of the information recipient and consent giver; the items assessed from the medical record were age, marital status, GCS score, and the presence or absence of psychiatric disorders. Data analysis is descriptive of the accuracy of the parties receiving information and giving consent. This research has obtained a certificate of ethical feasibility from the Health Research Ethics Committee of Sultan Ageng Tirtayasa University with number 12/UN43.20/KEPK/2024. This research has also obtained permission from Public Hospital of Banten Province with letter number 900/PEP-0103/III/2024, and from dr. Drajat Prawiranegara Regional Hospital with letter number 800/Tim Kordik 117/III/2024.

Results

Figure 1 shows that 28 information and consents were received and given by the appropriate parties. The accuracy of the party receiving the information and giving consent was assessed by observing the patient's identity and data in the medical record, which indicated whether the patient was classified as competent or incompetent. The data assessed were the patient's age, marital status, level of consciousness using the Glasglow Coma Scale, and mental health condition. Of the 28 consents, 20 were from children under 18 years old and unmarried, represented by their parents, 6 were incompetent patients represented by their next of kin, and 2 were competent patients who signed themselves. Meanwhile, 66 (70.2%) consents were signed by inappropriate parties. In the condition that all patients were competent, spouses signed 33, 20 were signed by fathers/mothers, biological children signed 9, and relatives signed 4.

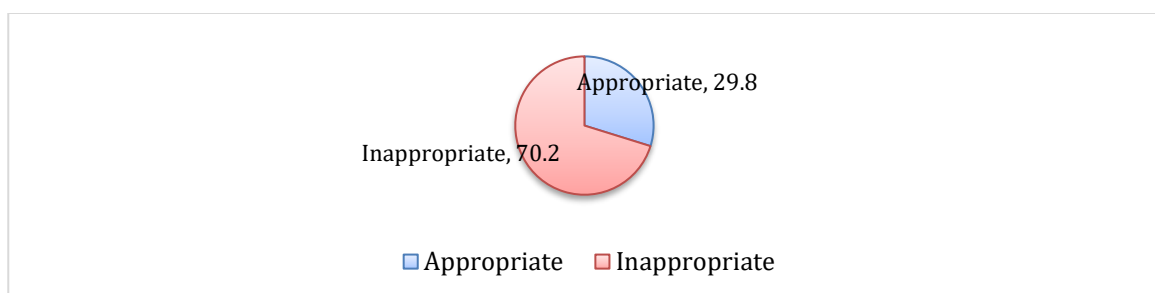


Figure 1. Accuracy of Parties Receiving Information and Giving Consent.

Discussion

An overview of the accuracy of the recipient of the information and the consent of medical actions at Public Hospital of Banten Province and dr. Drajat Prawiranegara Public Hospital is still largely inaccurate, which is 70.2%. The accuracy of the recipient of the information and the consent giver in this study was assessed by observing patient data to determine the suitability of the patient's condition (competent or not) with the party who signed the informed consent sheet. The accuracy of the recipient of information and the consent giver in this study in both hospitals was quite low, with a greater number of medical procedure consent sheets signed by inappropriate parties.

Based on Article 293 paragraph (6) of Law No. 17 of 2023 concerning Health, informed consent can be submitted by the closest family representative, including husband/wife, biological father/mother, biological children, and adult siblings, only if the patient's condition is incompetent. If, in the case of a competent patient, the person giving consent is not the patient, the doctor must refuse and ask the competent patient for consent again (8). In this study, there were still many inappropriate parties to give consent, especially many whom the patient's spouse represented. This can occur because patients are considered less able to understand the explanation and also because of the limited time so that the explanation and approval are given directly to the patient's companion, who is considered able to receive information and give consent more quickly (9,10).

Research on informed consent in Indonesian healthcare settings reveals significant challenges and areas for improvement in communication and consent processes. Studies indicate that while informed consent holds a strong legal position in Indonesian civil law, its implementation often falls short of ideal standards (6,11). The introduction of Law Number 17 of 2023 concerning Health aims to strengthen the foundation for informed consent implementation, emphasizing it as both a medical duty and a patient's right (6). However, gaps persist between theoretical principles and practical implementation, accentuated by resource limitations, law enforcement variations, and understanding among healthcare providers (12).

Interestingly, while most patients felt treated as unique, a significant gap exists in respecting cultural values and beliefs during decision-making (13). This highlights the need for healthcare providers to improve cultural sensitivity and patient engagement. In the context of cancer care, healthcare professionals appreciate the value of disclosing accurate information to patients but face challenges such as inadequate time for information disclosure, lack of privacy, and poor documentation (14). In Indonesia, the legal and ethical landscape surrounding medical decision-making is complex.

Conclusion

The accuracy of the recipient of the information and the consent giver of medical actions at Public Hospital of Banten Province and dr. Drajat Prawiranegara Hospital is still largely inaccurate, which is 70.2%. Future researchers who will conduct similar studies can analyze the relationship between the accuracy of the recipient of information and the consent giver of medical actions with the doctor's knowledge of informed consent and then assess the accuracy and quality of the form's contents.

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Conflicts of Interest: The authors declare no conflict of interest.

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