Efficacy of the Informed Consent Process for Surgical Procedures: A Review of the Literature

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Abstract

BACKGROUND: Informed consent is a communication process between a patient and their healthcare team to acquire a patient's approval to undergo a medical intervention. It is essential to the delivery of legal, safe, and patient-centred health care. Despite this, it is often inadequately implemented in clinical practice which frequently contributes to patients having little understanding and can lead to unfavourable outcomes. Furthermore, interventions to improve the consent process are not well recognized. Ultimately, the evaluation of these factors in this review will be of relevance in improving patient-centred care.

OBJECTIVES: Explore degree of understanding and retention of information amongst surgical patients during the informed consent process, identify outcomes of obtaining inadequate informed consent, and evaluate interventions that improve comprehension of surgical treatment.

METHODS: The first electronic search was conducted through EBSCOhost to identify relevant literature on MEDLINE, Academic Search Complete, and CINAHL Plus. A second search was completed through PubMed. Exclusion and inclusion filters were applied, and duplicates removed, which yielded 200 articles. Title/Abstract screening yielded 15 articles which have then undergone full text review to assess for eligibility. This generated the 10 articles used in this review.

RESULTS: Surgical patients have poor comprehension with regards to the benefits, risks, and alternatives of their procedure. Although most patients receive some information about their procedure, this was not suited to their personal goals and needs. Surgical patients also greatly benefited from interventions that were assessed to increase patient understanding and improve the informed consent process.

CONCLUSION: Informed consent is poorly delivered based on the analysis of patient understanding and outcomes. Further research on interventions to improve these elements are recommended as previous studies show notable improvement.

Introduction

Informed consent is a fundamental element of adequate patient communication (1). It is an ethical and legal requirement before proceeding with any form of surgical care (2) as well as emphasizing the concept of autonomy, giving patients the right to be informed about their well-being and to make decisions about their healthcare (1). Informed consent is said to be defined based on three main measures: sufficient delivery of knowledge regarding relevant risks and benefits of the procedure and alternatives; ensuring patient understanding; and obtaining patient's approval for treatment (1,3). Evidence shows that the communication quality correlates with patient comfort and knowledge with respect to their proposed treatment plan (3). Satisfactory patient knowledge will bring about an effective discussion with their physician to create a treatment plan that meets the patient's medical, social, emotional, and economical demands (3). However, patient understanding relating to surgical informed consent is often poor and effectiveness of interventions to improve this remains unknown (2). The literature calls attention to health professionals training needs when facilitating informed consent within clinical consultations (2). This proposes the requirement to identify the level of patient understanding with regards to acquiring informed consent to determine the appropriate approach to best meet the patient's needs (4). Failure to adequately address informed consent violates the principles of biomedical ethics: beneficence, autonomy ,justice and nonmaleficence and exposes the doctor to professional and legal sanction (5). Hence, the focus of this paper is to search for and assess literature with regards to patient understanding, outcomes and communication interventions related to informed consent from surgical patients, to assess the efficacy of this process.

OBJECTIVES:

1. Explore the degree of understanding and recall of information amongst surgical patients during the process of informed consent
2. Identify the outcomes of obtaining inadequate informed consent from surgical patients
3. Evaluate the interventions put in place to aid patients in comprehending surgical treatment

Methodology

SEARCH STRATEGY: Two electronic data bases were organized on EBSCOhost and PubMed to gather relevant literature with regards to the aim and objectives of this review. The following keywords were used on EBSCOhost using Boolean operators:

"patient" AND "informed consent" AND "surgical"

The following databases yielded the maximal results through EBSCOhost:

1. MEDLINE
2. Academic Search Complete
3. CINAHL Plus with Full Text

PubMed was searched separately (using the same keywords as above) and yielded relevant publications.

PROCESS OF SELECTION

Figure 1 below shows a summary of the selection process. The searches on EBSCOhost and PubMed with the keywords "patient" and "informed consent" and "surgical" were conducted. This yielded the maximum results in MEDLINE, Academic Search Complete and CINAHL Plus with Full Text databases through EBSCOhost. PubMed also yielded results, giving a total of 3912 results combined, 1,201 results from MEDLINE, 555 results from Academic Search Complete, 466 results from CINAHL and 1690 results from PubMed. Initial inclusion criteria were selected (see table 1), and these filters were applied: articles that were in available in full text, available in English, published in academic journals between 2000 and 2021, and only qualitative and quantitative studies. This yielded 620 results in total, 138 results from MEDLINE, 203 results from Academic Search Complete, 95 results from CINAHL Plus with Full Text, and 184 results from PubMed. Next, a filter criterion of only adults who are 19+ years was selected leaving 220 articles, excluding articles with only specific age ranges such as just 45–50-year-olds. Duplicates were removed using Zotero reference manager and 200 articles remained. Exclusion/inclusion criteria (see table 1) were applied while abstract screening and this yielded a total of 15 articles. Full text review (see table 3) produced 10 articles meeting criteria for inclusion in this study.

SELECTION CRITIERIA

Table 1: Exclusion and inclusion criteria

Inclusion Criteria	Exclusion Criteria
Available in the English Language	Unavailable in the English Language
Available in full text	No full text available
Available through University College Cork Library	Not available through University College Cork Library or required subscription
Quantitative and qualitative studies reporting original research only	Systematic reviews, literature reviews, protocols, meta-analysis
Published in academic journals and peer reviewed between 2000 and 2021	Non-peer reviewed literature (ex: magazine articles) and published literature before 2000
Population included all adults (19+) who do not required assisted decision making	Patients under 19, specific adult ranges only, and patients who required assistance in decision making
Surgical patients in a hospital setting	Patients who are receiving non-surgical interventions or not receiving surgical treatment at a hospital (ex: in a clinic or ambulatory care center)
Studies investigating the interventions that aid in comprehending surgical treatment	Studies investigating interventions that aid in comprehending post operation treatment

Table 2: Reasons for exclusion of articles during full text review

Reason for Exclusion	Number of Articles
Guideline protocol	2
Not exclusively consent for surgical treatment	3
Total excluded	5
Remaining articles	10

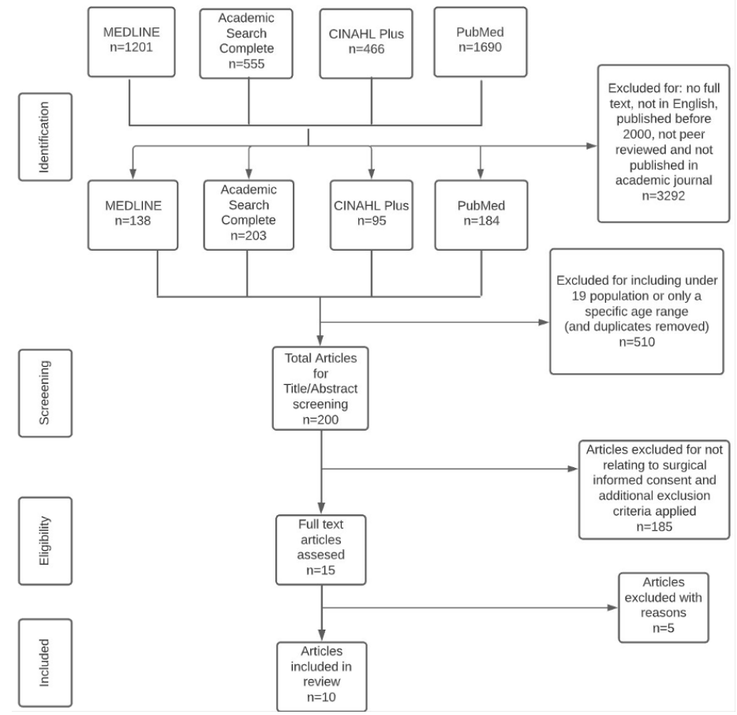

Figure 1: Summary of study selection process

Results

During the selection process, ten articles meeting study criteria were included. Of the ten, eight were quantitative (6–13) and two were qualitative (14,15). Specific study designs included four cross sectional studies (6,7,10,13), two narrative studies (14,15), two randomized control studies (8,12), and two prospective cohort studies (9,11). Many methods were used to collect data, such as structured questionnaires (6,7,11,13), semi-structured questionnaires (9), and interviews (14,15). The location of these studies varied with one study taking place in Croatia (6), one in Uganda (7), one in New Zealand (14), one in Australia (8), two in Britain (9,10), two in the USA (11,13), one in India (12) and one in Israel (15). The sample sizes ranged from 12 (15) to 371 (7) participants. The summary of each of the ten articles is included in Table 4.

ASSESSMENT OF STUDY QUALITY

The EBL appraisal tool was used for the eight quantitative studies (6–13). See appendix A for the EBL checklist. The CASP tool was used for the two remaining qualitative studies (14,15) selected for this literature review. The validity scores of the quantitative studies using the EBL critical appraisal tool checklist (16) are summarized in table 5 below along with the summary of the CASP checklist (17) for the qualitative studies in Table 6.

Table 3: Summary of selected articles

Author (Year), Title, Location	Aim(s), Design, Sample Size, Population	Study Methodology	Key Findings	Study Strengths and Limitations	Future Directions
Vucemilo *et al* (2013) Are physician-patient communication practices slowly changing in Croatia? – a cross-sectional questionnaire study (6) Zagreb, Croatia	Examine practices of doctor-patient communication while acquiring informed consent in hospitals Cross-sectional questionnaire study N= 250 Internal medicine and surgical patients	Two-part questionnaire given to 250 patients from five tertiary level hospitals Questionnaires were anonymous and focused on communication and informed consent Part one of questionnaire: 32 questions (20 on patient doctor communication and informed consent, 6 on doctor-patient relationship, and 6 on patient rights) Part two of questionnaire: 12 questions on socio-demographic aspects	Fifty seven percent of patients rated the comprehension level of benefits, risks, and alternatives as high, 37% as average and 5% as low Patients were informed about risks regarding a rejection of a surgical procedure in 69% of cases Of the total, 76% of patients received information on risks of proposed treatment Of the total, 46% of patients received information on other methods of treatment	*Strengths:* Large sample size Population had both sexes and range of age groups (18-86 years) Large response rate *Limitations:* Actual conversations between physicians and patients were not recorded so study relied on patients recall of information No qualitative analysis was done which can be of benefit	Further quantitative and qualitative data should be gathered Further assessment of communication practices in health care, particularly in Croatia Increase the importance of informed consent processes within hospitals in Croatia Have communication skills training for medical health professionals including medical students
Ochieng *et al* (2015) Informed consent in clinical practice: patients' experiences and perspectives following surgery (7) Uganda	Identify patients' events and viewpoints with regards to surgical informed consent Cross-sectional questionnaire study N=371 Post-operative patients from different surgical disciplines	Within two weeks after surgery, participants were given a semi structured questionnaire to complete Questionnaire composed of questions related to surgical details and the informed consent discussion with their medical professional	Eighty percent of participants have received explanations of their surgery and 56.1% had their concerns addressed before the surgery Of the total,17% of patients were not aware of the kind of surgery they had Seventeen percent of patients did not recall giving consent for surgery Of the total, 23.7% of participants can name the medical professional that received consent from them	*Strengths:* Participants portrayed a range of adult age groups Participants in the study had different education and social class Large sample size *Limitations:* Study was only conducted at major referral hospitals which have the most senior surgeons, findings may not be applicable for other hospitals Inclusion and exclusion criteria of participants not outlined	Improve patients' participation during decision making by providing education programs for doctors
Agnew *et al* (2012) Informed Consent: A Study of the OR Consenting Process in New Zealand (14) New Zealand	To address if the patient's comprehension of the procedure and the information given appropriate for the needs of each patient Qualitative study N=18 Surgical patients from 3 specialty areas: orthopaedics, general surgery, and urology	Telephone contact was made with patients ten to fourteen days after surgery that lasted 30 minutes Interviews were recorded and patients were asked to explain how they gave consent for surgery, to share how much information they received about their surgery and to describe things that they found to be positive and negative about the consenting process	One hundred percent of patients concluded that they were provided with some information with regards to their surgery One hundred percent of patients stated that the information was not given in an appropriate way and did not meet their personal goals and needs	*Strengths:* Qualitative study design is appropriate for the aims of the study One interviewer reduces chance of variability between observers Compares surgical patients from different speciality areas *Limitations:* Small number of participants General nature of information is hard to gather	Future research can focus on more specific populations such as gaining consent within different ethnic groups Perioperative nurses should receive specific training for the consenting process

Table 3: Summary of selected articles (continued)

Author (Year), Title, Location	Aim(s), Design, Sample Size, Population	Study Methodology	Key Findings	Study Strengths and Limitations	Future Directions
Fraval *et al* (2015) Internet based patient education improves informed consent for elective orthopaedic surgery: a randomized control trial (8) Australia	To determine if providing patients to educational websites as part of the consent process will improve the efficacy of the informed consent process Randomized control study N= 211 Surgical patients from orthopaedic outpatient clinic and were booked for orthopaedic procedures	Patients received standard informed consent discussion with their surgeon then randomized to either the control arm or intervention arm The experiment arm was asked to read the appropriate part of the website and then both groups were directed to complete the same survey	Clinically notable increase in patient knowledge for the intervention arm relative to the control arm ($p< 0.01$) Satisfaction of patient was improved in the intervention arm compared to control arm ($p=0.043$)	*Strengths:* Used validated survey to test comprehension First randomized control trial to examine effectiveness of a online education resource designed for hospital patients *Limitations:* No longitudinal follow up to assess if the enhancement in knowledge is still present	Future research focus on the efficacy of exposing patients to online resources before and after consent, particularly in elective orthopaedic procedures
Zarnegar *et al* (2015) Patient perceptions and recall of consent for regional anaesthesia compared with consent for surgery (9) Britain	Evaluate the efficacy of consent for interscalene block and compare this with consent for surgery Prospective observational Study N=46 Adult patients who had shoulder replacement procedures under general anaesthesia (interscalene brachial plexus block)	Participants were interviewed using a structured questionnaire comprised of 18 questions relating to interscalene brachial plexus block and shoulder arthroplasty consent	All patients stated that they agreed to undergo both interscalene block and the arthroplasty of their shoulder Of the total, 60% believed that once a consent form has been signed, they cannot change their mind Of the total, 60% of patients did not read the consent form for their surgery prior to signing Twenty four of the forty-six patients viewed the consent form as a way by which hospitals protect themselves against litigation Of the total, 33% of patients did not think the preoperative discussion concerning the general anaesthesia was as important as the consent form for surgery	*Strengths:* One of few studies that evaluate consent for anaesthetic procedures Compares patient experience and recall of consent of an anaesthetic procedure with a surgical procedure *Limitations:* Small sample size Examined patients who had a specific intervention in one speciality	Emphasize the importance of developing efficient strategies to increase patient comprehension of consent for anaesthetic procedures
Howlader *et al* (2004) Patients' views of the consent process for adult cardiac surgery: questionnaire survey (10) Britain	Examine patient perception and recollection of the surgical consent process Cross-sectional questionnaire study N=100 Patients who underwent cardiac surgery from January to February 2003 in the same London teaching hospital	Patients completed questionnaires after their surgery, and a day before they are discharged from the hospital Questionnaire was on information they were given during consent process	Eighty- nine percent of patients stated that information given at consent has been adequate Of the total, 38 % of patients stated that use of booklets alone in comparison with verbal explanations is less discouraging Thirty one percent of patients could recall the risk of surgery at time of discharge Themes emerged: most patients will not comprehend or recall risks that have been communicated to them verbally	*Strengths:* Cardiac surgery is suitable for assessing consent No other studies examining consent process for post-Bristol area *Limitations:* Recall bias as questionnaires were given prior to discharge	Use of booklets, audiotapes, and videotapes for consent process Communicate risks and probabilities to patients Research on optimum timing of consent

Table 3: Summary of selected articles (continued)

Author (Year), Title, Location	Aim(s), Design, Sample Size, Population	Study Methodology	Key Findings	Study Strengths and Limitations	Future Directions
Feiner *et al* (2016) Preoperative Surgical Discussion and Information Retention by Patients (11) USA	Assess the degree of information communicated to patients is comprehended and recalled after pre-operative discussion of upper limb procedures Prospective cohort study N=20 Patients who were scheduled to undergo elective upper extremity surgery	Patients given same 20 item questionnaire to complete twice, once after the first preoperative discussion (several weeks before surgery) and the second time after preoperative discussion two (one week before surgery)	0 out of the 20 patients did not retain 100% of information in any of the two visits There was less comprehension of the preoperative discussion during the second visit (patients retained 73% of information in first visit and 61% during the second visit) Of the total, 50% of patients stated that they comprehended 100% of the discussion but this value dropped to 10% after preoperative discussion two	*Strengths:* Easily reproducible Evaluates patient comprehension over time which can minimize recency effect *Limitations:* Small sample size Patient population only represents only one surgeons practice Data is quantitative and does not tell complete story of each patient	Investing time in educating patients about their operations is vital Continue further research that improves patient care
Karan *et al* (2014) The effect of multimedia interventions on the informed consent process for cataract surgery in rural South India (12) India	Test effect multimedia resources on the comprehension of cataract surgery if it is added to the informed consent process Randomized control study N=97 Patients at a private surgical hospital scheduled to undergo a cataract surgical procedure	Patients allocated randomly in intervention group and control group Intervention group was given a verbal informed consent with a educational pamphlet and a 3-D model of the eye Control group was still given informed consent but only verbally The two groups were tested using a quiz before informed consent, after informed consent and one day before surgery The quiz had a True/False/I don't know setup	Both groups showed enhancement in between scores of pre and post informed consent quizzes (P value on the order of 10^{-6}) more improvement in the intervention group (P value on the order of 10^{-16}) No notable differences observed in change of scores between post-informed consent and post-operative quizzes Multimedia aid is effective in improving patient comprehension even in a patient population with limited knowledge	*Strengths:* Appropriate representation of population due to non bias selection criteria *Limitations:* Absence of true randomization into control and intervention groups Small sample size Challenge to make sure there is complete standardization of informed consent experiences	Further research on usefulness of multimedia interventions in diverse patients Identify optimal multimedia images and models that target different patient populations

OBJECTIVE 1: DEGREE OF UNDERSTANDING AND RETENTION AMONGST SURGICAL PATIENTS DURING THE INFORMED CONSENT PROCESS

Seven of the studies evaluated patient comprehension of the informed consent process prior to surgical treatment (7–11,13,15). Feiner et al concluded that 0 of the 20 patients fully retained the surgical detail provided to them at preoperative discussions and 50% of patients expressed that they comprehended 100% of the discussion during the first preoperative discussion, however this figure dropped to 10% at their second preoperative discussion, one week prior to surgery (11). Another group of physicians in Britain focused on recall of information at time of discharge and found that 31 of the 100 patients were able to recall the risk of their completed surgery (10). On the other hand, Zarnegar et al assessed the consent process of anaesthetic procedures in comparison with consent for surgery and findings showed that 24 of the 46 patients only regarded consent forms as a method of protection from litigation for hospitals (9). A further study centred on patient's experiences of the informed consent process, following surgery (7). Seventeen percent of participants were unaware of the name of their surgical procedure (7).

OBJECTIVE 2: OUTCOMES OF ACQUIRING INADEQUATE INFORMED CONSENT FROM SURGICAL PATIENTS

The efficacy of the consent process was assessed in six studies, and several diverse outcomes were identified (6,7,9,10,14,15). The two qualitative studies found that patients were not given information concerning their surgical procedure that was suitable for their personalized needs (14,15). However, Howlader et al indicated that 89% of patients were satisfied with information

Table 3: Summary of selected articles (continued)

Author (Year), Title, Location	Aim(s), Design, Sample Size, Population	Study Methodology	Key Findings	Study Strengths and Limitations	Future Directions
Lorenzen et al (2008) Using Principles of Health Literacy to Enhance the Informed Consent Process (13) USA	Assess the use of health literacy in improving patient knowledge of medical interventions Cross-sectional questionnaire study N=41 Patients aged 26-80 years who underwent varying surgical procedures	Patients were given two different consent forms (original and new reader friendly) with access to surgery nursing staff for assistance Data collection was made through nurses filling out survey based on patient performance and comprehension	Common language used in surgical consent forms often surpass average reading level of US patients Of the total, 75% of patients do not read the consent documents Addition of reader friendly language makes it more likely patient will read consent documents (52% increase in reading of documents) Adding teach back methods performed by nurses increases patient understanding	*Strengths:* Study contributed to body of evidence-based practice Study evaluated the development of better practices in health literacy aspect of medical practice *Limitations:* Some patients were scheduled to undergo eye surgery and may have experienced vision problems while attempting to read consent documents which can have effect on results Methodology was not clearly stated enough for replication	Increase staff member awareness of health literacy concepts
Gabay et al (2019) What do patients want? Surgical informed-consent and patient-centered care - An augmented model of information disclosure (15) Israel	Identify the major concerns and preferences of patients concerning disclosure information prior to surgery Narrative study N=12 Patients who underwent major surgeries in public hospitals with varying ages and socio-demographic traits	Two interviews were carried out with each participant at their homes Interviews were from 90 minutes to 2 hours; the first interview was two days after discharge and the second interview was three weeks after Participants were asked to comment on the reason they came to the hospital and their experience	Participants expected that the information they were given would be tailored to their constraints and aims Participants wanted to be aware of the risks of the surgery to feel in-control Themes from narrative analysis: objectification of patients, intimidating scenarios and lack of information for patients	*Strengths:* Study supported the view of patient-centeredness Narrative study led to the creation of an augmented model of information disclosure *Limitations:* Restricted awareness of time constraints Controversy over what aspect of the organizational culture at the hospital had suboptimal surgical informed consent	Further research using narrative methods to fully acknowledge patients' experiences of surgical consent Future studies to determine challenges that surgeons face with application of the augmented model of surgical informed consent

Table 5: Validity scores of quantitative studies based on the EBL Quantitative Checklist

Study	Population validity (%)	Data Collection validity (%)	Study Design validity (%)	Results validity (%)	Overall validity (%)
Vucemilo et al. (2013)	100	87.5	100	100	95.8
Ochieng et al. (2015)	66.6	100	80	100	87.5
Fraval et al. (2015)	100	100	80	50	84
Zarnegar et al. (2015)	83.3	83.3	100	83.3	86.9
Howlader et al. (2004)	100	66.6	80	100	86.9
Feiner et al. (2016)	66.7	66.6	80	83.3	73.9
Karan et al. (2014)	75	66.6	80	83.3	76
Lorenzen et al. (2008)	66.6	50	80	83.3	69.5

provided (10). A range of 57-100% expressed that they received information regarding their surgery (7,10) but in another study, 60% of the total thought there was no withdrawal of consent after signing forms (9) and 57% of patients in the Vucemilo et al study stated they have highly obtained the benefits, risks, and alternatives of their recommended procedure (6). Another study in Uganda found that 17% of the 371 participants did not remember providing consent for surgery (7).

Table 6: Summary of qualitative studies' quality based on CASP assessment

Study	Was there a clear statement of the aims of the study?	Is qualitative methodology appropriate?	Was the research design appropriate to address the aims of the research?	Was the recruitment strategy appropriate to the aims of the research?	Was the data collected in a way that addressed the research issue?	Has the relationship between researcher and participants been adequately considered?	Have ethical issues been taken into consideration?	Was the data analysis sufficiently rigorous?	Is there a clear statement of the findings?	Are the research findings valuable?
Agnew et al. (2012)	Y	Y	Y	Y	Y	C	Y	Y	Y	Y
Gabay et al. (2019)	Y	Y	Y	Y	Y	C	Y	Y	Y	Y

Key: Y=Yes, N=No, C=Can't tell

OBJECTIVE 3: COMMUNICATION INTERVENTIONS PUT IN PLACE TO AID PATIENTS IN COMPREHENDING SURGICAL TREATMENT

Different types of interventions to help patients' comprehension of various aspects of their surgical procedure were assessed in three of the studies (8,12,13). Participants often showed improvements in understanding of surgical procedure and its elements of risks, benefits, and alternatives (8,13). Lorenzen et al first reported that seventy five percent of the participants signed the consent form without reading (13). But with the introduction of newly developed surgical consent forms with patient-friendly language and use of teach back methods while communicating with patients increased reading of surgical consent forms by 52% and patient understanding of their procedure by 12%, respectively (13). In another study, use of multimedia resources such as a pamphlet and 3-dimensional model of the eye was used to assess effect on patient comprehension of cataract surgery (12). The use of this intervention increased scores in the post-informed consent quiz by a notable amount compared to control (12).

Discussion

DEGREE OF UNDERSTANDING AND RECALL AMONGST SURGICAL PATIENTS THROUGHOUT THE INFORMED CONSENT PROCESS

The degree of understanding and level of retention among surgical patients was suboptimal according to the selected literature (7–11,13,15). Studies varied in time of patient approach, some focused on preoperative recall and comprehension (7,8,11,13) while others examined these two points postoperatively (9,10,15). Despite the time of recall, patients still exhibited poor recall diminishing the possibility of the results being due to recall bias. The analysis of comprehension and recall is a constructive tool for examining the efficacy of the informed consent process, which in turn reflects the collaboration between the patient and their doctor (7). This concept is supported by other literature, Shah et al conclude that by declaring informed consent was obtained, it is presumed the physician assessed patient understanding (18). These findings are pertinent since informed consent is said to be carried out, but its purpose is often not attained. It is expected to be a practice that enables patients to have sufficient information to make competent decisions, yet its implementation is hindered (7).

OUTCOMES OF OBTAINING INADEQUATE INFORMED CONSENT FROM SURGICAL PATIENTS AND ASSISTANCE INTERVENTIONS

The signed consent form does not inevitably constitute informed consent (19). This seems to be the case in modern medicine, nevertheless, adequate acquisition of informed consent is of increasing importance and physicians are required to maintain this to meet legal and ethical expectations. Several themes emerged as the review progressed. Participants did not feel like they received sufficient detail about their procedure and the discussion was not suitable for their intentions, affecting quality of co-decision making (6,7,10,14,15). This highlights the necessity to determine factors that contribute to these results. Previous studies show considering a patient's level of education, time constraints, use of confusing language and medical jargon, and patients who may not speak English as a first language are factors that play a role in poor comprehension and therefore lead to inadequate patient consent (2,4). The use of websites and models were associated with improvements in patient comprehension during pre-operative consultations (12,13). These findings signify the need for interventions that will improve not just patient understanding but the delivery of information by physicians. Previous studies show that templates provided to surgeons may facilitate general discussion and can remind surgeons of key details, but discussion must still be individualized for each patient (19). Further research can be conducted to identify ways in which consent discussions can be modified to meet each patient's ideas, concerns and expectations while still providing generic information.

STRENGTHS AND LIMITATIONS OF STUDIES

Although only ten articles were selected, varying strengths of each study provided relevant contributions to the aims of this review. In one study, there was a range in age groups and educational levels of participants and results were similar between them (7). This takes in consideration the poor efficacy of the informed consent process while eliminating confounding factors. Another study was one of the first to run a randomized control trial to test effectiveness of online educational tools (8). This is contributory to modern medical practice as technology plays a big role in the delivery of healthcare.

Certain limitations were present in the studies, and they were highlighted by using EBL and CASP critical appraisal tools. Six of the ten selected studies had a sample size under 100. This can affect the validity of results. Future research can aim to conduct studies with more appropriate sample sizes. Another limitation was failure to account for confounding variables in four of the studies (8,9,11,12). This provided a low score for the results section in the EBL checklist. For example, patient factors such as vision or hearing difficulties may contribute to inaccurate completion of questionnaires. For the qualitative studies, it was not clear whether the researcher-participant relationship was considered, which is essential for minimizing bias in qualitative research (14,15).

STRENGTHS AND LIMITATIONS OF REVIEW

This review included both qualitative and quantitative studies. This is advantageous for analysing aspects of informed consent since it is tailored on generalized human rights but also patient specific goals. The qualitative studies provided patient own experiences by using narrative methods while the quantitative studies were key in identifying prevailing issues using numerical data. This review also provides perspective from eight different countries in five different continents. This addresses the efficacy of the process of informed consent in various hospital healthcare systems. Therefore, similar findings listed above can be beneficial internationally and not confined to specific locations.

This review also had some limitations. Firstly, studies selected participants from different surgical departments. This may influence the results since surgical procedures are simpler to comprehend than others. Although patient comprehension is a key measure of the efficacy of informed consent, it is difficult to achieve a standardized assessment of patient comprehension when the surgeries are of different complexities. Therefore, further reviews could focus on comparing the efficacy of the consent process within similar surgical departments to determine consistency of results. This may propose research in areas of developing specific interventions that will be effective with helping patients undergoing different surgeries understand the aspects of informed consent. Secondly, only ten articles were chosen, and they were in English and chosen if available from the University College Cork library which could have modified results. Finally, this review was done by one researcher leading to a reduction in quality and limited interpretative viewpoint.

CONCLUSION

Existing literature claims that some aspects of collaborative decision making during the informed consent-obtaining process are present, but patient-doctor communication appears to be suboptimal according to the level of understanding in patients and poor outcomes of the informed consent process. However, interventions established to support this process are proven to be of high effectiveness. This literature review highlighted the necessity for improvements in surgical consultations to facilitate informed consent. More research on the quality of informed consent within other medical specialties and doctor and patient factors that affect efficacy of this process is recommended. The paramount goal of research in this area is enhancing patient-centred care in practice.

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Appendix

Appendix A: EBL Critical Appraisal Checklist

EBL Critical Appraisal Checklist		Vucemilo et al. (2013)	Ochieng et al. (2015)	Fraval et al. (2015)	Zarnegar et al. (2015)
Section A: Population	Is the study population representative of all users, actual and eligible, who might be included in the study?	Y	Y	Y	Y
	Are inclusion and exclusion criteria definitively outlined?	Y	N	Y	Y
	Is the sample size large enough for sufficiently precise estimates?	Y	Y	Y	N
	Is the response rate large enough for sufficiently precise estimates?	Y	Y	Y	Y
	Is the choice of population bias-free?	Y	N	Y	Y
	If a comparative study: Were participants randomized into groups? Were the groups comparable at baseline? If groups were not comparable at baseline, was incomparability addressed by the authors in the analysis?	N/A	N/A	 Y Y N/A	N/A
	Was informed consent obtained?	Y	Y	Y	Y
Section B: Data Collection	Are data collection methods clearly described?	Y	Y	Y	Y
	If a face-to-face survey, were inter-observer and intra-observer bias reduced?	N/A	N/A	N/A	N/A
	Is the data collection instrument validated?	Y	Y	Y	U
	If based on regularly collected statistics, are the statistics free from subjectivity?	U	Y	N/A	N/A
	Does the study measure the outcome at a time appropriate for capturing the intervention's effect?	Y	Y	Y	Y
	Is the instrument included in the publication?	Y	Y	Y	Y
	Are questions posed clearly enough to be able to elicit precise answers?	Y	Y	Y	Y
	Were those involved in data collection not involved in delivering a service to the target population?	Y	Y	Y	Y
Section C: Study Design	Is the study type / methodology utilized appropriate?	Y	Y	Y	Y
	Is there face validity?	Y	U	U	Y
	Is the research methodology clearly stated at a level of detail that would allow its replication?	Y	Y	Y	Y
	Was ethics approval obtained?	Y	Y	Y	Y
	Are the outcomes clearly stated and discussed in relation to the data collection?	Y	Y	Y	Y
Section D: Results	Are all the results clearly outlined?	Y	Y	Y	Y
	Are confounding variables accounted for?	Y	Y	N	U
	Do the conclusions accurately reflect the analysis?	Y	Y	Y	Y
	Is subset analysis a minor, rather than a major, focus of the article?	Y	Y	U	Y
	Are suggestions provided for further areas to research?	Y	Y	Y	Y
	Is there external validity?	Y	Y	U	Y

Key: Y= Yes, N=No, U=Unclear, N/A=Not applicable

Appendix

Appendix B: EBL Critical Appraisal Checklist

	EBL Critical Appraisal Checklist	Howlader et al. (2004)	Feiner et al. (2016)	Karan et al. (2014)	Lorenzen et al. (2008)
Section A: Population	Is the study population representative of all users, actual and eligible, who might be included in the study?	Y	Y	Y	Y
	Are inclusion and exclusion criteria definitively outlined?	Y	N	Y	N
	Is the sample size large enough for sufficiently precise estimates?	Y	N	N	N
	Is the response rate large enough for sufficiently precise estimates?	Y	Y	Y	Y
	Is the choice of population bias-free?	Y	Y	Y	Y
	If a comparative study: Were participants randomized into groups? Were the groups comparable at baseline? If groups were not comparable at baseline, was incomparability addressed by the authors in the analysis?	N/A	N/A	 N Y N/A	N/A
	Was informed consent obtained?	Y	Y	Y	Y
Section B: Data Collection	Are data collection methods clearly described?	Y	Y	Y	N
	If a face-to-face survey, were inter-observer and intra-observer bias reduced?	N/A	N/A	N/A	N/A
	Is the data collection instrument validated?	N	U	U	N
	If based on regularly collected statistics, are the statistics free from subjectivity?	N/A	N/A	N/A	N/A
	Does the study measure the outcome at a time appropriate for capturing the intervention's effect?	Y	Y	Y	Y
	Is the instrument included in the publication?	N	U	U	U
	Are questions posed clearly enough to be able to elicit precise answers?	Y	Y	Y	Y
	Were those involved in data collection not involved in delivering a service to the target population?	Y	Y	Y	Y
Section C:Study Design	Is the study type / methodology utilized appropriate?	Y	Y	Y	Y
	Is there face validity?	U	U	U	Y
	Is the research methodology clearly stated at a level of detail that would allow its replication?	Y	Y	Y	N
	Was ethics approval obtained?	Y	Y	Y	Y
	Are the outcomes clearly stated and discussed in relation to the data collection?	Y	Y	Y	Y
Section D: Results	Are all the results clearly outlined?	Y	Y	Y	Y
	Are confounding variables accounted for?	Y	N	N	Y
	Do the conclusions accurately reflect the analysis?	Y	Y	Y	Y
	Is subset analysis a minor, rather than a major, focus of the article?	Y	Y	Y	U
	Are suggestions provided for further areas to research?	Y	Y	Y	Y
	Is there external validity?	Y	Y	Y	Y

Key: Y= Yes, N=No, U=Unclear, N/A=Not applicable