Cardiology in the Young

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A descriptive assessment of the informed consent document used by congenital cardiac surgery centres

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Abstract

Background: Informed consent for surgery is a complex process particularly in paediatrics. Complexity increases with procedures such as CHD surgery. Regulatory agencies outline informed consent contents for surgery. We assessed and described CHD surgical informed consent contents through survey dissemination to paediatric CHD centres across United States of America. *Methods:* Publicly available email addresses for 125 paediatric cardiac clinicians at 70 CHD surgical centres were obtained. Nine-item de-identified survey assessing adherence to The Joint Commission informed consent standards was created and distributed via RedCap® 14 March, 2023. A follow-up email was sent 29 March, 2023. Survey link was closed 18 April, 2023. *Results:* Thirty-seven surveys were completed. Results showed informed consent documents were available in both paper (25, 68%) and electronic (3, 8%) format. When both (9, 24%) formats were available, decision on which format to use was based on centre protocols (1, 11%), clinician personal preference (3, 33%), procedure being performed (1, 11%), or other (4, 45%). Five (13%) centres' informed consent documents were available only in English, with 32 (87%) centres also having a Spanish version. Review of informed consent documents demonstrated missing The Joint Commission elements including procedure specific risks, benefits, treatment alternatives, and expected outcomes. *Conclusions:* Informed consent for CHD surgery is a complex process with multiple factors involved. Majority of paediatric CHD surgical centres in the United States of America used a generic informed consent document which did not uniformly contain The Joint Commission specified information nor reflect time spent in discussion with families. Further research is needed on parental comprehension during the informed consent process.

Introduction

Each year, approximately 1% (40,000) of babies in the United States of America are born with CHD.[1] Of the babies born with CHD, one in four are identified as being critical or require surgery or other invasive interventional procedures during the first year of life.[2] Informed consent is required prior to surgical encounters. Informed consent is a complex process that involves multiple individuals and has been documented as being poorly understood by patients and families.[3–8] It is during the informed consent process that the provider explains the risks, benefits, and alternatives to the procedure.[9] There are several guidelines (legal and best practices) for the informed consent process, the topics to be covered, and what the document to be signed should contain.[10–14] Importantly, the clinician should present a surgical option in which they believe there is an overall benefit to the patient, in addition to ensuring that it is presented in a manner that can be easily understood by the patient so that an informed decision can be made.[15]

There are inherent challenges in parental comprehension of CHD. First, CHD is considered a complex condition which adds additional layers to an already complicated process.[16–20] Second, as critical CHD requires hospitalisation and clinical or surgical intervention so early in the life of the child, this can add additional stress on parents who will be participating in the informed consent discussion.[21–23] Third, as surgical or procedural complexity increases, there is an increased likelihood that the complexity of informed consent process also increases. Therefore, research is needed to understand the informed consent process for caregivers and providers of patients with CHD.

Institutional variation in the type of information included in the informed consent document, including whether this information varies by procedure is unknown. Federal

regulations specify various items that must be included in the informed consent document. Some of these items include the surgical procedures risks, benefits, and alternatives to treatment.[24] A systematic review of the informed consent process performed by Giudici-Wach et al. examined medical malpractice cases in France and the information or lack thereof that led to the judges' decisions.[25] The authors demonstrated that studying case law in a particular area (i.e. informed consent) could lead to identification of processes needing improvement.

One area of malpractice identified was the 'lack of proof of information' or the lack of written documentation of information discussed during the informed consent process.[25] This lack of proof could either be documentation by the health care team member performing the informed consent discussion or in the informed consent document itself. In our clinical experience, the same informed consent document was used throughout the institution regardless of the procedure being performed. This is potentially problematic because the informed consent document does not contain procedure-specific information such as risks, benefits, or alternative treatments.[26] The purpose of this study was to evaluate only the contents of informed consent documents used for paediatric congenital heart surgery across cardiac centres in the United States of America and determine whether the content included critical information recommended by The Joint Commission. Evaluation of centre-specific informed consent documents (provided by the sites) was also performed. Centre-specific informed consent processes, documentation by health care provider performing the informed consent discussion, or additional educational information provided to families to assist in the informed consent process, were not assessed as part of this study.

Methods and materials

A multicentre observational study was completed to assess the informed consent document used at paediatric congenital cardiac surgical centres in the United States of America and Canada. The institutional review board at the University of Alabama at Birmingham reviewed and approved this study with a waiver of informed consent. (IRB-300010833, approval date 08 March 2023). A survey (both qualitative and quantitative) was created and distributed in RedCAP® with questions based on adherence to current standards for clinical informed consent components from The Joint Commission. Prior to dissemination, survey questions were reviewed by four independent reviewers for wording, context, and relationship to study aims. Three of the reviewers (KG, RS, and HZ) were selected based on their clinical expertise in paediatric CHD and their experience with the informed consent process and the informed consent document used in CHD. The final survey included nine questions in which provider's responded with: yes, no, or I do not know to whether their informed consent assesses the following components: (1) risks of procedure, (2) benefits of procedure, (3) alternative treatments, (4) expected procedural outcomes, and (5) if centres have a separate consent document specific for paediatric congenital heart surgery. Whether they used paper or electronic informed consent forms and the number and types of languages of the informed consent document were also assessed.

Seventy paediatric congenital heart centres were identified in the United States of America and Canada. Email addresses for 125 clinicians (Pediatric Cardiologist, Paediatric Cardiac Intensivists, and Congenital Cardiac Surgeons) associated with the 70 centres were obtained through publicly available online resources. The initial email with the survey link was sent to the clinicians on 14 March, 2023. Respondents were asked to identify their clinical role within their centre (i.e., cardiac intensivist, paediatric cardiologist, surgeon). The email also asked for the recipients to forward the survey link to individuals at their centre who participated in the surgical informed consent discussion. Respondents' names, centre or university names, or locations were not collected. Respondents were also asked to upload a de-identified copy of their current cardiac surgery informed consent document. On 29 March, 2023 the survey link was re-mailed to the recipients in an attempt to increase the number of respondents. The survey link was closed on 18 April, 2023.

Study results are presented as descriptive statistics with continuous variables presented as median with interquartile range and categorical variables presented as frequencies and percentages.

Results

Of the 125 clinicians at 70 unique cardiac centres who were invited to participate in the survey, 37 responded. Of the 37 individuals who completed the questionnaire, 22 (59%) were part of the surgical team who have direct involvement in the informed consent process. Table 1 shows a list of individual roles of those who completed the questionnaire. Based on the responses, the majority of centres do not have a separate consent form specific for paediatric cardiac surgery [24 (65%)], 10 (27%) centres have an informed consent document specific to paediatric cardiac surgery, and 3 (8%) of the respondents did not know. Only 12 (32%) centres do not have a separate section on their informed consent document that explains the risks of the procedure being performed. For those informed consent documents that do contain a separate section explaining procedure risks (22/37) (59%), 13 (36%) are annotated based on the specific surgical procedure while 9 (24%) have standard risks listed as part of the consent form template. The majority of centres do not have a separate section explaining the benefits of the procedure [24 (65%)] or an explanation of alternative treatments [28 (76%)]. Thirty-one (84%) of the centres' informed consent documents do not contain a separate section for expected postoperative outcomes.

The majority of centres have an informed consent document that is available in paper only format [25 (68%)], while 9 (24%) have both a paper and electronic format. For the nine centres that have both, the reasoning behind which format to use had a range of responses, from being protocol driven [1 (11%)], personal preference of the clinician performing the informed consent discussion [3 (33%)], determined by which surgical procedure was being performed [1 (11%)], and various other responses [4 (45%)]. One centre stated that even though the informed consent document is available in both formats, their centre always uses the paper version. Two centres stated that computer complications are what determined which version to use as well as the setting (inpatient or outpatient).

When questioned about which languages the informed consent document was available in, 32 (87%) had a language other than English, all had a Spanish version of their consent document [37 (100%)], 2 (6%) had a French version, and 3 (9%) had a version other than English, Spanish, or French (1-Somali version, 2-five or more languages available in addition to Spanish).

Only six centres provided a de-identified version of their centres' informed consent document. All six informed consent documents were multipurpose (i.e., surgery, diagnostic treatment, administration of blood products, and administration of anaesthesia) and none of them contained information specific to cardiac

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Table 1. Informed consent questionnaire for N = 37 providers that completed the survey.

Question	Results
Time from email sent until questionnaire completed, days	0.93 (0.18, 2.01)
Role of individual completing questionnaire, n (%)	
Intensivist	10 (27)
Cardiologist	5 (13)
Physician's Assistant	6 (16)
Surgeon	11 (30)
RN	1 (3)
Nurse Practitioner	4 (11)
Separate consent form for cardiac surgery, n (%)	
No	24 (65)
Yes	10 (27)
I do not know	3 (8)
Section explaining risks, n (%)	
No	12 (32)
Yes, written in based on operation	13 (36)
Yes, part of the consent form template	9 (24)
I do not know	3 (8)
Section explaining benefits, n (%)	
No	24 (65)
Yes	10 (27)
I do not know	3 (8)
Section explaining alternative treatment, n (%)	
No	28 (76)
Yes	8 (21)
I do not know	1 (3)
Section for expected outcomes	
No	31 (84)
Yes	2 (5)
I do not know	3 (8)
Did not answer	1 (3)
Formats available for consent documents, n (%)	
Paper	25 (68)
Electronic	3 (8)
Both	9 (24)
If consent available in both formats how do you choose, n (%)	N = 9
Protocol driven	1 (11)
Personal preference	3 (33)
Depends on the procedure	1 (11)
Other	4 (45)
Language other than English, n (%)	
Yes	32 (87)
No	2 (5)
I do not know	3 (8)
Spanish, n (%)	N = 32
Yes	32 (100)
French, n (%)	N = 32
Yes	2 (6)
No	35 (94)
Language other than Spanish or French, n (%)	N = 32
Yes	3 (9)
No	34 (91)
Submitted consent forms, n (%)	6 (16)

surgery. Only one of the six informed consent documents provided contained information describing potential risks. Information regarding potential benefits, alternative treatments, or potential outcomes of the procedures being performed was not included across all six of the informed consent documents.

Discussion

Paediatric congenital heart surgery is an exceedingly complex procedure, and it is imperative that the informed consent process facilitates sufficient understanding among caregivers to ensure that they make the best medical decision given the circumstances for their child. With that in mind, the intent of this study was to evaluate the content of informed consent documents. This multisite descriptive survey study revealed that a majority of informed consent documents for paediatric congenital heart surgery do not contain specific sections for all elements specified in the Federal Regulations.[24] In addition, specific information on risks, benefits, and alternative treatments is often not adequately described within the informed consent document. In the absence of interviews with individuals obtaining comj nsent, or an assessment of parental comprehension, we were unable to quantify the extent to which we believe the procedure, its risks and benefits and alternative treatments are discussed, which was not the intent of this study. However, it is possible that the absence of this information on the generic institutional informed consent forms may contribute to a poor understanding and retention of the verbal discussion between caregivers and healthcare professionals, including when there is the need for an interpreter, although this is only speculation. Moreover, we recognise that customised informed consent forms for every cardiac procedure has the potential to create challenges, especially as procedures change and are often times personalised for the patient. This lack of written information emphasises one of the potential barriers to the informed consent process in that patients are presented with the information the clinical team deems important and not always the information the patient wants to hear.[27]

Despite widespread availability of electronic health records, only 8% of the informed consent documents reported in this study were available electronically. As medicine and technology advance, the use of electronic medical records is becoming more widely used in health care centres. This has the potential to help enhance the

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Table 2. Assessment of centre-specific IC documents.

Component	Centre 1	Centre 2	Centre 3	Centre 4	Centre 5	Centre 6
Services covered by single IC document						
Procedure/operation	Yes	Yes	Yes	Yes	Yes	Yes
Treatment/therapy	Yes	Yes	No	No	No	Yes
Performing of tests	Yes	Yes	No	No	No	Yes
Administration of blood products	No	No	Yes	No	No	No
Retention or disposal of tissue	No	No	Yes	No	No	No
Anaesthesia/analgesic	No	No	No	Yes	Yes	Yes
Cardiac surgery specific IC document	No	No	No	No	No	No
Section explaining risks	No	No	No	Yes	No	No
Section explaining benefits	No	No	No	No	No	No
Section explaining alternative treatment	No	No	No	No	No	No
Section for expected outcomes	No	No	No	No	No	No

informed consent process, including customisation for specific procedures.[28] A systematic review by Kiernan et al showed that the use of electronic informed consent forms had a positive effect on the informed consent process.[8] Electronic informed consent documents allow for the addition of supplemental information to be added into the document when certain conditions are met (i.e., risks, benefits, and alternatives). A surgical team could work with their information technology department to customise the informed consent document based on a particular procedure. For CHD surgical procedures, the electronic informed consent document could populate information specific to the use of cardiopulmonary bypass, risk of cardiac arrest and/or death, risk of infection, or risk of arrhythmias to name a few. However, even in these circumstances, paper versions or print outs of electronic versions should still be available for parents wish to reference the material at a later time.

Results of the qualitative assessment of the six consent forms generally supported the results of the survey outcomes (Table 2). All of the provided informed consent documents contained a single sentence stating that the surgical procedure risks, benefits, and alternatives had been explained to the parents/guardians but did not contain any information regarding what information was covered, how the information was presented, or who discussed the information with the parents/legal guardian. Several studies have shown that individuals retain information better when it is presented in formats other than just verbal discussion.[4–6,27,29] Glaser et al performed a systematic review assessing ways to improve patient comprehension for medical and surgical procedures. This review showed that written material provided to patients at a 2nd grade reading level in addition to the informed consent document was best understood when compared to the standard informed consent document alone.[30] The current standard regulation for informed consent documents is to be written at an 8th grade level.[14]

Each informed consent discussion is unique and based on the individual patient's cardiac lesion and the procedure being performed. This can be a complex and nuanced discussion for clinicians, not only because of the complicated types of repairs but also because they are engaging in this discussion most often with a proxy to the patient (parents, legal guardians, or medical proxies).[6,29,31] The Society of Thoracic Surgeons had developed a mortality assessment score, which is assigned to each congenital heart surgical procedure and is based on the complexity of the surgery and risk of mortality.[32] Cardiac surgical procedures with a mortality score of 5 will inherently have more risks than those whose mortality score is 1. However, this study has shown that the same informed consent document is used to consent patients for all mortality categories and that it contains the same information regardless of the procedure being performed. While we are not marginalising the extensive discussions that take place between the surgeon and patient and parent/guardian, we do want to highlight opportunities for process improvement in the extisting informed consent documents evaluated from the multiple participating institutions.

For cyanotic congenital heart lesions that require intervention within the neonatal period, the alternatives to treatment include death.[33–38] In such complex and stressful decision-making situations, the comprehension of the consenting adult may be impaired and may result in decisions based on fear of death versus true understanding. In instances such as these, there is an informed consent discussion that occurs, there is an informed consent document that is signed, but in reality, the consenting adult is providing consent for the procedure to be performed but to call it an informed decision may be an exaggeration. Indeed, future studies focusing on qualitative assessments of the process and parental comprehension are needed. This concept of informed consent is often a common theme in research on improvement of the informed consent process as healthcare advances and changes are made to move from practices grounded in paternalism to those that truly encompass shared decision making.[8,39,40]

This descriptive study has several limitations. First, the questionnaire was only emailed mainly to Paediatric Cardiologists and Paediatric Cardiac Intensivists whose email addresses are publicly available online (only three surgeons were emailed directly), the 22 members of the surgical team who completed the questionnaire had it forwarded to them by the receiving clinician, thus requiring further steps and likely reducing the response rate from the surgical team who are obtaining consent. Second, responses were de-identified, making it impossible to discern whether more than one response was obtained

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from a single centre. Third, although the questions asked via the questionnaire were designed to be objective, several responses were very subjective, suggesting the informed consent process is indeed a process and not a set protocol. Lastly, this questionnaire did not assess items involved in the informed consent process (i.e., length of informed consent discussion, information provided to individuals prior to the informed consent discussion to improve comprehension, time of the informed consent discussion in relation to the surgical procedure being performed).

This descriptive study provides a glimpse into the informed consent document used for these surgical procedures. The informed consent document used for congenital cardiac surgery does not always contain the information as outlined by federal regulations, which may have negative impacts on the decision making of the parents/legal guardians. Further research is needed into the informed consent process for congenital cardiac surgery and how information regarding procedural risks, benefits, and alternatives is provided to the parents/legally authorised representatives and ways to improve comprehension so that true informed consent can be obtained.

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Ethical standard. This manuscript does not involve human or animal experimentation.

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