


The Relationship Between Informed Consent Provision and Anxiety in Patients Undergoing Elective Surgery at RSUD Waled, Cirebon Regency

Ouve Rahadiani Permana¹, Bambang Wibisono², Meilianda Ezizah³

Department Medical Education and Bioethics, Faculty of Medicine, Universitas Swadaya Gunung Jati, Jl. Terusan Pemuda, Sunyaragi, Kec. Kesambi, Kota Cirebon, Jawa Barat¹, Department Forensic and Ethicmedicolegal, Faculty of Medicine, Universitas Swadaya Gunung Jati, Jl. Terusan Pemuda, Sunyaragi, Kec. Kesambi, Kota Cirebon, Jawa Barat², Medical Student, Faculty of Medicine, Universitas Swadaya Gunung Jati, Jl. Terusan Pemuda, Sunyaragi, Kec. Kesambi, Kota Cirebon, Jawa Barat³

Article Info	ABSTRACT
Keywords: Informed Consent Anxiety Elective Surgery	The incidence of medical errors in Indonesia remains high, one of which is related to the provision of informed consent. Surgical procedures require informed consent, and one effort to reduce patient anxiety is by providing comprehensive information about the surgery through informed consent. Additionally, this process helps patients feel more confident and trusting toward the medical procedures performed by doctors. This study aims to analyze the relationship between informed consent provision and the level of anxiety in patients undergoing elective surgery at RSUD Waled, Cirebon Regency. This research is an analytical observational study with a cross-sectional design. Primary data were collected through questionnaires distributed to elective surgery patients at RSUD Waled, Cirebon Regency. The results showed that 67.1% of patients received complete informed consent, while 32.9% received incomplete informed consent. The levels of patient anxiety were categorized as follows: no anxiety (31.5%), mild anxiety (26.0%), moderate anxiety (9.6%), severe anxiety (8.2%), and very severe anxiety (21.9%). The findings indicate a significant correlation between informed consent provision and the level of anxiety in patients undergoing elective surgery at RSUD Waled, Cirebon Regency.
This is an open access article under the CC BY-NC license 	Bambang Wibisono Universitas Swadaya Gunung Jati Jl. Terusan Pemuda, Sunyaragi, Kec. Kesambi, Kota Cirebon, Jawa Barat bambangwibisono86@gmail.com

INTRODUCTION

Surgery is a form of medical therapy that can affect both the physiological and psychological conditions of patients. This procedure often triggers anxiety in both patients and their families, as it is perceived as a major event with significant risks, ranging from mild to severe complications, including permanent disability or even death. According to data from the (World Health Organization, 2020) approximately 230 million major surgical procedures are performed worldwide each year, with a medical error rate of 4%. Of these cases, 70% result in temporary disability, while 14% lead to death. In Indonesia, the incidence of medical errors remains relatively high. Reports on patient safety incidents in hospitals reveal that most

incidents are related to surgical procedures, with more than half classified as Unexpected Events (Kejadian Tidak Diharapkan, KTD).

One of the factors contributing to patients' fear of surgery is the lack of information about the procedure (Goldberger et al., 2011). Preoperative anxiety can be triggered by various factors, such as fear of anesthesia, surgical outcomes, changes in body image, and the risk of death (Zeb et al., 2018). Previous studies by (Fischbeck et al., 2021) have shown that patients who do not receive complete information tend to experience higher levels of anxiety and lower preparedness for surgery. Therefore, providing clear and comprehensive informed consent is one strategy to minimize patient anxiety before surgery. This aligns with (Undang-Undang (UU) Nomor 29 Tahun 2004 Tentang Praktik Kedokteran, 2004) and (Peraturan Menteri Kesehatan Nomor 290/MENKES/PER/III/2008 Tentang Persetujuan Tindakan Kedokteran, 2008) which state that every medical procedure must obtain patient consent after the doctor provides adequate and easily understandable information regarding the patient's condition and the planned procedure.

A previous study by (Wagiu et al., 2017) conducted at RSUP Prof. Dr. R.D. Kandou Manado found that patients who received complete informed consent tended to have lower anxiety levels compared to those who received incomplete informed consent. Based on this, the present study aims to examine the relationship between the provision of informed consent and the level of anxiety in patients undergoing elective surgery at RSUD Waled, Cirebon Regency.

METHODS

This study is an analytical observational study with a cross-sectional approach, aiming to analyze the relationship between the provision of informed consent and the level of anxiety in patients undergoing elective surgery at RSUD Waled, Cirebon Regency. The study includes patients who have undergone elective surgery and are willing to participate as respondents, as well as adult patients who have undergone surgery with general anesthesia for a maximum duration of two hours. However, patients who remained unconscious after surgery or were admitted to the ICU postoperatively were excluded from the study.

The consecutive sampling technique was used for sample selection, where all patients meeting the inclusion criteria were included in the study until the required number of respondents was reached. Based on Slovin's formula, the minimum required sample size for this study is 73 respondents. In this research, informed consent serves as the independent variable, while patient anxiety is the dependent variable. Data collection was carried out using questionnaires and patient records, which were then analyzed using univariate and bivariate methods to obtain comprehensive results.

RESULTS AND DISCUSSION

However, it is essential to consider direct guidance for mothers who still face limitations in accessing digital promotional media. Health promotional media plays a vital role in enhancing public awareness and knowledge about health and diseases. Media such as television, radio, social media, and brochures help disseminate accurate and effective health information,

enabling the public to make informed health decisions. Moreover, health promotion media can also help transform public behavior, encouraging healthier lifestyles and disease prevention.

Overview of Respondent Characteristics

Table 1. Frequency by Gender

Gender	Number (n)	Percentage (%)
Male	32	43.8%
Female	41	56.2%
Total	73	100%

Based on the table above, it can be seen that the majority of patients undergoing elective surgery at RSUD Waled, Cirebon Regency, in January 2022 were female, with a total of 41 patients (56.2%), compared to male patients, who accounted for 32 individuals (43.8%).

Table 2. Frequency Distribution by Age

Age Group	Number (n)	Percentage (%)
20-29 years	13	17.8%
30-39 years	21	28.8%
40-49 years	17	23.3%
50-59 years	10	13.7%
>60 years	12	16.4%
Total	73	100%

Based on the table above, the majority of patients undergoing elective surgery at RSUD Waled, Cirebon Regency, in January 2022 were aged 30-39 years, totaling 21 patients (28.8%). This was followed by patients aged 40-49 years with 17 individuals (23.3%), those aged 20-29 years with 13 individuals (17.8%), patients over 60 years old with 12 individuals (16.4%), and the 50-59 years age group, which had the lowest number of patients at 10 individuals (13.7%).

Table 3. Frequency by Last Education Level

Last Education Level	Number (n)	Percentage (%)
Elementary School (SD)	29	39.7%
Junior High School (SMP)	20	27.4%
Senior High School (SMA)	24	32.9%
Total	73	100.0%

Based on Table 3, the information on the patients' education levels reveals that 29 patients (39.7%) have completed Elementary School (SD), 20 patients (27.4%) have completed Junior High School (SMP), and 24 patients (32.9%) have completed Senior High School (SMA).

Table 4. Frequency by Completeness of Informed Consent

Completeness of Informed Consent	Number (n)	Percentage (%)
Complete	49	67.1%
Incomplete	24	32.9%
Total	73	100.0%

Based on Table 4 regarding informed consent, the information shows that 49 patients (67.1%) received a complete informed consent, while 24 patients (32.9%) received incomplete informed consent.

Anxiety Level

Table 5. Frequency by Anxiety Level

Anxiety Level	Number (n)	Percentage (%)
No Anxiety	23	31.5%
Mild Anxiety	19	26.0%
Moderate Anxiety	9	12.3%
Severe Anxiety	6	8.2%
Very Severe Anxiety	16	21.9%
Total	73	100.0%

Based on Table 5 regarding anxiety levels, the data shows that 6 patients (8.2%) were classified as having severe anxiety, while 16 patients (21.9%) had very severe anxiety. Additionally, 19 patients (26.0%) experienced mild anxiety, 9 patients (12.3%) had moderate anxiety, and 23 patients (31.5%) showed no symptoms of anxiety.

Correlation Test and Crosstabs Analysis

The correlation test in this study aims to examine the relationship between the independent variable (informed consent) and the dependent variable (anxiety), assessing the strength and direction of the relationship between these two variables.

Table 6. Correlation Test and Crosstabs Analysis

Informed Consent	Anxiety Level										T	P Value	r
	No Anxiety		Mild		Moderate		Severe		Very Severe				
	N	%	N	%	N	%	N	%	N	%			
Complete	23	31,5	19	26.0	7	9.6	0	0.0	0	0.0	49	0.000	0.830
Incomplete	0	0.0	0	0.0	2	2.7	6	8.2	16	21.9	24		
Total	23	31,5	19	26.0	9	12.3	6	8.2	16	21.9	73		

Based on the Crosstab Table above, it was found that among the patients who received complete informed consent, 23 patients (46.9%) reported no anxiety, 19 patients (38.8%) experienced mild anxiety, and 7 patients (14.3%) had moderate anxiety. Notably, none of the patients with complete informed consent experienced severe anxiety or very severe anxiety. In contrast, among those who received incomplete informed consent, no patients reported having no anxiety or mild anxiety. However, 2 patients (8.3%) reported moderate anxiety, 6 patients (25.0%) experienced severe anxiety, and 16 patients (66.7%) experienced very severe anxiety. The results suggest a significant relationship between the completeness of informed consent and the level of anxiety experienced by patients.

The results of this study show that patients who underwent elective surgery received informed consent in full, while some others received informed consent that was not fully

complete. This finding is consistent with the research conducted by (Kurniawan et al., 2023) which reported that 68% of patients had knowledge about the information provided regarding the surgery through informed consent, thus considering the informed consent obtained as complete. A similar study by (Simanjuntak & Wismona, 2018) also revealed that the completeness of informed consent in preoperative cataract patients at SMEC Eye Hospital Medan reached only 58%, indicating it was not fully complete. The deficiencies in informed consent were particularly found in the prognosis section (9.1%), alternative risks (41.8%), and information regarding other actions to save the patient (41.8%).

Informed consent is a written document that indicates the patient's agreement to undergo medical procedures or surgery. This consent is regulated by the Regulation of (Peraturan Menteri Kesehatan Nomor 290/MENKES/PER/III/2008 Tentang Persetujuan Tindakan Kedokteran, 2008) concerning Medical Action Consent. According to Article 9, Paragraph 1 of this regulation, it is explained that "Medical information must be provided in full using language that is easy to understand or through other methods that can help clarify the patient's understanding.

The results showed that patients who underwent elective surgery at RSUD Waled, Cirebon Regency, in January 2022, generally exhibited symptoms of anxiety. This finding is consistent with the study by (Novianti & Nurmaguphita, 2024) which revealed that 54.8% of preoperative Caesarean section patients at the Central Surgical Installation of RSUD Dr. Haryanto Lumajang experienced anxiety symptoms with a moderate level of anxiety. Factors influencing this anxiety include experience, education level, income, gender, occupation, ethnicity, age, and belief systems. A similar result was found in the study by (Hasibuan et al., 2023) , which reported that 44.4% of patients undergoing elective surgery at RSUP Dr. M. Djamil Padang experienced preoperative anxiety.

Anxiety in preoperative patients is an important issue that often occurs in patients who are about to undergo surgery. This anxiety begins once the surgery schedule is set. The feeling of anxiety is not only related to the surgical procedure itself but also to concerns about potential complications that may arise after the surgery. Each individual shows signs of preoperative anxiety in different ways. Some patients may express their anxiety through numerous questions, speaking quickly, frequently changing the topic, or asking the same question repeatedly. Others may not verbally express anxiety, but their behavior reflects restlessness or fear. Meanwhile, some patients may choose to avoid discussing the surgical procedure, give short answers, or respond with only one or two words (Dewi, 2021).

Anxiety can lead to other issues such as physical, psychological, and emotional problems. Furthermore, it is important because anxiety has the potential to affect preoperative preparation, the perioperative period, and the recovery phase (Tamah et al., 2019). Based on the results of the bivariate correlation analysis, this study shows a strong and significant relationship between the informed consent variable and the fear variable. The more complete the informed consent provided to the patient, the lower the anxiety level of the patient undergoing elective surgery. Conversely, if the patient gives incomplete consent, their anxiety level will increase. These findings are supported by the research of (Suleman, 2018) which

shows a relationship between preoperative information provided in the operating room at RS Ciamis and preoperative anxiety in patients.

A study by (Aggresmawati et al., 2018) also showed a relationship between the explanation of informed consent and the level of preoperative anxiety in patients at Mitra Husada Hospital. This indicates that inadequate explanation of informed consent poses a 5,500 times higher risk compared to the anxiety level of patients. Another study by (Murdiman et al., 2019) showed a relationship between informed consent and anxiety in patients undergoing preoperative appendectomy at RSUD Konawe. The results of this study are supported by research by (Astuti & Kulsum, 2018) which demonstrated a reduction in anxiety in patients undergoing preoperative appendectomy. The anxiety level in the intervention group, after receiving an intervention in the form of informed consent, had a significant impact on reducing preoperative anxiety in patients.

To address this anxiety, providing information and explanations through informed consent is also one of the strategies to manage it. This includes providing information about the diagnosis elements, planned procedures, alternative treatments, risks that may arise if the procedure is not performed, the patient's capacity to make decisions, and the patient's willingness to give consent. The information provided must be communicated effectively and clearly. When providing information through informed consent, it is important to understand the medical process and the patient's level of anxiety before the surgery (Novarianti, 2021).

CONCLUSION

The results of the study revealed several key findings regarding the informed consent and anxiety levels of patients undergoing elective surgery at RSUD Waled in Cirebon Regency. First, it was found that 67.1% of patients received full informed consent before their surgeries. In terms of anxiety levels, the study indicated that 8.2% of patients experienced severe anxiety, 21.9% had very severe anxiety, 26.0% exhibited mild anxiety, and 12.3% showed moderate anxiety. Notably, 31.5% of the patients displayed no symptoms of anxiety at all. Furthermore, the research identified a strong and significant correlation between the provision of informed consent and the anxiety levels of patients undergoing elective surgeries at RSUD Waled. This suggests that the completeness of informed consent plays a crucial role in influencing the anxiety experienced by patients prior to surgery.

REFERENCE

- Aggresmawati, S., Ardina, R., Sari, R., & Vellyana, D. (2018). Informed Consent Pada Tingkat Kecemasan Pasien Pre Operative. *Jurnal Ilmiah Kesehatan*, 7(2), 101–104.
- Astuti, D., & Kulsum, U. (2018). Pengaruh Pemberian Informed Consent Terhadap Kecemasan Pada Pasien Pre Operasi Sectio Caesarea. *Jurnal Ilmu Keperawatan Dan Kebidanan*, 9(2), Article 2. <https://doi.org/10.26751/jikk.v9i2.464>
- Dewi, L. S. (2021). *Hubungan Pemberian Informasi Persiapan Operasi Oleh Perawat Dengan Tingkat Kecemasan Pasien Pre Operasi Di Rsu Kabupaten Tangerang*. <http://eprints.wdh.ac.id/1512/>

- Fischbeck, S., Petrowski, K., Renovanz, M., Nesbigall, R., Haaf, J., & Ringel, F. (2021). Anxiety is associated with unfulfilled information needs and pain at the informed consent consultation of spine surgery patients: A longitudinal study. *European Spine Journal*, 30(8), 2360–2367. <https://doi.org/10.1007/s00586-021-06824-1>
- Goldberger, J. J., Kruse, J., Kadish, A. H., Passman, R., & Bergner, D. W. (2011). Effect of informed consent format on patient anxiety, knowledge, and satisfaction. *American Heart Journal*, 162(4), 780–785.e1. <https://doi.org/10.1016/j.ahj.2011.07.006>
- Hasibuan, B., Medison, I., & Anggrainy, F. (2023). The Effect of Dexamethasone on IL-6 Levels in Confirmed COVID-19 Patients Treated at RSUP Dr. M. Djamil Padang. *Jurnal Respirologi Indonesia*, 43(3), Article 3. <https://doi.org/10.36497/jri.v43i3.426>
- Kurniawan, H. D., Hartono, M., Ismandani, R. S., & Natanael, N. (2023). Hubungan Pemberian Informed Consent Praoperasi Dengan Tingkat Kepuasan Pasien Di Rumah Sakit Dr. Oen Kandang Sapi Solo. *KOSALA: Jurnal Ilmu Kesehatan*, 11(1), Article 1. <https://doi.org/10.37831/kjik.v11i1.270>
- Murdiman, N., Harun, A. A., L, N. R. D., & Solo, T. P. (2019). Hubungan Pemberian Informed Consent Dengan Kecemasan Pada Pasien Pre Operasi Appendisitis Di Ruang Bedah BLUD Rumah Sakit Konawe. *Jurnal Keperawatan*, 2(03), Article 03. <https://doi.org/10.46233/jk.v2i03.258>
- Novarianti, W. (2021). *Analisis Faktor Yang Mempengaruhi Tingkat Kecemasan Pre Operasi Pada Pasien Sc Di Instalasi Bedah Sentral Rsud Dr. Haryoto Lumajang* [Skripsi, STIKES MAJAPAHIT]. <http://libstikesmajapahit@gmail.com>
- Novianti, I. C., & Nurmaguphita, D. (2024). Hubungan tingkat kecemasan dengan bullying pada siswa siswi SMP Muhammadiyah 1 Minggir. *Prosiding Seminar Nasional Penelitian dan Pengabdian Kepada Masyarakat LPPM Universitas 'Aisyiyah Yogyakarta*, 2, 918–924.
- Peraturan Menteri Kesehatan Nomor 290/MENKES/PER/III/2008 Tentang Persetujuan Tindakan Kedokteran, Pub. L. No. 290 (2008).
- Simanjuntak, E., & Wismona, S. A. (2018). Analisis Kelengkapan Informed Consent Pasien Pra Operasi Katarak Di Rs. Khusus Mata Smec Medan Tahun 2018. *Jurnal Ilmiah Perekam Dan Informasi Kesehatan Imelda (JIPKI)*, 3(2), Article 2. <https://doi.org/10.52943/jipiki.v3i2.61>
- Suleman, H. K. (2018). *Hubungan Antara Pemberian Informasi Pra Bedah Dengan Kecemasan Pasien Pre Operasi Di Ruang Bedah RSUD Ciamis*. <http://repository.unigal.ac.id:8080/handle/123456789/803>
- Tamah, Z. G., Mulyadi, S. Y., & Yulia, S. (2019). Hubungan Pemenuhan Informasi Pre Operasi dengan Tingkat Kecemasan Pasien. *Jurnal Berita Ilmu Keperawatan*, 12(1), 31–36.
- Undang-Undang (UU) Nomor 29 Tahun 2004 Tentang Praktik Kedokteran, Pub. L. No. 29 (2004).
- Wagiu, C. G., Kristanto, E. G., & Lumunon, T. (2017). Informed consent di Instalasi Gawat Darurat RSUP Prof. Dr. R. D. Kandou Manado. *Jurnal Biomedik:JBM*, 9(1), Article 1. <https://doi.org/10.35790/jbm.9.1.2017.15321>

World Health Organization. (2020). *Safe surgery*. <https://www.who.int/teams/integrated-health-services/patient-safety/research/safe-surgery>

Zeb, A., Ziad, M., Ullah, I., Bibi, A., & Hussain, A. (2018). Role of Informed Consent in Reducing Pre-Operative Anxiety. *Journal of Nursing & Healthcare*, 3(1), 1–4.