Understanding the Effectiveness of Informed Consent in Pediatric Surgery

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Abstract - English

Background: The consent conversation is an essential part of the pre-operative decision-making process. The manner in which this consent conversation is led has significant consequences, yet the process is imperfect. We aim to improve the teaching of effective consenting processes in pediatric surgery by identifying and sharing evidence based on the literature and a clinical study. Ultimately, our research addresses the knowledge gap surrounding the effectiveness of informed consent and emphasizes the importance of the patient perspective in the process.

Methods: The first phase of this project is a systematic literature review identifying the best practices of informed consent, followed by two clinical phases that involve pediatric surgeons at the Montreal Children's Hospital. The second phase consisted of interviews in which the surgeons will be asked to consent a standardized parent for their child's surgery. The videos were filmed and evaluated using a questionnaire by patient's and families of various medical and surgical backgrounds.

Results: Our research has identified strengths and weaknesses of the current informed consent process in pediatric surgery. Aspects of the process that have been found to be effective include the use of multimedia, adequate time, surgeon empathy, the possibility of multiple conversations, and adopting an individualized shared decision-making approach. Some areas of the process that may need improvement include better use of language by the surgeon, more time for questions, recognition of parental anxiety and improvement of recall, and consideration of the child and their rights.

Conclusions: Our results highlight potential areas for improvement in the current process. Upon completion of this work, we hope to compile the information from the clinical study and the

literature concerning effective consent processes and use it to create new consenting videos that can be disseminated as a teaching resource for medical students and surgical residents.

Keywords: informed consent, pediatric, surgery, consenting, shared decision making

Résumé - Français

Contexte : Le consentement éclairé est un élément essentiel du processus de décision préopératoire. La manière dont cette conversation est conduite a des conséquences importantes, et cependant le processus est imparfait. Nous espérons améliorer l'enseignement de processus de consentement favorables en chirurgie pédiatrique en identifiant et en partageant des connaissances fondées sur la littérature et une étude clinique. En fin de compte, notre recherche comble le manque de connaissances sur l'efficacité du consentement éclairé et souligne l'importance de la perspective du patient dans le processus.

Méthodes : La première phase de ce projet est une revue systématique de la littérature identifiant les meilleures pratiques du consentement éclairé, suivie d'une phase clinique impliquant des chirurgiens pédiatriques de l'Hôpital de Montréal pour enfants. La deuxième phase consisterait en des entrevues dans lesquelles nous demanderions aux chirurgiens de faire consentir un parent standardisé pour la chirurgie de leur enfant. Les vidéos ont été filmées et évaluées à l'aide d'un questionnaire par des patients et des familles ayant vécu diverses expériences médicales et chirurgicales.

Résultats : Notre recherche a permis d'identifier les forces et les faiblesses du processus actuel de consentement éclairé en chirurgie pédiatrique. Les aspects du processus qui se sont avérés efficaces incluent l'utilisation du multimédia, une durée suffisante, l'empathie du chirurgien, la possibilité de plusieurs conversations et l'adoption d'une approche individualisée de prise de décision partagée. Les aspects du processus qui pourraient être améliorés incluent une meilleure utilisation du langage par le chirurgien, plus de temps pour les questions, la reconnaissance de l'anxiété des parents et l'amélioration du rappel, ainsi que la prise en compte de l'enfant et de ses droits.

Conclusions : Nos résultats soulignent les domaines potentiels d'amélioration du processus actuel. Une fois que ce travail sera terminé, nous espérons compiler les informations provenant de l'étude clinique et de la littérature concernant les processus de consentement efficaces et les utiliser pour créer de nouvelles vidéos sur le consentement qui pourront être distribuées comme ressource pédagogique pour les étudiants en médecine et les résidents en chirurgie.

List of Abbreviations

CMPA: Canadian Medical Protective Association

EOE: Ethics of Expertise

MCH: Montreal Children's Hospital

NICU: Neonatal Intensive Care Unit

SDM: Shared Decision Making

Table of Contents

Chapter 1: Introduction

Overview and Knowledge Gaps

The consent conversation is an essential part of the pre-operative decision-making process. It is a process that is taught, learned, and practiced on a regular basis, and often varies from surgeon to surgeon. Nonetheless, there is a lack of knowledge concerning the critical components of such conversations as well as the best practices (1–4).

Consenting or the *informed consenting process* are mentioned in reference to several related terms in the literature, including shared decision-making and risk communication. We see consent as a process that involves both, with the patient/family and healthcare team both involved in every aspect of this process. Frameworks such as the Common Morality Framework (5) and the Ethics of Expertise (6) framework are important to discuss in order to better understand the fundamental principles of informed consent.

Shared Decision Making

Shared decision-making (SDM) involves an "exchange of ideas between patient and physician and collaboration in the decision itself" (7). The process recognizes the importance of patient opinion and contribution to decision-making, and has been shown to avoid decisional conflict and regret (8). Despite the intuitive appropriateness of this process, there are certain challenges, such as communication barriers and lack of familiarity with the procedure and its risks or benefits (9). Additionally, the decision-making may reflect a power imbalance in which patients feel intimidated or less knowledgeable than the medical professional (9), which may compromise their ability to make a decision (10). It is important to also consider the social forces and the

power imbalances inherent to the healthcare system, such as differences in role, status and knowledge as they can all undermine the effectiveness of informed consent (11).

Risk Communication

Risk communication, "the open two-way exchange of information and opinion about risk" (12), is the process by which providers communicate the need and risks of anticipated procedures or treatments with their patients. Unlike SDM, which entails a more comprehensive discussion and decision, risk communication is concerned solely with the communication of risk information. The risk discussion process entails several challenges and pitfalls that may lead to undesirable outcomes for the patient surrounding misinterpretation or misinformation (1). There are multiple communication barriers arising from the interaction of stakeholders with different understandings, perspectives and cultures (9), and these barriers must be addressed in order to avoid mistrust and ensure comprehension of the information conveyed (9). In addition, providers should be aware of the risk biases that patients may hold, such as the Availability Bias ("patients underestimate a risk that receives substantial notoriety") or Compression ("patients overestimate small risks and underestimate large risks") (1). Ultimately, a better understanding of ways to communicate risk information effectively is necessary in order to improve SDM. There is also a key educational prerogative for risk communication, as students at all levels in the health professions need to see models of effective consent conversations, as judged by both experts and patients, as part of their training.

Common Morality Framework

This framework was introduced by Gert *et al* in 1997, and provides insight into the practice and teaching of informed consent processes (5). Current literature surrounding informed consent

focuses on the procedure rather than the ethical foundations of the process (13). The authors provide an analytical model for informed consent that considers the legal and policy aspects, but emphasizes underlying ethical concepts. They argue that a "common morality exists" and that features include a clear process for differentiating a good moral concept from a bad one, a public morality that is applicable to all persons at all times, prohibitions of harms, and finally an understanding that paternalistic actions must be justified according to the system (5). The framework focuses on what is not moral rather than what is, and therefore encourages informed consent to emphasize harms (13). The authors explain that the use of this framework will improve the patient-provider relationship and patient trust while meeting the administrative needs of the conversation. The framework emphasizes obtaining informed consent as a relationship, rather than a checklist that needs to be fulfilled (13).

Ethics of Expertise (EOE) Framework

This framework was developed for scientists and practitioners based on the concept that "scientists have responsibilities to provide information in a way that promotes autonomous decision-making on the part of the public and its representatives" (6). The authors emphasize that scientists also have moral obligations to disseminate scientific information to the public. According to this framework, physicians should provide information in a way that those with diverse beliefs and values can use the expert information to guide their own decisions (6). Ultimately, it serves as a basis for obtaining informed consent from a patient as it enables them to make decisions that may affect their well-being (6). This framework reinforces some of the fundamental ethical principles of informed consent, beneficence and respect for autonomy (14).

EOE also relates to the concept of shared decision-making, which emphasizes the provision of adequate information for patients and families to make an informed and involved decision (7).

Knowledge Gaps

The manner in which the consent conversation is led has significant consequences, yet the process is fraught with multiple potential pitfalls and can lead to undesirable outcomes. Considering the frequent and significant use of informed consents, the literature exploring and assessing their effectiveness in pediatric surgical practice is very limited. In order to examine the effectiveness of the consent process, one must acknowledge *who* is assessing the quality of the consent. Many Canadian resources describe the desirable steps and processes of obtaining consent from the viewpoint of legal stakeholders (15) and clinician experts (11) Yet, the ultimate judge of the quality of this process should be the patient undergoing the procedure. An emphasis on both clinical evidence and patient preferences is crucial when obtaining informed consent.

There are discrepancies within the literature with regards to the definition, purpose, and key elements of informed consent. The definition of informed consent is variable and differs depending on the context - as it may be used for legal, ethical, or administrative purposes (11). These purposes often overlap, but it is important to acknowledge their differences in order to identify specific criteria for adequacy and effectiveness of the consent (11). According to Glaser et al., the four key elements of informed consent are understanding the risks, benefits, alternatives, and general knowledge about the procedure (16). These elements demonstrate risk communication as well as aspects of SDM. In a systematic review of 44 studies examining interventions to improve patient comprehension in informed consent, researchers concluded that only 6 of 44 studies assessed all four of the previously mentioned elements of understanding

(17). Similarly, Leclercq and his team outlined three elements of informed consent: assessment of preconditions, provision of information, and stage of consent (3). The assessment of preconditions verified the patient's competence and willingness to make an informed decision (3). The provision of information is the discussion of diagnosis as well as the recommendation and alternatives, all with a focus on patient education and comprehension. Finally, the stage of consent represents the actual consenting of the patient and the recording of this authorization (3). Their findings suggest that only 55% of their surgeon cohort were familiar with these three elements of informed consent (3). This emphasizes the importance of risk communication and SDM in the informed consent content. A more concrete and comprehensive definition of informed consent and its purposes needs to be identified and widely acknowledged in order to improve the process.

Another aspect of the informed consent conversation that needs to be improved is parent comprehension. Researchers have looked at parental comprehension of informed consent for pediatric cataract surgery. Their results show that 58% of parents overestimated their understanding of the informed consent conversation (18). Similarly, a study by Agozzino et al. concluded that written informed consent is not sufficient for ensuring patient comprehension (10).

Additionally, there is a need for appropriate tools for widespread teaching and implementation of effective consenting guidelines. According to a recent article published by White et al. (2020), improvement of surgical informed consent relies on three aspects: ensuring attendings are sufficiently competent in fundamental aspects of informed consent, defining

informed consent as a core clinical skill that requires intentional teaching, and assessing and providing feedback through direct observation (19).

It is commonly agreed in the literature that the current practice of informed consent generally differs from the ideal (4). Ultimately, this research aims to address the gap in the literature surrounding the effectiveness of informed consent, as well as to emphasize the importance of patient perspective in this process in order to reduce undesirable outcomes and promote patient autonomy and satisfaction. The unique perspectives, knowledge and understanding of various stakeholders must be also considered when evaluating the effectiveness of this process.

Objectives & Aims

The overall aim of this project is to better understand the practice of effective consent processes in pediatric surgery by compiling information from the literature and feedback from various stakeholders.

Specific Aims

1. Compile through a scoping literature review best practices in the consenting process for pediatric surgery from the perspectives of key stakeholders;
2. Create a set of recorded expert consenting activities in pediatric surgery and evaluate them by patients and other stakeholders for process, content, and comprehension.

Hypothesis

These series of studies will be the first to provide patient-centered data on the consenting process with parents of children facing surgical interventions. We hypothesized that identified characteristics of effective and ineffective consent conversations from the literature may overlap with those identified from patient feedback, and these can be used to formulate new recommendations and guidelines for consent conversations in pediatric surgery.

Research Questions

1. What are the critical components of effective consent processes and conversations in pediatric surgery?
2. How do various stakeholders rate the quality of consent conversations?
3. How can we improve the practice and teaching of the consenting process based on multi-stakeholder input?

Thesis Outline

The project has been conducted in two consecutive phases: Systematic-Scoping Literature Review (Chapter 2) and Expert Video Tool Development and Evaluation (Chapter 3).

Chapter 2: Systematic-Scoping Review

The initial manuscript was submitted to the Journal of Pediatric Surgery on February 10, 2022. The journal responded with comments and suggested revisions, for which a revised version of the manuscript was finalized on May 15, 2022. The following is a transcript of the revised manuscript.

Understanding the Effectiveness of Consent Processes and Conversations in Pediatric Surgery: A Systematic-Scoping Review

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Highlights:

1. There is a perceived lack of knowledge concerning the best practices of informed consent processes in pediatric surgery.
2. Effective consent conversations are characterized by the use of multimedia, individualized communication and multiple conversations. Ineffective consent conversations are characterized by large amounts of information, poor parental comprehension and parental anxiety.

Abstract

Background: The consent conversation in pediatric surgery is an essential part of pre-operative care which, when inadequate, can lead to significant adverse consequences for the child, parents, surgeon, other healthcare workers and the healthcare system. We reviewed the published literature on what key stakeholders perceive are the components of effective and ineffective consenting processes in pediatric surgery.

Methods: A medical librarian searched seven databases to retrieve articles looking at the informed consenting process in surgical care for the pediatric population. Two independent reviewers screened all publications and categorized them by stakeholder perspectives (patient/family, surgical team, other healthcare team, and hospital administration or policy maker). General study characteristics, interventions to improve consent and features of effective and ineffective consent conversations were extracted.

Results: 5079 titles and abstracts were screened, resulting in 88 full-text studies and 43 articles included in the final review. Most publications (51%) discussed informed consent only from the

patient/family perspective, while 21% added surgeon's perspective. No study approached the consenting process from the perspective of all stakeholder groups. Effective consent components identified included use of multimedia, presence of multiple conversations prior to surgery, and individualized communication catered to unique family knowledge and needs. In contrast, ineffective conversations did not include a clear assessment of parental understanding, delivered too much information, and did not address parental anxiety.

Conclusions: The literature on the consenting process in pediatric surgery is narrow in stakeholder perspectives. Our findings highlight gaps in the literature and opportunities to improve the informed consent processes prior to pediatric surgery.

Key Words (6): Consenting; Communication; Shared Decision Making; Perspectives; Risk Communication

Level of evidence: IV

Abbreviations used:

AHRQ	Agency for Healthcare Research and Quality
AMSTAR	A MeaSurement Tool to Assess systematic Reviews
CASP	Critical Appraisal Skills Programme
CMPA	Canadian Medical Protective Agency
ENT	Ear, Nose, Throat

JBI	Joanna Briggs Institute
MINORS	Methodological Index for Non-Randomized Studies
NICE	National Institute for Health and Care Evidence
RCT	Randomized Control Trial
SANRA	Scale for the Assessment of Narrative Review Articles
SDM	Shared Decision Making

Introduction

There are many published descriptions of the definitions, purposes, and key elements of informed consent. While the definition of informed consent is variable, it has been described to have legal, ethical, and administrative purposes (1). In an informed consent conversation, a provider should provide general knowledge about the procedure and educate the patient about the risks, benefits, and alternatives (2,3). In order to obtain valid expressed consent from a patient, the following requirements are provided by the Canadian Medical Protective Association (CMPA): "The consent must have been **voluntary**, the patient must have had the **capacity** to consent and the patient must have been **properly informed** (4)."

In surgery, the consent conversation is an essential part of the pre-operative decision-making process. It is a process that is taught, learned, and practiced on a regular basis. "Consenting" is also considered an essential task in surgical training and program evaluation (5,6). The way informed consent is obtained varies from provider to provider, but these various

methods have rarely been explored and compared in the literature. There is a perceived lack of knowledge concerning the best practices of such processes (1). The manner in which this consent conversation is led has significant consequences and the process is fraught with multiple potential pitfalls, potentially leading to undesirable outcomes. Such outcomes include mistrust with the surgical team, misinformation, and a lack of familiarity with the risk and benefits of the surgery (7–9). Considering the ubiquitous use of informed consent, the literature exploring and assessing its effectiveness is relatively limited (10).

In pediatric surgery, the consenting dynamic is especially unique due to the involvement of proxy decision-makers, such as the parent or caregiver (11). While there is some literature describing the ethics of proxy consent (12,13), there is little published on how to best involve these decision makers in pediatric surgery. In order to examine the effectiveness of the consent process, one must consider *who* is or are the stakeholders who are assessing the quality of the consent. There exist several guidelines and recommendations for obtaining informed consent, but they take the perspectives of legal stakeholders (4) or clinician-experts (1).

Importantly, there is a paucity of research exploring the various perspectives of this process. Individual perspectives are explored independently and very few studies examine the views of several different stakeholders. This review considers four stakeholder groups: (1) patients and their families, (2) surgeons or surgical trainees, (3) other healthcare professionals and (4) hospital administrators or professional policy-makers. There is a need for a review of the literature in pediatric surgical informed consent which collates these various perspectives.

Our research is guided by three questions: 1. What is informed consent in pediatric surgery and from which perspective? 2. What is considered an effective consenting process in

pediatric surgery and from which perspective? 3. How can we improve the informed consent process in pediatric surgery?

Methods

To address these questions, we conducted a systematic scoping review according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Statement (14,15).

A senior medical librarian created a detailed search strategy and ran it in the following databases from their inception until July 21, 2020: Medline (Ovid), Embase (Ovid), Cochrane (Wiley), Global Health (Ovid), Web of Science (Clarivate Analytics), Africa Wide Information (Ebsco) and Global Index Medicus (WHO). The search strategy used variations in text words found in the title, abstract or keyword fields, and relevant subject headings to retrieve articles looking at informed or parental consent in pediatric surgery found both in the academic and the grey literature. No additional articles were found in the grey literature. Articles were limited to English or French. See Supplementary material for the full search strategy. The PRISMA-S extension for literature searches was used for reporting and is included in the Supplementary material (16).

Following the Joanna Briggs Institute (JBI) protocol for scoping review source selection (17) and using the PRISMA flow diagram for reporting (18), the articles were screened by two independent screeners (ZA, RA) based on the specific inclusion and exclusion criteria. Any disagreements were solved by adjudication of a third reviewer (DP). An initial title and abstract screen was performed following a full-text screen of selected articles using the Rayyan software

(19). The subsequent full-text screening was also done independently by the same two screeners (ZA, RA) and discrepancies were addressed as with the title/abstract screening.

Studies were included if they met the following inclusion criteria: pediatric population (<18 years), surgery/surgical care, informed consent/consenting process, and written in English or French. Studies were excluded if they involved the adult population, consent for non-surgical interventions, animal studies, or studies addressing Shared Decision Making (SDM) or risk communication alone.

Extraction of information included general article characteristics, stakeholder perspective represented, interventions to improve consent, and characteristics of effective and ineffective consent conversations. Any potential bias was assessed using the JBI Critical Appraisal Checklist for Systematic Review and Research Synthesis (20).

A Risk of Bias (ROB) analysis was conducted for all 43 included articles. Due to the heterogeneity of included articles, analysis was conducted using several tools: the National Institute for Health and Care Evidence (NICE) Checklist Critical Appraisal of qualitative studies (21), the Scale for the Assessment of Narrative Review Articles (SANRA) (22), the Methodological Index for Non-Randomized Studies (MINORS) (23), the Critical Appraisal Skills Programme (CASP) checklist for cohort studies (24), the Cochrane Collaboration's tool critical appraisal for RCTs (25), the Joanna Briggs Institute (JBI) checklist for critical appraisal of expert opinion publication (26), the Agency for Healthcare Research and Quality (AHRQ) checklist for cross-sectional studies (27) and A MeaSurement Tool to Assess systematic Reviews (AMSTAR) (28).

Details of the protocol for this review are registered on PROSPERO (ID: CRD42020206530) and can be accessed at www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42020206530.

Results

The search found 5489 references and following removal of duplicates, 5079 titles and abstracts were screened. This resulted in 88 full-text studies reviewed, of which 43 articles were finally included in the review (Figure 1). Table 1 displays all included articles.

a. Characteristics of Included Studies

The main surgical speciality represented was general pediatric surgery (30%), followed by otolaryngology (17.5%). Multi-specialty studies (22.5%) were also found (Figure 2). 37% discussed various interventions to improve the consenting process. Of these studies, 50% used an informational document or visual aid, 19% used informational videos/videotaped counseling, 12% used a Powerpoint presentation, and the remaining used an online information platform, improved consent forms, and a checklist for physicians. The remainder of the 43 articles in this review describe the current informed consent process through results of administered questionnaires, qualitative studies, expert opinion and narrative reviews.

The included articles were published across several countries, with the majority (49%) being in the United States of America (USA) (Table 1). The most common types of studies were Randomized Control Trials (RCTs) (26%) and qualitative studies (26%).

b. Evaluation Methods for Informed Consent

The majority of studies included in this review incorporated an element of appraisal when discussing the consenting process. Studies often appraised tools developed for improving the

consenting process, or offered opinions regarding what an optimal consent discussion should include based on prior knowledge. 16 % used structured interviews to elicit patient perspectives and assess parental knowledge following the consent process (29–35), while 18 (42%) used questionnaires to collect information (36–53). Only one study used a combination of structured interviews and a questionnaire (54). 12% incorporated an analysis of recorded/transcribed consent discussions as a method of evaluation (11,55–58).

Eighteen studies (42%) incorporated an evaluation of parental recall of facts and risks following the consenting process, or an assessment of global parental knowledge regarding surgical management (30–32,35,36,39,40,43,44,46–53,59). Thirteen studies (30%) included an evaluation of patients' perspectives regarding how useful the consent process was, along with overall satisfaction (29,33,36,37,39,41,43,45,46,48,50,54,57). Nine studies (21%) aimed to evaluate informed consent by measuring parameters of the process itself, such as the degree of consistency between patients or the amount and detail of information included (11,34,37,38,41,56,60–62). In addition, four studies (9%) included a measurement of parental anxiety while going through the consenting process (36,41,43,47). Interestingly, only one group assessed healthcare provider satisfaction of the consent process via questionnaires as a way to measure process efficacy (42).

c. Effective Consent Processes & Conversations

Several studies representing all four stakeholder perspectives discussed the benefits of using multimedia (such as a Powerpoint presentations or video recorded information) during the consent conversation (Figure 3) (11,36,38,39,42,46,47,49,53,58,59,61,63). Additionally, the use of written information was helpful for patients and their families (31,43,45).

Regarding the process of informed consent, multiple studies discussed the importance of adequate timing and opportunities for families to ask questions (29,38,39,50,56,57,64–66). Notably, individualized communication with patients and families was found to be very effective (11,45,47,60,64,65). Several studies also discussed the importance of active patient participation in the discussion and shared decision-making (35,55,56,65). Other aspects found to promote effective consent conversations include physician empathy (29,58), physician trust (29), repeated encounters, and follow-up conversations (38,40,58,65).

Other areas of importance suggested in the reviewed literature include addressing and decreasing parental anxiety (35), providing structured (35) and adequate (67) information to parents, gaging parental comprehension (35), considering the moral values and beliefs of patients (64), disclosing the surgeon's level of expertise (45), using a consent checklist (41), and providing realistic goals for the patient (68).

d. Ineffective Consent Processes & Conversations

Multiple studies found that overall patient understanding and recall of the informed consent discussion was poor (Figure 4) (11,30–32,40,44,46,48–52,62). Identified barriers to comprehension included the discussion of large amounts of information in one setting, the presence of added stress during the consent conversation, and parental preoccupation with having a child in the room (29,40,45,55). Other studies identified poor communication between surgeons and patients as the cause of poor parental recall, and too much parental reliance upon internet-based sources of inaccurate information (31,48). Many parents were reported to have difficulties comprehending health materials, and also demonstrated limited language skills (42). Despite this, one study showed that parents tend to overestimate their understanding of risks (54).

Several studies reported that the consent process was frequently inconsistent between similar cases (34,37,53,62). Additionally, physicians were noted to occasionally omit pertinent complications during the consenting process (37), and inconsistently disclose the role of surgical trainees to parents (34). It was suggested that surgeons may occasionally exaggerate the gravity of a patient's situation in order to increase the patient's regard for the surgeon, and ultimately improve parental gratitude (65). Others reported that some parents reported feeling as though they were left to ask too many questions, and wished more information was offered to prevent them from feeling inadequately informed (11,38).

Multiple studies reported high levels of parental anxiety and stress throughout the consenting process (29,43,47,55). However, many patients reported that this anxiety stemmed from fear regarding proposed treatment options, rather than from the discussion itself (43,47). Patients expressed the desire for physicians to recognize the novelty of this situation for most families (29). Some parents reported a large power imbalance between physicians and patients, mostly presumed to be based on discrepancies in medical knowledge and the emotional vulnerability of patients (64).

Some parents reported feeling disempowered during the consent process, largely due to socioeconomic challenges that placed a burden on their child's care and long term follow up (58). Also contributing to a sense of stress, some parents believed hospital consent forms were only designed to protect the hospital in case of mishaps (50,60,62), and were too complicated to understand (42). As well, it was suggested that currently used informed consent forms do not adequately take into account children and their rights, and focus solely on parents (33). Some surgeons reported partaking in partial disclosure verbally and then providing patients with

written comprehensive disclosure, which actually seemed to decrease parental decisional confidence (37). While some studies deemed the use of written information aids helpful during the consenting process, others did not find that they improved patient recall (35).

Further issues not addressed in our study arise when physicians are obtaining consent in the setting of experimental treatments. Often conflation of clinical and research goals are perceived to exist (68). Research subjects are inherently more vulnerable, as their well-being, while still a major consideration, is not the only primary outcome of interest (68).

e. Individual Stakeholder Perspectives

The four stakeholder groups considered for this review are: (1) patients and their families, (2) surgeons or surgical trainees, (3) other healthcare professionals such as other non-surgical physicians or nurses and (4) hospital administrators or professional policy-makers (Figure 5). The majority of articles in this review (51%) discussed informed consent from the perspective of the patient/family only. The second most common perspective combined input from the patient/family and the surgeon/surgical trainees (21%). None of the articles in this review discussed the consenting process from the perspective of all four stakeholder groups.

Surgeons and patients/families agreed upon several aspects of effective informed consent conversations. Both stakeholder groups emphasize the usefulness of SDM, the importance of multiple conversations and follow ups, the need for individualized communication with each family, and supported ample opportunities for questions. Surgeons and patients/families also agreed that the current process is inconsistent. The literature implies a fine balance between consistency in consenting processes and creating individualized conversations, as individualized communication practices should still include the exchange of necessary information.

While surgeons focused on the poor quality of and biased information contained in some consent forms, family members highlighted low parental risk recall, high parental anxiety and low parental understanding.

The healthcare worker stakeholder group expressed support for multimedia use, opportunity for questions, follow up conversations during the consenting process. Moreover, articles from this perspective also highlighted low parental understanding, inconsistent processes, biased information, and issues with the consent form as ineffective aspects of current consent conversations.

Only 5 articles (12%) mentioned the perspective of hospital administrators or professional policy makers with regards to efficacious and non efficacious characteristics of consent conversations. The majority of these articles (60%) focused on biased information within the consent processes as an ineffective aspect.

Risk of Bias Analysis

The two most common types of articles were qualitative studies (26%) and RCTs (26%). The risk of bias analysis showed that the majority of the qualitative studies were of good quality (82%). While RCTs were of average quality overall, 91% of them were indeterminate or high-risk for participant blinding. Cohort, cross-sectional, and expert opinion studies had generally a low risk of bias (see Supplementary materials).

Discussion

The best practices of informed consent in pediatric surgery are not clearly set, and the process is far from standardized (41). To the best of our knowledge, only one prior review of informed

consent in pediatric surgery has been published (69), which focused only on parental consent and was limited to clinical trials. Its authors noted that studies evaluating surgeon and parent perceptions regarding the content, delivery, and interchange of information as well as comprehension and satisfaction are lacking. However, they emphasized the importance of using information adjuncts (brochures, Web pages, and smartphone apps), prioritizing defined time to address parental concerns and/or questions, and optimizing the setting in which informed consent is obtained to improve overall satisfaction with the informed process. Notably, Chotai et al screened approximately 180 articles, while the current review screened over 5000 articles. In addition, the current review considers multiple stakeholder perspectives within the evaluation of the informed consent process.

Characteristics of Included Studies

Studies exploring specific interventions to improve informed consent limited their focus to improving some specific aspect of the process (70), as exemplified by a recent systematic review highlighting interventions for improving *patient comprehension* in informed consent processes (2). While patient comprehension is an important aspect of informed consent, other aspects such as trust, patient engagement, and decision-making are equally important to consider. The studies included in this review were mainly conducted in the USA. There is little representation in the literature of consent processes in other countries, which may differ greatly from North American consent standards. Considering the stakeholder groups, there was little to no representation of other healthcare team members, hospital administration staff, and medicolegal stakeholders. The CMPA provides standard consenting guidelines for all surgeons (4), yet their perspective has not been considered in the current literature. This highlights the question of how we define expertise

when it comes to informed consent, and the critical necessity of including a multitude of perspectives in order to offer optimal solutions to this complex and essential process.

Evaluation Methods of Informed Consent

The criteria and methods of evaluation were quite heterogeneous within the literature. Most studies incorporated a combination of multiple criteria when evaluating the consenting process, which reaffirms the inherent complexity associated with the discussion of consent. Interestingly, many of the evaluation methods described relied upon evaluating parental risk on recall. While recall may indeed be important to the overall process, its use as an isolated measure of efficacy of the consent process is questionable. Poor recall may not necessarily equate to poor consent quality, as the patient and their family may have felt informed, actively involved and satisfied during the process despite not remembering certain details after the fact.

Effective Consent Conversations

Based upon the literature reviewed, specific practices within the consenting process were often shown to be effective, despite not always being discussed from multiple stakeholder perspectives. As such, the literature broadly supports the following recommendations when engaging with the consenting process prior to surgery:

1. *Incorporating repeat encounters and discussions with families during the consenting process*

The opportunity for repeat meetings with the surgical team may afford patients and families more time to process the conversation and come to an informed decision. Although not explicitly explored in this review, there may be significant variations and unique challenges for informed consent in urgent situations compared to elective ones. With elective surgeries, families can

decide to schedule multiple conversations with their surgical team and have more time to make an informed decision. For emergency surgery, research has shown that families have very poor recall of potential complications discussed (32). There is also a need for families to develop trust in their surgical team in a very short amount of time, which evidently involves unique challenges. An article included in this review discussed a decrease in autonomy that families may feel in emergency settings (46).

2. *Emphasizing individualized communication and interpersonal relationships*

The consent conversation varies from family to family due to differing patient needs, medical history, and unique circumstances. While adequate information for patients has been found to be important, the amount of information necessary may vary depending on the family. This circles back to the importance of individualized communication and catering an informed consent conversation to a specific patient and their family. Too many details and an overload of information may simply overwhelm the family. On the other hand, too little information may leave families wishing that they were more informed. Finding this balance for each family is key to optimizing the quality of the consent conversation. Families want the surgical team to acknowledge that their input is valid and adopt a shared decision making approach. *Shared decision-making (SDM)* involves an "exchange of ideas between patient and physician, and collaboration in the decision itself" (71). The SDM process recognizes the importance of patient opinion and contribution to decision making, and has been shown to avoid decisional conflict and regret (72). An emphasis on both clinical evidence *and* patient preferences is crucial when obtaining surgical consent, as this may promote a more effective and informed process.

There exists a significant gap in the literature with regards to the interpersonal domains of consenting. Only two articles discussed the positive effects of physician empathy (29,58) and

only one discussed physician trust (29). These areas, if explored, may provide avenues for better quality consent conversations which are built upon a stronger patient - provider relationship.

3. *Incorporating multimedia and supporting informational documents within the consenting process*

The most discussed feature of effective consent conversations was the use of multimedia during the consent process. Visual tools such as images, videos, or presentations during the consent conversation seem to be appreciated by both the patients and their families, and the surgical team themselves. Interestingly, a visual presentation on a computer can facilitate preoperative education in emergency consent conversations (46). The CMPA recommends that such materials should be supplemental to consent conversations. They explain that "the essential element of consent is the dialogue and sharing of information between physician and patient (4)." If supplementary documents such as handouts and other materials wish to be used, they should be made available adequately in advance for patients to consider them prior to providing their consent (4).

Ineffective Consent Conversations

In order to avoid suboptimal or inappropriate consent conversations in future practice, it is important for surgeons to be aware of the characteristics of ineffective conversations suggested by the literature. The following recommendations may improve the quality of consent conversations.

1. *Recognition and efforts to improve poor parental understanding and reduce parental anxiety*

Our results support the frequent reports of low-quality consent conversations in the literature and poor patient/family understanding. The patient/family stakeholder group in particular express dissatisfaction with low parental risk recall, high parental anxiety and low parental understanding. Some factors were found to contribute to poor comprehension, including parental stress and preoccupation, and receiving large amounts of information. Additionally, parental anxiety can significantly impact the quality of the process. Interestingly, anxiety was a unique patient perspective, rarely encountered in surgeons' perspectives. Despite the intuitive appropriateness of a shared decision-making approach to the consenting process, there are multiple challenges to these processes, particularly in surgery (72,73). These include communication barriers and lack of familiarity with the procedure and its risks or benefits (9), both of which should be addressed to promote more effective consent conversations.

2. *Consideration of social forces and inherent power-imbalance at play.*

Additionally, the decision-making process may reflect a *power imbalance* in which patients feel intimidated or less knowledgeable than the medical professional (9) - which may compromise their ability to make a decision (8). It is important to also consider the social forces and the power imbalances inherent to the healthcare system, such as differences in role, status and knowledge which can easily undermine the effectiveness of informed consent (1).

3. *Consideration of children and their rights.*

Another cited feature of ineffective consent conversation was that they do not adequately take into account children and their rights, and focus solely on parents (33). In pediatric surgery, there are important medicolegal considerations to be made surrounding assent which requires approval or agreement of decisions by the minor. Assent may be conceptually and clinically challenging for surgeons when dealing with adolescents who are knowledgeable about their

condition (65). While it is important to involve them in the process (13), assessing their ability and voluntariness to provide assent is complex and may be problematic (74). After a certain age, a child or adolescent becomes more competent to be involved in the decision making process. In Canada, there is generally no standard age of consent and it is determined by the child's physical, mental and emotional maturity (75). Notably, Quebec differs from the rest of Canada as the age of consent is 14 years of age, given competence (75). It is important to also discuss the fundamental concept of "a child's right to an open future", initially described by Joel Feinberg. This concept explains that children have rights in trust, which protects them from having important life decisions determined for them and enables them to exercise their own life decisions once of age(76). An ethical discussion on informed consent supports the involvement of children and adolescents in the decision making process and can "foster the moral growth and development in young patients"(77). Given that children are the foremost stakeholder in pediatric surgery, we speculate that this may be an area for future improvement.

4. *Improvement of the informed consent form.*

Additionally, some articles indicate that the consent form may be potentially problematic and inadequate. Surgeons in particular express that the current consent forms were of poor quality and that they contained some biased information. This may be because they are much more familiar with the consent document, its faults and limitations and what information should be communicated.

Importantly, the consent form itself does not replace the process of consenting a patient (4). This process necessarily involves a discussion between the surgeon and the patient/family. The consent form is a legal requirement which provides evidentiary confirmation of the discussion and agreement on the course of action (4).

Limitations

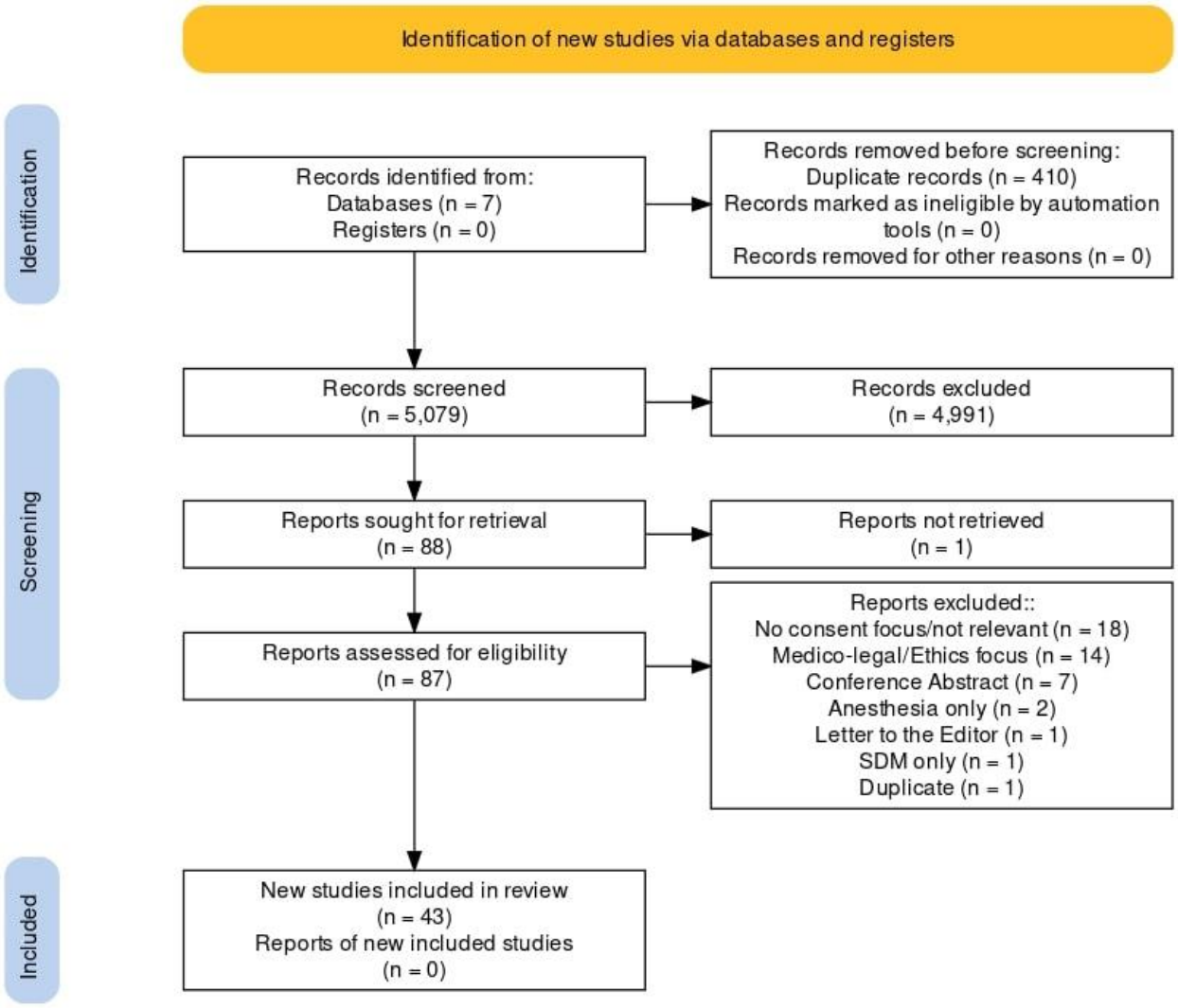
While this review discusses the informed consent process only in the context of pediatric surgery, informed consent is relevant across all fields of medicine and in research, in both pediatric and adult populations. As such, the scope of this study was quite limited. Additionally, this review was restricted to articles published in English or in French. While there is literature in other languages that may identify important cultural differences in the consent process, it comprised less than 5% of all publications regarding consent in pediatric surgery. Another key limitation of this review is the low number of evidence-based studies, notably the small percentage of RCTs.

Conclusion

This review characterizes the informed consent process in pediatric surgery, highlighting strengths, weaknesses, and gaps in the process. Several characteristics of perceived effective consent conversations were identified in the literature, such as the use of multimedia, multiple conversations and individualized communication, which should be prioritized in future practice. Likewise, characteristics of non-effective conversations should be carefully considered in order to avoid future pitfalls. These include poor parental understanding, large amounts of information and parental anxiety. Surgeons should consider the social factors that may influence the dynamics of the consent conversation and also recognize the child's rights in decision making and for an open future. Additionally, there is a need for better representation of all stakeholder perspectives. The findings from this review will permit us to design interventions to improve the consenting process not just from the perspective of patients and surgeons but from other stakeholders' perspectives.

Tables & Figures

Figure 1: PRISMA Flow diagram



From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

Table 1: General Characteristics of Included Articles

Authors	Title	Year of Publication	Country (where study was conducted)	Surgical Specialty	Study Design	Stakeholder Perspective
Al-Taha, M. T.-//-Butler, M. B.-//-Hong, P.-//-Bezuhly, M.	The effect of written information on recall of surgical risks of primary cleft palate repair: a randomized controlled study	2019	Canada	Plastic Surgery	RCT	Patient/Family
Berg, A. L.-//-Herb, A.-//-Hurst, M.	Cochlear implants in children: ethics, informed consent, and parental decision making	2005	USA	ENT	Narrative review	Patient/Family & Surgeon
Bhanot, K.-//-Chang, J.-//-Grant, S.-//-Fecteau, A.-//-Camp, M.	Training surgeons and the informed consent discussion in paediatric patients: a qualitative study examining trainee participation disclosure	2019	Canada	Multi-Specialty	Qualitative study	Surgeon
Book, F.-//-Goedeke, J.-//-Poplawski, A.-//-Muensterer, O. J.	Access to an online video enhances the consent process, increases knowledge, and decreases anxiety of caregivers with children scheduled for inguinal hernia repair: A randomized controlled study	2020	Germany	General Pediatric Surgery	RCT	Patient/Family
Byrne, P. J.-//-Murphy, A.	Informed consent and hypoplastic left heart syndrome	2005	Canada	Cardiac Surgery	Expert Opinion	Surgeon
Cegala, D. J.-//-Chisolm, D. J.-//-Nwomeh, B. C.	Further examination of the impact of patient participation on physicians' communication style	2012	USA	General Pediatric Surgery	Qualitative study	Patient/Family & Surgeon

Cegala, D. J.-//-Chisolm, D. J.-//-Nwomeh, B. C.	A communication skills intervention for parents of pediatric surgery patients	2013	USA	General Pediatric Surgery	RCT	Patient/Family & Surgeon
Chantry, C. J.-//-Byrd, R. S.-//-Sage, A. C.-//-Calvert, E. E.	Video versus traditional informed consent for neonatal circumcision	2010	USA	Pediatric Urology	RCT	Patient/Family
Chotai, P. N.-//-Nollan, R.-//-Huang, E. Y.-//-Gosain, A.	Surgical informed consent in children: a systematic review	2017	USA	Multi-Specialty	Systematic Review	Patient/Family & Surgeon
Christensen-Szalanski, J. J.-//-Boyce, W. T.-//-Harrell, H.-//-Gardner, M. M.	Circumcision and Informed Consent: Is More Information Always Better?	1987	USA	Pediatric Urology	Qualitative Study	Patient/Family & Surgeon
Ciesielski-Carlucci, C.-//-Milliken, N.-//-Cohen, N. H.	Determinants of decision making for circumcision	1996	USA	Pediatric Urology	Cross-sectional	Patient/Family & Surgeon & Other healthcare professional
Enzenauer, R. W.-//-Powell, J. M.-//-Wiswell, T. E.-//-Bass, J. W.	Decreased circumcision rate with videotaped counseling	1986	USA	Pediatric Urology	RCT	Patient/Family
Erraguntla, V.-//-De la Huerta, I.-//-Vohra, S.-//-Abdolell, M.-//-Levin, A. V.	Parental comprehension following informed consent for pediatric cataract surgery	2012	Canada	Ophthalmology	Cross sectional	Patient/Family
Firdouse, M.-//-Wajchendler, A.-//-Koyle, M.-//-Fecteau, A.	Checklist to improve informed consent process in pediatric surgery: A pilot study	2017	Canada	Multi-Specialty	Cross sectional	Patient/Family & Surgeon
Guinand, J.-//-Gapany, C.-//-Simon, J. P.-//-Wasserfallen, J. B.-//-Joseph, J. M.	A survey on surgeons' perceived quality of the informed consent process in a Swiss paediatric surgery unit	2015	Switzerland	General Pediatric Surgery	Qualitative Study	Surgeon
Hansson, M. G.-//-Kihlbom, U.-//-Tuvemo, T.-//-Olsen, L. A.-//-Rodriguez, A.	Ethics takes time, but not that long	2007	Sweden	General Pediatric Surgery	Qualitative Study	Patient/Family

Hyde, M.-//-Power, D.	Informed parental consent for cochlear implantation of young deaf children: social and other considerations in the use of the 'bionic ear'	2000	Australia	ENT	Expert Opinion	Surgeon
Johnson, B. L.-//-Rosenfeld, E. H.-//-Carter, B. D.-//-Lopez, M. E.-//-DeMello, A. S.-//-Wesson, D. E.-//-Brandt, M. L.	An assessment of provider satisfaction with the use of a standardized visual aid for informed consent for appendectomy in children	2020	USA	General Pediatric Surgery	Cross-sectional	Surgeon & Other Healthcare Professional
Jones, J. W.-//-McCullough, L. B.-//-Richman, B. W.	Informed consent: it's not just signing a form	2005	USA	General Pediatric Surgery	Expert Opinion	Surgeon & Hospital Administrator/Policy Maker
Landier, M.-//-Villemagne, T.-//-Le Touze, A.-//-Braik, K.-//-Meignan, P.-//-Cook, A. R.-//-Morel, B.-//-Lardy, H.-//-Binet, A.	The position of a written document in preoperative information for pediatric surgery: A randomized controlled trial on parental anxiety, knowledge, and satisfaction	2018	France	Multi-Specialty	RCT	Patient/Family
Lashley, M.-//-Talley, W.-//-Lands, L. C.-//-Keyserlingk, E. W.	Informed proxy consent: communication between pediatric surgeons and surrogates about surgery	2000	Canada	Multi-Specialty	Qualitative Study	Patient/Family & Surgeon
Li, F. X.-//-Nah, S. A.-//-Low, Y.	Informed consent for emergency surgery--how much do parents truly remember?	2014	Singapore	General Surgery	Cohort Study	Patient/Family
Mercurio, P.-//-Shaffer Ellis, A.-//-Schoettker, P. J.-//-Stone, R.-//-Lenk, M. A.-//-Ryckman, F. C.	Using improvement science methods to increase accuracy of surgical consents	2014	USA	Multi-Specialty	Qualitative Study	Surgeon & Other Healthcare Professional & Hospital Administrator/Policy Maker

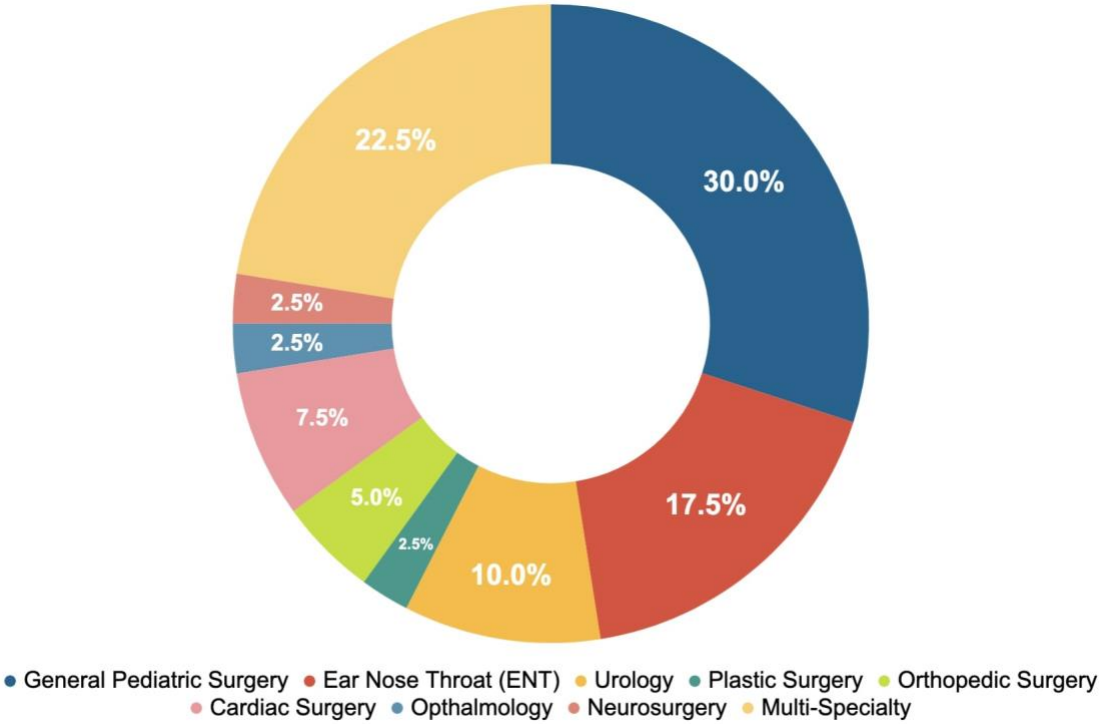
Morris, D. P.-//-Rothera, M. P.	The application of computer-enhanced imaging to improve preoperative counselling and informed consent in children considering bone anchored auricular prosthesis surgery	2000	England	Orthopedic surgery	Expert Opinion	Patient/Family & Surgeon
Nadeau, D. P.-//-Rich, J. N.-//-Brietzke, S. E.	Informed consent in pediatric surgery: Do parents understand the risks?	2010	USA	ENT	RCT	Patient/Family
Niyogi, A.-//-Clarke, S. A.	Elective paediatric surgery: what do parents really want to know?	2012	England	General Pediatric Surgery	Cross-sectional	Patient/Family & Surgeon
Nwomeh, B. C.-//-Waller, A. L.-//-Caniano, D. A.-//-Kelleher, K. J.	Informed consent for emergency surgery in infants and children	2005	USA	Multi-Specialty	Narrative Review	Surgeon & Hospital Administrator/Policy Maker
Nwomeh, B. C.-//-Hayes, J.-//-Caniano, D. A.-//-Upperman, J. S.-//-Kelleher, K. J.	A parental educational intervention to facilitate informed consent for emergency operations in children	2009	USA	General Surgery	Non-randomized Interventional study	Patient/Family
Papsin, E.-//-Haworth, R.-//-Chorney, J. M.-//-Bezuhly, M.-//-Hong, P.	Pediatric otoplasty and informed consent: do information handouts improve parental risk recall?	2014	Canada	ENT	RCT	Patient/Family
Paris, J. J.-//-Moore, M. P.-//-Schreiber, M. D.	Physician counseling, informed consent and parental decision making for infants with hypoplastic left-heart syndrome	2012	USA	Cardiac Surgery	Expert Opinion	Patient/Family & Surgeon & Hospital Administrator/Policy Maker
Paton, E. A.-//-Davis, S. K.-//-Gaylord, N.-//-Cao, X.-//-Gosain, A.	Impact of a multimedia teaching tool on parental anxiety and knowledge during the informed consent process	2018	USA	General Surgery	Non-randomized interventional study	Patient/Family

Wehrmann, D.-//-Green, G. E.-//-Weatherwax, K. J.-//-Shuman, A. G.	Navigating the Informed Consent Process When Using Innovative Surgery	2020	USA	ENT	Expert Opinion	Surgeon & Hospital Administrator/Policy Maker
Wasserzug, O.-//-Fishman, G.-//-Sternbach, D.-//-Reindorf-Kfir, E.-//-Averbuch, E.-//-Fliss, D. M.-//-Oestreicher-Kedem, Y.-//-Derowe, A.	Informed consent for tonsillectomy: Do parents comprehend the information we provide?	2016	Israel	ENT	Cross-sectional	Patient/Family
Vivian, L. M. H.-//-Hunter, C.-//-Tan, L.-//-Comitis, G.-//-Neveling, G.-//-Lawrenson, J.	Found in translation: navigating uncertainty to save a child's heart. Paediatric cardiac surgery in Cape Town, South Africa	2020	South Africa, Australia & Denmark	Cardiac surgery	Qualitative Study	Patient/Family
Theologis, A. A.-//-Anaya, A.-//-Sabatini, C.-//-Sucato, D. J.-//-Parent, S.-//-Erickson, M.-//-Diab, M.	Surgical Consent of Children and Guardians for the Treatment of Adolescent Idiopathic Scoliosis is Incompletely Informed	2016	USA	Orthopedic surgery	Cohort Study	Patient/Family
Tait, A. R.-//-Voepel-Lewis, T.-//-Malviya, S.-//-Philipson, S. J.	Improving the readability and processability of a pediatric informed consent document: effects on parents' understanding	2005	USA	General Pediatric Surgery	RCT	Patient/Family
Steven, M.-//-Broadis, E.-//-Carachi, R.-//-Brindley, N.	Sign on the dotted line: parental consent	2008	Scotland	Multi-Specialty	Cross-sectional	Patient/Family
Silva, A. H. D.-//-Wijesinghe, H.-//-Mundil, N.-//-Lo, W.-//-Walsh, A. R.-//-Solanki, G. A.-//-Rodrigues, D.	Consent in paediatric neurosurgery: adequacy of documentation and parental perspectives	2019	England	Neurosurgery	Qualitative Study	Patient/Family
Short, M.-//-Willetts, I.	Consent in paediatrics	2010	England	General Pediatric Surgery	Expert Opinion	Hospital Administrator/Policy Maker

Rymeski, B.-//-Marchildon, M.-//-Katz, D. A.-//-Vinocur, C. D.-//-Dunn, S. P.-//-Reichard, K. W.-//-Cassity, J.-//-Gould, D.-//-Murphy, S. G.	Pilot study using an Internet-based program in informed consent	2010	USA	General Pediatric Surgery	RCT	Patient/Family
Rosenfeld, E. H.-//-Lopez, M. E.-//-Yu, Y. R.-//-Justus, C. A.-//-Borges, M. M.-//-Mathai, R. C.-//-Karediya, A.-//-Zhang, W.-//-Brandt, M. L.	Use of standardized visual aids improves informed consent for appendectomy in children: A randomized control trial	2018	USA	General Pediatric Surgery	RCT	Patient/Family
Pianosi, K.-//-Gorodzinsky, A. Y.-//-Chorney, J. M.-//-Corsten, G.-//-Johnson, L. B.-//-Hong, P.	Informed Consent in Pediatric Otolaryngology: What Risks and Benefits Do Parents Recall?	2016	Canada	ENT	Cohort Study	Patient/Family
Pfeil, M.	Parents' experience of giving consent for their child to undergo surgery	2011	England	Multi-Specialty	Qualitative Study	Patient/Family

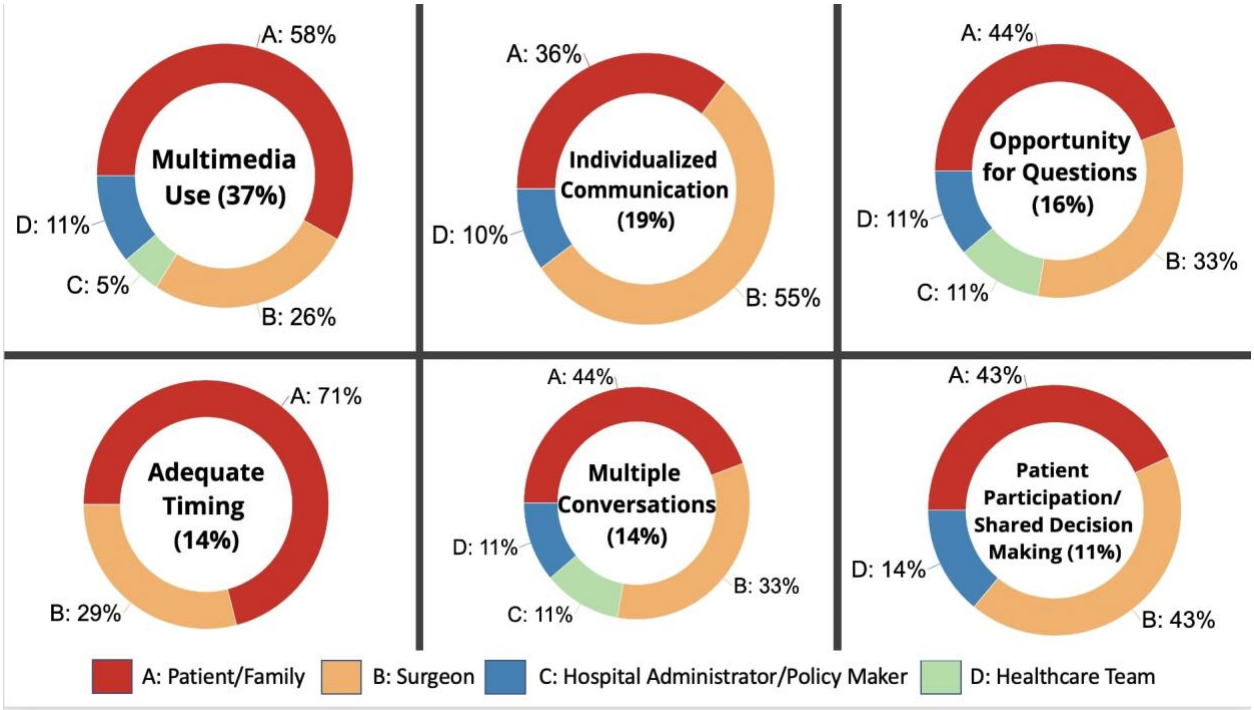
Legend	
ENT	Ear, Nose, and Throat
USA	United States of America
RCT	Randomized Controlled Trial

Figure 2: Representation of Surgical Specialties



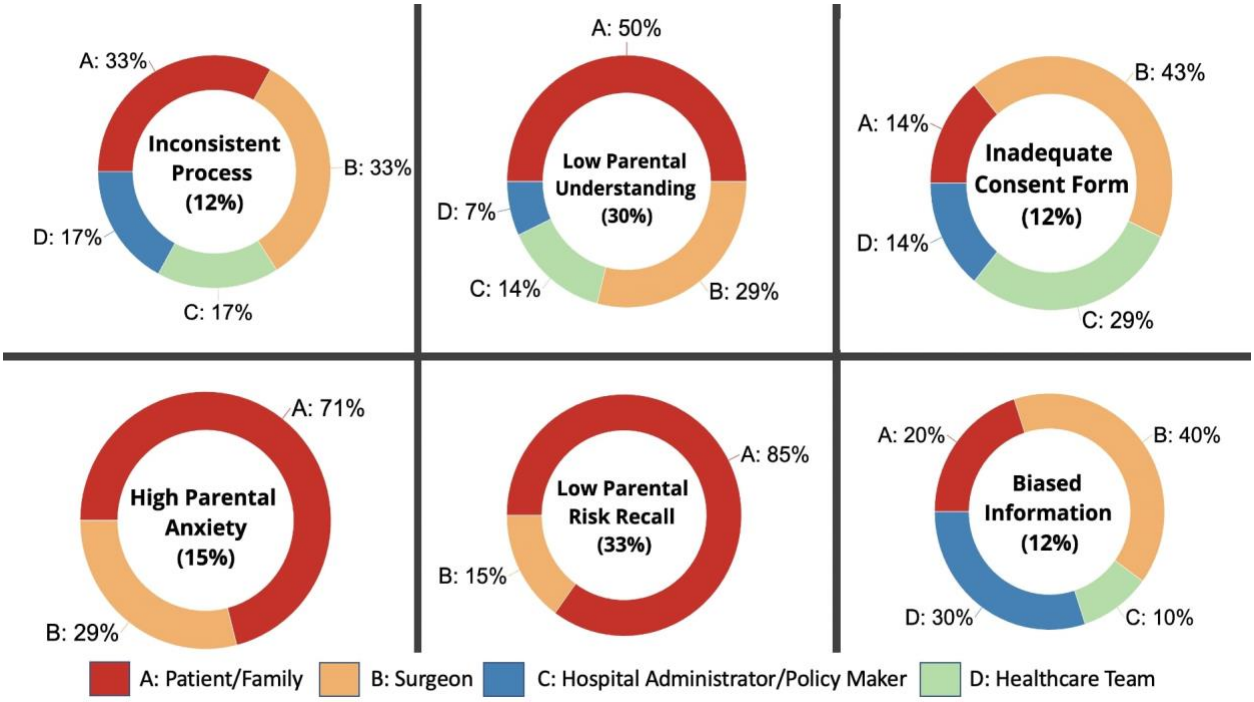
Distribution of surgical specialties represented in included articles.

Figure 3: Characteristics of Effective Consent Conversations



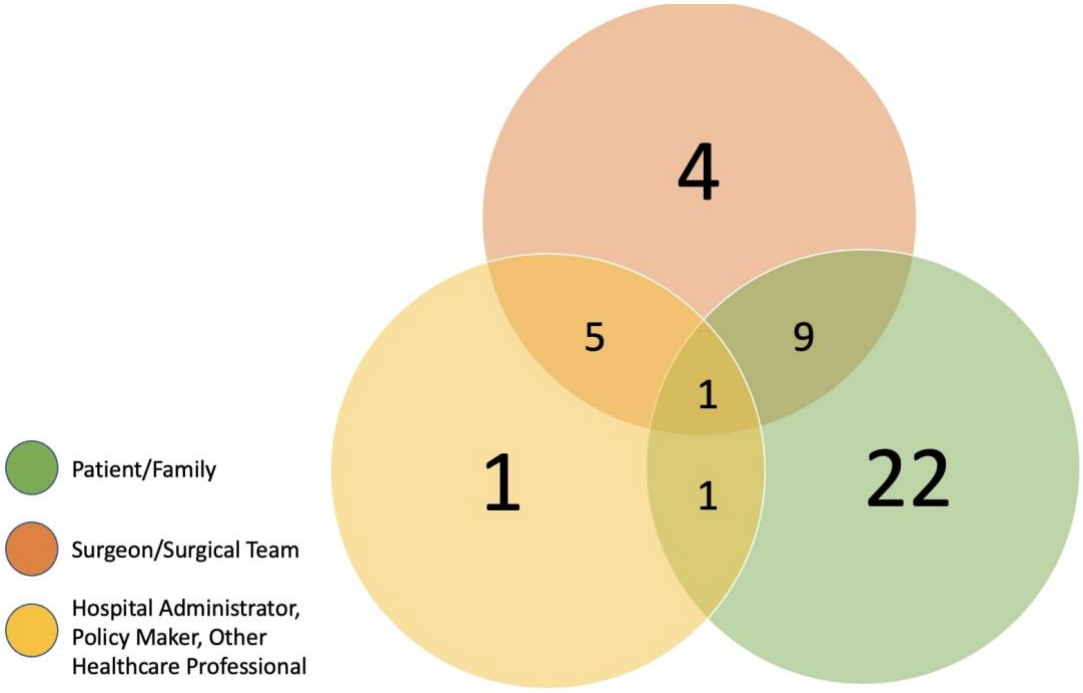
Key characteristics of effective consent conversations identified from the literature. Percentage in center represents the number of included articles which discussed that characteristic. Surrounding percentages specify the distribution of stakeholder perspectives which were represented in those particular articles.

Figure 4: Characteristics of Ineffective Consent Conversations



Key characteristics of ineffective consent conversations identified from the literature. Percentage in center represents the number of included articles which discussed that characteristic. Surrounding percentages specify the distribution of stakeholder perspectives which were represented in those particular articles.

Figure 5: Number of Studies Included by Stakeholder Perspective



Out of a total of 43 articles, this venn diagram demonstrates the distribution of stakeholder perspectives and specifies the number of articles that represented more than one perspective.

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Supplemental Materials

Supplemental Document 1: PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	p.4
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	p.2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	p.3
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	p.3
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	p.5
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	p.4
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Supplementary Materials
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	p.5
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	p.5
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	p.5
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	p.5
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	p.5, p.11
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	N/A
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	p.5

Section and Topic	Item #	Checklist item	Location where item is reported
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	N/A
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	N/A
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	N/A
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	N/A
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	N/A
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	p.6
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Figure 1
Study characteristics	17	Cite each included study and present its characteristics.	Table 1
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Supplementary Materials
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	p.6-11
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	p.11
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	N/A
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N/A
DISCUSSION			

Section and Topic	Item #	Checklist item	Location where item is reported
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	p.11-16
	23b	Discuss any limitations of the evidence included in the review.	p.15
	23c	Discuss any limitations of the review processes used.	p.15
	23d	Discuss implications of the results for practice, policy, and future research.	p.16
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	p.6
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	p.6
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Title Page
Competing interests	26	Declare any competing interests of review authors.	Title Page
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	N/A

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: http://www.prisma-statement.org/

Supplemental Document 2: PRISMA-S Checklist

Section/topic	#	Checklist item	Location(s) Reported
INFORMATION SOURCES AND METHODS			
Database name	1	Name each individual database searched, stating the platform for each.	p. 4 & Included in Supplementary Material
Multi-database searching	2	If databases were searched simultaneously on a single platform, state the name of the platform, listing all of the databases searched.	p. 4 & Included in Supplementary Material
Study registries	3	List any study registries searched.	N/A
Online resources and browsing	4	Describe any online or print source purposefully searched or browsed (e.g., tables of contents, print conference proceedings, web sites), and how this was done.	Conference proceedings included primarily within Embase (Ovid) as well as other databases.
Citation searching	5	Indicate whether cited references or citing references were examined, and describe any methods used for locating cited/citing references (e.g., browsing reference lists, using a citation index, setting up email alerts for references citing included studies).	N/A
Contacts	6	Indicate whether additional studies or data were sought by contacting authors, experts, manufacturers, or others.	N/A
Other methods	7	Describe any additional information sources or search methods used.	N/A
SEARCH STRATEGIES			
Full search strategies	8	Include the search strategies for each database and information source, copied and pasted exactly as run.	Included in Supplementary Material
Limits and restrictions	9	Specify that no limits were used, or describe any limits or restrictions applied to a search (e.g., date or time period, language, study design) and provide justification for their use.	p. 4
Search filters	10	Indicate whether published search filters were used (as originally designed or modified), and if so, cite the filter(s) used.	MUHC Pediatric filter used
Prior work	11	Indicate when search strategies from other literature reviews were adapted or reused for a substantive part or all of the search, citing the previous review(s).	N/A

Updates	12	Report the methods used to update the search(es) (e.g., rerunning searches, email alerts).	N/A
Dates of searches	13	For each search strategy, provide the date when the last search occurred.	p. 4
PEER REVIEW			
Peer review	14	Describe any search peer review process.	Used PRESS (McGowan J, Sampson M, Salzwedel DM, Cogo E, Foerster V, Lefebvre C. PRESS Peer Review of Electronic Search Strategies: 2015 Guideline Statement. J Clin Epidemiol. 2016 Jul;75:40-6. doi: 10.1016/j.jclinepi.2016.01.021).
MANAGING RECORDS			
Total Records	15	Document the total number of records identified from each database and other information sources.	Included in Supplementary Material
Deduplication	16	Describe the processes and any software used to deduplicate records from multiple database searches and other information sources.	Initial deduplication done via Endnote X9.3.3 using modified version of Bramer WM, Giustini D, de Jonge GB, Holland L, Bekhuis T. De-duplication of database search results for systematic reviews in EndNote. Journal of the Medical Library Association : JMLA. 2016;104(3):240-243. doi:10.3163/1536-5050.104.3.014 (see McGill KS guide). Further deduplication manually performed

			in EndNote then in Rayyan online software.

PRISMA-S: An Extension to the PRISMA Statement for Reporting Literature Searches in Systematic Reviews
Rethlefsen ML, Kirtley S, Waffenschmidt S, Ayala AP, Moher D, Page MJ, Koffel JB, PRISMA-S Group.
Last updated
February 27, 2020.

Supplementary Table 1: Risk of Bias Analysis using the National Institute for Health and Care Evidence (NICE) Checklist Critical Appraisal of qualitative studies [61]

	Appropriate approach	Clear aim	Defensible methodology	Data collection	Role of researcher stated	Described context	Reliable methods	Rigorous data analysis	"Rich" data	Reliable analysis	Convincing findings	Relevant findings	Conclusions	Ethics reporting
Bhanot et al.	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Vivian et al.	+	?	+	+	+	+	+	+	+	+	+	+	+	+
Silva et al.	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Pfeil, M.	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cegala et al.	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Christensen-Szalanski et al.	+	+	?	+	?	+	?	+	?	?	?	+	+	?
Erraguntla et al.	+	+	+	+	?	+	+	+	+	+	+	+	+	+
Guinand et al.	+	+	+	+	+	+	+	-	?	?	+	+	+	?
Hansson et al.	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Lashley et al.	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Mercurio et al.	+	+	+	+	+	+	+	+	+	+	+	+	+	?

+	Appropriate
?	Unclear
-	Inappropriate

Supplementary Table 2: Risk of Bias Analysis using the Scale for the Assessment of Narrative Review Articles (SANRA) [62]

	Relevancy justification	Concrete aims	Literature search described	References	Scientific reasoning	Data presentation
Nwomeh et al.	+	+	-	+	+	+
Berg et al.	+	+	-	+	+	+

+	Score of 2/2
-	Score of 0/2

Supplementary Table 3: Risk of Bias Analysis using the Methodological Index for Non-Randomized Studies (MINORS) [63]

	Clear aim	Consecutive patients	Prospective data collection	Appropriate endpoints	Endpoint assessment	F/U period	Loss to F/U	Prospective study size	Control group	Contemporary groups	Equivalent characteristics	Statistical analysis
Nwomeh et al.	+	+	+	+	+	+	+	-	+	+	+	+
Paton et al.	+	+	+	+	+	-	-	+	+	?	+	+

+	Reported and Adequate
?	Reported and Inadequate
-	Not Reported

Supplementary Table 4: Risk of Bias Analysis using the Critical Appraisal Skills Programme (CASP) checklist for cohort studies [64]

	Clear focused issue	Cohort recruitment	Exposure measured to reduce bias?	Outcome mesured to reduce bias?	Confounding factors identified	Considered confounding factors in analysis?	Complete F/U	Long enough F/U
Pianosi et al.	+	+	+	+	+	+	+	+
Li et al.	+	+	+	+	+	+	+	+
Theologis et al.	+	+	+	+	+	+	+	+

+	Yes

Supplementary Table 5: Risk of Bias Analysis using the Cochrane Collaboration's tool critical appraisal for RCTs [65]

	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other sources of bias
Book et al.	+	?	-	?	+	+	+
Tait et al.	+	?	-	?	+	+	+
Rymeski et al.	+	?	-	?	+	+	+
Rosenfeld et al.	+	+	?	?	+	+	+
Cegala et al.	+	+	?	?	+	+	+
Chantry et al.	+	+	?	?	-	+	+
Enzenauer et al.	?	?	?	?	+	+	+
Landier et al.	+	+	-	?	+	+	+
Nadeau et al.	+	+	?	?	+	+	+
Papsin et al.	+	+	+	+	+	+	+
Al-Taha et al.	+	+	-	+	+	+	+

+	Low risk of bias
?	Unclear risk of bias
-	High risk of bias

Supplementary Table 6: Risk of Bias Analysis using the Joanna Briggs Institute (JBI) checklist for critical appraisal of expert opinion publication [66]

	Source of opinion	Field of expertise	Relevant population	Analytical process	References	Logical congruence
Wehrmann et al.	+	+	+	+	+	+
Short & Willetts	+	+	+	+	+	+
Byrne & Murphy	+	+	+	+	+	+
Hyde & Power	+	+	+	+	+	+
Jones et al.	+	+	+	+	+	+
Paris et al.	+	+	+	+	+	+
Morris & Rothera	+	+	+	+	+	+

+	Yes

Supplementary Table 7: Risk of Bias Analysis using the Agency for Healthcare Research and Quality (AHRQ) checklist for cross-sectional studies [67]

	Source of information	Inclusion/Exclusion criteria	Time period	Consecutive subjects or not	Evaluators masked	Quality assurance	Exclusions from analysis	Control of confounding	Handling of missing data	Summarize patient responses	Follow-up
Wasserzug et al.	+	+	+	-	?	-	NA	-	NA	+	NA
Steven et al.	+	+	+	+	+	-	NA	-	NA	+	NA
Firdouse et al.	+	+	-	-	?	-	+	-	NA	+	NA
Johnson et al.	+	+	+	+	?	-	NA	-	NA	+	NA
Niyogi & Clarke	+	+	+	+	?	-	NA	-	NA	+	NA
Ciesielski-Carlucci et al.	+	+	-	+	?	-	NA	-	NA	+	NA
Erraguntla et al.	+	+	+	+	?	+	NA	-	NA	+	NA

+	Yes
?	Unclear
-	No
NA	Not Applicable

Supplementary Table 8: Risk of Bias Analysis using A MeaSurement Tool to Assess systematic Reviews (AMSTAR) [68]

	"A priori" design?	Duplicate study selection & extraction	Literature Search	Satus of publication as inclusion criterion	List of studies	Characteristics of included studies	Assessment of scientific quality	Appropriate use of scientific quality in assessment	Appropriate methods	Assessment of publication bias	Conflict of interest stated
Chotai et al.	-	+	+	-	-	+	-	NA	+	-	+

+	Yes
-	No
NA	Not Applicable

Supplemental Document 4: Search Strategy

Africa-Wide Information [EBSCO] (July 21, 2020)

S19	S13 OR S14 OR S15 OR S16 OR S17 Limiters - Language: English, French	153
S18	S13 OR S14 OR S15 OR S16 OR S17	163
S17	TI(informed consent* and satisfaction*)	15
S16	TI(parental consent*)	8
S15	TI((shared and consent*))	2
S14	TI((informed consent*) and (surg* or medical* or treatment* or procedure*))	74
S13	S11 AND S12	58
S12	TI(newborn* or new-born* or neonat* or neo-nat* or infan* or child* or adolesc* or paediatr* or pediatr* or baby* or babies* or toddler* or kid or kids or boy* or girl* or juvenile* or teen* or youth* or pubescen* or preadolesc* or prepubesc* or preteen or tween or parent* or mother* or father* or mom* or dad? or family* or families* or caregiver* or care-giver*) OR AB(newborn* or new-born* or neonat* or neo-nat* or infan* or child* or adolesc* or paediatr* or pediatr* or baby* or babies* or toddler* or kid or kids or boy* or girl* or juvenile* or teen* or youth* or pubescen* or preadolesc* or prepubesc* or preteen or tween or parent* or mother* or father* or mom* or dad? or family* or families* or caregiver* or care-giver*)	379,315
S11	S9 AND S10	158
S10	TI(surger* or surgical* or surgeon? or operation? or repair? or procedure* or reoperat* or laparoscop* or laparotom* or preop* or pre-op* or presurg* or pre-surg* or perop* or periop* or peri-op* or perisurg* or peri-surg* or intraop* or intra-op*) OR AB(surger* or surgical* or surgeon? or operation? or repair? or procedure* or reoperat* or laparoscop* or laparotom* or preop* or pre-op* or presurg* or pre-surg* or perop* or periop* or peri-op* or perisurg* or peri-surg* or intraop* or intra-op*)	140,511
S9	S5 AND S8	904
S8	S6 OR S7	55,909
S7	TI(communication* or comprehension*) OR AB(communication* or comprehension*)	40,838
S6	TI(decision* N1 (make* or making* or tool? or aid or aids or share* or sharing or resource* or choice* or (support* N2 technique*))) OR AB(decision* N1 (make* or making* or tool? or aid or aids or share* or sharing or resource* or choice* or (support* N2 technique*)))	16,157
S5	S1 OR S2 OR S3 OR S4	4,715
S4	TI((informed or consent* or surg* or preop* or pre-op*) and (treatment* N1 decision*)) OR AB((informed or consent* or surg* or preop* or pre-op*) and (treatment* N1 decision*))	97
S3	TI(((preop* or pre-op*) N1 info*) or (verbal* N1 counsel*)) OR AB(((preop* or pre-op*) N1 info*) or (verbal* N1 counsel*))	39
S2	TI((consent or permission*) N1 (form? or material? or process* or preop* or patient? or obtain* or parental or operative or surgical or procedural* or standard or structured or verbal* or written or presumed)) OR AB((consent or permission*) N1 (form? or material? or process* or preop* or patient? or obtain* or parental or operative or surgical or procedural* or standard or structured or verbal* or written or presumed))	1,780

S1	TI ((inform? or informing or informed*) N1 (consent* or permission* or process* or decision? or patient? or choice*)) OR AB((inform? or informing or informed*) N1 (consent* or permission* or process* or decision? or patient? or choice*))	3,834

Cochrane [Wiley] (July 21, 2020)

#1	((inform? or informing or informed*) NEAR/1 (consent* or permission* or process* or decision? or patient? or choice*)):ti,ab,kw	59853
#2	((consent or permission*) NEAR/1 (form? or material? or process* or preop* or patient? or obtain* or parental or operative or surgical or procedural* or standard or structured or verbal* or written or presumed)):ti,ab,kw	19528
#3	(((preop* or pre-op*) NEAR/1 info*) or (verbal* NEAR/1 counsel*)):ti,ab,kw	212
#4	((informed or consent* or surg* or preop* or pre-op*) and (treatment* NEAR/1 decision*)):ti,ab,kw	677
#5	#1 OR #2 OR #3 OR #4	68564
#6	(decision* NEAR/1 (make* or making* or tool? or aid or aids or share* or sharing or resource* or choice* or (support* NEAR/2 technique*))):ti,ab,kw	14937
#7	(communication* or comprehension*):ti,ab,kw	20272
#8	#6 OR #7	33585
#9	#5 and #8	3330
#10	(surger* or surgical* or surgeon? or operation? or repair? or procedure* or reoperat* or laparoscop* or laparotom* or preop* or pre-op* or presurg* or pre-surg* or perop* or periop* or peri-op* or perisurg* or peri-surg* or intraop* or intra-op*):ti,ab,kw	416690
#11	#9 and #10	1295
#12	(newborn* or new-born* or neonat* or neo-nat* or infan* or child* or adolesc* or paediatr* or pediatr* or baby* or babies* or toddler* or kid or kids or boy* or girl* or juvenile* or teen* or youth* or pubescen* or preadolesc* or prepubesc* or preteen or tween or parent* or mother* or father* or mom* or dad? or family* or families* or caregiver* or care-giver*):ti,ab,kw	331757
#13	#11 AND #12	406
#14	#12 AND ((informed consent*) and (surg* or medical* or treatment* or procedure*)):ti	23
#15	#12 AND ((shared and consent*)):ti,kw	6
#16	parental consent*:ti	65
#17	(informed consent* and satisfaction*):ti	21
#18	#13 OR #14 OR #15 OR #16 OR #17 [Note 2 editorials in this set, so 495 exported]	497*

Embase [Ovid] (July 21, 2020)

Embase Classic+Embase 1947 to 2020 July 17

1	informed consent/	107899
2	((inform? or informing or informed*) adj1 (consent* or permission* or process* or decision? or patient? or choice*)).tw,kw.	105597
3	((consent or permission*) adj1 (form? or material? or process* or preop* or patient? or obtain* or parental or operative or surgical or procedural* or standard or structured or verbal* or written or presumed)).tw,kw.	27268
4	(((preop* or pre-op*) adj info*) or (verbal* adj counsel*)).tw,kw.	1490
5	((informed or consent* or surg* or preop* or pre-op*) and (treatment* adj decision*)).tw,kw.	8280
6	or/1-5	176309
7	exp *interpersonal communication/	194566
8	interpersonal communication/	170118
9	medical information system/	20888
10	information dissemination/	21005
11	information seeking/	3367
12	exp *counseling/	39167
13	exp *decision making/	82034
14	decision support system/	22322
15	(decision* adj1 (make* or making* or tool? or aid or aids or share* or sharing or resource* or choice* or (support* adj2 technique*))).tw,kw.	218792
16	(communication* or comprehension*).ti,kw. or (communication* or comprehension*).ab. /freq=4	104117
17	comprehension/	30475
18	exp *nonverbal communication/ or nonverbal communication/	22656
19	exp *verbal communication/	114385
20	*persuasive communication/	3398
21	*clinical decision making/	5829
22	personalized medicine/	43667
23	uncertainty/	29690
24	or/7-23	798639
25	6 and 24	29554
26	exp surgery/	5286180
27	su.fs.	2167141
28	(surger* or surgical* or surgeon? or operation? or repair? or procedure* or reoperat* or laparoscop* or laparotom* or preop* or pre-op* or presurg* or pre-surg* or perop* or periop* or peri-op* or perisurg* or peri-surg* or intraop* or intra-op*).tw,kw.	4681649
29	or/26-28	7534242
30	25 and 29	9083

31	exp parent/ or exp family/ or caregiver/	620399
32	exp pediatrics/ or exp adolescent/ or exp child/ or exp infant/	3885408
33	(newborn* or new-born* or neonat* or neo-nat* or infan* or child* or adolesc* or paediatr* or pediatr* or baby* or babies* or toddler* or kid or kids or boy* or girl* or juvenile* or teen* or youth* or pubescen* or preadolesc* or prepubesc* or preteen or tween or parent* or mother* or father* or mom* or dad? or family* or families* or caregiver* or care- giver*).tw,kw.	4757601
34	or/31-32	4208284
35	30 and 34	1487
36	34 and (informed consent* and (surg* or medical* or treatment* or procedure*)).ti.	132
37	34 and (shared and consent*).ti,kw.	28
38	(informed consent* adj3 (surg* or clinical or medical* or treatment* or decision*)).ab. /freq=2	274
39	30 and child/ and *informed consent/	102
40	*informed consent/ and (*interpersonal communication/ or *comprehension/) and Patient*.hw. and (decision making/ or uncertainty/)	147
41	*risk Assessment/ and Comprehension/ and Patient*.hw. and (decision making/ or uncertainty/)	16
42	parental consent*.ti.	210
43	parental consent*.kw. and (parent* or child* or consent*).ti.	68
44	(informed consent* and satisfaction*).ti,kw.	94
45	((pre-op* or preop* or pre-surg* or presurg* or pre-procedur* or preprocedur*) and (educ* or inform*) and (child* or paediatr* or pediatr* or parent* or (patient? adj (satisf* or understand*)))).ti,kw.	101
46	or/35-45	2423
47	remove duplicates from 46	2399
48	(31271973 OR 30173996 OR 32192884 OR 27258537 OR 23241795 OR 28987933 OR 24460266 OR 22335782 OR 29720150 OR 14983610 OR 27099185 OR 7486239 OR 15005431 OR 15132278 OR 15132277 OR 15132279 OR 31489334 OR 30660226 OR 18239638 OR 22166961 OR 13791856 OR 11575761 OR 24671518 OR 28195873 OR 22424362 OR 9820931 OR 27665096 OR 24961716 OR 16265512 OR 28726247 OR 20861149 OR 30616673 OR 9171552 OR 25339067 OR 20083367 OR 18841453 OR 14966735 OR 22439079 OR 17219938 OR 31198589 OR 24829668 OR 25981282 OR 26239668 OR 12285802 OR 26608424 OR 16602331 OR 31162356 OR 11654800 OR 22413920 OR 15933463 OR 1404277 OR 11220847 OR 17854964 OR 8664799 OR 25645175 OR 11650982 OR 15667679 OR 26044608 OR 31040455 OR 26600450 OR	2747
	15199939 OR 10323500 OR 25990943 OR 25820987 OR 7617491 OR 31127918 OR 16650361 OR 10461596 OR 30281603 OR 17891536 OR 22828044 OR 31933321 OR 11990916 OR 30946228 OR 24107658 OR 22789546 OR 18725660 OR 26676378 OR 11659205 OR 11660331 OR 21788223 OR 21775875 OR 26103711 OR 11644367 OR 19813681 OR 26675607 OR 31533708 OR 31307831 OR 23234655 OR 17277283 OR 20640368 OR 8019460 OR 29974359 OR 25450589 OR 15049015 OR 21491309 OR 29778349 OR 2211083 OR 2603858 OR 28949898 OR 11664233 OR 11660993 OR 11664342 OR 4847003 OR 11664649 OR 11664546 OR 1242066 OR 11664637 OR 69061 OR 12277895 OR 477929 OR 7363219 OR 11655545 OR 11644275 OR 3922514 OR 2858672 OR 3092918 OR 12282179 OR 2330252 OR 2226749 OR 12284517 OR 12285432 OR 12345151 OR 12345150 OR 12286472 OR 12286313 OR 8416412 OR 12345705 OR 12318750 OR 8049773 OR 7898222 OR 12320458 OR 12291324 OR 8628623 OR 12321265 OR 12292549 OR 12292101 OR 9141975 OR 10569072 OR 10429022 OR 11826770 OR 12408120 OR 15832472 OR 12882043 OR 15926273 OR 18523671 OR 23909192 OR 23841155 OR 28333813 OR 30045205 OR 31651630 OR 31441821 OR 31441826 OR 28109951 OR 11699991 OR 20392403 OR 11657319 OR 3200278 OR 11660290 OR 10484948 OR 24158054 OR 11656658 OR 11659963 OR 11309872 OR 17138844 OR 12493680 OR 29455243 OR 11659318 OR 21093107 OR 12222246 OR 15923959 OR 11833668 OR 7873895 OR 8700613 OR 7626926 OR 11885101 OR 9419914 OR 23492877 OR 11276405 OR 7649964 OR 30985607 OR 11652231 OR 11660503 OR 24991375 OR 11658431 OR 10553384 OR 30906542 OR 7260413 OR 17278860 OR 16682916 OR 15789315 OR 26754407 OR 11759714 OR 2945540 OR 31776178 OR 27001504 OR 20434630 OR 30020958 OR 8485413 OR 10633288 OR 27658770 OR 12289437 OR 2305729 OR 27474699 OR 23857795 OR 24458282 OR 19467903 OR 21311985 OR 27697792 OR 30274848 OR 24597420 OR 31391620 OR 28032576 OR 25143027 OR 21982854 OR 8089388 OR 12923519 OR 12285567 OR 12321065 OR 30830698 OR 29516345 OR 21895453 OR 28727801 OR 11654801 OR 20422304 OR 11475953 OR 23149214 OR 10831079 OR 31870323 OR 28112612 OR 28949840 OR 26859796 OR 15468489 OR 7141151 OR 11658459 OR 4086738 OR 11716796 OR 27113077 OR 14567264 OR 28229855 OR 8875660 OR 25999701 OR 30234701 OR 27351051 OR 10124087 OR 26054910 OR 8902169 OR 11660108 OR 26474268 OR 22441499 OR 11159638 OR 20871753 OR 15637948 OR 16789582 OR 20444064 OR 10802276 OR 26053685 OR 11660758 OR 24246900 OR 22432867 OR 9044538 OR 9607165 OR 9447641 OR 20688457 OR 11964338 OR 29903853 OR 32366702 OR 21098797 OR 31714037 OR 21766726 OR 1628716 OR 28087390 OR 11664591 OR 11645694 OR 12186063 OR 86383 OR 28088214 OR 30472665 OR 7390420 OR 16302550 OR 29598870 OR 16086484 OR 11659979 OR 10182216 OR 25947100 OR 15074762 OR 17927624 OR 11654846 OR 2979476 OR 18572357 OR 15465460 OR 16415417 OR 11656642 OR 759316 OR 26242945 OR 27227982 OR 22939727 OR 21199584 OR 22518045 OR 26578087 OR 11658756 OR 27669132 OR 30242078 OR 32147349 OR 21484486 OR 25907277 OR 22871511 OR 29548834 OR 31414057 OR 21438850 OR 29456223 OR 16264113 OR 26070661 OR 6785686 OR 23138369 OR 19726022 OR 11958247 OR 26733328 OR 26401048 OR 25289257 OR 22511191 OR 31792497 OR 28114238 OR 20094021 OR 3160924 OR 26399676 OR 7941531 OR 26087668 OR 25870957 OR 691018 OR 18758928 OR 10086441 OR 30511705 OR 3800080 OR 25747298 OR 8006482 OR 18650629 OR 11643719 OR 27313410 OR 24810190 OR 22250019 OR 30514552 OR 31685270 OR 24425705 OR 25058197 OR 23401380 OR 26434998 OR 19094003 OR 30170039 OR 16148572 OR 27560831 OR 26645531 OR 11816936 OR 2667332 OR 30964880 OR 10636343 OR 29081031 OR 11892507 OR 10818853 OR 26464072 OR 11650595 OR 17291343 OR 21440966 OR 10612318 OR 9192250 OR 27338601 OR 11644291 OR 2870397 OR 2869343 OR 2567955 OR 2567837 OR 23383858 OR 11343981 OR 28645640 OR 6370015 OR 25837233 OR 3959971 OR 16719041 OR 15278979 OR 18651981 OR 12239664 OR 20511352 OR 31697460 OR 18183749 OR 18625699 OR 11665158 OR 22465877 OR 27030483 OR 7363529 OR 28110270 OR 30865868 OR 11652014 OR 10280352 OR 12737171 OR 1025710 OR 16109343 OR 14552306 OR 22921135 OR 27288096 OR 19375012 OR 22021506 OR 1565807 OR 19519752 OR 17524044 OR 1617889 OR 17236317 OR 11126997 OR 14604623 OR 20554149 OR	

14967081 OR 12650730 OR 1486819 OR 24325146 OR 11660317 OR 20204949 OR 11649884 OR 20846232 OR 2264971 OR 10185178 OR 31379268 OR 28363739 OR 20023605 OR 12547553 OR 24233796 OR 25307710 OR 28183557 OR 12284992 OR 29408289 OR 15807957 OR 29628757 OR 9560863 OR 6950435 OR 11658348 OR 16203668 OR 21117527 OR 18999916 OR 32232746 OR 29614924 OR 18554643 OR 21492287 OR 29396272 OR 20559476 OR 22462383 OR 25350898 OR 31188791 OR 12041073 OR 32596079 OR 21385429 OR 8752070 OR 23463629 OR 11649915 OR 11664341 OR 11649908 OR 29183264 OR 28939000 OR 28730397 OR 11387143 OR 12744268 OR 8037929 OR 11658747 OR 3953915 OR 24325658 OR 16192541 OR 30687677 OR 8668717 OR 2523612 OR 3594393 OR 11663064 OR 27105058 OR 32528858 OR 31542833 OR 31504791 OR 24361016 OR 22560252 OR 23602210 OR 301166 OR 11998416 OR 11661939 OR 9451609 OR 24619521 OR 12795733 OR 28500035 OR 23760576 OR 12431168 OR 20723238 OR 14581440 OR 28317002 OR 20551191 OR 16246853 OR 17960770 OR 26820288 OR 11657318 OR 27934774 OR 2578222 OR 29523662 OR 27681601 OR 30710147 OR 12044131 OR 25735517 OR 26545589 OR 3277030 OR 27019669 OR 30243428 OR 31145695 OR 23116909 OR 26182482 OR 25258207 OR 31634920 OR 22486249 OR 24999924 OR 23615058 OR 26069283 OR 2309810 OR 1451354 OR 17365448 OR 12069463 OR 25066199 OR 22917709 OR 11664481 OR 11644058 OR 26620620 OR 18171493 OR 25160963 OR 27428683 OR 30789542 OR 18552701 OR 31568159 OR 28259489 OR 25795649 OR 28601314 OR 21121994 OR 7963200 OR 18677570 OR 26476281 OR 27328055 OR 19362992 OR 8718729 OR 29633740 OR 7659546 OR 8183219 OR 17704678 OR 26558649 OR 27235300 OR 27269751 OR 2038754 OR 31208865 OR 11651558 OR 2809815 OR 8215753 OR 8109617 OR 21597109 OR 23641835 OR 12813220 OR 17760802 OR 28145837 OR 9284225 OR 31249026 OR 3224479 OR 32115875 OR 16801202 OR 12043661 OR 28115537 OR 28333821 OR 30400995 OR 30841872 OR 18500213 OR 19139027 OR 20580363 OR 11659291 OR 21656146 OR 4671690 OR 20373659 OR 28212252 OR 9543964 OR 11660787 OR 1575073 OR 28578097 OR 30653623 OR 32661073 OR 30232675 OR 25190120 OR 21788401 OR 30690645 OR 18757103 OR 30367362 OR 12794792 OR 11664833 OR 23118468 OR 21586195 OR 2015239 OR 6976143 OR 10388928 OR 3276464 OR 7479124 OR 11651710 OR 2292993 OR 24565345 OR 30130993 OR 23966424 OR 23014383 OR 11659585 OR 26416688 OR 20228855 OR 29024214 OR 25745117 OR 32469644 OR 31465855 OR 28124394 OR 25875993 OR 22169525 OR 18978595 OR 31330335 OR 28296536 OR 20822335 OR 27756401 OR 8834326 OR 29445845 OR 24893933 OR 17299520 OR 30626421 OR 24532934 OR 32313703 OR 11697385 OR 20739247 OR 14662053 OR 15309468 OR 11715992 OR 11954259 OR 19845196 OR 2587390 OR 27721646 OR 19136342 OR 8158593 OR 30604669 OR 32009466 OR 15371809 OR 11231714 OR 32356360 OR 25521973 OR 12884032 OR 21057077 OR 24917616 OR 21943406 OR 11658904 OR 14740350 OR 27664497 OR 23259352 OR 18800206 OR 29053523 OR 20542617 OR 22178984 OR 29685869 OR 29209695 OR 26210560 OR 12497733 OR 18757622 OR 31634258 OR 31033855 OR 11655188 OR 20050454 OR 19932035 OR 31395692 OR 21158491 OR 7845277 OR 9221065 OR 10183297 OR 11659556 OR 24753868 OR 24603131 OR 27467465 OR 32134012 OR 11664107 OR 6677881 OR 29020932 OR 25183289 OR 25168636 OR 10275556 OR 26194409 OR 7861423 OR 25555022 OR 31043830 OR 8668715 OR 30367648 OR 11828358 OR 12587134 OR 19845198 OR 9192259 OR 23933874 OR 21726363 OR 28816023 OR 27677435 OR 11656041 OR 11927888 OR 15631400 OR 21590657 OR 18771038 OR 24902683 OR 30896738 OR 19376270 OR 15046274 OR 26780634 OR 25502322 OR 30285534 OR 30658684 OR 17728687 OR 19845197 OR 31959569 OR 19568019 OR 2083416 OR 7286175 OR 7286173 OR 6667731 OR 12346847 OR 23131417 OR 22107084 OR 4574958 OR 19809485 OR 8165379 OR 11533435 OR 29356351 OR 27431491 OR 17961008 OR 6748193 OR 9669179 OR 28419019 OR 22309587 OR 19880703 OR 24251638 OR 15580724 OR 31486381 OR 31892617 OR 25328024 OR 11649913 OR 17369758 OR 29895213 OR 11664542 OR 11658905 OR 11649885 OR 8530273 OR 11649916 OR 3092980 OR 11643132 OR 11644864 OR 11644924 OR 23240989 OR 28541177 OR 11532412 OR 15799666 OR 25715543 OR 9650110 OR 20172391 OR 7979774 OR 29302597 OR 25953252 OR 31556702 OR 9643593 OR 11659661 OR 6462204 OR 19223803 OR 22285247 OR 10786489 OR 23614706 OR 12715809 OR 15156878 OR 23678835 OR 22817625 OR 30271513 OR 31135699 OR 20411377 OR 9253281 OR 17367106 OR 31349214 OR 14710061 OR 11659113 OR 11660407 OR 11659371 OR 24169168 OR 20956831 OR 25557414 OR 3339493 OR 23813901 OR 25403504 OR 12467316 OR 28584069 OR 26324158 OR 3715536 OR 23057616 OR 4728655 OR 28661741 OR 7659454 OR 31149017 OR 22560413 OR 10183266 OR 18441216 OR 10538786 OR 19554828 OR 32355968 OR 11660478 OR 25869766 OR 21443835 OR 31085631 OR 28507990 OR 11664680 OR 10306863 OR 12108482 OR 31969458 OR 16850080 OR 11658427 OR 22037076 OR 29607852 OR 1577182 OR 10343984 OR 7137431 OR 20881153 OR 24145110 OR 19716887 OR 17208553 OR 15574636 OR 29686145 OR 22789583 OR 30319013 OR 14572427 OR 19097539 OR 12210453 OR 10249190 OR 15797498 OR 26324111 OR 11652652 OR 29076946 OR 11780655 OR 11659593 OR 32037122 OR 30113400 OR 23221948 OR 4950881 OR 4905016 OR 11660499 OR 11787503 OR 19132609 OR 32508134 OR 11834760 OR 7793710 OR 10066968 OR 25348207 OR 29706558 OR 30689228 OR 11659754 OR 23256400 OR 11659551 OR 12283721 OR 20562609 OR 28216078 OR 11649904 OR 3092145 OR 30456328 OR 30659439 OR 11654930 OR 16523564 OR 30573357 OR 31713712 OR 17329394 OR 2229863 OR 29924808 OR 23280227 OR 2108103 OR 8668716 OR 28576618 OR 30206091 OR 31372747 OR 15835557 OR 31986114 OR 28993074 OR 15467062 OR 511519 OR 17287221 OR 12755146 OR 10635505 OR 32368851 OR 20233979 OR 27871308 OR 28689263 OR 17511596 OR 11658261 OR 8194300 OR 12289462 OR 9693485 OR 16257615 OR 16712850 OR 29714576 OR 12091927 OR 25839930 OR 7083055 OR 23859354 OR 10349417 OR 19067660 OR 19403495 OR 23392912 OR 26616895 OR 21245476 OR 28304099 OR 26034870 OR 27975042 OR 11658339 OR 27834803 OR 28121856 OR 11584505 OR 22332066 OR 24836837 OR 30463554 OR 17851364 OR 17505381 OR 26131830 OR 18610704 OR 31660956 OR 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49	47 not 48	1235
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1	((inform? or informing or informed*) adj1 (consent* or permission* or process* or decision? or patient? or choice*)).ti,ab,id.	7564
2	((consent or permission*) adj1 (form? or material? or process* or preop* or patient? or obtain* or parental or operative or surgical or procedural* or standard or structured or verbal* or written or presumed)).ti,ab,id.	2068
3	(((preop* or pre-op*) adj info*) or (verbal* adj counsel*)).ti,ab,id.	25

4	((informed or consent* or surg* or preop* or pre-op*) and (treatment* adj decision*)).ti,ab,id.	140
5	or/1-4	9313
6	(decision* adj1 (make* or making* or tool? or aid or aids or share* or sharing or resource* or choice* or (support* adj2 technique*))).ti,ab,id.	20827
7	(communication* or comprehension*).ti,id. or (communication* or comprehension*).ab. /freq=4	6158
8	or/6-7	26768
9	5 and 8	1284
10	(surger* or surgical* or surgeon? or operation? or repair? or procedure* or reoperat* or laparoscop* or laparotom* or preop* or pre-op* or presurg* or pre-surg* or perop* or periop* or peri-op* or perisurg* or peri-surg* or intraop* or intra-op*).ti,ab,id.	245280
11	9 and 10	156
12	(newborn* or new-born* or neonat* or neo-nat* or infan* or child* or adolesc* or paediatr* or pediatr* or baby* or babies* or toddler* or kid or kids or boy* or girl* or juvenile* or teen* or youth* or pubescen* or preadolesc* or prepubesc* or preteen or tween or parent* or mother* or father* or mom* or dad? or family* or families* or caregiver* or care-giver*).ti,ab,id.	753927
13	11 and 12	39
14	12 and (informed consent* and (surg* or medical* or treatment* or procedure*)).ti,id.	6
15	(informed consent* adj3 (surg* or clinical or medical* or treatment* or decision*)).ab. /freq=2	1
16	parental consent*.ti.	16
17	(informed consent* and satisfaction*).ti,id.	1
18	((pre-op* or preop* or pre-surg* or presurg* or pre-procedur* or preprocedur*) and (educ* or inform*) and (child* or paediatr* or pediatr* or parent* or (patient? adj (satisf* or understand*)))).ti,id.	2
19	or/13-18	64
20	remove duplicates from 19	64
21	limit 20 to (english or french)	62

Global Index Medicus [WHO] (July 21, 2020)

2	tw:((tw:(inform* consent* OR inform* permission* OR consent form* OR verbal consent* OR written consent*)) AND (tw:(communication* OR comprehension* OR decision making OR shared decision*)) AND (tw:(surger* OR surgical* OR surgeon? OR operation? OR repair? OR procedure* OR reoperat* OR laparoscop* OR laparotom* OR preop* OR pre-op* OR presurg* OR pre-surg* OR perop* OR periop* OR peri-op* OR perisurg* OR peri-surg* OR intraop* OR intra-op* OR postop* OR postsurg*)) AND (tw:(newborn* OR new-born* OR neonat* OR neo-nat* OR infan* OR child* OR adolesc* OR paediatr* OR pediatr* OR baby* OR babies* OR toddler* OR kid OR kids OR boy* OR girl* OR juvenile* OR teen* OR youth* OR pubescen* OR preadolesc* OR prepubesc* OR preteen OR tween OR parent* OR mother* OR father* OR mom* OR dad?))) AND (la:("en" or “fr”))	29

1	tw:((tw:(inform* consent* OR inform* permission* OR consent form* OR verbal consent* OR written consent*)) AND (tw:(communication* OR comprehension* OR decision making OR shared decision*)) AND (tw:(surger* OR surgical* OR surgeon? OR operation? OR repair? OR procedure* OR reoperat* OR laparoscop* OR laparotom* OR preop* OR pre-op* OR presurg* OR pre-surg* OR perop* OR periop* OR peri-op* OR perisurg* OR peri-surg* OR intraop* OR intra-op* OR postop* OR postsurg*)) AND (tw:(newborn* OR new-born* OR neonat* OR neo-nat* OR infan* OR child* OR adolesc* OR paediatr* OR pediatr* OR baby* OR babies* OR toddler* OR kid OR kids OR boy* OR girl* OR juvenile* OR teen* OR youth* OR pubescen* OR preadolesc* OR prepubesc* OR preteen OR tween OR parent* OR mother* OR father* OR mom* OR dad?)))	88

Medline [Ovid] (July 21, 2020)

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to July 17, 2020>

1	exp *Informed Consent/	19471
2	Informed Consent/	36411
3	Presumed Consent/	542
4	Patient Education Handout/	5154
5	((inform? or informing or informed*) adj1 (consent* or permission* or process* or decision? or or choice*)).tw,kf.	54776
6	((consent or permission*) adj1 (form? or material? or process* or preop* or patient? or obtain* or or operative or surgical or procedural* or standard or structured or verbal* or written or d)).tw,kf.	13618
7	(((preop* or pre-op*) adj info*) or (verbal* adj counsel*)).tw,kf.	1047
8	((informed or consent* or surg* or preop* or pre-op*) and (treatment* adj decision*)).tw,kf.	4750
9	or/1-8 [Informed Consent]	98884
10	exp *Communication/	166785
11	Communication/	83836
12	Health Information Exchange/	870
13	Information Dissemination/	16730
14	Information Seeking Behavior/	2397
15	Health Communication/	2326
16	exp Counseling/mt	7341
17	exp *Decision Making/	94948
18	decision support techniques/	20327
19	(decision* adj1 (make* or making* or tool? or aid or aids or share* or sharing or resource* or or (support* adj2 technique*))).tw,kf.	160276
20	(communication* or comprehension*).ti,kf. or (communication* or comprehension*).ab. /freq=4	82611

21	Comprehension/	14453

22	exp nonverbal communication/	27901
23	persuasive communication/	3670
24	Clinical Decision-Making/	9102
25	Precision Medicine/	17967
26	Uncertainty/	12596
27	or/10-26 [Communication/DM]	551057
28	9 and 27 [Informed Consent & Communication]	19199
29	exp specialties, surgical/	198716
30	exp surgical procedures, operative/	3138209
31	su.fs.	1982445
32	perioperative care/	14176
33	exp Preoperative Period/	7500
34	(surger* or surgical* or surgeon? or operation? or repair? or procedure* or reoperat* or laparoscop* or laparotom* or preop* or pre-op* or presurg* or pre-surg* or perop* or periop* or peri-op* or perisurg* or peri-surg* or intraop* or intra-op*).tw,kf.	3350490
35	or/29-34	5479763
36	28 and 35 [Informed Consent & Communication & Surgery]	5909
37	exp Parents/ or exp Family/ or Caregivers/	342559
38	exp pediatrics/ or exp adolescent/ or exp child/ or exp infant/	3572053
39	(newborn* or new-born* or neonat* or neo-nat* or infan* or child* or adolesc* or paediatr* or pediatr* or baby* or babies* or toddler* or kid or kids or boy* or girl* or juvenile* or teen* or youth* or pubescen* or preadolesc* or prepubesc* or preteen or tween or parent* or mother* or father* or mom* or dad? or family* or families* or caregiver* or care- giver*).tw,kf.	3629199
40	or/37-39	5434802
41	36 and 40 [Informed Consent & Communication & Surgery & Peds]	1833
42	40 and (informed consent* and (surg* or medical* or treatment* or procedure*)).ti,kf.	329
43	40 and (shared and consent*).ti,kf.	31
44	(informed consent* adj3 (surg* or clinical or medical* or treatment* or decision*)).ab. /freq=2	185
45	35 and Child/ and *Informed Consent/	325
46	*Informed Consent/ and (Communication/ or Comprehension/) and Patient*.hw. and (Decision Making/ or Uncertainty/)	276
47	*Risk Assessment/ and Comprehension/ and Patient*.hw. and (Decision Making/ or Uncertainty/)	28
48	parental consent*.ti.	195
49	parental consent*.kf. and (parent* or child* or consent*).ti.	66
50	(informed consent* and satisfaction*).ti,kf.	53
51	((pre-op* or preop* or pre-surg* or presurg* or pre-procedur* or preprocedur*) and (educ* or inform*) and (child* or paediatr* or pediatr* or parent* or (patient? adj (satisf* or understand*)))).ti,kf.	62

52	or/41-51	3044
53	remove duplicates from 52	3035
54	limit 53 to (english or french)	2903

Web of Science [Clarivate Analytics] (July 21, 2020)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All years

# 21	702	(#18 NOT #19) *AND* **LANGUAGE:** (English OR French)
# 20	738	#18 NOT #19
# 19	2,160	PMID=(31271973 OR 30173996 OR 32192884 OR 27258537 OR 23241795 OR 28987933 OR 24460266 OR 22335782 OR 29720150 OR 14983610 OR 27099185 OR 7486239 OR 15005431 OR 15132278 OR 1513227 7 OR 15132279 OR 31489334 OR 30660226 OR 18239638 OR 22166961 OR 13791856 OR 11575761 OR 24671518 OR 28195873 OR 22424362 OR 9820931 OR 27665096 OR 24961716 OR 16265 512 OR 28726247 OR 20861149 OR 30616673 OR 9171552 OR 25339067 OR 20083367 OR 18841453 OR 14966735 OR 22439079 OR 17219938 OR 31198589 OR 24829668 OR 25981282 OR 262 39668 OR 12285802 OR 26608424 OR 16602331 OR 31162356 OR 11654800 OR 22413920 OR 15933463 OR 1404277 OR 11220847 OR 17854964 OR 8664799 OR 25645175 OR 11650982 OR 15 667679 OR 26044608 OR 31040455 OR 26600450 OR 15199939 OR 10323500 OR 25990943 OR 25820987 OR 7617491 OR 31127918 OR 16650361 OR 10461596 OR 30281603 OR 17891536 OR 22828044 OR 31933321 OR 11990916 OR 30946228 OR 24107658 OR 22789546 OR 18725660 OR 26676378 OR 11659205 OR 11660331 OR 21788223 OR 21775875 OR 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OR 11659318 OR 21093107 OR 12222246 OR 15923959 OR 11833668 OR 7873895 OR 8700613 OR 7626926 OR 11885101 OR 9419914 OR 23492877 OR 11276405 OR 7649964 OR 30985607 OR 11652231 OR 11 660503 OR 24991375 OR 11658431 OR 10553384 OR 30906542 OR 7260413 OR 17278860 OR 16682916 OR 15789315 OR 26754407 OR 11759714 OR 2945540 OR 31776178 OR 27001504 OR 2 0434630 OR 30020958 OR 8485413 OR 10633288 OR 27658770 OR 12289437 OR 2305729 OR 27474699 OR 23857795 OR 24458282 OR 19467903 OR 21311985 OR 27697792 OR 30274848 OR 24597420 OR 31391620 OR 28032576 OR 25143027 OR 21982854 OR 8089388 OR 12923519 OR 12285567 OR 12321065 OR 30830698 OR 29516345 OR 21895453 OR 28727801 OR 11654801 O R 20422304 OR 11475953 OR 23149214 OR 10831079 OR 31870323 OR 28112612 OR 28949840 OR 26859796 OR 15468489 OR 7141151 OR 11658459 OR 4086738 OR 11716796 OR 27113077 OR 14567264 OR 28229855 OR 8875660 OR 25999701 OR 30234701 OR 27351051 OR 10124087 OR 26054910 OR 8902169 OR 11660108 OR 26474268 OR 22441499 OR 11159638 OR 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23118468 OR 21586195 OR 2015239 OR 6976143 OR 1038928 OR 327
# 18	1,373	#13 OR #14 OR #15 OR #16 OR #17
# 17	42	TI=(informed consent* and satisfaction*)
# 16	282	TI=parental consent*
# 15	20	#12 AND TI=((shared and consent*))
# 14	103	#12 AND TI=((informed consent*) and (surg* or medical* or treatment* or procedure*))
# 13	987	#11 AND #12
# 12	5,631,374	TS=(newborn* or new-born* or neonat* or neo-nat* or infan* or child* or adolesc* or paediatr* or pediatr* or baby* or babies* or toddler* or kid or kids or boy* or girl* or juvenile* or teen* or youth* or pube scen* or preadolesc* or prepubesc* or preteen or tween or parent* or mother* o r father* or mom* or dad? or family* or families* or caregiver* or care-giver*)
# 11	4,930	#9 and #10
# 10	3,697,666	TS=(surger* or surgical* or surgeon? or operation? or repair? or procedure* or reoperat* or l aparoscop* or laparotom* or preop* or pre-op* or presurg* or pre-surg* or perop* or periop* or peri-op* or perisurg* or peri- surg* or intraop* or intra-op*)
# 9	18,537	#5 and #8
# 8	1,577,535	#6 OR #7

# 7	1,111,139	TS=(communication* or comprehension*)
# 6	502,471	TS=(decision* NEAR/1 (make* or making* or tool? or aid or aids or share* or sharing or resource* or choice* or (support* NEAR/2 technique*)))
# 5	85,070	#1 OR #2 OR #3 OR #4
# 4	6,844	TS=((informed or consent* or surg* or preop* or pre-op*) and (treatment* NEAR/1 decision*))
# 3	1,696	TS=(((preop* or pre-op*) NEAR/1 info*) or (verbal* NEAR/1 counsel*))
# 2	26,522	TS=((consent or permission*) NEAR/1 (form? or material? or process* or preop* or patient? or obtain* or parental or operative or surgical or procedural* or standard or structured or verbal* or written or presumed))
# 1	66,716	TS=((inform? or informing or informed*) NEAR/1 (consent* or permission* or process* or decision? or patient? or choice*))

Database	Before Duplicate Removal	After Duplicate Removal	
Africa-Wide Information	**153**	**92**	
Cochrane	**495**	**354**	
Embase	**1145**	**1092**	
Global Health	**29**	**3**	
Global Index Medicus	**62**	**26**	
Medline	**2903**	**2899**	
Web of Science	**702**	**613**	
Totals	***5489***	***5079***	

Chapter 3: Clinical Study

This chapter includes a manuscript in preparation for submission to the Journal of Pediatric Surgery, for which the abstract has been accepted for a podium presentation at the Canadian Association of Pediatric Surgery annual conference in September 2022. This is a follow up study to the systematic review of informed consent in pediatric surgery. The goal of this subsequent research is to receive feedback from patients and families on the current informed consent process and compare it to the findings from the literature.

"Your Child Needs Surgery": Evaluation of Simulated Consent Conversations by Parents

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Abstract

Background:

Consent conversations in pediatric surgery are essential components of pre-operative care which, when inadequate, can lead to significant adverse consequences for the child, parents, surgeon, and others in the healthcare system. The aim of this study is to explore expert consenting practice from the parents' perspective.

Methods:

Four senior attending pediatric surgeons consented a standardized mother of a child requiring surgery in two scenarios: a low-risk elective surgery (inguinal hernia repair - Video 1), and a high-risk emergency surgery (intestinal atresia - Video 2). All sessions were recorded. Families of children who had undergone minor or major surgery and without medical or surgical background were invited to view and evaluate the videos using a semi-structured questionnaire.

Results:

Out of 188 distributed surveys 33 responses were received. Twenty participants (60.6%) evaluated video 1 and 13 (39.4%) video 2. Overall, 14 (70%) respondents to video 1 and 10 (76.9%) respondents to video 2 were "very satisfied" with the consenting process they watched. Qualitative responses shared common themes of an appreciation for empathy, adequate time and use of visual aids in the consent conversation. Suggestions for improvement include language use, more time for questions and personalized communication.

Conclusion:

Our data identifies advantages and gaps in the current consent process from the perspective of patients and families. Identified areas for improvement in the informed consent process based on multi-stakeholder input will guide the planned development of a consent educational video tool.

Introduction

Informed consent is a critical component of medical and surgical care. In pediatric surgery, consent conversations are essential components of pre-operative care which, when inadequate, can lead to significant adverse consequences for the child, parents, surgeon, and others in the healthcare system. Importantly, ineffective consent conversations may lead to patients being inadequately informed, and potentially a lack of trust in the patient-provider relationship (1–3). This lack of trust can subsequently have several consequences for patient satisfaction and surgical outcomes (4–6).

The current literature on pediatric informed consent does not provide clear recommendations for effective and appropriate consent conversations. Studies have been published examining specific interventions to improve informed consent, but they often limit their focus to improving only a specific aspect of the process such as comprehension or risk recall (7,8). A recent systematic review has identified specific interventions for improving patient comprehension (8), but beyond that relatively little is known about the usefulness and the critical components of informed consent (1,9,10). Ultimately, the current process is not optimal for patient care and there is a need for more standardized guidelines concerning the best practices in pediatric surgical informed consent (11,12). Additionally, there is a need for appropriate tools for widespread teaching and implementation of effective guidelines (13).

The aim of this study is to explore expert consenting practice from the parents' perspective. Our goal is to create a set of recorded expert consenting activities in pediatric surgery and evaluate them by patients for process, content, and comprehension. Our research is

guided by the following questions: 1. What are the critical components of effective consent processes and conversations in pediatric surgery? 2. How do parents rate the quality of consent conversations? 3. How can we improve the practice and teaching of the consenting process based on multi-stakeholder input?

Methods

A mixed-method study on the evaluation by parents of recorded expert concert conversation was conducted. Before recruiting participants, all study materials were prepared. This includes the development of consent scenarios, recordings of simulated consent conversations, and preparation of the video evaluation questionnaire.

Scenario Development

Two scenarios were created for which the consenting of a mock (“standardized") mother. The first scenario is a young boy in need of an elective inguinal hernia repair, which is generally a low-risk surgery. The second scenario is a newborn girl with intestinal atresia, which is considered a high-risk surgery. The scenarios were written and created by DP and ZA. All five attending surgeons in the division of pediatric surgery at the Montreal Children’s Hospital reviewed the scenarios and provided feedback to improve their consonance with and generalizability to real life.

Tool Development: Video Creation

A series of 8 video recordings of model expert consenting processes were created. For this purpose, the research student (ZA) trained as a standardized patient and posed as a mother of a child requiring surgery in the two aforementioned scenarios. The sessions took place virtually using the MSSS Zoom platform adapted for standard remote patient care. Four senior attending general surgeons at the Montreal Children's Hospital were invited to participate in this exercise. They were asked to consent the mother for the procedure in question, with a maximum allotted time of 15 and 25 minutes for the low- and high-risk scenarios, respectively. All sessions were recorded. Half of the recorded interactions were in French and half in English. One high-risk and one low-risk video in each language was chosen based on video quality and length. Videos were uploaded to Vimeo, an online video sharing platform. These videos were only accessible via a secure link included in the recruitment packages mailed out to participants.

Evaluation Questionnaire

The evaluation questionnaire was created using the McGill version of Limesurvey. The survey included modified items from the following validated patient instruments: the Combined Outcome Measure for Risk Communication and Treatment Decision Making Effectiveness (COMRADE) scale (14), the Physician Trust Scale (5) and the Patient's Perception of Physician Empathy scale (15). The questionnaire also included demographic questions, as well as feedback concerning the language clarity and time sufficiency of the consent processes. The draft questionnaire was shared with the patient partners in our research group. Seven patient partners read the survey and provided feedback and suggested various additions. With the help of this

feedback, an updated evaluation questionnaire was created with additional questions. This version was piloted with ten additional individuals, none of whom have a background in medicine or surgery, to ensure language clarity, understanding, and cohesion. After several revisions, the final version of the evaluation questionnaire was produced.

The questionnaire consists of a total of 30 questions. The first section consists of demographic questions and questions about the patient's past surgical history and experience(s). The following 12 questions ask the family's opinion about the process of consenting in the videos, using a Likert scale to answer each statement. Finally, there are free-text questions.

Participant Recruitment

For this study, we recruited patients with various medical and surgical backgrounds. Patients were identified using service lists from 2018-2020 of the pediatric surgery department at the Montreal Children's Hospital (MCH). The patients were categorized into one of the following groups: Previous Low-Risk Surgery, Previous High-Risk Surgery, Previous Neonatal Intensive Care Unit (NICU) Patient, Previous Medical In-Patient. Patients were then identified in the MCH electronic medical record to ensure that they indeed belonged to the appropriate study group and to extract mailing address, contact information, and preferred language. Children with no medical or surgical history were also recruited through contact by a research team member. For each patient, a letter in their preferred language will be mailed inviting a parent, caregiver or the patient to evaluate the recordings online. Participants were asked to evaluate two videos, but may have only evaluated one if they preferred. Using the questionnaire that was developed to evaluate

the videos, participants were asked to rate the quality of the interactions, their understanding of the risks and benefits of the procedures, and their perceived trust in the provider.

Data Analysis

Given the descriptive and mixed-method nature of this study, we sought thematic saturation of the qualitative data rather than a quantitative sample size. Demographic data was presented as mean with standard deviation for continuous variables and frequency percentage for categorical variables. Survey responses were grouped according to risk category and reported as frequency with percentage. Low-risk vs. high-risk survey responses were compared using Fisher's exact test. Responses to qualitative questions were categorized into themes by independent reviewers ZA and SR and presented as frequency and percentage. Statistical analyses were performed using RStudio, an open-source statistical platform (Version 1.4.1717). P-values less than 0.05 were considered statistically significant.

Results

Out of 188 distributed surveys, 33 responses were received. Twenty participants (60.6% of responses) evaluated video 1 and 13 (39.4% of responses) video 2. The mean age of respondents was 37.7 years and most respondents were female (73%). The majority (42%) were part of the low risk surgery group. 25 (73%) of all participants have had surgery. Respondent demographics are summarized in Table 1.

Data suggests that 70% of participants evaluating video 1 and 92.3% of those evaluating video 2 strongly agree that the surgeon gave the caregiver enough information about the

suggested treatment and any other options. Moreover, 70% of those evaluating video 1 and 84.6% of those evaluating video 2 strongly agree that the surgeon communicated with the caregiver in a way that was easy to understand. Additionally, 65% of respondents to video 1 and 92.3% of respondents to video 2 strongly agree that the surgeon gave the caregiver a chance to express their opinions or concerns about the treatment suggested and any other options, if available. The following questions had 4 (12% of total) or more responses marked as either 'neutral', 'disagree', or 'strongly disagree' to the given statement: "The surgeon gave the caregiver enough information about any long-term effects of the treatment or possibilities of another surgery" (Q4), "The surgeon gave the caregiver reliable resources for further information or a point of contact for more information" (Q8), "The surgeon gave the caregiver a chance to be involved in the decisions during the consultation" (Q9), "The surgeon and caregiver agreed about which treatment was best for the patient" (Q11), and "Overall, the caregiver seemed satisfied with the information that they were given" (Q12). Key results are summarized in Figure 1. A complete table with all responses to the Likert scale questions can be found in the supplemental material (Supplementary Table 1).

Overall, 14 (70%) respondents to video 1 and 10 (76.9%) respondents to video 2 were "very satisfied" with the consenting process they watched (Table 2). Qualitative (free-text) responses were coded into categories of similar themes. The following themes were identified by participants as *most* valued during the consent conversation they had watched: surgeon empathy (50% of video 1 respondents, 31% of video 2 respondents), adequate time and thorough explanations (50% video 1, 38% video 2), and the use of visual aids (31% video 2). The

following negative themes in the consenting process were identified by participants: surgeon communication, which includes a lack of validation and empathy (30% video 1, 46% video 2). The presence of environmental distractions was also identified as a negative theme by some patients and families (5% video 1, 8% video 2). Suggestions for improvement include better surgeon communication (25% video 1, 31% video 2) which included responses describing a need for better language use, more time for questions and personalized communication (Supplementary Table 2). Furthermore, 10% of video 1 respondents and 31% of video 2 respondents believe additional resources can improve the consent conversation. When asked which resources would be most helpful, respondents suggested visual aids (45% video 1, 46% video 2) and written resources (30% video 1, 15% video 2).

Discussion

To our knowledge, this is the first study to have patients and families evaluate the informed consent process in pediatric surgery through recordings of mock expert consent conversations. Previous work from another research group discusses audio-recordings of 90 patient-surgeon consent conversations that were evaluated by the research team (16). Their results demonstrated that surgeons often fail to discuss "the patient's role in the decision, their daily life, uncertainty, understanding, or patient preference" (16).

The current study is a follow-up to the systematic-scoping review on effective and ineffective consent conversations conducted by the same research group. The results of the systematic-scoping review highlighted areas of strength and weakness in the current consent

process. There is evident overlap in the effective and ineffective characteristics identified in the literature with those identified from participants in this study.

The methodology used in this study is unique as the videos and questionnaire were created by the research team. While initially the sample size was expected to be larger, recruiting participants to complete the study proved to be more difficult than anticipated. Ideally, participants would watch and evaluate both videos, yet this soon became unrealistic due to the time required to participate. The authors decided to instead ask participants to watch only one video and two videos if they had more time.

In Section A of the questionnaire, five of the twelve statements had 4 or more responses (12%) marked as either ‘neutral’, ‘disagree’, or ‘strongly disagree’. The first of these statements discussed the exchange of adequate information during the consent conversation. Receiving adequate information was found to be important by patients and their families in the systematic-scoping review. Also, when patients and families are satisfied with the amount of information they have received, they are more likely to feel confident with their decision and adhere to treatment (17). Importantly, the amount of information necessary can also vary from family to family, as sometimes too much information may contribute to parental anxiety and overwhelm the family. The second statement discusses providing additional resources or a point of contact should questions or concerns arise after the conversation. Supplemental documents may be helpful and patients and families generally appreciate the use of multimedia such as slide presentations or video recordings (18–30). The interest in a point of contact may also indicate that the opportunity for a follow up conversation may be appreciated by patients and families,

which is a characteristic of effective consent conversations identified in the systematic-scoping review. Moreover, the following statement evaluated by parents looked at patient involvement in the decision-making process. Ensuring patient involvement is key to a shared decision-making approach, which has been shown to benefit patients and families (31,32). Next, the statement discussed patient-surgeon agreement on the treatment. This furthers the importance of a shared-decision-making approach and coming to a decision that both the surgeon and the patient feel involved with. Finally, the last statement that may indicate a potential area for improvement is the satisfaction with the information received by the patient. As mentioned, finding a balance in the amount of information shared with a patient can be challenging. The results of the systematic-scoping review have demonstrated that practicing individualized communication can be helpful in avoiding dissatisfaction with the consent process. A study that used a personalized patient letter with relevant information about the surgery demonstrated that these patients had better recall of the surgery and its potential risks and were overall more satisfied with the consent process (33).

Furthermore, the free text responses highlighted potential areas for improvement in the current process. The qualitative feedback was analyzed and grouped into similar categories including an appreciation for surgeon empathy, adequate time for conversations and not feeling rushed and use of visual aids. These identified characteristics overlap with results from the systematic-scoping review and may be used to provide stronger evidence for consent recommendations.

Importantly, 73% of participants had a surgical history. Many of these patients had a positive experience (75%) and the others had a neutral (12.5%) or negative experience (12.5%). To our knowledge, no literature exists looking at the effect of past surgical experience on the evaluation of a consent process. Due to the limited sample size, statistical analysis was not done to look at differences in results between those grouped as having had a positive surgical experience compared to those who expressed a negative experience, although there may be a potential influence of past experience.

Limitations

The differences observed in the comparisons between groups are likely due to chance given an appropriate sample size has not been reached to detect a difference. Additionally, the mock mother was played by the research student (ZA) after training through discussions with the principal investigator (DP) and shadowing standardized patients at the McGill Simulation Center for half a day. Despite best efforts, responses may have been different in real situations which may have prompted different behavior from the surgeon. Two participants indicated that they had challenges with video 1, which may have influenced their responses on the questionnaire. Another key limitation is that the group sizes are very limited, especially the 'previous NICU' group with only one participant. As a consequence, subgroup analyses can not be performed at this point in our research. Finally, our data is based on MCH records only. We did not have access to the patient's other medical or surgical records therefore our identification of their

groups is based on MCH records only. Despite this, the questionnaire asks about surgical history so patients/parents have a chance to disclose if they have had a surgery.

Conclusion

Our data identifies advantages and gaps in the current consent process from the perspective of patients and families. According to qualitative feedback, aspects that were appreciated by families include surgeon empathy, feeling that there is adequate time for discussion and questions in a consent conversation and using visual aids or presentations to convey the information. Family feedback also suggested that more appropriate and simpler language as well as personalized communication can improve their satisfaction with the consent process. Identified areas for improvement in the informed consent process based on multi-stakeholder input will guide the planned development of a consent educational video tool.

Tables/Figures

Table 1: Survey Respondent Demographics

Respondents	33 (18%)
Age (Mean (SD)**)**	37.37 (8.02)
Gender = Female	24 (73%)
Group	
Complex Surgery	9 (27.2%)
Low Risk Surgery	14 (42.4%)
No Medical or Surgical History	4 (12.1%)
Previous Medical In-Patient	5 (15.2%)
Previous NICU Patient	1 (3%)
Patient had surgery?	
Yes	25 (76%)
No	7 (21%)
Experience communicating with surgical team	
Yes	16 (48.5%)

· Positive	12 (75%)
· Negative	2 (12.5%)
· Neutral	2 (12.5%)
Video	
Video 1	20 (60.6%)
Video 2	13 (39.4%)
Difficulty understanding	2 (6%)
Video 1	2 (10%)
Video 2	0 (0%)

Figure 1: Patient Responses to Selected Questions by Video Type

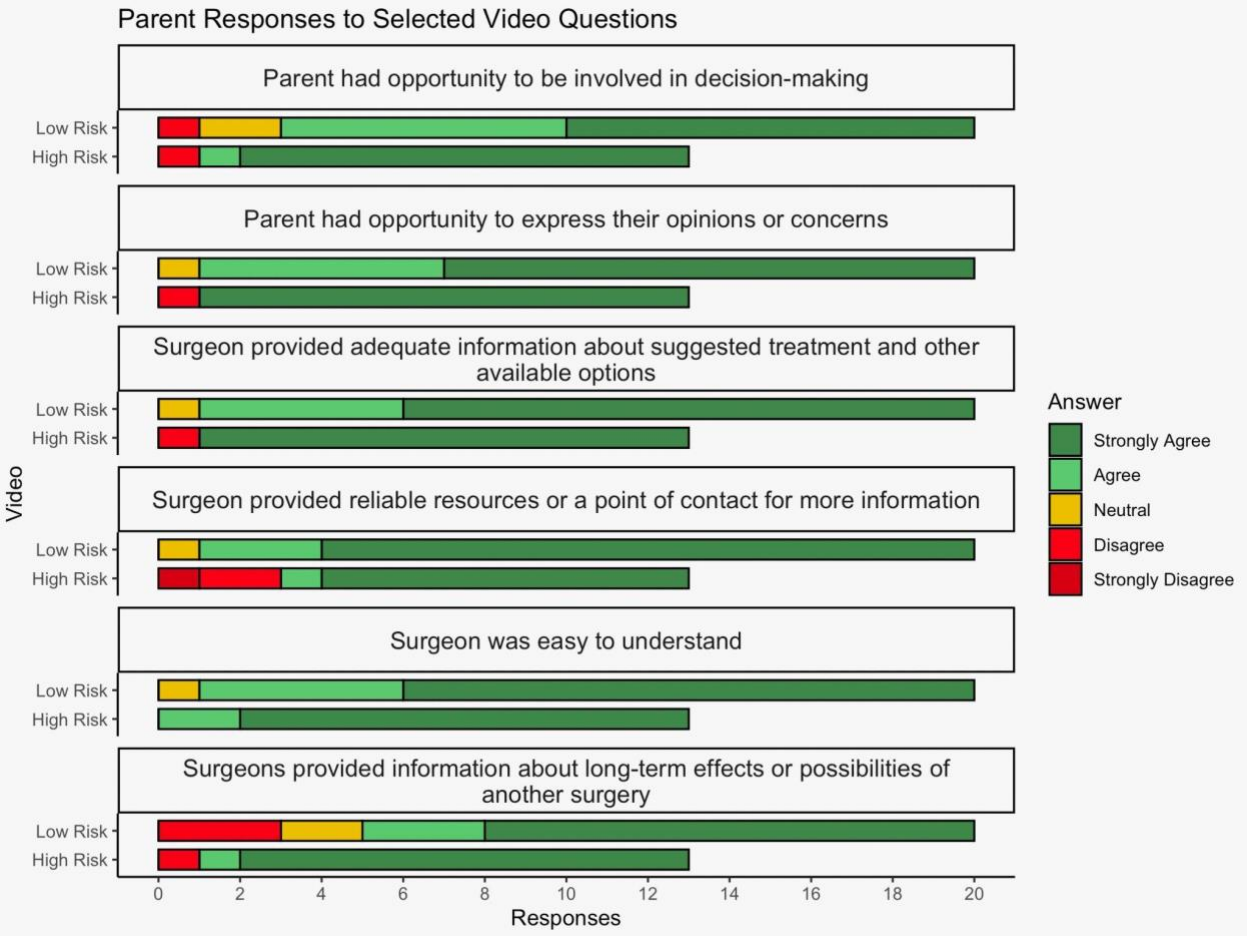

Table 2: Participant Rating of Satisfaction of Consent Process

	Video 1 (low risk) N=20	Video 2 (high risk) N=13	Total N=33	P-value
Q20: If you were in the place of the caregiver, how satisfied would you have been with this consenting process?				
Very Satisfied	14(70%)	10(76.9%)	24(72.7%)	
Satisfied	5(25%)	1(7.7%)	6(18.2%))	
Not Very Satisfied	1(5%)	1(7.7%)	2(6.1%)	
Dissatisfied	0	0	0	
Very Dissatisfied	0	1(7.7%)	1(3%)	0.394

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Supplemental Materials

Sup. Table 1: Complete Responses to Likert Scale Questions by Video Type

	Video 1 (low risk) N=20	Video 2 (high risk) N=13	Total N=33	P-value
Q1: The surgeon made the caregiver aware of the treatment suggested and any other options, if available.				
Strongly Agree	12(60%)	12(92.3%)	24 (72.7%)	
Agree	8(40%)	1(7.7%)	9 (27.3%)	
Neutral	0	0	0	
Disagree	0	0	0	
Strongly Disagree	0	0	0	0.042*
Q2: The surgeon gave the caregiver enough information about the suggested treatment and any other options, if available.				
Strongly Agree	14(70%)	12(92.3%)	26 (78.8%)	
Agree	5(25%)	0	5 (15.2%)	
Neutral	1(5%)	0	1 (3%)	
Disagree	0	1(7.7%)	1 (3%)	
Strongly Disagree	0	0	0	0.115
Q3: The surgeon gave the caregiver enough information about what to expect in the short term regarding the treatment and potential problems.				
Strongly Agree	11(55%)	10(76.9%)	21(63.6%)	
Agree	9(45%)	2(15.4%)	11(33.3%)	
Neutral	0	0	0	
Disagree	0	1(7.7)	1(3%)	
Strongly Disagree	0	0	0	0.122
Q4: The surgeon gave the caregiver enough information about any long-term effects of the treatment or possibilities of another surgery.				
Strongly Agree	12(60%)	11(84.6%)	23(69.7%)	
Agree	3(15%)	1(7.7%)	4(12.1%)	
Neutral	2(10%)	0	2(6.1%)	
Disagree	3(15%)	1(7.7%)	4(12.1%)	
Strongly Disagree	0	0	0	0.444
Q5: The surgeon gave the caregiver a chance to express their opinions or concerns about the treatment suggested and any other options, if available.				
Strongly Agree	13(65%)	12(92.3%)	25(75.5%)	
Agree	6(30%)	0	6(18.2%)	
Neutral	1(5%)	0	1(3%)	
Disagree	0	1(7.7%)	1(3%)	
Strongly Disagree	0	0	0	0.076

Q6: The surgeon gave the caregiver a chance to ask for as much information as needed about the treatment and any other options, if available.				
Strongly Agree	15(75%)	11(84.6%)	26(78.8%)	
Agree	5(25%)	1(7.7%)	6(18.2%)	
Neutral	0	0	0	
Disagree	0	1(7.7%)	1(3%)	
Strongly Disagree	0	0	0	0.231
Q7: The surgeon communicated with the caregiver in a way that was easy to understand.				
Strongly Agree	14(70%)	11(84.6%)	25(75.8%)	
Agree	5(25%)	2(15.4%)	7(21.2)	
Neutral	1(5%)	0	1(3%)	
Disagree	0	0	0	
Strongly Disagree	0	0	0	0.545
Q8: The surgeon gave the caregiver reliable resources for further information or a point of contact for more information.				
Strongly Agree	16(80%)	9(69.2%)	25(75.5%)	
Agree	3(15%)	1(7.7%)	4(12.1%)	
Neutral	1(5%)	0	1(3%)	
Disagree	0	2(15.4%)	2(6.1%)	
Strongly Disagree	0	1(7.7%)	1(3%)	0.220
Q9: The surgeon gave the caregiver a chance to be involved in the decisions during the consultation.				
Strongly Agree	10(50%)	11(84.6%))	21(63.6%)	
Agree	7(35%)	1(7.7%)	8(24.2%)	
Neutral	2(10%)	0	2(6.1%)	
Disagree	1(5%)	1(7.7%)	2(6.1%)	
Strongly Disagree	0	0	0	0.151
Q10: The caregiver was able to make an informed decision.				
Strongly Agree	12(60%)	11(84.6)	23(69.7%)	
Agree	8(40%)	1(7.7%)	9(27.3%)	
Neutral	0	0	0	
Disagree	0	1(7.7%)	1(3%)	
Strongly Disagree	0	0	0	0.073
Q11: The surgeon and caregiver agreed about which treatment was best for the patient.				
Strongly Agree	12(60%)	10(76.9%)	22(66.7%)	
Agree	5(25%)	2(15.4%)	7(21.2%)	
Neutral	3(15%)	0	3(9.1%)	
Disagree	0	1(7.7%)	1(3%)	
Strongly Disagree	0	0	0	0.244
Q12: Overall, the caregiver seemed satisfied with the information that they were given.				

Strongly Agree	11(55%)	8(61.5%)	19(57.6%)	
Agree	7(35%)	3(23.1%)	10(30.3%)	
Neutral	1(5%)	1(7.7%)	2(6.1%)	
Disagree	1(5%)	1(7.7%)	2(6.1%)	
Strongly Disagree	0	0	0	0.893

Sup. Table 2: Complete Coded Responses to Qualitative Questions by Video Type

	Responses/Themes	Video 1 (N=20)	Video 2 (N=13)
Q13: Did you feel as though there was enough time to discuss everything?	Yes	18(90%)	13(100%)
	No	2(10%)	0
Q14: Did you feel as though the caregiver had enough opportunities to ask questions and that they were welcomed to do so?	Yes	20(100%)	13(100%)
	No	0	0
Q15: What did you appreciate the most about the consent conversation you just watched?	Empathy (comforting, shared discussion)	10(50%)	4(31%)
	Time, thorough	10(50%)	5(38%)
	Visual aids	0	4(31%)
Q16: What did you appreciate the least about the consent conversation you just watched?	Interaction (Validation, empathy, tone)	6(30%)	6(46%)
	Environment (distractions)	1(5%)	1(8%)
	Nothing	13(65%)	6(46%)
Q17: What changes do you believe would improve the informed consent process?	Communication (language, time for questions, more personal)	5(25%)	4(31%)
	Additional resources	2(10%)	4(31%)
	Nothing	13(65%)	5(38%)
Q18: Was there any part of the consent conversation you just watched that you feel should NOT have been included?	Too detailed	1(5%)	1(8%)
	Drawings	0	1(8%)
	No	19(95%)	11(86%)
Q19: What additional tools or materials would be useful to	Visual aids	9(45%)	6(46%)
	Written aids	6(30%)	2(15%)
	Nothing else	5(25%)	5(38%)

improve comprehension during the informed consent process?			

Chapter 4: Discussion

Informed consent is a process that is taught, learned, and practiced on a regular basis, and often varies from surgeon to surgeon. The practice of informed consent in pediatric surgery needs to be improved. The current practice is far from ideal and there is often a disconnect between patient and surgeon satisfaction (20). Research presented in this thesis demonstrates that there is a need for better communication and adoption of an individualized shared decision making approach with each patient.

The Current Informed Consent Literature

Chapter 2 of this thesis presents the submitted manuscript of the Systematic-Scoping review. While not the focus of this systematic-scoping review, important themes in informed consent such as shared decision-making and risk communication were introduced. The focus was to identify characteristics of effective and ineffective consent conversations in order to guide future recommendations for practice. Of importance, the review demonstrates that there exists a significant gap in the literature with regards to the interpersonal domains of consenting. Only two articles discussed the positive effects of physician empathy (21,22) and only one discussed physician trust (22). These areas, if explored, may provide avenues for better quality consent conversations which are built upon a stronger patient - provider relationship. It is also important to further discuss the quality of evidence in the systematic review and how that may have influenced the results, as well as to expand on the creation of standardized recommendations.

Physician Trust and Empathy

In a traditional and paternalistic view, informed consent between a patient and a surgeon is inherently based on respect and trust in the physician's abilities, as patients often had no other means of seeking information (23). Today nonetheless, the informed consent process is a crucial time to build trust between the patient and the surgical team (22). When a patient has genuine trust in their surgical team, their autonomy is preserved while also adhering to the surgeon's intention of best medical practice (23). Trust can be illustrated as a patient asking their surgeon "what do you think is best" regarding their treatment options (23). In order to build trust, there should ideally be adequate time. With a time restraint such as in a surgical emergency, this key feature of the surgeon-patient relationship may be compromised (22). In order to promote trust in such situations, communication tools such as caring body language, eye contact, sitting next to the patient and using an empathetic tone when speaking with them can be helpful (20). These tools can help strengthen the relationship between the patient and their provider, which serves as an important foundation for better outcomes. It is also important to ask about patient concerns and allow them to share their thoughts in order to create an open and trustworthy environment (20). A surgeon must also consider the patient/family's knowledge and concerns in order to adopt an individualized approach to communicating surgical risks and information (24). Moreover, an empathetic tone is very important for effective communication with patients and parents (22). A surgeon should strive to convey information that is specific to a particular family's knowledge and understanding in a caring and sensitive manner (24).

Quality of Evidence

In order to address the quality of the evidence identified in this systematic-scoping review, we performed a thorough risk of bias assessment (outlined in the Methods section of the manuscript). A third of included studies discussed interventions to improve the process, but the majority of the articles were limited to simple descriptions of the current informed consent process. Only 24% of articles included were RCTs, which were of overall average quality. The low number of RCTs represents a lack of evidence-based recommendations in the current literature. The types of articles included in the review as well as their quality influences the reliability of our recommendations for practice. Despite this, we believe that the overall quality of all included articles is adequate to draw conclusions from (see Supplementary Materials). Upon revision of our data, we were unable to identify any significant relationship between study design and specific results. Therefore, we have drawn recommendations equally from all included articles, no matter the study type. Additionally, it is important to note that the majority of articles discussed consent in the context of general pediatric surgery. Although, several other specialties were also represented as well as cross-specialty studies. Our data demonstrates that there is no evident association between a particular specialty and suggested consent practices Therefore, our recommendations can be considered for consent practices in all pediatric surgery departments.

Creating Standardized Guidelines

The revised manuscript outlines recommendations for improving the practice of pediatric informed consent. The literature surrounding effective consent conversations is lacking concrete conclusions and we believe our work begins to fill the gap of effective consent guidelines.

Potential ways to implement these recommendations into practice is through the development of educational videos and additional training available for students, residents and attending surgeons. Using a checklist to remind surgeons or trainees of certain consent guidelines may help with the standardization of the process (25). However, there is no strong evidence to support the use of consent checklists to evaluate parent/patient understanding and satisfaction during the consent process (25,26). Dissemination of these recommendations will be done through publication in an academic journal, presentation at conferences and discussions with colleagues.

Additionally, it is important to acknowledge that surgical trainees are often involved in consent conversations. Importantly, we suggest that they be aware of these recommendations. Also, trainees must clearly state their role with the patient and family. This is a requirement according to Canadian Medical Protective Association (CMPA) guidelines (27). They should share their level of training and discuss that they are training under an attending surgeon, who will be leading the operation.

Evaluation of Expert Consent Conversations

Chapter 3 of this thesis presents preliminary results of our clinical study with families regarding informed consent in pediatric surgery. After thorough revision of the consent videos and video evaluation questionnaire, several patients and their families were contacted to participate. The preliminary results of the questionnaire show some overlap with those of the systematic review. Notably, characteristics that were important to patients and families in both studies include adequate time during the consent conversation and the use of supplemental materials or using multimedia to present the information.

It is difficult to draw conclusions from the Likert scale responses as participants are responding to whether or not specific aspects were observed in the videos and are not providing their opinion of each statement. Furthermore, the opportunity for free text responses to specific questions about improving the informed consent process allowed us to identify aspects of the informed consent process that are appreciated or not appreciated by patients and families. Upon completion of this study, we hope to recruit a minimum of 25 participants in each group. This will allow us to better identify potential differences between the groups and have a more generalized representation of patients and families with varied medicals and surgical history. The final results can be used to improve the recommendations for consent provided in the systematic-scoping review.

Shared Decision-Making in Urgent vs Elective Surgery

The choice to include two scenarios, a high-risk emergency surgery and a low-risk elective surgery was made in order to potentially compare feedback from two importantly different situations. In a high risk surgery such as intestinal atresia, there is much more urgency to operate and a failure to intervene in a timely manner may result in serious consequences for the child, including death. When considering the importance of a shared decision-making approach, it seems like there is less room for patient decision in such urgent or high risk scenarios. When no reasonable alternatives are available, the patient and family will feel an inherent lack of autonomy in the situation (7,28). This reflects the idea that “the patient cannot be empowered to make choices that do not exist” (7). Rather than providing several alternatives which are likely not available in such situations, the focus of an SDM approach should be modified. It is important to ensure that the family is aware of all the risks, potential complications and possible

outcomes of the surgery, as recall of risks and complications have been shown to be poor in emergency situations (29). On the other hand, a lower risk, often elective surgery such as an inguinal hernia repair in a young boy, has a different opportunity for shared decision making. In these situations, there are more alternative options available, more time for discussion and potentially multiple conversations, and less urgency allowing patients and families to feel more informed and involved in their decision.

Future Direction

Expert Video Tool as Educational Exemplar

There is a need for better teaching of informed consent for both medical students and residents (19,30,31). A new set of recorded consent activities (for a low-risk and high-risk procedure, in both languages) will be prepared by the research team based on stakeholder feedback complemented by input from the literature review. These videos will be then distributed as a learning resource and made available for medical students and surgical residents in order to help improve the teaching of effective consent.

This research will be the first to provide patient-centered data on the consenting process with parents of children facing surgical interventions and will generate a unique tool in teaching the consent process to medical students and surgical residents. The study findings and developed educational tools will be disseminated across the McGill Faculty of Medicine and Health Sciences, advocating for the integration of the videos in both the undergraduate and postgraduate medical curricula. Dissemination to the wider North American pediatric and pediatric surgical community will occur through presentations at national/international meetings and publication in

peer-reviewed journals. Ultimately, there is a need for a better understanding of the informed consent process as well as widespread teaching and implementation of effective guidelines.

Limitations of this Thesis

In addition to the limitations mentioned in Chapters 2 and 3 of this thesis, there are some overall factors that are important to consider. Firstly, in both the systematic review and the clinical study evaluating consent videos, all results are descriptive. At this point, it may be difficult to draw inferences on these results. Upon completion of the clinical study, statistical analyses outlined in the methods of Chapter 3 will be performed which may provide stronger evidence for particular recommendations for practice. Moreover, as the results are descriptive, the findings are based on the reviewers' subjective interpretation of the results. In both studies, the research team identified and grouped similar characteristics and subsequently coded them for the purpose of demonstrating results, which potentially has room for bias and error. However, in both studies, two independent researchers coded the characteristics to reduce the risk of error or bias.

Conclusion

Informed consent is a fundamental part of all medicine, surgery and research. The literature surrounding effective and appropriate consent conversations in pediatric surgery lacks strong evidence for specific recommendations of effective consent practice. Our research has identified strengths and weaknesses of the current consent process in pediatric surgery and provides broad guidelines for practice. Upon completion of this three phase project, we hope to improve the teaching of effective and appropriate consent conversations, as informed by various stakeholder groups.

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