

A WELL-UNDERSTOOD SURGICAL INFORMED CONSENT : A SCOPING REVIEW

Rieke Cahya¹, Diah Melly Maryana¹, Adik Wibowo²

¹Hospital Administration Studies Program, Faculty of Public Health Universitas Indonesia, ²Health Policy and Administration Department Faculty of Public Health, Universitas Indonesia
E-mail: riekecahyabudi@yahoo.com

Abstract

The implementation of surgical consent has shifted from simply getting a signature to a focus on doctor-patient communication. Providing adequate information is very important for patients in making decisions so that patients do not feel forced to agree. Good understanding is required before a patient gives consent, but many patients have difficulty understanding and doctors fail to provide correct information. The aim of this scoping review is to investigate and evaluate patient comprehension of surgical informed consent provided by standard procedure or other methods and factors affecting patient comprehension. Three electronic database searches (ProQuest, ScienceDirect, and Scopus) were performed from 2017 until 2022. A total of 391 articles were identified and 25 articles were selected according to the PRISMA guidelines and the PCC framework. 9 of 11 articles stated that patient understanding level was low. Factors that influence it include education level, age and language limitations. 12 studies (85%) showed that patient understanding improved with the use of additional information media. Overall patient comprehension of surgical informed consent is low. This depending on the communication between the doctor and the patient. An interesting interventions can be used to improve patient understanding of surgical informed consent.

Keywords: *Patient Comprehension, Patient Knowledge, Patient Understanding, Surgical Informed Consent.*

Introduction

Patient safety in healthcare has received significant attention over the last few decades. The attention is a form of awareness that humans must have made mistakes. However, in the development of health services, a system has been created that aims to reduce and prevent errors. The implementation of this system is based on the understanding that the health services provided must focus on patient, service and patient safety. One application in the health care system is well-understood informed consent.(Khan, 2012; Mudiyansele, Eshana, Mathangasinghe, Sarath, & Banagala,

2019; Richardson, 2013) 'Informed consent' is the process of providing information to the patient as a consideration for the patients to make a voluntary decision to undergo or refuse medical procedure.(Pallett et al., 2018; Villanueva, Talwar, & Doyle, 2018)

The recognition of informed consent has expanded significantly not only with regard to medical practice but also to clinical research. This began from a legal decision based on the principle of patient autonomy in 1905. However, the principle of "informed consent" remained unknown until in 1957 a legal decision that identified and focuses on the need to inform patients about the benefits and risks of each documented medical procedure.(Bazzano, Durant, & Brantley, 2021; Cocanour, 2017) It is stated that the patient must have sufficient knowledge and understanding as a reference in making the right decision. This statement identified several important items, namely the information provided and the patient understanding. Information is defined as an explicit explanation to the patient about the diagnostic or therapeutic medical procedure that will be given and contains specific elements that contain the purpose of the procedure, benefits, risks, steps to overcome risks, alternatives and opportunities for the patient to ask questions and allow the patient to withdraw at any time from the procedure to be performed.(Bazzano et al., 2021) The purpose of presenting "key information" is to facilitate comprehension. Comprehension become one of the important issues in informed consent before the patient gives consent.(Bazzano et al., 2021)

Currently, informed consent has become an ethical concept as outlined in the law on medical practice.(Cocanour, 2017; Khoshrang et al., 2021; Moeini, Shahriari, & Shamali, 2020) It is stated that informed consent is more than just signing legal document. Informed consent facilitates the patients to be actively involved in the decision-making process on medical procedure.(Lin et al., 2017) We need to remember that not all patients who agree and sign the informed consent document have understood all the information explained by the doctor.(Dewar, Pieters, & Fried, 2021) The three basic criteria needed to obtain consent for a planned medical procedure are that the patient must be competent, adequately informed and not coerced.(Cocanour, 2017; Lin et al., 2019)(Pucher et al., 2019) They must be able to understand the information provided, inform their decisions and understand the consequences of the decisions they make. The Physician's efforts to provide adequate information and to assess the patient's understanding are a critical measure for the success of the informed consent process.(Cocanour, 2017; Lin et al., 2017)

Providing information about medical procedures in medical terms that are difficult for patients to understand can cause anxiety and confusion for patients, especially surgery which could be a frightening experience. Limited time in communication due to urgency of the operating process, acute and vulnerable condition, emotional stress, physical pain due to injury and fear of planning surgery affect the patient's ability to listen and interfere patient comprehension of the information provided by the physician.(Agozzino et al., 2019; Lin et al., 2017, 2019; Nuraeni, 2016)

It is a challenge for health workers, especially surgeons, to provide important information about surgical plans in lay language that is easy for patients to understand. Most patients find it difficult to understand medical terms and clinical concepts used by surgeons, this is often not realized and is the biggest cause of a surgeon's failure to provide information to patients.(Villanueva et al., 2018) These conditions are challenging especially understanding that a good informed consent process can improve the patient-physician relationship.(Khoshrang et al., 2021) Accordance to various methods of delivering informed consent, the level of patient understanding that is formed also varies. The language barrier, the patient's education level and the doctor's ability to communicate affect the patient's understanding of informed consent. These three things are the most common barriers to communication between doctors and patients.(Cocanour, 2017; Fink et al., 2010; Fudman et al., 2019)

However, the process of implementing informed consent and the patient understanding of informed consent has not fully achieved the expected results. An American study conducted by Hall et al concluded that sixty-nine percent of patients decided to undergo surgery even before seeing surgeon, and 47% patients stated that the surgeon did not influence their decision. Most (68%) patients consider informed consent only as a legal formality and have little influence on the decision-making process.(Hall et al., 2012) Many medical consent forms fail to be a simple and clear communication because the language contained in them is difficult for patients to understand.(Zimmermann, Pilarska, Gaworska-Krzemińska, Jankau, & Cohen, 2021)

In Indonesia, not much research has been done on surgical informed consent, especially regarding the patient understanding. Ulfa et al in their research revealed that the implementation of surgical informed consent had not been properly carried out, the completeness and accuracy in filling out informed consent documents had not reached 100%, the contributing factor was the low awareness of medical personnel in charge of carrying out informed consent properly.(Ulfa, 2018) Herfiyanti et al in their research at Hasan Sadikin Hospital Bandung stated that the medical information provided by doctors was incomplete, which was in the explanation of prognosis (54.1%), alternatives & risks (52.5%), and complications (50.8%).(Herfiyanti, 2015) Susanto et al in their research in the city of Malang stated that the patient's ability to understand informed consent was very low and necessary to create a media by the hospital to facilitate health workers in providing medical information to patients and to help improve patient understanding.(Susanto, Pratama, & Hariyanto, 2017) Good results were obtained by Alvionita et al, specifically the explanation of informed consent in elective surgery patients at Pirngadi Hospital Medan went smoothly, detailed explanations had been given by the doctor in accordance with the provisions contained in the regulations and filling out the informed consent in accordance with the procedure.(Alvionita, Harahap, & Aini, 2021)

Failure to implement informed consent gives the conclusion how difficult to get the patient understanding of the information regarding the surgery given. Many questions arise from this statement, about how is patient comprehension regarding

surgical informed consent, factors affect that patient comprehension level and what are the challenges in the informed consent process, and whether the use of additional information media can improve patient comprehension of surgical informed consent. By answering the question, a doctor can determine the best strategies and methods that can be used to provide information about the planned surgery. The aims of this scoping review are to investigate and evaluate patient comprehension of surgical informed consent provided by standard procedure or other methods and to determine factors affecting patient comprehension.

Method

The selection of this scoping review was based on the consideration that a scoping review is a suitable method for summarizing findings that is heterogeneous in a research method. A literature search of the ProQuest, Science Direct and Scopus databases was conducted in 2017 until 2022. The search strategy for each included database is presented in table 1. The following search terms included all identified keywords : *patient comprehension, patient understanding, patient knowledge, surgical informed consent*; and Boolean operators “OR” and “AND” to ensure a far-reaching capture of existing works. This framework for scoping reviews was compiled with the Joanna Briggs Institute Methodology for scoping reviews.

The following question based upon the PCC (Population, Concept and Context) are :

- Population : Adult surgical patient
- Concept : Patient's understanding of the informed consent given by the doctor
- Context : Hospital

Tabel 1.
Search Strategy

Database	Keywords And Boolean
Proquest	((MAINSUBJECT.EXACT("Knowledge") OR MAINSUBJECT.EXACT("Acceptance") OR comprehension) AND (MAINSUBJECT.EXACT("Informed consent") AND MAINSUBJECT.EXACT("Surgery"))) AND (at.exact("Article") AND stype.exact("Scholarly Journals") AND pd(20170521- 20220521))
Scopus	<i>Comprehension Or Understanding Or Knowledge And Patient And Informed And Consent And Surgical* And Hospital</i> And (Limit-To (Pubstage , "Final")) And (Limit-To (Oa , "All")) And (Limit-To (Pubyear , 2022) Or Limit-To (Pubyear , 2021) Or Limit-To (Pubyear , 2020) Or Limit-To (Pubyear , 2019) Or Limit-To (Pubyear , 2018) Or Limit-To (Pubyear , 2017)) And (Limit-To (Doctype , "Ar")) And (Limit-To (Subjarea , "Medi")) And (Limit-To (Exactkeyword , "Informed Consent")) And (Limit-To (Language , "English")) And (Limit-To (Srctype , "J"))
Science Direct	Title, abstract, keywords: comprehension OR understanding OR knowledge AND adult AND patient AND surgical procedure AND informed AND consent AND hospital

Desired articles include published articles, English articles and full text articles. All articles are studies assessing patient understanding, factors influencing patient

understanding and interventions to improve patient understanding of surgical informed consent. We excluded studies evaluating approval for clinical research, screening, diagnostics, and research into drug prescription; research on geriatric patients, unconscious patients and patients unable to give informed consent.

Three reviewers evaluated the title and abstract of the article sought. After the search process, all selected articles will be collected and uploaded to the Mendeley Reference Manager and duplicates removed. Differences of opinion between reviewers regarding the data extraction process were resolved through discussion and the final decision was determined by agreement between the three. Data is presented in tabular form.

The search results and inclusion process of articles in this scoping review are described and presented according to the preferred reporting format for systematic review and meta-analysis extension for scoping review (PRISMA-ScR) flowchart.(Tricco et al., 2018) The prismatic study selection is shown in Figure 1.

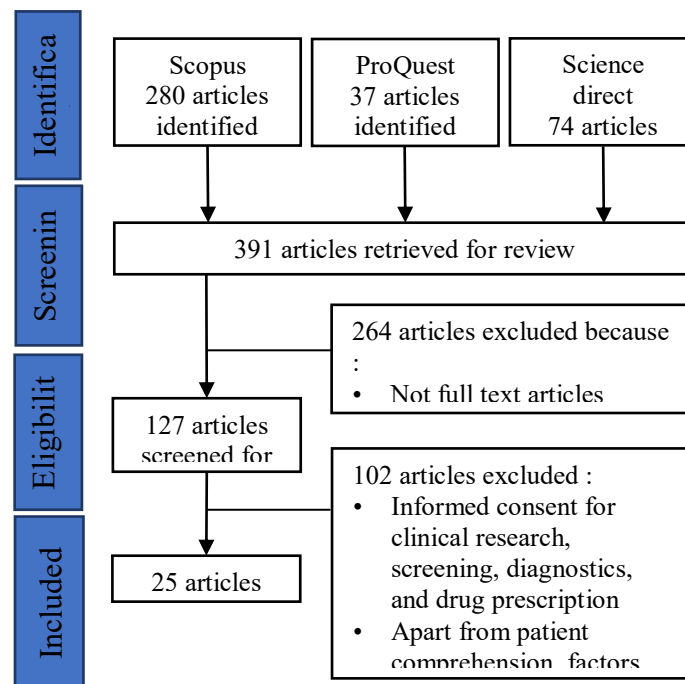


Figure 1. PRISMA-ScR Research Diagram

Results

391 articles were identified in this scoping review in the initial search. After removing duplication, language barriers and full text only articles, a total of 127 articles were screened for eligibility. After filtering the abstracts on the articles obtained, 102 articles were successfully excluded and 25 articles were found at the end of the search. The articles obtained are summarized in table 3.

Articles included in this scoping review are composed of publications from 14 countries, starting from America, Asia, Australia, Africa and Europe, but 57,1% of the articles (n=8) were from the United States. Further investigation into the types of

studies revealed that most articles were observational and experimental studies design, two studies were systematic review. The number of participants in the articles obtained was quite varied, ranging from 10 to 420 patients. The characteristics of the articles in this scoping review are presented in table 2.

Table 2.
Characteristics of The Studies

Place	
America	8
Australia	2
Asia	6
Europe	5
Africa	2
Methods	
Observational	11
Experimental	12
Systematic review	2
Year of publications	
2017-2019	21
2020-2022	4
Participant	
<100	16
100-200	2
200-300	4
>300	3

11 articles determined the patient comprehension level of surgical informed consent and the influencing factors. Assessment of patient understanding was carried out after giving informed consent through a standard procedure, namely during the surgical informed consent process, the patient met and received important information about the surgical procedure from the surgeon verbally and then used that information to express consent and sign the operating agreement. After that, the patient was given a questionnaire to assess the patient understanding of the surgical consent. 4 articles were used structured questionnaire, 2 articles were used specific questionnaire, 2 articles were used open-ended questionnaire and 2 articles were used multiple choice questionnaire. Most of questionnaires were assessed by Likert scale. 6 articles evaluate patient understanding immediately, and 5 articles evaluate within days to months. 9 out of 11 articles (81.8%) stated that the patient comprehension of surgical informed consent was low. Factors affecting the level of understanding of those patients included education level, age and language limitations.

14 articles compared the patient understanding of surgical informed consent with the standard informed consent process compared with the patient understanding using the addition of information media to the standard informed consent process. Additional information media used varied, ranging from written information media (pamphlets and leaflets), mobile applications, websites, and multimedia sources such as videos, cartoon illustrations or interactive presentations. Overall, 12 studies (85%)

demonstrated that patient understanding had improved when using various additional information media in providing surgical consent.

Table 3
Selected Studies Regarding Patient Comprehension Of Surgical Informed Consent.

No	Title	Country and year of publication	Study design	Study aims	Result
1	Surgical Decision-Making for Temporal Lobe Epilepsy: Patient Experiences of the Informed Consent Process	United States, 2021	A systematic analysis	To describe the informed process of anterior temporal lobectomy.	Patients' beliefs and expectations about treatment affect the consent process. Decisions are often made before meeting with the surgeon
2	Informed consent for clinical treatment in low-income setting: evaluating the relationship between satisfying consent and extent of recall of consent information	Nigeria, 2017	Cross sectional	To evaluate a patient understanding of informed consent by assessing the extent to which the patient can recall information believed to have been given	78,3% respondent could recall appropriately. A higher level of patient education affects the comprehension level and ability to remember the information that has been given.
3	Effect of Consent and Educational Adjuncts to Consent on Patient Perceptions About Colonoscopy	United States, 2018	Cohort	To assess intervention to improve the consent process.	The patient's ability to recall the information that has been given is increased with the use of additional educational methods
4	Development, piloting, and evaluation of an evidence-based informed consent form for total knee arthroplasty (evab-Pilot): a	Germany, 2021	Mixed methods	To evaluate the effects of evidence-based informed consent forms in comparison with standard consent	Evidence-based and understandable presentation of risk in informed consent forms strengthening the patients' competence

	protocol for a mixed methods study				
5	Cultural competency of a mobile, customized patient education tool for improving potential kidney transplant recipients' knowledge and decision-making	United States, 2017	Multistage analysis	To evaluate the use of animated illustrations on mobile applications to provide information about surgical procedures as a reference for patients in making decisions	The use of animated images on mobile applications significantly provides a reference for patients in making the right decisions
6	Ethical challenges of obtaining informed consent from surgical patients	Iran, 2017	Descriptive cross-sectional	To evaluate the effect of ethical challenges on the surgical informed consent process	Many factors affect the low quality of informed consent, it is necessary to create a framework to identify difficulties in the surgical informed consent process
7	Visual teaching aids improve patient understanding and reduce anxiety prior to a colectomy	United States, 2020	A randomized pilot study	To evaluate visual images as a medium of additional information on informed consent for colectomy	The use of visual images during the consent process for a colectomy is useful for helping patients recall surgical risk memories, reduce anxiety, and improve understanding
8	Patients understanding of terminology commonly used during combined orthodontic-orthognathic treatment	United Kingdom, 2019	Cross sectional	To evaluate the effect of using medical terminology that is often used by doctors on patient understanding	The use of medical terms commonly used by doctors cannot be understood, this understanding can be influenced by differences in language and patient education level
9	Impact of a multimedia support on the understanding of medical information by hearing-	France, 2017	A prospective single-centre single-blind study	To compare the use of verbal, written and digital forms of information ("multimedia"	The use of digital information media significantly improves patient understanding, especially in patients with hearing loss

	impaired patients before cochlear implantation) in surgical informed consent	
10	Use of Surgical Risk Preoperative Assessment System (SURPAS) and Patient Satisfaction during Informed Consent for Surgery	United States, 2018	Cohort	To compare the effectiveness of using the Surgical Risk Preoperative Assessment System (SURPAS) compared to the standard informed consent process	The SURPAS tool significantly improves patient understanding compared to the standard consent process
11	The effectiveness of handout assisted versus verbal consent on post-operative recall and understanding – A randomized control study	Malaysia, 2017	Randomized prospective study	To assess the effectiveness of using leaflet information media compared to verbal information in improving patient understanding and the patient's ability to recall information that has been given after surgery is performed	Although the use of leaflets can increase patient satisfaction, it does not significantly increase patient understanding
12	Informed Consent for Patients Undergoing Transsphenoidal Excision of Pituitary Adenoma: Development and Evaluation of a Procedure-Specific Online Educational Resource	United Kingdom, 2018	Cohort	To assess the effectiveness of using multimedia on the website as an interactive medium in the approval process	The use of interactive multimedia information on multimedia websites can assist in the informed consent process

13	Improving informed consent in cardiac surgery by enhancing preoperative education	Australia, 2017	A systematic review	To evaluate preoperative education in improving patient's memory and understanding of surgical informed consent	The patient's ability to remember and understand information is significantly improved with the use of various additional information media
14	Assessing adequacy of informed consent for elective surgery by student-administered interview	Singapore, 2018	A prospective cross-sectional	To evaluate the quality of informed consent by assessing the patient understanding and ability to recall the information provided	Patient understanding of surgical information and complications is generally low, especially in geriatric patients
15	Consent for spine surgery: an observational study	Australia, 2019	A prospective observational study	To analyze the effect of using videotape on the surgical informed consent process	The patient is only able to understand part of the information provided by the surgeon
16	Knowledge and Perception of Ethiopian Surgical Patients to Informed Consent Practice for Surgical Procedures	Ethiopia, 2018	Cross-sectional	To assess the patient's perception and understanding of surgical consent	In general, patients have limited knowledge, perception and understanding of surgical informed consent
17	Development and pilot testing of an informed consent video for patients with limb trauma prior to debridement surgery using a modified Delphi technique	Taiwan, 2017	Pilot study	To evaluate the use of educational videos on the knowledge, understanding and satisfaction of patients with the informed consent process	Educational videos can be used to increase patient knowledge and satisfaction
18	How to	Taiwan,	A	To evaluate	The patient's memory

	effectively obtain informed consent in trauma patients: a systematic review	2019	systematic review	the use of various methods of providing information to improve patients' understanding of surgical informed consent	and understanding of the risks of surgery both on the use of written or video information media than if the information is given verbally
19	Informed consent and responses of surgical patients: A study in North India	India, 2021	Cross-sectional	To evaluate the patient's perspective and understanding of the contents of the informed consent	The patient's level of awareness, perception and understanding of surgical informed consent was found to be good
20	Informed consent through 3D virtual reality: a randomized clinical trial	Italy, 2017	Prospective, single-centre, randomized controlled clinical trial	To evaluate the effect of using the new 3D anatomy visualizer in improving the quality of communication between doctors and patients on the surgical informed consent process	3D virtual reality significantly assists surgeons in establishing communication, increasing patient understanding without increasing anxiety
21	Lost in translation: Informed consent in the medical mission setting	United States, 2017	Mixed-methods study	To evaluate the information content provided by the surgeon, the patient's understanding and the overall quality of informed consent	The patient has limited memory or understanding. Influenced by the surgeon's use of language in providing information
22	Patient comprehension necessary for informed consent for	United States, 2018	Single centre, prospective, cross-sectional	To evaluate the patient's level of understanding of the basic	The patient understanding of the basic information provided by the surgeon is low

	vascular procedures is poor and related to frailty		study	information on surgical informed consent	
23	Personalized 3D printed Model for Informed Consent for Stage I Lung Cancer: A Randomized Pilot Trial	Seoul, 2018	A Randomized Pilot Trial	To evaluate the use of personalized 3D printed models to improve patient understanding of informed consent for lung cancer resection surgery	The use of personalized 3D printing is technically feasible and has the potential to improve patient understanding of informed consent
24	Use of an ipad application in preoperative counseling for pelvic reconstructive surgery: a randomized trial	United States, 2018	A nonblinded, randomized, controlled trial	To evaluate the effect of using additional information media using the iPad application on the informed consent process for pelvic organ prolapse surgery (POP).	Aplikasi ipad berbasis POP tidak meningkatkan pemahaman pasien terhadap informed consent bedah
25	The quality of informed consent obtained for orthopedic surgeries— elective versus trauma: A prospective interview-based study	Israel, 2018	A prospective interview-based cohort study	To evaluate the quality of the informed consent process in emergency surgery in trauma patients versus elective orthopedic surgery	Patient understanding of emergency surgery in trauma patients is lower than in elective orthopedic surgery

Discussion

Patient comprehension on surgical informed consent

The purpose of this scoping review is to evaluate the patient understanding of surgical informed consent. The reviewers identified twenty five studies for analysis and found that most of the articles mentioned that patients had poor comprehension of surgical informed consent that has been given. The patient's low understanding of

surgical informed consent is not only obtain in elective surgery patients but also in trauma patients undergoing emergency surgery, these results are listed in a study conducted by Shemesh.(Shemesh et al., 2019)

The lack of patient understanding is a worrying phenomenon. Only two articles in this scoping review mentioned a good patient comprehension level in the studies they had done. Nnabugwu et al, in their research found that 78.3% of respondents have the ability to remember information. The ability to recall information explained by doctors during the surgical informed consent process illustrates the level of patient understanding of a good.(Nnabugwu, Ugwumba, Udeh, Anyimba, & Ozoemena, 2017) Singh et al also explained the same thing, in their study it was stated that the patient's level of understanding of surgical informed consent was good.(Singh, Rochwani, & Oberoi, 2021).

Factors affecting patient comprehension on surgical informed consent

There were many obstacles in providing optimal informed consent in medical practice.(Overcarsh, Arvizo, & Harvey, 2019) This caused the patient's understanding of surgical informed consent was still low. It is not easy for a surgeon to provide information to the patient and make the patient understand what is being explained, but this must be done. It is important to describe the causes of the patient's low level of understanding so that we can arrange strategies to deal with each obstacle.

In order to understand the reasons for the patient's poor understanding of surgical informed consent, we need to review essential aspects of the surgical informed consent process, which the patient understanding of important information in surgical informed consent, including the risks, benefits of surgery, and alternative surgical procedures; patient competence; and patient consent given without coercion.(Lin et al., 2019; Overcarsh et al., 2019) A good informed consent process is when the patient is able to receive, understand and recall important information provided by the doctor and use that information as a reference in giving voluntary consent. The process is formed from adequate communication between the patient and the surgeon and it is very important to be done before the operation.

An important things that must be conveyed in the communication and discussion between doctors and patient are expected course of illness; proposed surgical intervention; morbidity and mortality associated with proposed surgical intervention; common complications of surgery; risk and benefits of proposed operation; perioperative expectations; alternative treatment options; disclosure of surgical team members and role in surgical care.(Overcarsh et al., 2019) All those information must be conveyed by the surgeon to the patient to form a good understanding, but some doctors fail to convey information properly and many patients are unable to remember the diagnosis, surgical procedure, risks and benefits of surgery and complications.(Lin et al., 2019)

Ruske et al suggested that one possible explanation for the patient's low understanding is the inadequate information and education provided by the surgeon. They have found that patients were often not fully informed about their procedure even

if patient are capable to understand.(Ruske et al., 2021) Surgeon were frequently unaware that in the informed consent process, a relationship of disclosure and trust is built with the patient and promote mutual understanding to reduce unnecessary litigation in unexpected event.(Lemmu, Megersa, Abebe, & Abebe, 2020; Ruiz López, 2013) Besides, not all surgeons are aware of the importance of providing medical information to patients in their clinical work. Some surgeons believe that because all the information provided is included in the surgical consent, there is no need to explain to the patient verbally the details of the procedure. But unfortunately, as mentioned in the study conducted by Lemmu et al, many patients did not read the informed consent letter before signing it.(Lemmu et al., 2020; Lin et al., 2019; Ruiz López, 2013)

Education level and age plays a major role in the ability of patients to understand the information presented to them.(García-García, Sánchez-Sabater, Medrano-Morte, & Luna-Maldonado, 2019; Ruske et al., 2021) The low level of patient education as the cause of the patient's low understanding of surgical informed consent was found in the study conducted by Sceats et al, therefore it is important to convey information in an easy-to-understand way.(Sceats et al., 2019) Shemesh et al also showed a correlation between the comprehension of informed consent and the level of education, with a significantly better comprehension in patients with post-high-school education.(Shemesh et al., 2019) Nnabugwu et al revealed that patient might not be unconnected when surgeon provide the information.(Nnabugwu et al., 2017) In the study of Moeini et al, it was found that the higher the education level of the patients, the more they are willing to receive information. Information to patients should be based on their level of education, and presenting the same information to all patients is inappropriate.(Moeini et al., 2020)

Chia et al stated that the surgical informed consent process in geriatric patients is more complicated because geriatric patients have many comorbidities, weakness and even cognitive impairment. A different approach to providing informed consent by surgeons is needed, more time and repeated reinforcement is needed.(Chia, Chan, Ng, Rao, & Singaporewalla, 2019) Zimmermann et al found a strong correlation between patient understanding and age, in that study it was stated that young people (aged up to 39 years) were significantly more aware of the surgical informed consent given.(Zimmermann et al., 2021) A different result in this review is the study by Nnabugwu et al. which stated that there was no difference in the level of understanding among young people compared to older people. This is due to the limited access of our younger patients to other appropriate sources of medical information including the internet which makes younger and older patients share a common knowledge base.(Nnabugwu et al., 2017)

A study by García-García et al revealed that education level was significantly related to gender and age. They found that the percentage of women who were uneducated was higher than men, and the percentage of women studying at university was twice than men.(García-García et al., 2019) This gender difference is related to the opportunity for men to pursue higher education.

Various studies mentioned that limitation in language and surgeon communication skill were the factors that affects the patient's level of understanding.(Sceats et al., 2019) Differences in language and the complexity of medical terms used by surgeons are obstacles in the communication process. Research by Benning et al. evaluated that the specific terms used to describe medical concepts, diagnoses and most of the terms commonly used by doctors were poorly understood by patients, not easy for patients to understand medical terminology.(Benning, Madadian, Seehra, & Fan, 2021) In addition, Shemesh et al stated that the complete informed consent process was time consuming. very likely the patient loses attention when the doctor gives information and ignores important things. Patients are generally only able to understand "basic" elements rather than more complex information.(Shemesh et al., 2019) Li Ching Ng et al in their research said that the surgeon's inconsistency in explaining the information needed to obtain informed consent was the cause of the low level patient comprehension of surgical informed consent.(Li Ching Ng et al., 2021)

Therefore, improvement of communication quality is highly important for all surgeons. Surgeons need to enhance their communication skills, use structured conversation, choose words more carefully and maintain consistency in providing information.(Agozzino et al., 2019) The use of terms that are easily understood by patients as well as effective use of time will increase the validity of informed consent.(Benning et al., 2021; Shemesh et al., 2019) To make all that easier, can be considered other means of communication in giving informed consent.

Improving patient comprehension on surgical informed consent

The information submitted by the doctor verbally in the standard informed consent process fails to provide a good understanding to the patient. Several strategies are used to promote better patient understanding, including use of additional information media after verbal information. It is stated that the patient's ability to remember and understand the information given before surgery is significantly improved with the use of various educational tool. The use of additional information media allows patients to better understand medical information and becomes the basis of reference in the decision-making process.(Paterick, Paterick, & Paterick, 2020)

Most studies use written information as addition to the discussion. Written information sheets are very useful because they can be given before the day of surgery, enabling patients and families to review the information they need repeatedly. There are many studies that aim to find out whether the use of written information can improve patient comprehension. One of them is the study of Zimmermann et al which stated that there are significant results on patient understanding using written informed consent.(Zimmermann et al., 2021) However the article found in this scoping review contradicts some of the studies above. Kong et al found that the use of handouts as written information was not significant help the patient to remember.(Koong, Rajandram, Sidambram, & Narayanan, 2021) This statement is supported by research by Agozzino et al which stated that the written informed consent forms are not

sufficient to provide information and make the patients understand of choices they made for their health.(Agozzino et al., 2019)

Three reasons underlie those findings: first, many patients showed infrequent interest in informed consent documents. Patients with a high level of education and less than 60 years are more likely to read consent forms.(Agozzino et al., 2019) Wong et al in their research in Canada confirmed that written information media that was read and understood by patients could improve patient understanding. Patient motivation and the ability to understand this information are important factors that play a role in it.(Wong et al., 2016) Second, the surgeon may show a lack of interest in the document, seeking only the signature without providing adequate motivation to the patient for the importance of reading the document. Third, leaflets were given on the day of consent or even just a few hours before the surgical procedure, thereby not allowing enough time for the patient to fully appreciate the information.(Agozzino et al., 2019)

It can be concluded from studies of Kong et al that written informed consent alone is not sufficient. With advances in technology, there are many information media that can be used as additional tools in the informed consent process. Three articles found in the scoping review demonstrated the use of visual aids such as cartoon illustrations or other 3D images that could potentially improve patients' understanding of surgical informed consent. The use of colour images attracts patients to read and makes it easier for patients to understand surgical procedures that are difficult for ordinary people to understand.(Perin et al., 2021; Stewart et al., 2021; Yoon et al., 2019)

Current technological advances offer many multimedia applications that can be used to simplify the health care process, including the process of giving informed consent. There were 6 articles in this scoping review use audio-visual presentations, mobile applications and other interactive educational websites as tools to provide information about surgical procedures and get significant results in improving the level of patient comprehension.(Axelrod et al., 2017; Fudman et al., 2019; Lin et al., 2017; Marcus, Jain, Grieve, & Dorward, 2018; Rouf et al., 2017; Weise et al., 2021; Wiesen et al., 2020) The use of interesting audio visuals provides answers for patients with physical limitations. Rouf et al stated that digital support improves the understanding of patients with hearing loss in cochlear implantation surgery (Rouf et al., 2017).

Interesting and interactive information media can be used in the informed consent process, but good verbal communication is an important part and should not be replaced by other forms of communication (Kinman et al., 2018).

Conclusion

Numerous articles review the patient's understanding of surgical informed consent. From the results obtained, the patient's level of understanding is still low. It is not easy to create a well informed consent process in a surgical setting. Many factors influence patient understanding including the surgeon's level of education and communication skills. Providing adequate, structured and comprehensive education in the preoperative communication process to patients is very important. Several

informational methods can be used to improve the patients comprehension of surgical informed consent.

BIBLIOGRAPHY

- Agozzino, Erminia, Borrelli, Sharon, Cancellieri, Mariagrazia, Carfora, Fabiola Michela, Di Lorenzo, Teresa, & Attena, Francesco. (2019). Does written informed consent adequately inform surgical patients? A cross sectional study. *BMC Medical Ethics*, 20(1), 4–11. <https://doi.org/10.1186/s12910-018-0340-z>.
- Alvionita, Vinny, Harahap, Juliandi, & Aini, Nur. (2021). Analysis of the Implementation of Informed Consent. *Journal of Healthcare Technology and Medicine*, 7.
- Axelrod, David A., Kynard-Amerson, Crystal S., Wojciechowski, David, Jacobs, Marie, Lentine, Krista L., Schnitzler, Mark, Peipert, John D., & Waterman, Amy D. (2017). Cultural competency of a mobile, customized patient education tool for improving potential kidney transplant recipients' knowledge and decision-making. *Clinical Transplantation*, 31(5), 1–9. <https://doi.org/10.1111/ctr.12944>.
- Bazzano, Lydia A., Durant, Jaquail, & Brantley, Paula Rhode. (2021). A modern history of informed consent and the role of key information. *Ochsner Journal*, 21(1), 81–85. <https://doi.org/10.31486/toj.19.0105>.
- Benning, Amanveer, Madadian, Matin Ali, Seehra, Jadbinder, & Fan, Kathleen. (2021). Patients understanding of terminology commonly used during combined orthodontic-orthognathic treatment. *Surgeon*, 19(5), e193–e198. <https://doi.org/10.1016/j.surge.2020.09.012>.
- Chia, Clement L. K., Chan, Kai Siang, Ng, Marcus J. M., Rao, Anil D., & Singaporewalla, Reyaz. (2019). Assessing adequacy of informed consent for elective surgery by student-administered interview. *ANZ Journal of Surgery*, 89(6), 677–682. <https://doi.org/10.1111/ans.15214>.
- Cocanour, Christine S. (2017). Informed consent—It's more than a signature on a piece of paper. *American Journal of Surgery*, 214(6), 993–997. <https://doi.org/10.1016/j.amjsurg.2017.09.015>
- Dewar, Sandra R., Pieters, Huibrie C., & Fried, Itzhak. (2021). Surgical Decision-Making for Temporal Lobe Epilepsy: Patient Experiences of the Informed Consent Process. *Frontiers in Neurology*, 12(December), 1–12. <https://doi.org/10.3389/fneur.2021.780306>.
- Fink, Aaron S., Prochazka, Allan V., Henderson, William G., Bartenfeld, Debra, Nyirenda, Carsie, Webb, Alexandra, Berger, David H., Itani, Kamal, Whitehill, Thomas, Edwards, James, Wilson, Mark, Karsonovich, Cynthia, & Parmelee, Patricia. (2010). Predictors of Comprehension during Surgical Informed Consent. *Journal of the American College of Surgeons*, 210(6), 919–926. <https://doi.org/10.1016/j.jamcollsurg.2010.02.049>.
- Fudman, David I., Papamichael, Konstantinos, Roemi, Lilach, Rao, Varun, Falchuk,

- Kenneth R., Leffler, Daniel A., & Feuerstein, Joseph D. (2019). Effect of Consent and Educational Adjuncts to Consent on Patient Perceptions about Colonoscopy. *Journal of Clinical Gastroenterology*, 53(8), e316–e321. <https://doi.org/10.1097/MCG.0000000000001093>.
- García-García, E. M., Sánchez-Sabater, B., Medrano-Morte, I., & Luna-Maldonado, A. (2019). Sociodemographic factors affecting the comprehension of clinical information by inpatients undergoing trauma surgery. *Revista Española de Cirugía Ortopédica y Traumatología (English Edition)*, 63(5), 355–360. <https://doi.org/10.1016/j.recote.2019.04.005>.
- Hall, Daniel E., Morrison, Penelope, Nikolajski, Cara, Fine, Michael, Arnold, Robert, & Zickmund, Susan L. (2012). Informed consent for inguinal herniorrhaphy and cholecystectomy: Describing how patients make decisions to have surgery. *American Journal of Surgery*, 204(5), 619–625. <https://doi.org/10.1016/j.amjsurg.2012.07.020>.
- Herfiyanti, Leni. (2015). Kelengkapan Informed Consent Tindakan Bedah Menunjang Akreditasi Jci Standar Hpk 6 Pasien Orthopedi. *Jurnal Manajemen Informasi Kesehatan Indonesia*, 3(2), 81–88. <https://doi.org/10.33560/.v3i2.89>.
- Khan, Robyna Irshad. (2012). Patient Safety and the Importance of Informed Consent. In *Urolithiasis: Basic Science and Clinical Practice* (pp. 543–546). https://doi.org/10.1007/978-1-4471-4387-1_68.
- Khoshrang, Hossein, Taramsari, Morteza Rahbar, Alavi, Cyrus Emir, Soleimani, Robabeh, Rimaz, Siamak, Sedighinejad, Abbas, Habibi, Mohammad Reza, & Bayat, Zoleikha. (2021). Research Paper: The Quality of Informed Consent Obtaining Before Electroconvulsive Therapy: A Report From a Referral, Academic Hospital. *Caspian Journal of Neurological Sciences*, 7(1), 37–41. <https://doi.org/10.32598/CJNS.7.24.6>.
- Kinman, Casey L., Meriwether, Kate V., Powell, Cayse M., Hobson, Deslyn T. G., Gaskins, Jeremy T., & Francis, Sean L. (2018). Use of an iPad™ application in preoperative counseling for pelvic reconstructive surgery: a randomized trial. *International Urogynecology Journal*, 29(9), 1289–1295. <https://doi.org/10.1007/s00192-017-3513-2>.
- Koong, Jun Kit, Rajandram, Retnagowri, Sidambram, Naveendran, & Narayanan, Vairavan. (2021). The effectiveness of handout assisted versus verbal consent on post-operative recall and understanding - A randomized control study. *Surgeon*, (xxxx), 1–8. <https://doi.org/10.1016/j.surge.2021.04.002>.
- Lemmu, Befekadu, Megersa, Abebe, Abebe, Engida, & Abebe, Kirubel. (2020). Knowledge and Perception of Ethiopian Surgical Patients to Informed Consent Practice for Surgical Procedures. *Open Access Surgery*, 13, 65–70. <https://doi.org/http://dx.doi.org/10.2147/OAS.S268009>.

- Li Ching Ng, Angela, McRobb, Lucinda S., White, Sarah J., Cartmill, John A., Cyna, Allan M., & Seex, Kevin. (2021). Consent for spine surgery: an observational study. *ANZ Journal of Surgery*, Vol. 91, pp. 1220–1225. <https://doi.org/10.1111/ans.16348>.
- Lin, Yen Ko, Chen, Chao Wen, Lee, Wei Che, Lin, Tsung Ying, Kuo, Liang Chi, Lin, Chia Ju, Shi, Leiyu, Tien, Yin Chun, & Cheng, Yuan Chia. (2017). Development and pilot testing of an informed consent video for patients with limb trauma prior to debridement surgery using a modified Delphi technique. *BMC Medical Ethics*, 18(1), 1–12. <https://doi.org/10.1186/s12910-017-0228-3>.
- Lin, Yen Ko, Liu, Kuan Ting, Chen, Chao Wen, Lee, Wei Che, Lin, Chia Ju, Shi, Leiyu, & Tien, Yin Chun. (2019). How to effectively obtain informed consent in trauma patients: A systematic review. *BMC Medical Ethics*, 20(1). <https://doi.org/10.1186/s12910-019-0347-0>.
- Marcus, Hani J., Jain, Abhiney, Grieve, Joan, & Dorward, Neil L. (2018). Informed Consent for Patients Undergoing Transsphenoidal Excision of Pituitary Adenoma: Development and Evaluation of a Procedure-Specific Online Educational Resource. *World Neurosurgery*, 118, e933–e937. <https://doi.org/10.1016/j.wneu.2018.07.102>.
- Moeini, Sanaz, Shahriari, Mohsen, & Shamali, Mahdi. (2020). Ethical challenges of obtaining informed consent from surgical patients. *Nursing Ethics*, 27(2), 527–536. <https://doi.org/10.1177/0969733019857781>.
- Mudiyanselage, Udagedara, Eshana, Jayami, Mathangasinghe, Yasith, Sarath, Anura, & Banagala, Kumara. (2019). *Are predominantly western standards and expectations of informed consent in surgery applicable to all? A qualitative study in a tertiary care hospital in Sri Lanka*. <https://doi.org/10.1136/bmjopen-2018-025299>.
- Nnabugwu, Ikenna I., Ugwumba, Fredrick O., Udeh, Emeka I., Anyimba, Solomon K., & Ozoemena, Oyiogu F. (2017). Informed consent for clinical treatment in low-income setting: Evaluating the relationship between satisfying consent and extent of recall of consent information. *BMC Medical Ethics*, 18(1), 1–8. <https://doi.org/10.1186/s12910-017-0227-4>.
- Nuraeni, RIna. (2016). Relationship of surgical procedure knowledge with level anxiety of adult surgical patients in the surgical room of ciders hospital period of May–June 2015. *Journal of Nursing and Health, II*.
- Overcarsh, Patricia, Arvizo, Cynthia, & Harvey, Lara. (2019). Informed consent in gynecologi surgery. *Current Opinion in Obstetrics and Gynecology*, 31(4), 240–244. <https://doi.org/10.1097/GCO.0000000000000550>.
- Pallett, Alicia C., Nguyen, Bao T., Klein, Natalie M., Phippen, Neil, Miller, Caela R., & Barnett, Jason C. (2018). A randomized controlled trial to determine whether a video presentation improves informed consent for hysterectomy. *American Journal of Obstetrics and Gynecology*, 219(3), 277.e1–277.e7.

<https://doi.org/10.1016/j.ajog.2018.06.016>.

- Paterick, Zachary R., Paterick, Timothy Edward, & Paterick, Barb Block. (2020). Medical informed choice: Understanding the element of time to meet the standard of care for valid informed consent. *Postgraduate Medical Journal*, 96(1141), 708–710. <https://doi.org/10.1136/postgradmedj-2019-137278>.
- Perin, Alessandro, Galbiati, Tommaso Francesco, Ayadi, Roberta, Gambatesa, Enrico, Orena, Eleonora Francesca, Riker, Nicole Irene, Silberberg, Hagit, Sgubin, Donatella, Meling, Torstein Ragnar, & DiMeco, Francesco. (2021). Informed consent through 3D virtual reality: a randomized clinical trial. *Acta Neurochirurgica*, 163(2), 301–308. <https://doi.org/10.1007/s00701-020-04303-y>.
- Pucher, Philip H., Johnston, Maximilian J., Archer, Stephanie, Whitby, Jack, Dawson, Peter M., Arora, Sonal, & Darzi, Ara. (2019). Informing the Consent Process for Surgeons: A Survey Study of Patient Preferences, Perceptions, and Risk Tolerance. *Journal of Surgical Research*, 235(0), 298–302. <https://doi.org/10.1016/j.jss.2018.09.046>.
- Richardson, Victoria. (2013). Patient comprehension of informed consent. *Journal of Perioperative Practice*, 23(1–2), 26–30. <https://doi.org/10.1177/1750458913023001-204>.
- Rouf, C. E., Lescanne, E., Villeneuve, A., Reffet, K., Kim, S., & Bakhos, D. (2017). Impact of a multimedia support on the understanding of medical information by hearing-impaired patients before cochlear implantation. *European Annals of Otorhinolaryngology, Head and Neck Diseases*, 134(6), 387–392. <https://doi.org/10.1016/j.anorl.2017.05.001>.
- Ruiz López, Pedro. (2013). Informed Consent in Surgery. Distance Between Theory and Practice. *Cirugía Española (English Edition)*, 91(9), 551–553. <https://doi.org/10.1016/j.cireng.2013.12.015>.
- Ruske, Jack, Sharma, Gaurav, Makie, Kevin, He, Katherine, Ozaki, C. Keith, Menard, Matthew T., Belkin, Michael, & Shah, Samir K. (2021). Patient comprehension necessary for informed consent for vascular procedures is poor and related to frailty. *Journal of Vascular Surgery*, 73(4), 1422–1428. <https://doi.org/10.1016/j.jvs.2020.06.131>.
- Sceats, Lindsay A., Morris, Arden M., Narayan, Raja R., Mezynski, Ana, Woo, Russell K., & Yang, George P. (2019). Lost in translation: Informed consent in the medical mission setting. *Surgery (United States)*, 165(2), 438–443. <https://doi.org/10.1016/j.surg.2018.06.010>.
- Shemesh, S., Sidon, E., Heller, S., Cohen N, Kosashvili, Y., Dovrat, R., Velkes, S., & Burg, A. (2019). The quality of informed consent obtained for ortho.pdf. *Journal Of Orthopaedic Surgery* 27(2), 27(2), 1–8.

- Singh, Aman, Rochwani, Ritu, & Oberoi, Simmi. (2021). Informed consent and responses of surgical patients: A study in North India. *National Journal of Physiology, Pharmacy and Pharmacology*, 11(8), 1. <https://doi.org/10.5455/njppp.2021.11.06217202109072021>.
- Stewart, James A., Wood, Lauren, Wiener, Jameson, Kennedy, Gregory D., Chu, Daniel I., Lancaster, Jeffrey R., & Morris, Melanie S. (2021). Visual teaching aids improve patient understanding and reduce anxiety prior to a colectomy. *American Journal of Surgery*, 222(4), 780–785. <https://doi.org/10.1016/j.amjsurg.2021.01.029>.
- Susanto, Dewangga Primananda, Pratama, Bramantya Surya, & Hariyanto, Tuti. (2017). Analysis of Factors Affecting Patient Understanding of Informed Consent in Hospitals. *Indonesian Journal of Health Management*, 5(2), 73–81. <https://doi.org/10.14710/jmki.5.2.2017.73-81>.
- Tricco, Andrea C., Lillie, Erin, Zarin, Wasifa, O'Brien, Kelly K., Colquhoun, Heather, Levac, Danielle, Moher, David, Peters, Micah D. J., Horsley, Tanya, Weeks, Laura, Hempel, Susanne, Akl, Elie A., Chang, Christine, McGowan, Jessie, Stewart, Lesley, Hartling, Lisa, Aldcroft, Adrian, Wilson, Michael G., Garritty, Chantelle, Lewin, Simon, Godfrey, Christina M., MacDonald, Marilyn T., Langlois, Etienne V., Soares-Weiser, Karla, Moriarty, Jo, Clifford, Tammy, Tunçalp, Özge, & Straus, Sharon E. (2018). PRISMA extension for scoping reviews (PRISMA-ScR): Checklist and explanation. *Annals of Internal Medicine*, 169(7), 467–473. <https://doi.org/10.7326/M18-0850>.
- Ulfa, Henny Maria. (2018). Analisa Kelengkapan Informed Consent Tindakan Operasi di Rumah Sakit Sansani Pekanbaru. *Jurnal INOHIM*, 6(1), 21–26.
- Villanueva, Claudia, Talwar, Arpit, & Doyle, Mathew. (2018). Improving informed consent in cardiac surgery by enhancing preoperative education. *Patient Education and Counseling*, 101(12), 2047–2053. <https://doi.org/10.1016/j.pec.2018.06.008>.
- Weise, Alina, Lühnen, Julia, Bühn, Stefanie, Steffen, Felicia, Zacher, Sandro, Lauberger, Julia, Ates, Deha Murat, Böhmer, Andreas, Rosenau, Henning, Steckelberg, Anke, & Mathes, Tim. (2021). Development, piloting, and evaluation of an evidence-based informed consent form for total knee arthroplasty (EvAb-Pilot): a protocol for a mixed methods study. *Pilot and Feasibility Studies*, 7(1), 1–11. <https://doi.org/10.1186/s40814-021-00843-x>
- Wiesen, Brett M., Bronsert, Michael R., Aasen, Davis M., Singh, Abhinav B., Lambert-Kerzner, Anne, Henderson, William G., Hammermeister, Karl E., & Meguid, Robert A. (2020). Use of Surgical Risk Preoperative Assessment System (SURPAS) and Patient Satisfaction During Informed Consent for Surgery. *Journal of the American College of Surgeons*, 230(6), 1025-1033.e1. <https://doi.org/10.1016/j.jamcollsurg.2020.02.049>.
- Wong, Alison L., Martin, Janet, Tang, David, Leblanc, Martin, Morris, Steven F., Paletz, Justin, Stein, John, Wong, Michael J., & Bezuhy, Michael. (2016). The

Effect of Written Information on Recall of Surgical Risks of Carpal Tunnel Release Surgery: A Randomized Controlled Study. *Plastic and Reconstructive Surgery*, 138(6), 1011e-1018e. <https://doi.org/10.1097/PRS.0000000000002771>.

Yoon, Soon Ho, Park, Samina, Kang, Chang Hyun, Park, In Kyu, Goo, Jin Mo, & Kim, Young Tae. (2019). Personalized 3D-Printed Model for Informed Consent for Stage I Lung Cancer: A Randomized Pilot Trial. *Seminars in Thoracic and Cardiovascular Surgery*, 31(2), 316–318. <https://doi.org/10.1053/j.semtcvs.2018.10.017>.

Zimmermann, Agnieszka, Pilarska, Anna, Gaworska-Krzemińska, Aleksandra, Jankau, Jerzy, & Cohen, Marsha N. (2021). Written informed consent—translating into plain language. A pilot study. *Healthcare (Switzerland)*, 9(2). <https://doi.org/10.3390/healthcare9020232>.

Copyright holder:

Rieke Cahya, Diah Melly Maryana, Adik Wibowo (2022)

First publication right:

Syntax Literate: Jurnal Ilmiah Indonesia

This article is licensed under:

