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Co-designing the Assessment of Multimedia Resources to Assist Guardian Understanding of Surgical Consent Prior to Spinal Surgery in Pediatric Patients - a Quasi-Experimental Study

by

Marina Rosa Filezio

A THESIS

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Abstract

Informed consent is mandatory prior to any surgical procedure in medical practice. Consent requires voluntary agreement, the capacity to consent, and proper prior information. Literature shows that traditional methods of informing patients and guardians may not provide enough understanding of all risk, benefits and expectations associated with scoliosis surgery in pediatric patients.

Scoliosis is the most common spinal disorder in pediatric patients. Treatment depends on curvature size and skeletal maturity, and surgery is reserved for curvatures greater than 45 degrees.

This study aims to assess the impact of introducing a co-developed multimedia tool to improve guardians' understanding of the surgical discussion and informed consent prior to PSIF. The primary objective is to measure the effect of this intervention using the results from test and post-test. Secondary objective includes observing if this tool improves guardians' perceived understanding. It is hypothesized that the multimedia tool will improve comprehension and perceived understanding when compared to traditional methods. Specific aims involved describing, quantifying, and comparing questionnaire results in three distinct educational times during the pre-operative process, as well as results from the patient engagement evaluation tool.

A quasi-experimental, repeated measures, multi methods approach was applied to analyze the results of a multiple-choice questionnaire between two groups (Pathway A and Pathway B), about the pre-operative surgical discussion process and content. Quantitative and qualitative data were obtained from the public and patient engagement evaluation tool to assess the patient engagement strategy implemented for the co-development of the educational video tool.

Seventeen participants were included in this study, eight assigned to Pathway A and nine to Pathway B. No significant difference was seen between results from Pathway A and Pathway B. However, the effect of knowledge acquisition over time was significant, indicating a substantial temporal progression on the outcome.

The results demonstrate promising outcomes regarding knowledge acquisition over time when introducing a secondary information delivery method to the current consent process. Patient engagement evaluation tool findings display positive results reinforcing the efforts to ensure the CIHR guiding principles during the creation of the educational video.

Preface

This thesis is original, unpublished, independent work by the author, Marina Rosa Filezio. The interventions reported in this thesis were covered by Ethics Certificate number 21-1864, issued by the University of Calgary Conjoint Health Ethics Board on April 07, 2022.

Acknowledgments

I would like to thank several individuals that were essential in my success to complete this thesis.

Firstly, I extend my heartfelt thanks to my supervisor, Dr Maria Santana, for embracing this role with grace, especially under the most drastic circumstances. You provided invaluable guidance, encouragement, and expertise, helping me thrive both academically and professionally. I am very grateful and honored to have been mentored by you.

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A very special thank you to the members of the Pediatric Spine Clinic at the Alberta Children's Hospital. Heather Sawyers, your efforts in accommodating data collection during appointments and assisting with recruitment are truly appreciated. Dr Parsons, thank you for allowing me to recruit patients from your clinic and for providing feedback and guidance during the script and video creation. To our patient partners, thank you for contributing and collaborating with the co-creation of this video, your insights allowed us to transform this project idea into a meaningful and impactful tool. To all the guardians that participated in this project, thank you for taking the time to participate in this research, your commitment and cooperation made this research possible.

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I would also like to thank my boyfriend, Paul Ehmann, for all the emotional support, for making me meals and snacks during my classes and writing sessions, for helping me create quality time to write, and for the constant “you can do it” encouragements you provided.

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Dedication

To Dr Fabio Ferri-de-Barros:

This is by far the hardest section for me to write. I would never imagine that this ambitious project, that started during such a cheerful and exciting time, would be completed with me writing you a dedication like this.

The impact you had in my life is hard for me to express in words. You believed in me many years ago, when I came all the way from Brazil as a visiting resident to shadow your practice for a few weeks. You convince me to trade my future Trauma fellowship for Pediatric Spine. You told me to study hard, do all the exams, and come to Calgary for a surgical fellowship. After taking your advice and doing all of that, you once again told me to think further, and to apply for a master's degree and for the Surgeon Scientist Program. After that, you encourage me to apply for the Charlie Fischer Fellowship. You embrace the idea to not only supervise me during the fellowship, but also during this academic journey.

All these achievements would not have been possible without your support.

I hope, from the bottom of my heart, that this project made justice to your vision and our initial idea. Completing this thesis gives me a bittersweet taste. From one side, I still cannot believe you are not here to see me defending and obtaining my degree - I think you would be proud. On the other hand, I view this project as a way of honoring your memory, your commitment to access of care, and your goal to improve and innovate in the Pediatric Spine field.

Thank you for teaching me to always look forward, not to settle for anything less than what I deserve, and to always believe in myself.

Foi uma honra ter tido a chance de te conhecer, de ter trabalhado com você, e de poder te chamar de mentor.

Você faz muita falta.

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List of Abbreviations and Nomenclature

AHS	Alberta Health Services
AIS	Adolescent Idiopathic Scoliosis
C	Control
CMA	Canadian Medical Association
CMPA	Canadian Medical Protective Association
CPSA	College of Physicians and Surgeons of Alberta
CIHR	Canadian Institute of Health Research
I	Intervention
ID	Study Identification Number
IV	Intravenous
MeSH	Medial Subject Headings
OR	Operating Room
PICO	Population, Intervention, Control, and Outcomes
PICU	Pediatric Intensive Care Unit
PPEET	Public and Patient Engagement Evaluation Tool
PSIF	Posterior Spinal Instrumentation and Fusion
QR	Quick Response
RCT	Randomized Control Trial
RN	Registered Nurse
SDM	Shared Decision Making
SPOR	Strategies for Patient-Oriented Research
T1	Research Time One

T2	Research Time Two
T3	Research Time Three

Chapter One

INTRODUCTION

Informed consent is a critical and mandatory step preceding any elective surgical treatment (CMPA, 2022). To obtain surgical consent, patients and guardians must be able to comprehend risks, benefits, and possible complications related to a surgical procedure, which is mainly explained during a pre-operative surgical discussion (Chang et al, 2020). According to the Canadian Medical Protective Association, the surgical consent must be voluntary, the patient and/or guardian must have the capacity to provide consent and must also be properly informed prior to providing consent (CMPA, 2022). For pediatric patients, consent must be obtained from someone that holds guardianship status of that patient, which could include not only biological parents but also foster or adoptive parents.

Recent studies have suggested that the conventional, verbal-only models of delivering the preoperative information for patients and guardians has fallen short of the intent of elucidating all risks, benefits, and expectations related to surgical care for scoliosis (curvature of the spine that causes a deformity) patients (Theologis et al., 2016; Raper et al., 2021; Chan et al., 2020; Glaser et al., 2020). Some studies have linked poor comprehension of the delivered content to guardians to feelings of being distressed and overwhelmed (Murtha et al., 2020; Everett et al. 2005; Abujarad et al. 2018). These feelings can lead to a lack of confidence in the surgical team and decrease adherence to processes, such as post-operative routine, as well as increase post-operative anxiety and number of follow-up appointments attended.

Scoliosis is the most common spinal disorder seen in pediatric patients and is the medical term that defines a curvature of the spine greater than 10 degrees, often seen as an “S” or “C”

shape of the spine, depending on the type of scoliosis. More than 80% of scoliosis cases are of unknown cause, called Idiopathic Scoliosis. Other less common types of scoliosis are Neuromuscular (often associated with diseases such as Cerebral Palsy, Spinal Muscle Atrophy, and other musculoskeletal disorders), Syndromic (which could be associated to other diseases, such as Myopathic disorders or Marfan and Ehnlers-Danlos Syndrome, as well as genetic conditions such as Dwarfism or Down Syndrome), and Congenital (SRS, 2023).

The most common type of scoliosis is called Adolescent Idiopathic Scoliosis (AIS) and is found in individuals between 11 to 18 years of age. AIS corresponds to 90% of the cases of scoliosis in the pediatric population, with an overall prevalence of 0.47- 5.2%, affecting girls more than boys (3:1) (Konieczny et al. 2013; Cheng et al. 2015).

There are different treatment options for scoliosis, depending mainly on the curvature size and skeletal maturity (Maruyama et al. 2003; Bunnell, 1986). Surgery is reserved for patients with curves greater than 45 degrees while still growing or greater than 50 degrees for patients that have completed their growth (Abbott, 2013; Negrini, 2015). There are several surgical techniques that could be used for the different types of scoliosis, but the most performed worldwide is the Posterior Spinal Instrumentation and Fusion (PSIF), where the spine is assessed by a posterior approach and the curvature is corrected and fixed with the help of surgical hooks, screws, and rods (Olgun, 2013; Harrington, 1962; Suki 2011).

In our current clinical setting, on the day the scoliosis patient is booked for surgery, there is a consent signed by the guardian after the surgical discussion is performed with the surgeon in clinic (Time 1 = T1). During the discussion, the guardian receives “one on one” teaching with an Orthopedic Registered Nurse (RN) (Control = C). In this project, we propose a new intervention (I) by introducing an additional form of teaching (the animated video) to the preoperative routine

for scoliosis patients (including Idiopathic, Syndromic, Neuromuscular and Congenital scoliosis pediatric patients). T2 and T3 are considered the second and third teaching module received, respectively. Those providing consent for scoliosis treatment that agree to enroll in this research will either follow pathway A (T1+ C at T2 + I at T3) or the pathway B (T1+ I at T2 + C at T3).

1.1 Thesis Objectives

The primary objective of this study is to measure the effect of using multimedia teaching on the guardians' understanding of the pre-operative surgical discussion and informed consent for PSIF to manage scoliosis, by measuring the test- and post-test results obtained from a multiple-choice questionnaire. The secondary objectives are to observe if the introduction of a multimedia piece to the teaching process improves guardians' perceived understanding of the information given.

1.2 Thesis Hypothesis and Specific Aims

Hypothesis: We hypothesize that the multimedia resource may enhance guardians' comprehension of the content delivered during a pre-operative discussion, as well as their perceived understanding of the information given, versus the traditional (verbal) pre-surgical process. We also hypothesize that the pre-surgical multimedia content might improve scoliosis patient's post-operative status.

Specific Aim One: Describe, quantify, and compare the test (T1) and post-test (T2 and T3) results obtained from a multiple-choice questionnaire developed to evaluate guardians'

understanding of the pre-operative surgical discussion after introducing an animated educational video (intervention – I) to the pre-operative process.

Specific Aim Two: Describe and compare the results obtained from the guardians' perceived understanding of the surgical consent at T1, T2 and T3, as well as the results obtained from the patient engagement evaluation tool.

1.3 Thesis Outline

This thesis is presented in six chapters, and includes:

Chapter One provides an introduction of this thesis, including the background on surgical consent and gaps in knowledge and current practices related to the management of different types of scoliosis. This chapter also outlines the objectives, hypothesis and aims of the study.

Chapter Two is a literature review on current patient and guardian understanding of informed consent, the use of multimedia content sources as informed consent in the setting of surgical procedures, the standardization of the surgical consent, and the possible post-operative implications of including a multimedia piece on the pre-operative surgical discussion.

Chapter Three presents the historical and environmental context of the COVID-19 pandemic in which this research was conducted. This chapter also delves into the direct implications that this context had on several aspects of this thesis.

Chapter Four details the methodology used in this study, encompassing the study's design, population, control, intervention, and outcomes. This chapter also provides an in-depth exploration of the literature review process, the patient engagement strategy, and the collaborative video creation process. It further outlines the specifications on the validated multiple-choice questionnaire used to measure the outcomes, as well as information on the public and patient engagement evaluation tool chosen to evaluate the patient engagement strategy.

Chapter Five describes and analyzes the results found on this study on patient understanding of the pre-operative surgical content after the introduction of the educational video. This chapter also assess guardian's perceived understanding of the surgical consent at T1, T2 and T3, as well as possible perceived knowledge acquisition over time. Moreover, this chapter includes the results from the evaluation of the patient engagement strategy implemented in this thesis.

Chapter Six looks critically into the COVID-19 context's direct impact on this research, followed by a comprehensive discussion of both quantitative and qualitative findings. This chapter also discuss the implications of these findings for research and clinical practices. Emphasis is given to the dissemination strategy, as well as the knowledge translation plan. Additionally, future imitative are outlines and a conclusion of this thesis is presented.

Chapter Two

LITERATURE REVIEW

In this chapter, the comprehensive scoping review of the literature performed is presented, exploring patient and guardian comprehension regarding informed consent, the utilization of multimedia sources as means of improving informed consent in the context of surgical procedures, the current efforts related to standardizing the surgical consent process, as well as the possibility of post-operative implications as a result of the incorporation of multimedia tools into the pre-operative surgical discussion.

The methodology employed for this literature review is presented in Chapter Four of this thesis, providing a detailed account of the review process performed.

2.1 Patient and Guardian Understanding of Informed Consent

2.1.1 The Informed Consent

Clinical informed consent is a mandatory step prior to any invasive surgical procedure, and obtaining informed consent is a medical obligation (from both legal and ethical standards) and a patient's right. Informed consent is usually obtained after a communication between the physician and the patient (or the patient's guardian) takes place, and it must include four key elements: the risks, the benefits, the alternative treatments, and general information about the proposed procedure (Glaser et al., 2020).

To be considered valid, the informed consent requires adequate understanding of the discussed content by the individual signing it. Failure to properly obtain a valid informed consent

can jeopardize the patient's autonomy, as well as provide risks to the patient's safety and may constitute medical negligence or battery (Schenker et al., 2011).

The Canadian Medical Protective Association (CMPA) ascribes to the Oxford Dictionary definition of consent: "the voluntary agreement to or acquiescence in what another person proposes or desires; agreement to a course of action". Deficient or inadequate surgical consent is often claimed by patients against physicians and can lead to allegations of assault and battery, when no consent was given at all, when the treatment provided was not the one discussed in the consent, or when the information provided by the physician to the consenter results in misrepresentation or lack of comprehension of the surgical procedure (CMPA, 2021).

2.1.2 The Informed Consent for Pediatric Patients

In pediatric settings, multiple steps must be considered to assure that the consent obtained is valid and legal. The individual providing consent must be considered mature to provide consent (which might not necessarily be equivalent as the legal age maturity of 18 in some cases). Currently, there are validated ways to determine if a minor has the physical, mental, and emotional capacity to fully appreciate and understand all the aspects and consequences involved in a proposed procedure and to consequently be considered as a "mature" individual. Even if a patient is deemed "mature", complex surgical procedures might still require the parents or legal guardian of the patient to authorize the consent to treat on the patient's behalf, considering that the individual has the patient's best interests in mind (CMPA, 2021).

Moreover, studies suggest that parents and guardians that are in a medically stressful situation (such as individuals that have a minor admitted to the Pediatric Intensive Care Unit - PICU), might have a harder time comprehending the content presented in an informed consent.

Murtha et al. (2020) demonstrated that most parents and guardians who were offered an opportunity to participate in a research study, and provided informed consent in the PICU setting, presented a significant lack of understanding in paramount aspects of the proposed research. Decreased comprehension was noticed on specific risks of the proposed study (80%), on why their child was eligible to participate (70%), and on the confidentiality standards proposed to participate in the study (70%). Furthermore, some guardians also commented on feelings of being overwhelmed when approached to discuss or sign a consent. Murtha et al. (2020) suggested that the stressful PICU environment may inhibit parent/guardian ability to provide proper, valid consent.

2.1.3 Understanding the Informed Consent

As described in section 2.1.1, to be considered valid, the informed consent must be signed once an adequate level of understanding on its content is achieved by the consenter. Everett et al. presented in 2004 a prospective qualitative study that aimed to determine the understanding and satisfaction of the informed consent process for spinal surgery in adults. In this study, patients described that the main areas of concern about the informed consent included their desire for more information on the procedure itself, its risks, benefits, and possible alternative treatments available. Patients also demonstrated difficulty recalling the potential risks and alternatives to the procedure and suggested that the availability of a video of the procedure might assist with the understanding of the given information.

However, how can we effectively measure the patient's and guardians' understanding of the given information? It is common for the individuals providing consent to wrongly report full understanding of the information given due to multiple reasons, such as: Individual's false

perception of comprehension while being very poorly informed; the need to appear competent and show responsibility to the health care team; and embarrassment to report that they are still confused and might not have fully understood what was explained (Kreps, 2018). Moreover, Kreps (2018) also recommends the use of tests and validated questionnaires to directly and objectively determine patients' comprehension of the information provided. Validated questionnaires are widely used in research, and can assist with obtaining relevant, reliable, and valid information from patients (Taherdoost, 2018).

Schenker et al (2011) presented a systematic review supporting the idea of including other communication methods to improve comprehension of the written informed consent. This was supported by a systematic review by Glaser et al in 2020, which also mentioned the use of test/posttest components as a superior way of measuring consenter comprehension. Both publications emphasized the need for further studies in vulnerable populations, such as pediatric patients.

2.1.4 Understanding the Surgical Consent in the Pediatric Setting

As described earlier in this section, in the case of pediatric patients, generally an adult individual that holds guardianship of the pediatric patient is the one responsible for signing the consent, but often the patient is also involved in the consent process. In the pediatric setting, we should look for not only the understanding of the guardian, but also the pediatric patient's comprehension and satisfaction. Theologis et al. (2016) assessed children's and guardian's understanding of the traditional (verbal) surgical consent for Adolescent Idiopathic Scoliosis by applying a validated questionnaire that measured the understanding of the risks, benefits and expected results of the proposed treatment, as well as overall comprehension of the process. This

study concluded that patients and guardians only understood approximately 60% of the content presented in the surgical consent, resulting in a possible incompletely informed consent.

While the studies presented in this section contributed valuable insights related to the comprehension of the informed consent, a noticeable gap appears to persist in the literature. During our literature review, no studies were found comparing guardians' rate of understanding of the surgical consent by using different methods of delivering information (traditional – oral, in comparison to multimedia resources) in the pediatric spinal surgery setting.

2.2 The Use of Multimedia Sources as Informed Consent Prior to Surgical Procedures

2.2.1 Traditional versus Multimedia

The traditional method used to obtain informed consent prior to any surgical procedure includes a conversation with someone from the medical team responsible for explaining the procedure, risks, benefits, alternatives, and postoperative care; as well as a written consent that includes this information and provides a space to collect the date and signature from the individual responsible for signing the consent (Wasserman et al., 2013).

Lately, multiple health centers and research institutes are exploring new approaches to present the content included on the informed consent to patients and guardians in a more understandable and patient-friendly way. In 2005, Everett et al. identified that other sources of information (besides oral or written) should be added to the informed consent to assist patients' deeper understanding of surgical procedures, as well as its risks and benefits. Bollschweiler et al. confirmed the same hypothesis in 2008 in a multicenter randomized controlled trial of patients prior to being submitted to a cholecystectomy, concluding that multimedia sources improved patients' perceived understanding of their diagnosis and possible treatments.

Multiple organizations have been introducing and testing the use of video-assisted informed consent in order to improve patient understanding and satisfaction with the use of video-assisted informed consent. A pilot prospective study developed by The British Association of Spinal Surgeons in 2019 evaluated 20 adult participants' (mean age of 56 years. SD=16.26) satisfaction with the use of a video consent prior to elective spinal surgery and found that the use of a video resource as a compliment to traditional preoperative consent (oral or written) significantly increased patient satisfaction. In the setting of urgent surgeries from the emergency department, a prospective randomized controlled trial (Lin et al., 2018) enrolled 142 adult patients, and identified that the knowledge score obtained by the group assigned to the informed consent educational video was higher than the one seen by the control group (conventional informed consent). This study also demonstrated significant improvement in the patients' perceived comprehension and satisfaction with the process in the video-assisted group in comparison to the control group.

2.2.2 Multimedia Tool as a Patient-Centered Approach

Multiple risks can be associated with the lack of comprehension of an informed consent, including risks to patient safety and quality of care. Patient-centered approaches and techniques can be valid tools to improve patient safety and care in a meaningful way, and in the setting of the informed consent, the creation of multimedia tools could be described as a patient-centered approach to prevent those risks. An example can be seen in Abujarad et al. (2018), where a multimedia tool was created and tested to provide patient-centered virtual multimedia informed consent, by including a virtual coach and a virtual library containing video clips, animations, and presentations explaining the risks, benefits, and alternatives of a proposed treatment. This tool

also tested patient's understanding with automated quizzes, allowing them to assess their own comprehension of the information given. In this study, patient partners were included as co-investigators, and they were actively present in all aspects of the project, including its design, development, implementation, and evaluation. Moreover, the user-focused approach seen in this study resulted in a tool that was usable, acceptable, efficient, and meaningful to patients (Abujarad et al. 2018).

In 2018, Manafo et al. presented a scoping review of 10 years of research in patient engagement in Canada. In this study, the authors provide evidence-based data on the role and scope of patients as part of the research team in health research, and how this partnership can improve patient and healthcare outcomes. Furthermore, patient engagement strategies were noted as a predictor of quality and patient-centered care, which lead to quality improvement initiatives. According to the Canadian Institute for Health Research's Strategy for Patient Outcome Research (SPOR), the inclusion of patient engagement strategies in research occurs when they have a meaningful and active collaboration in governance, priority setting and conduction of research, including summarizing, distributing, and assisting with knowledge translation of the research project, as seen in the Abujarad et al. (2018) study. This approach can result in outcomes at multiple levels (from individual to systems), including improved health, improved access to healthcare system, and provide cost-effective contributions to the healthcare system (Manafo et al. 2018).

When analyzing not only patients' comprehension, but also patients' satisfaction, patient-oriented research studies demonstrate that the introduction of video tools can be a positive addition to medical processes and can help patients address concerns and doubts about medical conditions and procedures. In 2018, Lopes-Olivo et al. developed and tested a multimedia patient

education tool (video) for patients with orthopedic conditions such as osteoarthritis, osteoporosis, and rheumatoid arthritis, by incorporating educational patient story lines in order to produce didactic and user-friendly content about those conditions. This study showed significant difference in knowledge scores before and after the video tool ($P<0.0001$), as well as increased clarity and acceptability of the tool by most patients. Moreover, all participants in the study (60) provided a favorable evaluation of the tool in terms of comprehension of the information delivered. Furthermore, Mawhinney et al. (2019) presented a high patient satisfaction score (30.2/32) with the use of a video consent as an adjunct to the traditional consenting methods for spinal surgery in adults. This study also demonstrated that patients watched the video two to three times (median), suggesting most individuals need the information to be repeated to result in better comprehension and higher satisfaction.

2.2.3 The Use of Multimedia Tools in the Pediatric Setting

When analyzing the use of multimedia tools exclusively for the pediatric population, the introduction of non-traditional methods might present a positive effect in the child's comprehension of a specific procedure or study. Tait et al. (2015) evaluated the difference in comprehension of the information regarding a clinical trial by comparing results from the traditional format (paper) versus the non-traditional (interactive multimedia program). In this study, 135 children were randomized and evaluated with a pretest and post-test format, and the multimedia group presented a significantly greater post-test understanding in comparison to the traditional group. Participants also reported that the multimedia tool was "easier to follow" and "more effective" in presenting information than the paper format.

As mentioned, in the pediatric setting of consenting for a complex procedure, the responsible guardian of the patient will be the one providing consent. Having a child in a complex medical setting can increase guardian's anxiety and the feeling of being overwhelmed (Murtha et al., 2020). However, a randomized control trial demonstrated that the use of multimedia tools to obtain informed consent prior to pediatric surgery can also assist with reducing parental anxiety and improve their comprehension and overall satisfaction, demonstrating that the multimedia tool can be an effective supplement in the parental preoperative education and consent process (Shreyas et al. 2023).

During the literature review, a gap in the literature was noticed when looking into the use of multimedia tools to improve the informed consent of pediatric patients submitted to PSIF due to multiple scoliosis diagnosis.

2.3 The Standardization of the Surgical Discussion

2.3.1 The Legal Aspects of the Surgical Discussion and Informed Consent

The College of Physicians and Surgeons of Alberta (CPSA) provide a "standard of practice" to its regulated members in order to facilitate and ensure proper informed consent is obtained prior to an examination, assessment, treatment or procedure. Consent can be given in multiple ways, such as implied, expressed orally or in writing, depending on the assessment provided or procedure proposed. Expressed consent should be obtained when the proposed treatment might be more than mildly painful, and when it implies possible reasonable risks to the patient. The CMPA reports that written consent should be obtained prior to any surgical operation or invasive procedure, and it should be archived in the patient's records or charts (CMPA, 2022).

In 2017, Hanson & Pitt presented a CMPA report of a 5-year period demonstrating that 65% of the medical legal actions related to informed consent were related to surgery, and among the cases that were presented, only 21% resulted in favorable outcomes for the surgeon. Over the years, multiple high-profile cases have been reviewed by The Supreme Court of Canada, and in cases like *Reibl v Hughes* and *Ciarlariello v Schacter*, the Supreme Court placed the responsibility of ensuring patient understanding on the physicians (Burningham et al., 2013), confirming the duty described by multiple professional registered organizations. According to the Supreme Court of Canada, physicians have the duty to not only inform patients of the possible risks, indications, benefits, and other possible treatments associated with their condition, but they also have the legal obligation of ensuring patient understanding of the provided information. As per the Canadian Medical Association's Code of Ethics, physicians may take "every reasonable effort to communicate with (…) patients in such a way that information exchanged is understood" (CMA, 2018).

Burningham et al. (2013) was able to present the existence of a significant gap between what is demanded by law and what happens during a surgical discussion and the informed consent process. As described above, physicians are legally obligated to ensure full understanding from patients during this process, however, physicians often have trouble recognizing when patients do not fully understand the information given, and patients also can struggle to recognize their own misunderstanding, making it difficult for physicians to meet their ethical and legal obligations. Moreover, the authors provided evidence that some interventions (including the use of multimedia resources) might improve patients' knowledge of risks and assist physicians to meet their professional obligations.

2.3.2 Patient-Centered Care and Shared Decision Making

In 2016, Spatz et al. presented that most informed consents used today contain information intended to protect the most responsible physician and/or the hospital from any legal action patients might take against them in the future, due to the significant legal aspects related to the surgical discussion and informed consent process. Moreover, the authors concluded that the information presented is often generic and written using medical terminology that might be difficult for a layperson to understand and may not include all aspects deemed important by patients. Best et al. (2016) demonstrates how most informed consent forms are made to serve physicians and institutions instead of patients, and how this can overwhelm and compromise the patients' decision-making capacity during this process.

In 2015, a case reviewed by the United Kingdom Supreme Court ruled that physicians should inform patients of the risks, benefits, and alternative treatments that would be deemed important by the patient, and not only by what the physician believes might be relevant to the patient (*Montgomery v Lanarkshire Health Board*, 2015). Moreover, countries like the United States have also started to adopt this same patient-centered and shared-decision method when providing information during the informed consent process by including the patient's perspective on what matters to them (Spatz et al, 2016; Glaser et al., 2020).

Furthermore, patient- and family-centered initiatives for the surgical discussion and informed consent can promote patient autonomy and are currently considered an ethical approach to provide shared decision making between physicians and patients in the pre-surgical setting (Whitney et al., 2004).

Shared decision making (SDM) is a process that considers evidence-based medical practices and the patient's perspective (including their values and preferences), and it is

considered a patient-centered approach focused in a balanced and meaningful collaboration aiming to improve all aspects of patients' clinical care (Tonelli & Sullivan, 2019). The process of SDM empowers patients and guardians to have autonomy and be more proactive in consideration of their health, especially when deciding for a specific treatment or procedure (Smith, 2016). When deciding on whether to consent to medical treatment, the process must include patient engagement, discussion, and shared decision phases, which should promote a meaningful collaboration between all parties to positively enhance patient care (Prince, 2015).

A SDM approach to create a standardized script for the surgical discussion of Posterior Spinal Instrumentation and Fusion (PSIF) for scoliosis can ensure that the legal and ethical obligations are properly addressed during the informed consent process.

2.4 The Pre, Peri and Post-operative Implications of Introducing Multimedia Content to the Surgical Discussion Process

2.4.1 Anxiety and Stress

Almost half of all patients undergoing surgery worldwide reported feeling anxious prior to any surgical procedure according to a 2020 systematic review and meta-analysis (Abate et al., 2020). The extent of preoperative anxiety depends on multiple factors, including the type of surgery, gender of the patient, interactions with the medical team, previous personal experiences with surgical procedures, and how the patient copes during stressful situations, among others (Bedaso et al., 2022).

In 2010, Jlala et al. analyzed the effect of introducing preoperative multimedia information about the anaesthesia process for upper or lower extremity orthopaedic surgery. In

this study, the use of multimedia resources (short films) decreased anxiety prior to and immediately after the procedure in the intervention group in comparison to the control group.

A similar approach was taken by Doering et al. in 2000, where an informative video was presented to patients undergoing total hip replacement. In this study, the intervention group that watched the video presented with significantly less anxiety and stress levels on the morning before surgery and the following two days post-procedure, as well as a significant decrease in the number of patients with increased systolic blood pressure (associated with anxiety) intraoperatively and decreased use of analgesic medication after surgery.

In the pediatric setting, anxiety is also one of the most common symptoms seen in guardians that have a child being submitted to a surgical procedure. The use of multimedia tools during the surgical discussion and informed consent procedure appears to be an effective approach to reduce pre-operative parental anxiety (Paton et al., 2018; Shreyas et al., 2023).

2.4.2 Pain

Pain is a very complex symptom that includes discriminative, emotional-affective, and cognitive components. Post-operative pain severity can depend on multiple factors, such as extent of traumatized tissue, inadequate analgesia, and the emotional status of the patient including their anxiety levels. Moreover, studies show that high pre-operative anxiety has a positive correlation with increased post-operative pain, as well as increased analgesic and opioids consumption (Tadesse et al., 2022; Vaughn et al. 2007).

Yilmaz et al (2021) evaluated the effect of introducing a video-based multimedia information tool for female patients prior to a gynecological surgical procedure. In this study, the implementation of the multimedia teaching piece was associated with less anxiety and less

severe post-operative pain in comparison to patients receiving only written information about their procedure.

In the orthopedic setting, Wang et al. (2022) also evaluated the effects of pre-operative education with a multimedia tool (animated video) for patients with femoral fractures. This study demonstrated that the pre-operative multimedia tool is more effective than the traditional oral instructions in decreasing adult patients' post-operative anxiety and pain levels.

Furthermore, when looking into pediatric patients and their guardians, caregiver anxiety appears to be associated with pediatric patient increased pain in the post-operative process. A cross-sectional study evaluated the correlation between caregiver anxiety and their children's self-reported pain after elective surgeries. In this study, a significant correlation between caregiver pre-operative anxiety and patient post-operative pain was reported, demonstrating the importance of reducing not only the patients' pre-operative anxiety, but also their caregivers (Knoetze et al., 2020).

The use of multimedia tools can assist with decreasing guardian's anxiety prior to a pediatric surgical procedure and may help decrease the patient's associated post-operative reported pain. As reported here, studies suggest a direct correlation between the use of multimedia tools and decreased post-operative pain in adult patients. However, it is noticed a gap in the literature in regards to evaluating the effects of introducing multimedia tools to the surgical discussion and pediatric patients' post-operative pain and analgesic/opioid use.

In this thesis, we hope to fill the multiple gaps in the literature presented throughout the sections of this review, including gaps in the comprehension of the informed consent, in the use of multimedia tools as a way to improve informed consent in pediatric setting, in the creation of

a SDM approach to standardize the informed consent, and in the possible correlation between the use of multimedia tools pre-operatively and patients' post-operative pain and medication use.

In the following chapter, a detailed exploration of the historical and challenging environment in which this research was conducted is presented. This contextualization aims to shed light on certain limitations faced during multiple steps of this research, as well as offer a comprehensive background for the subsequent discussion of results and findings seen later in this thesis.

Chapter Three

RESEARCH CONTEXT

Prior to explaining the methodology implemented in this study, and to contextualize the study's findings, as well as its limitations, it is important to describe the specific environment and historical characteristics that influenced the development of this thesis work.

3.1 Conducting Research During COVID-19

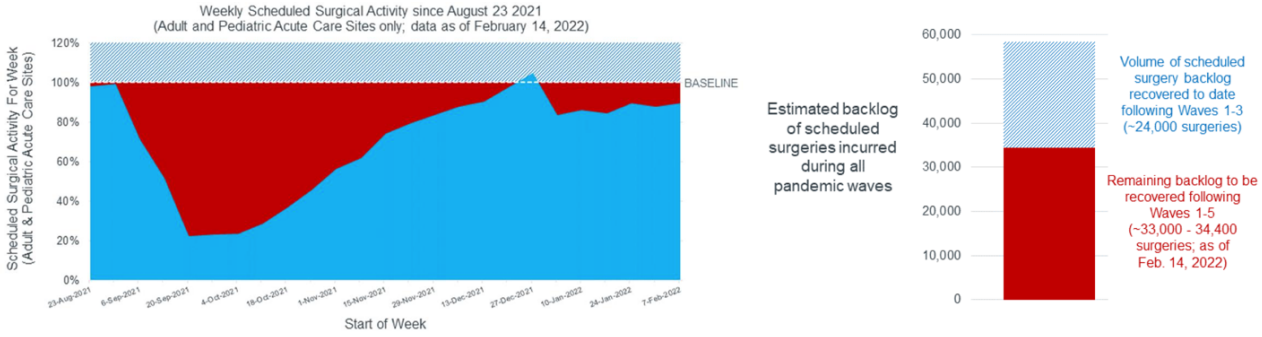
Overall, the COVID-19 pandemic impacted the way health care research is normally conducted. Specifically this project was affected by: the dramatic decrease in availability for non-urgent patients to be seen in clinical and surgical settings, the consequently restricted of the number of guardians allowed to accompany their children to consults and medical procedures, the hospital restrictions on the number of beds and operating room time available for elective surgeries, the relocation of medical and nursing staff to front line roles, the lack of confidence that patients and guardians developed towards the medical system, the apprehension of patients and parents to attend non-urgent medical appointments, as well as the increase number of medical professionals that experienced burnout and other mental health issues during this period.

Surgeries impacted by COVID-19 in Canada

The World Health Organization (WHO) officially declared COVID-19 as a pandemic in March 2020. Sauro et al. (2023), describes how Canadian provinces (when relocating resources to address the COVID-19 pandemic) decided to reduce their hospitals' surgical capacity, consequently delaying a significant number of non-urgent surgical procedures.

The Alberta Surgical Initiative released a report in February 2022 describing the impacts the pandemic had on the already saturated surgical waitlist in Alberta. This document reported a service reduction of 60% (approximately 25,000 surgeries) during the first wave of COVID-19 (from March 2020 to May 2020), followed by a reduction of 10% during the second wave (from October 2020 to February 2021), and a subsequent reduction of 10% during the third wave (from April 2021 to May 2021). Moreover, Figure 1 illustrated the estimated total provincial surgical backlog (including both Adult and Pediatric patients), as a result of the measures taken during the COVID-19 waves 1 through 5 (until February 2022).

Figure 1: Estimated surgical backlog due to COVID-19 Pandemic in Alberta, Canada until February 2022. (Data source: AHS Provincial Surgery Data & Analytics, 2023)



The data obtained from AHS Provincial Surgery Data and Analytics presented above estimated a total backlog of scheduled surgeries between 57,000 to 58,400 procedures from March 2020 to February 2022. [Alberta Surgical Initiative Performance Dashboard, 2023].

Additionally, Figures 2 to 5 provide information on the pediatric surgical waitlist in Alberta, through 4 different times in the pandemic (July 2020, January 2022, March 2023, and October 2023). Those specific times were chosen to better illustrate the tendencies experienced by pediatric health care centers, as well as to provide context directly related to the patient recruitment timeline of this thesis.

Figure 2: Pediatric surgical waitlist backlog in July 2020, in Alberta, Canada (Data Source: Alberta Surgical Initiative Performance Dashboard, 2023)

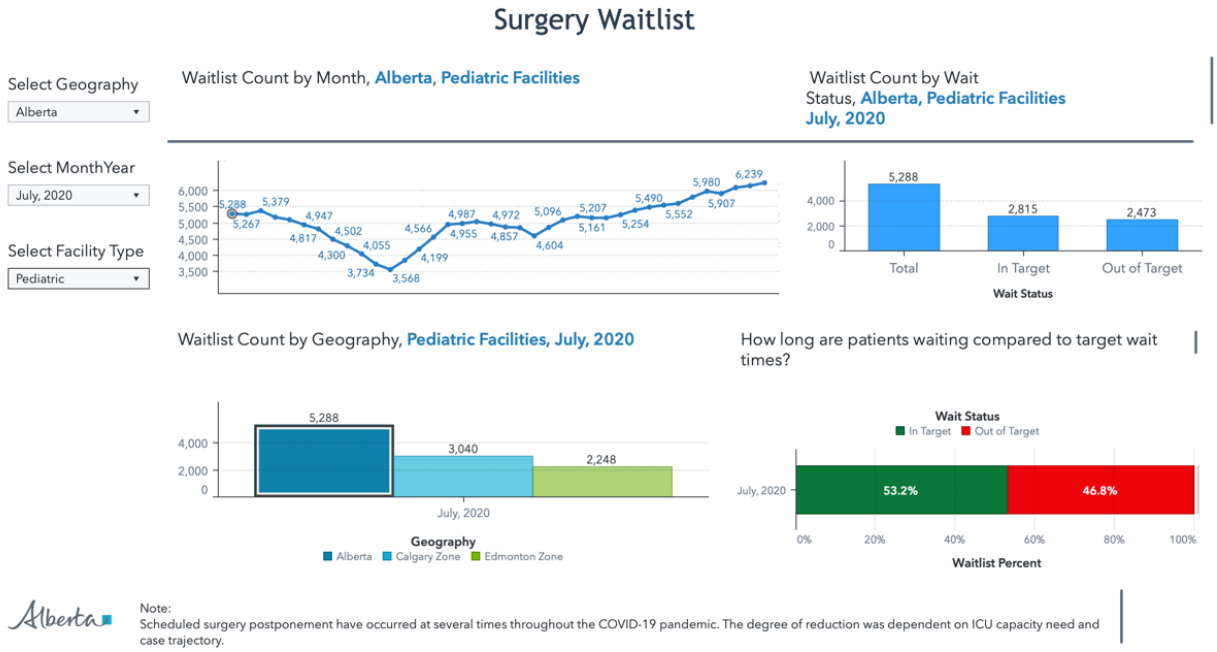
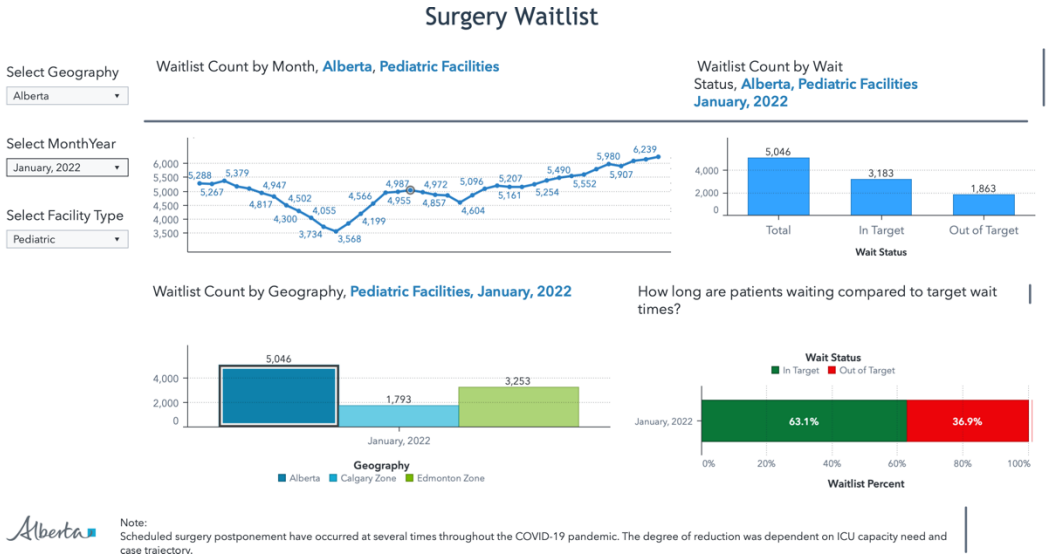


Figure 2 provides the first available pediatric data on the surgical waitlist in Alberta (July 2020), showing the impact on wait status immediately after the end of the first wave and the implementation of first service reduction measures. In this figure, it can be observed that 46.8% of pediatric surgical procedures were out of their targeted schedule, which corresponds to over 2400 surgeries.

Figure 3: Pediatric surgical waitlist backlog in January 2022, in Alberta, Canada. (Data Source: Alberta Surgical Initiative Performance Dashboard, 2023)



In January 2022, after waves 2 to 4, and at the beginning of wave 5, there is a slight decline in the total number of surgeries out of date (36.9%). However, this decline is due to the improvements in the return of pediatric surgeries in Edmonton Zone, while Calgary Zone still presented a substantial decrease in the number of surgical procedures being performed (from 3040 procedures in July 2020 to 1793 in January 2022).

Figure 4: Pediatric surgical waitlist backlog in March 2023, in Alberta, Canada. (Data Source: Alberta Surgical Initiative Performance Dashboard, 2023)

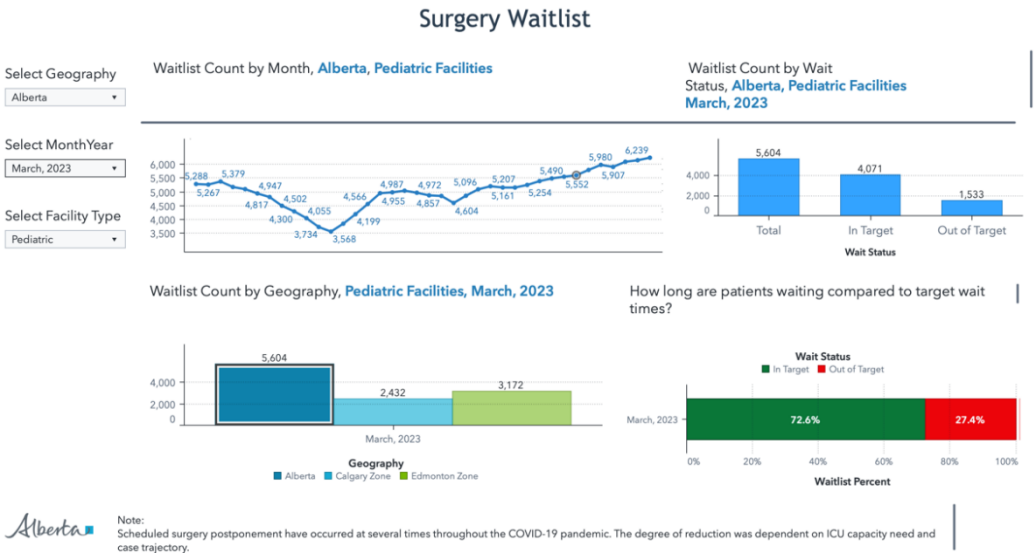
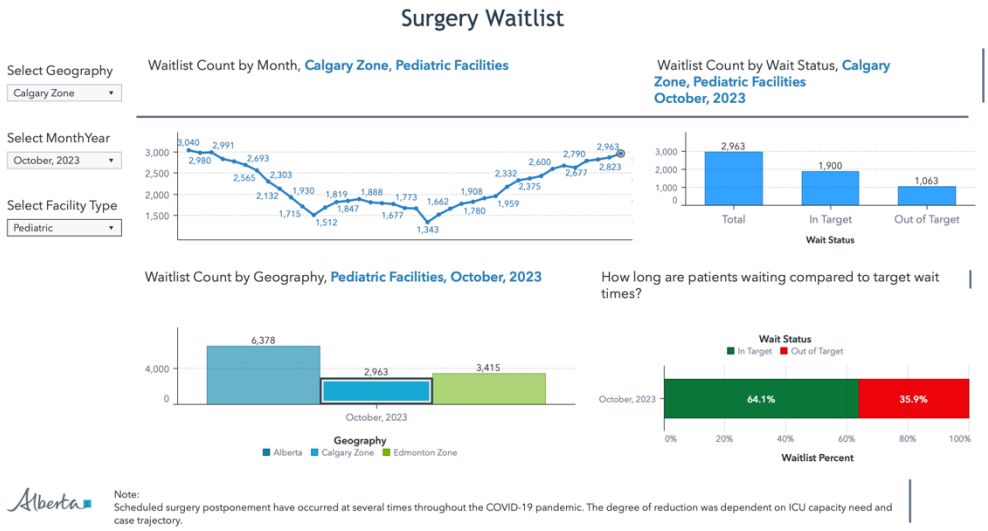


Figure 5: Pediatric surgical waitlist backlog in October 2023, in Alberta, Canada. (Data Source: Alberta Surgical Initiative Performance Dashboard, 2023)



When comparing the results observed from March 2023 (Figure 4) to those in October 2023 (Figure 5), the total number of pediatric procedures in the Calgary Zone remained lower (2432 in March and 2963 in October) than those recorded at the beginning of the pandemic (3040 in July 2020). Additionally, the surgeries performed in Calgary Zone were notably lower by percentage when compared to the numbers from Edmonton Zone (3171 in March and 3415 in October). Furthermore, Figure 5 illustrates a current backlog of nearly 35.9% in pediatric surgeries, persisting for almost 43 months since the onset of the COVID-19 pandemic.

In the context of Pediatric Spine Surgeries performed at The Alberta Children's Hospital, the COVID-19 pandemic also introduced delays in the timeline from surgical discussions and consent processes to the actual surgical procedure. These delays were attributed to fluctuations in policies and operating room guidelines during different waves of the pandemic. Additionally, some patients contracted COVID-19 between the initial surgical discussion and the scheduled procedure, necessitating postponement until they recovered and a new surgery date became available.

This chapter provided a description of the direct impact the COVID-19 pandemic had in the surgical waitlist and surgical procedures performed from March 2020 until the present day. Those limitations directly influenced the conduction of this thesis, and each specific aspect affected will be described in Chapter Four.

Moreover, in the next chapter, the methodology used in this study is described in detail, including the literature review process, the co-design of the multimedia tool and the patient

engagement approach taken, as well as specific information on the questionnaire used to obtain the test- and post-test results, the assessment of guardians' perceived understanding, the study's population, how the intervention was performed, and the data analysis.

Chapter Four

METHODS

4.1 Overview

This is a quasi-experimental, repeated measures, multi methods study based on the test- and post-test results of an assessment questionnaire that explored two possible models of information delivery (conventional – verbal only and multimedia – educational video) during the pre-operative surgical discussion process prior to the application of the surgical consent.

The following PICO framework was implemented to formulate the study's research question:

1. Patient/Population (P): Guardians of pediatric patients on the surgical waitlist for PSIF surgical procedure to manage scoliosis.
2. Intervention (I): The introduction of a co-designed video to provide pre-operative information about the risks, benefits, available treatments, and post-operative recommendations for scoliosis surgery to pediatric patients.
3. Control (C): The clinical and literature review results from the conventional pre-operative surgical discussion process (verbal only nursing teaching).
4. Outcome (O): To assess the knowledge acquisition over time after the introduction of the intervention tool. By using the results from the multiple-question questionnaire.

The research question resulting from the describe framework is: "*For guardians of pediatric patients on the surgical waitlist for PSIF scoliosis surgery (P), does the introduction of a co-designed video (I) compared to the standard pre-operative discussion currently implemented and described in the literature (C), measured by a validated multiple-question questionnaire,*

lead to improved knowledge acquisition over time regarding the risks, benefits, available treatments, and post-operative recommendations for pediatric scoliosis surgery (O)?"

In this project, the overall multi methods approach was selected to include both quantitative and qualitative components of research. When considering the quantitative component, a quasi-experimental design was employed to compare both groups, using test- and post-test measurements. Additionally, this research project assessed guardians' perceived knowledge acquisition and gathered insights from closed-ended questions incorporated into the patient engagement strategy evaluation.

In addressing the qualitative component, open-ended survey questions were also obtained and analyzed during the assessment of the patient engagement strategy.

This proposed methodology provides the following strengths, limitations, potential bias, and opportunities to overcome bias:

Strengths

The use of both quantitative and qualitative methods provides a comprehensive understanding of the process and the consequences of introducing a co-designed video to the pre-operative process prior to pediatric spinal surgery. The quantitative aspect allowed the utilization of validated multiple-choice questionnaire results to obtain numerical data and generate statistical analysis regarding knowledge acquisition and perceived knowledge acquisition when testing our proposed intervention, offering generalizability and precision to this study. The qualitative approach taken during our patient engagement strategy evaluation allowed a more nuanced understanding of the patient partners perspectives and experiences during the co-creation of the intervention tool.

The repeated measures design also provides the following strengths to this study: Improved statistical power (since each participant serves as their own control, reducing variability and increasing sensitivity to detect true effects), efficient use of participants (allowing a better use of the presented limited resources), control for individual differences (since each participant is exposed to all conditions), reduced variability (variability associated with individual differences is minimized), temporal stability assessment (allow for examination of changes over time within the same individuals), enhanced precision (due to the reduced standard error of the mean, which is advantageous when dealing with small sample sizes), increased sensitivity to detect effects (this design is often more sensitive to detect subtle effects or changes over time), and minimization of cofounding variables (by controlling for individual differences and using the same participants).

Limitations

One of the limitations of quasi-experimental studies is the possibility of confounding variables (such as gender, age, and guardian's level of education) which were addressed and accounted for during the statistical analysis, as well as minimized by the use of a repeated measures design. Moreover, this study may have less generalizable results in comparison to pure randomized controlled trials (RCTs) due to both its relatively small sample size and the fact that it was conducted in a single center. The power to detect differences might also be affected by the presented sample size (one of the main limitations suffered from conducting this research during the COVID-19 pandemic, as mentioned in Chapter Two and described in further detail later on this chapter). However, given that this is a project aiming to assess not only knowledge acquisition over time after the implementation of the intervention but also supporting and

facilitating the co-design of the intervention tool used locally, the possible restricted generalizability does not diminish local utility.

Potential Bias

Quasi-experimental studies have higher chances of selection bias in comparison to RCTs. In this study, high enrollment of participants (94% of the potential participants were enrolled) and random allocation of participants in each group were strategies implemented in order to reduce the risk of potential selection bias.

Opportunity to Overcome Bias

Within this project, the opportunities to mitigate bias were included to its design and strategic considerations. As described above, the multi methods approach based on the complementary nature of quantitative and qualitative methods is one of the key strengths of this research, contributing to a more comprehensive understanding of the multiple findings obtained through this project. Moreover, the acknowledgement of potential cofounding variables and selection bias as part of the study's limitations highlights the methodological rigor applied throughout this thesis. Addressing and accounting for the possible confounding and selection bias during the statistical analysis improves the study's validity and precision while mitigating bias that could possibly be introduced by factors that are not directly influenced by the proposed intervention. Furthermore, recognizing that this study took place during the challenging times of COVID-19 introduces the opportunity to contextualize the results and the findings' discussion.

The transparency of the study's limitations, potential biases, and trade-offs presented above improves the comprehensive understanding of the research context and contributes to the overall credibility of the research findings.

Prior to starting this project, ethics approval was obtained from the University of Calgary's Conjoint Health Research Ethics Board (REB# 21-1864).

The following sections will explain in detail the study's literature review process, patient engagement strategy, video creation process, questionnaire utilized, study population, the different pathways explored in this pilot study, and the data analysis.

4.2 Literature Review Process

The literature review was conducted to gather relevant studies concerning informed consent, multimedia tools, and their impact on patient understanding and satisfaction. The search strategy performed used a combination of keywords and vocabulary related to informed consent, multimedia, surgical procedures, pediatric patients, and patient and guardian comprehension. A scoping review approach was the chosen method for the literature review in order to properly map and synthesize multiple key concepts and existing knowledge, as well as recognizing gaps in the literature (Colquhoun el at. 2014) related to the topics mentioned above.

Multiple bibliographic databases were systematically searched to ensure a broad and comprehensive selection of pertinent literature, including PubMed and Google Scholar. Additionally, specific medical and legal databases were explored, such as those provided by the Canadian Medical Protective Association (CMPA) and the College of Physicians and Surgeons of Alberta (CPSA), as well as the Supreme Court published reports.

The search focused on various types of studies, including systematic reviews, prospective qualitative studies, randomized controlled trials, cross-sectional studies, and scoping reviews. These study designs were chosen to provide a comprehensive view of the topic, allowing for an assessment of both qualitative and quantitative aspects related to informed consent and the integration of multimedia tools to the pre-operative process.

Inclusion Criteria

Studies included in the literature review met the following criteria:

1. Relevance to the topics of informed consent, multimedia tools, and their impact on patient and guardian understanding and satisfaction.
2. Publication in peer-reviewed journals or reputable medical databases.
3. Written in English.
4. Availability of full text for comprehensive analysis.

Exclusion Criteria

Studies were excluded if they:

1. Were not directly related to the topics of informed consent, multimedia tools, or their impact on patient comprehension and satisfaction.
2. Were not published in English.

Search Strategy

The search strategy involved a combination of medical subject headings (MeSH) and relevant keywords, tailored to each database. Boolean operators (AND, OR) were used to refine search queries. For example, in PubMed, the search string consisted of ("informed consent" OR

"surgical consent") AND ("multimedia" OR "video-assisted consent") AND ("patient comprehension" OR "pediatric surgery").

Study Selection Process and Data Extraction

The initial search provided a substantial number of articles. After removing duplicates, titles and abstracts of all articles were reviewed for relevance. Subsequently, full texts were obtained and assessed for eligibility based on the inclusion and exclusion criteria. Moreover, studies used in the bibliography of those articles were also reviewed, and if deemed relevant, they were also assessed in full-text format as part of the scoping review. Finally, the selected studies were subjected to data extraction and synthesis for the literature review presented in Chapter Two of this thesis.

4.3 The Patient Engagement Strategy

As described in section 2.2.2, this thesis has a particular focus on patient-centered approaches to create meaningful and impactful research outcomes to pediatric spine patients.

Throughout this project, three pairs of patient partners (previous scoliosis patients and their guardians) provided feedback on the methodology. The partnership with children with lived experience and their guardians ensures that this research is relevant and meaningful to them. More importantly, it is more likely to yield positive outcomes and improve scoliosis patient's safety and health.

Patient-centered research has a particular emphasis in actively involving patients, their families, and/or caregivers throughout the research process. These individuals can provide life-experience expertise as part of the research team, and they are called "Patient Partners" [AbSPORU, 2023]. The Canadian Institute of Health Research (CIHR) four guiding principles

for patient engagement in healthcare research (see below) were implemented as the framework for this study's patient engagement strategy, with the goal to improve the relevance of this project, as well as create a meaningful and useful tool to its end-users (Government of Canada-CIHR, 2019). This framework was originally created with the collaboration of Canada's Strategy for Patient-Oriented Research (SPOR) aiming for "*patients, researchers, health care providers and decision-makers to actively collaborate to building a sustainable, accessible and equitable health care system and bring positive changes in the health of people living in Canada*".

These four guiding principles were implemented as follows:

Inclusiveness

The patient partners invited to collaborate were treated with respect, and recognition to their unique perspectives, experiences and expertise was maintained throughout the project.

Support

Adequate support and flexibility were provided to ensure partners could have the chance to contribute equally during the co-development of the video tool. As an example, when asked about how they would like to communicate with the research team, all patient partners preferred email communications, for both logistical and safety reasons considering the co-development of the video happened during the peak of the COVID-19 pandemic.

Support was also provided to the rest of the research team involved, including discussions and teaching about the principles of patient engagement in healthcare research to the research members that did not have much knowledge about the possibility of this partnership.

Mutual Respect

Mutual respect was possible due to the training and educational sessions with the research team, ensuring everyone understood the value of patient partner's expertise and experiences.

Co-building

The research team was able to collaboratively co-develop the video tool implemented as the intervention in this pilot project.

Prior to starting the process of co-creating the video (see below), the project idea was discussed with a former scoliosis patient (that was surgically operated by the Alberta Children's Hospital Pediatric Spine team in the past) and their guardian. During this discussion, the patient and guardian were both offered to participate in the early stages of script creation as patient partners, to which they both agreed.

During the video creation process, two more patient/guardian partner pairs were recruited from the Pediatric Spine Clinic during their long-term post-operative follow-up visit by the scoliosis nursing team.

A discussion explaining the role of patient partners, their expected contribution, as well as the available support for them throughout this project was done separately with each patient partner pair, and they all had the chance to discuss those terms prior to agreeing on being part of the research team.

The three pairs of patient partners were in contact with the research team via email to provide feedback and comments during multiple phases of the video creation process. Their

comments and suggestions were incorporated during production before the video was finalized for implementation.

The evaluation of this partnership was performed by applying the Public and Patient Engagement Evaluation Tool (PPEET) (Version 2.0, August 2018) (See Appendix 2), and feedback was obtained from the diverse members of the research team, including partners (both patient with lived experience and their guardian), stakeholders involved in this project, and the thesis candidate. This questionnaire was answered anonymously, either online or in person, and the data was collected and organized free of identification.

The PPEET was developed by McMaster University during a collaborative process between researchers and public and patient engagement specialists, encompassing different types of questionnaires which can be used to evaluate patient engagement activities from the perspective of all members of the research team (Abelson et al. 2016). The PPEET includes twenty-one statements or questions, where some would ask participants to rate their level of agreement in response to a sentence and others would ask them to provide comments or feedback. This tool was chosen as the patient engagement evaluation method for this study after the review of Abelson et al. (2019), which demonstrate the PPEET appropriateness in multiple health system settings (including health research), as well as its user-friendly layout and simple applicability via either in-person or through electronic means.

4.3.1 The direct impact of COVID-19 in this project's patient engagement strategy

The patient partner collaboration in this project was directly affected by the COVID-19 pandemic.

Santana et al (2023) highlighted how COVID-19 has created barriers to patient partner recruitment in a patient and family co-development project. They also explored the impact of the pandemic on the study's work environment, as well as how some patient family advisors stepped down from their role in the project due to frustration with the perceived lack of patient engagement in AHS during COVID-19.

In the context of this thesis, the video creation process took place between October 2020 to October 2022, which corresponded to the beginning of wave 2 to the peak of wave 5. While no significant challenges were faced during the patient partner recruitment strategy, the logistics of the partnership were directly affected by the strict social and health restrictions applied at that time (such as social distancing, masking, and no in-person meetings or interactions).

The health recommendations implemented guided all the communications that followed the in-person recruitment done in clinic, to be done virtually between the research team and the patient partners. In this project, all partner pairs were comfortable with email communications, allowing greater flexibility in meeting deadlines for feedback and accommodating a more flexible time commitment, as opposed to scheduled meetings.

4.4 Video Creation Process

4.4.1 Motivation and Inspiration

The idea to create an animated educational video to assist with the pre-operative surgical discussion process came from another project implemented in the Pediatric Orthopedic Fracture clinic in 2020. In this project, an animated video was created in order to improve patient and guardian management of immobilization (by cast or splint) at home after a fracture occurred, including answers to their most common questions and doubts (link:

https://youtu.be/iiIWylfoBL0?si=dTwctMwZ7wc3tT58). During the clinical follow-up of a fracture, a Quick-Response (QR) code linked directly to the video was applied to the cast or splint in the form of a sticker. The QR code was also available on a contact card that was given to guardians at the end of the appointment. Guardians and patients were encouraged to scan the QR code and watch the video after being discharged and every time they had questions related to the immobilization process.

This video received very positive feedback from both guardians and patients, empowering them to better handle fracture management at home, as well as having fast and accurate answers to the most common issues that can arise from casting or splinting. The availability of the video also decreased the number of phone calls to the nursing line for the most common and non-urgent doubts related to the immobilization, according to the nurse's perception.

That project, as well as the encouraging feedback from guardians, patients, and the nursing team, inspired a similar approach for this thesis, but on the setting of scoliosis pre-operative assessment at the Pediatric Spine Clinic.

4.4.2 Co-creating the Video

The video co-development process started with the creation of a standardized script that included: a brief explanation about scoliosis, inclusion of possible treatments, why surgery was being recommended, the benefits of surgery, the intra-operative surgical process, the hardware utilized during surgery, the post-operative surgical process, and the risks and possible complications associated with the recommended scoliosis surgical procedure (PSIF).

The script incorporated data and up-to-date literature referenced during routine surgical discussions in the Pediatric Spine Clinic at the Alberta Children's Hospital. The content of each video was tailored according to the particularities seen in each different type of scoliosis studied in this research (Idiopathic and Neuromuscular). Some of those particularities were: The chances of infection associated with PSIF (1-2% for idiopathic cases [Figure 6] and 10-20% for neuromuscular patients [Figure 7]), and the post-operative routine where recommendations for ambulation (such as walking) for idiopathic patients might not apply to some neuromuscular individuals that are wheel-chair dependant.

Once the scripts were created, they were sent for feedback and comments from the supervisory committee members, the Pediatric Orthopedic Spine medical staff, the Pediatric Orthopedic Spine nursing team, the Pediatric Anesthesiology team, and to patient partners. Each of those teams provided very valuable and insightful rounds of comments, and the scripts were edited until full approval was obtained from multiple stakeholders involved.

Their feedback included the following topics and examples:

Translation of medical jargon to simplified lay language

In the context of why the surgical procedure was being recommended, the medical language "Prevent curvature progression" was modified to "Stop the curve from getting worse."

In the context of other medical professionals involved in the procedure, the formal title "Anesthesiologists" had the translation "Sleep Doctors" included on the same video frame.

Inclusion of post-operative expectations

The video guided viewers through a comprehensive overview of post-operative expectations, addressing potential pain, wound care protocols, the anticipated appearance of scar,

the physiotherapy routine, and the expectations regarding return to their regular activities (such as sports and school). Following the feedback obtained, additional details were incorporated to enhance the information provided for all those aspects.

The process of script creation, feedback, edits, and final approval took approximately 8 months.

Figure 6: Image from the co-designed video for idiopathic patients, demonstrating the risk of infection associated with the surgical procedure.

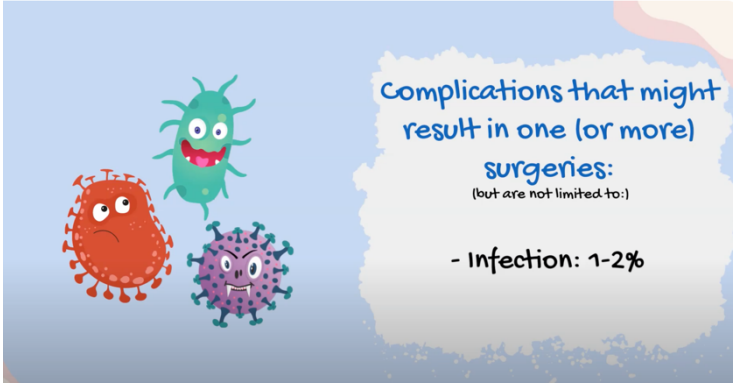
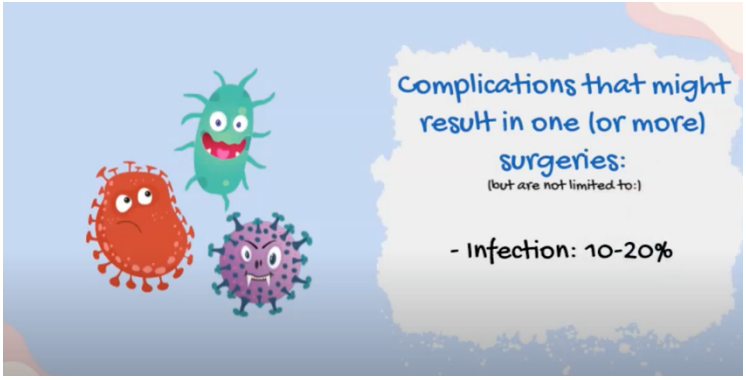


Figure 7: Image from the co-designed video for neuromuscular patients, demonstrating the risk of infection associated with the surgical procedure.



The next step was the creation of an animated video to illustrate all the content presented in the script. The first video prototype was created using Powtoon. In this first attempt, the main reservation noticed by the teams when providing feedback was the lack of body diversity available for the characters. In this software, all characters were very “straight”, “slim” and “not very friendly” (Figure 8) according to comments from both patient partners and other stakeholders.

Figure 8: Example of characters available on Powtoon.

The subsequent attempt was done by utilizing Power Point animation tools, but due to the multiple restrictions presented by this software (such as limited layouts and characters, and unintuitive animation tools available) this second attempt was not completed and did not reach the feedback phase.

The third software used was Doodly (v2.10-5), which provided a wider option of characters and allowed the import of illustration from other sources, such as Canvas and drawings done by the thesis candidate using Adobe Illustrator. During the time of video production, the paid full version of the three mentioned software above were obtained. After a relatively short learning curve (2 months), the animated videos were produced, and the same

teams offered another round of feedback, resulting in further editing until it received full approval from members involved in this process.

Their feedback included:

Appropriateness of the technical content

Firstly, there was an intention of including illustrations of medical devices utilized during the surgical procedure, such as skull-femoral traction (Figure 9) and intubation (Figure 10), both which were described as possibly “scary” or “traumatizing” by patient partners and other stakeholders, and were subsequently removed from the video.

Figure 9: Illustration of skull-femoral traction. (Source: Illustration done by the thesis candidate)

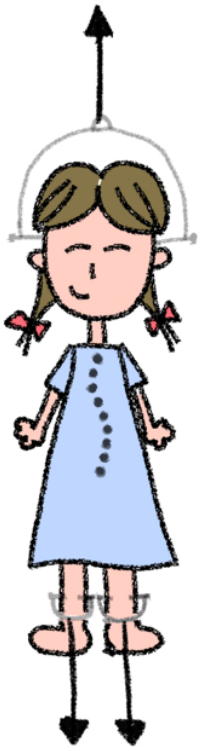
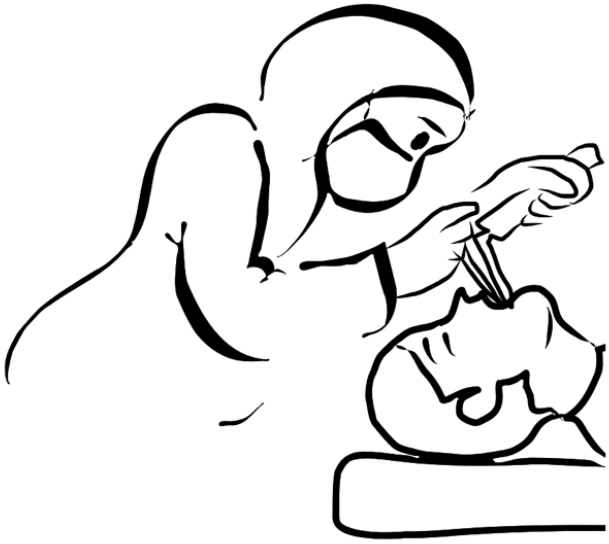


Figure 10: Illustration of intubation performed by an anesthesiologist. (Source: Illustration done by the thesis candidate)



Expected video length

Individuals from multiple teams described the first video attempt done with Doodly as "too slow" and "too long", especially because of the transitions between each frame. This was corrected and adapted during the edit rounds.

Background music

Multiple attempts were performed in order to find a suitable and relaxing background music that was deemed appropriate for patients and families going through a pre-surgical discussion.

During the video creation process, special emphasis was given to prioritize the development of ethically sound content suitable for both guardians and children, while also ensuring content was respectful to all ethnicities, religions, body shapes, and other diverse backgrounds, as shown by some of the characters illustrated on the video (Figure 11).

Figure 11: Some of the characters illustrated on the video exemplifying the goal to represent multiple backgrounds and body shapes.

The complete video co-development process took approximately 18 months, and over 350 hours of creation and editing before both final products were approved.

Both complete videos are available at:

Idiopathic Patients: https://youtu.be/ePikiJ8CAv4?si=udIi8tC5VLgHn51F

Neuromuscular Patients: https://youtu.be/mcpuHN8vaIk?si=X_PP0wRojuEGOX02

4.5 The Validated Multiple-choice Questionnaire

A multiple-choice, validated questionnaire was used to measure patient/guardian knowledge acquisition at different times (T1 *v* T2 *v* T3) in both treatment pathways (A and B).

The chosen questionnaire was first published by Theologis et al. in 2016. The Theologis questionnaire encompassed 11-item multiple-choice Likert-type questions with predefined response options, and it was utilized to assess understanding of the surgical consent process for Adolescent Idiopathic Scoliosis (AIS) patients in four different centers (three in the United States and one in Canada) (See Appendix 1). This questionnaire included questions focusing on the main risks, benefits, possible complications, and future expectations related to PSIF to manage AIS. These questions included: the risks of nerve injury, possible complications that could lead to a revision surgery, the chances of post-operative infection, the benefit of stopping curvature progression due to the spinal fusion, the expected lack of mobility of the spinal segment fused, the possibility of receiving blood and bone graft during the surgery, the expectation of post-operative pain and the availability of pain medication, the immediate post-operative mobilization plan and the availability of nursing and physiotherapy support, the expected medical equipment the child will have after the surgical procedure (such as an intra-venous [IV] access, a urinary foley catheter, and a possible oxygen or thoracic tube), the hardware implanted and its function, and the long term possible complications and expectations related to this surgical procedure). The proposed questionnaire also included one final question that aimed to assess individuals' perceived understanding of the discussed content. Demographic data (such as gender, parental level of education, age, and ethnicity) was also part of the assessment for descriptive data purposes and to account for possible confounders.

The questions regarding specific aspects related to the surgical procedure provided four different answer options (from a to d), with an additional option stating "I do not remember hearing this information" (e). There is only one correct answer for each question, as illustrated in the example above:

1. What is the chance of injury to your child's nerves during the operation?
    a. 100%
    b. 50%
    c. 5%
    d. About 0.5%
    e. I do not remember hearing this information

In this question, the correct answer is d. About 0.5%.

The final question, regarding participants' perceived understanding of the pre-operative surgical discussion included five answer options (from a to e) in a Likert-type ordinal scale, as seen above:

11. How well do you think you understand the risks, benefits and expected results of your child scoliosis surgery?

a. Not at all

b. A little

c. Pretty well

d. Really well

e. Totally

Through an extensive literature review (described in detail in section 3.2), this questionnaire emerged as the sole tool that included all mandatory elements of an adequate pre-operative surgical discussion (as described in section 2.1.1), providing precise and up-to-date percentages for risks and complications. Furthermore, validation was conducted through its application in a large population (176 pairs of patient/guardian, 352 total) during a multi-center

study (Theologis et al., 2016). The appropriateness of this questionnaire for the purposes of this thesis also hinges on its application in a comparable population to the one presented in the original study (guardians and patients with scoliosis being submitted to spinal surgery) mentioned above.

This study's patient partner team also assessed the questionnaire's relevance, ensuring that the questions not only satisfied the ethical and medical-legal aspects of the pre-operative surgical discussion and informed consent, but also held significant content for the patients and their families.

4.6 Study Population

Guardians of pediatric patients that were diagnosed with scoliosis who were recommended for surgery were offered to participate in this study in addition to their standard clinical care. To reduce any potential sense of pressure to participate in the study, recruitment and research consent process was conducted by the Orthopedic Spine nursing team, rather than the primary physician overseeing the patient's care.

Participants were recruited between March 2023 and November 2023. All procedures were approved by the University of Calgary's Conjoint Heath Research Ethics Board (REB# 21-1864) and informed written consent was obtained prior to enrolling in this study.

4.6.1 *The direct impact of COVID-19 in this project's data collection*

As described in Chapter Two, the COVID-19 pandemic, as well as the measures taken by Canada and Alberta health care authorities, dramatically influenced the surgical waitlists in Calgary. In the context of pediatric surgeries performed in the Calgary Zone (where this research

took place), the overall decrease in the number of surgical procedures led to a notable restriction in the availability for elective surgical procedures. Consequently, various patient groups were affected, including scoliosis patients who were on the waitlist for PSIF.

The described challenges directly influenced patient recruitment and the current restricted patient sample analyzed in this pilot project. With decreased Operating Room (OR) time available, extensive surgical backlog, and multiple surgical specialties facing the need to firstly operate on more urgent cases that were postponed during the pandemic, the number of patients submitted to PSIF to manage scoliosis were limited at the Alberta Children's Hospital in Calgary from March 2023 to November 2023 (data collection period). Consequently, fewer patients were schedule for pre-operative surgical discussions, reducing the pool of eligible candidates available participate in this study.

Out of the 18 pediatric patients submitted to PSIF to manage scoliosis between March 2023 and November 2023, 17 guardians (94.44%) agreed to participate in all the stages of this study, indicating high enrollment and adherence rates despite the relatively low total number of participants.

4.6.2 Inclusion Criteria

The inclusion criteria for this study consisted of guardians of patients between ages 10 to 17 years and 11 months, scheduled for primary PSIF to manage scoliosis (Idiopathic, Neuromuscular, Syndromic, or Congenital) at the Alberta Children's Hospital by the Pediatric Spine Orthopedic team. Participants had to have the legal guardianship of the patient and had to be capable of comprehending English without the need for an interpreter.

4.6.3 Exclusion Criteria

Guardians of patients being submitted to a secondary spinal procedure, that had previously participated in the surgical discussion process in the past, were excluded from this study. Guardians that needed the assistance of an interpreter or translator were also excluded from this project.

4.6.4 Data Sources

The surgical waitlist at the Pediatric Spine Orthopedic Clinic was reviewed to recruit participants for this study. A waiver of consent was obtained during the Ethics application to allow review of the surgical waitlist for recruitment purposes.

Participants were provided with information about the study and a written informed consent was signed prior to data collection.

To preserve participant confidentiality, there were no direct identifiers assigned to each study participant, except for the master sheet, which was exclusively used to schedule participants for survey completion.

Each participant was assigned a study identification (ID) number. The master sheet containing this information is kept in a lock-and-key cabinet in Orthopedic Spine Clinic at the Alberta Children's Hospital. All other information and data collected in this study is secured in a computer protected by password. The purpose of using identification was to verify the patient record from AHS sources and ensure that each case was only counted once. Also, when participants came for follow-up, it was important that they were not assigned a new study ID, but rather matched their following questionnaires to their previously assigned ID.

4.7 The Study's Pathway

4.7.1 Current Clinical Pathway

In the current clinical setting, on the day the scoliosis patient is recommended for surgery, they are automatically entered in the surgical waitlist if they want to proceed with the surgical proposal. In order to enter the waitlist, the guardian must sign a surgical consent after a surgical discussion is performed by the medical team in clinic. This is designated time one in the study (T1).

In a separate appointment, both patient and guardian receive "one-on-one" teaching about the surgical process with one of the Orthopedic Registered Nurses (RN). This corresponds to control (C) at time two (T2).

Currently, both T1 and T2 are performed in the conventional way, and information is only delivered orally. This study's inserted a new intervention (I) during a third educational opportunity (T3) by introducing an additional configuration of teaching in the form of an animated educational video, to the pre-operative routine for scoliosis patients, in addition to the oral, one-to-one teaching.

4.7.2 Intervention Pathways

In this study, participants were randomly assigned to two different pathways during the pre-operative surgical discussion process (Diagram 1), providing the educational video at two different times: Pathway A (T1 + C at T2 + I at T3) and Pathway B (T1+ I at T2 + C at T3).

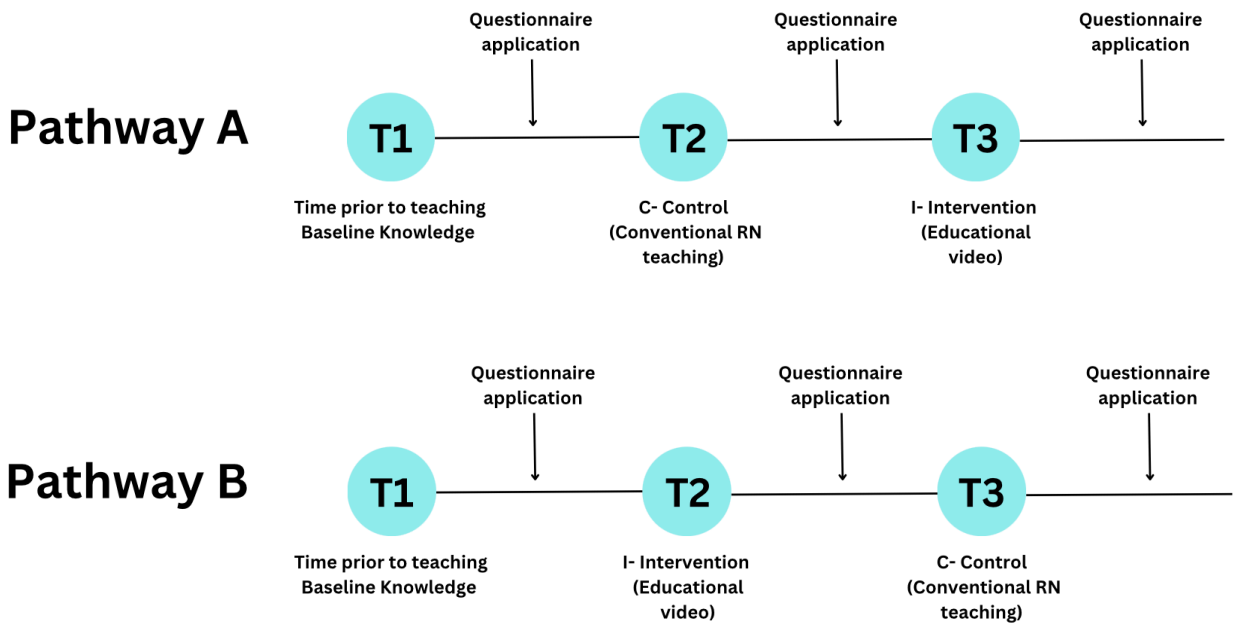


Diagram 1: Visual illustration of the sequence in which Control and Intervention were applied on Pathway A and Pathway B.

Research participants received information about this study from the Registered Nurse and were requested to sign an informed consent in order to enroll as participants. They were then asked to complete the Theologis questionnaire (Appendix 1) related to the peri-operative process, including risks, benefits, and expectations of the proposed procedure at T1, T2 and T3. T1 is considered the time prior to the first teaching mode in each group (before T2 and T3), in order to establish baseline knowledge on the subject and measure knowledge acquisition after each teaching modality. T2 is the second teaching module, and T3 consists of the third teaching session.

Pathway A consisted of conventional (verbal only) RN teaching mode first (C at T2), augmented with the video content (I at T3); Pathway B firstly received the multimedia (video) content (I at T2), followed by the conventional (verbal) RN teaching (C) at T3. The main

difference between both pathways was the order of content mode delivered, and all participants were exposed to both training modules (verbal and video).

As described above, this study follows a repeated measures design, in which each participant was submitted to multiple interventions sequentially, without the inclusion of a washout period. In some studies (like crossover for example), the washout period consists of an interval between treatment phases, which allow any residual effects of the previous treatment or intervention to diminish or "wash out" before the next phase begins. The washout period was absent in this study due to the restrictions to bring participants to multiple hospital visits during COVID-19, and the intent to protect surgical patients from being unnecessarily exposed to a hospital environment a few days or weeks prior to their procedure. Moreover, the design was carefully chosen to align with ethical principles to offer the best information available prior to a surgical procedure, allowing for a comprehensive assessment of the effect of introducing a new teaching module within the ethical framework of a pre-operative process.

4.8 Data Analysis

4.8.1 Quantitative Analysis

The data obtained from the application of the Theologis questionnaire was analyzed using statistical software R, version 4.2.2.

Repeated measures ANOVA test was conducted to compare questionnaire scores for Pathway A to Pathway B from three different times (T1, T2 and T3). Data distribution was assessed using the Shapiro-Wilk test and QQ-plots, allowing the assumption of normally distributed data. Sphericity assumption was also checked and confirmed.

For the purpose of robustness and sensitivity check of the results found, a secondary analysis was also performed (Mixed-effect model), and virtually identical results were seen in comparison to the ones presented from the repeated measures ANOVA test (Appendix 3).

The changes in questionnaire score over time were analyzed using a paired t-test. The Bonferroni method was applied to adjust for multiple comparison tests.

Additionally, quantitative analysis was performed in the frequency of the responses related to guardian's perceived understanding and to the multiple-choice questions derived from the PPEET. The multiple-choice question results were collected and organized in tables and graphs as presented in section 5.2.2 of this thesis.

A statistical expert was consulted to ensure appropriateness of the chosen statistical techniques and to effectively address potential confounding factors in this thesis.

4.8.2 Qualitative Analysis

The PPEET results were examined by both quantitative and qualitative perspectives to deeply review the patient engagement strategy taken in this study. The answers obtained from the open-ended questions were coded by the thesis candidate, and a thematic analysis was performed following the guidelines by Braun and Clarke (2008). NVivo 12 was used to organize the data, codes, and themes, and all the above data is presented in Chapter Five. Data saturation was achieved and established due to the sample characteristics, which included different perspectives and backgrounds (patient with lived experience, family member/caregiver, staff members and research team member).

All the electronic data collected during this project was stored in an encrypted, password-protected, secured network. Moreover, all paper data (questionnaires) were stored in a locking

file cabinet in the Pediatric Spine Clinic at the Alberta Children's Hospital, to which only authorized specific research team members had access. Additionally, all data collected and used in this project was de-identified and participant confidentiality was always ensured. Data will be retained for five years counting from the completion of this project as per the University of Calgary Research Ethics Board guidelines.

This chapter provided an overview of the methodology, including the strengths, limitations, potential bias, and opportunities to overcome biases associated to the study's design, as well as details about the literature review performed, the patient engagement strategy and evaluation, the co-development of the educational video, and the strategies and tools implemented to test the research hypothesis.

Chapter Five provides a comprehensive examination of the quantitative and qualitative results of this study, including guardian's questionnaire scores at T1, T2 and T3 for both Pathways A and B, along with potential changes in knowledge acquisition over time. Additionally, this chapter includes the results of the PPEET and the guardian's perceived understanding after each teaching module.

Chapter Five

RESULTS

In this chapter, the results obtained from this pilot project are presented according to each methodological approach (quantitative and qualitative) with the objective of respecting the unique nature of each type of data, enhancing the overall clarity and organization of the findings.

5.1 Quantitative Results

5.1.1 Results from Research Subjects

A cohort of eighteen guardians participated in this project. Seventeen of those completed all times proposed for either Pathway A or B, and one guardian (assigned to Pathway A) asked to be removed from the study after completing RN teaching at T2 due to personal commitments and unavailability of time to conclude their participation. Since this participant was not able to fully complete the questionnaire at T2 or T3, their data was removed from the study's dataset, and it was not accounted for during the results analysis.

Participants were randomly assigned to either Pathway A or Pathway B, with a randomization protocol deviation occurring in two cases. In these instances, two guardians participated in the same surgical discussion process, meaning that they were randomized as a "pair" and both assigned to the same pathway for logistic reasons. This did not alter the randomization process itself but rather created minor protocol deviation. Consequently, this study cannot use the term "randomization" without the preceding explanation.

5.1.1.1 Descriptive Statistics

Among the total of seventeen participants, eleven (65%) were guardians of patients with AIS. Additionally, six participants were guardians of patients with Neuromuscular scoliosis, accounting for 35% of the participant sample. No guardians of patients with other types of scoliosis (such as Syndromic or Congenital) were observed in our sample. Eight participants were assigned to Pathway A and nine to Pathway B.

When looking at the participants distribution within each pathway, Pathway A presented 63% (N=5) female participants and 37% (N=3) males, while Pathway B had 56% (N=5) females and 44% (N=4) males.

The study participants presented a diverse age range, from 39 to 72 years, with a mean of 46 years old. Six ethnic backgrounds were described in this study (African, Afro-Caribbeans, Asian, Asian-Canadian, Caribbean and Caucasian), with the majority self-reporting as Caucasian (70.6%), followed by 5.9% of the sample in each of the other five categories.

A total of thirteen participants provided information concerning their educational background. Among these individuals, 84.6% had successfully completed post-secondary education, while 7.7% held postgraduate qualifications. Additionally, the remaining 7.7% of participants completed education up to secondary level.

The statistics discussed above were described according to each pathway distribution, summarized in Table 1.

Table 1: Descriptive statistics comparing the demographic aspects from guardians in both Pathway A and Pathway B		
Pathway	**A**	**B**
Variable	**N** (%)	**N (%)**
Type of Scoliosis		
AIS	7 (87.50%)	4 (44.44%)
Neuromuscular	1 (12.50%)	5 (55.56%)
Guardian Age	49.5	50.22
Guardian Gender		
Female	5 (62.50%)	5 (55.56%)
Male	3 (37.50%)	4 (44.44%)
Guardian Ethnicity		
African	1 (12.50%)	0 (0%)
Afro-Caribbean	0 (0%)	1 (11.11%)
Asian	1 (12.50%)	0 (0%)
Asian-Canadian	1 (12.50%)	0 (0%)
Caribbean	0 (0%)	1 (11.11 %)
Caucasian	5 (62.50%)	7 (77.78%)
Guardian Education		
Post-secondary	5 (71.43%)	6 (100%)
Postgraduate	1 (14.29%)	0 (0%)
Secondary	1 (14.29%	0 (0%)

5.1.1.2 Statistical Analysis

In this study, a quasi-experimental repeated measures design was employed to investigate the impact of different intervention groups (Pathway A vs Pathway B), at three different time points (T1 to T2, T1 to T3 and T2 to T3) on the following measured outcomes (questionnaire scores and possible knowledge acquisition over time).

An analysis of the guardians perceived understanding results and the closed-ended questions of the patient engagement evaluation is also presented in this section.

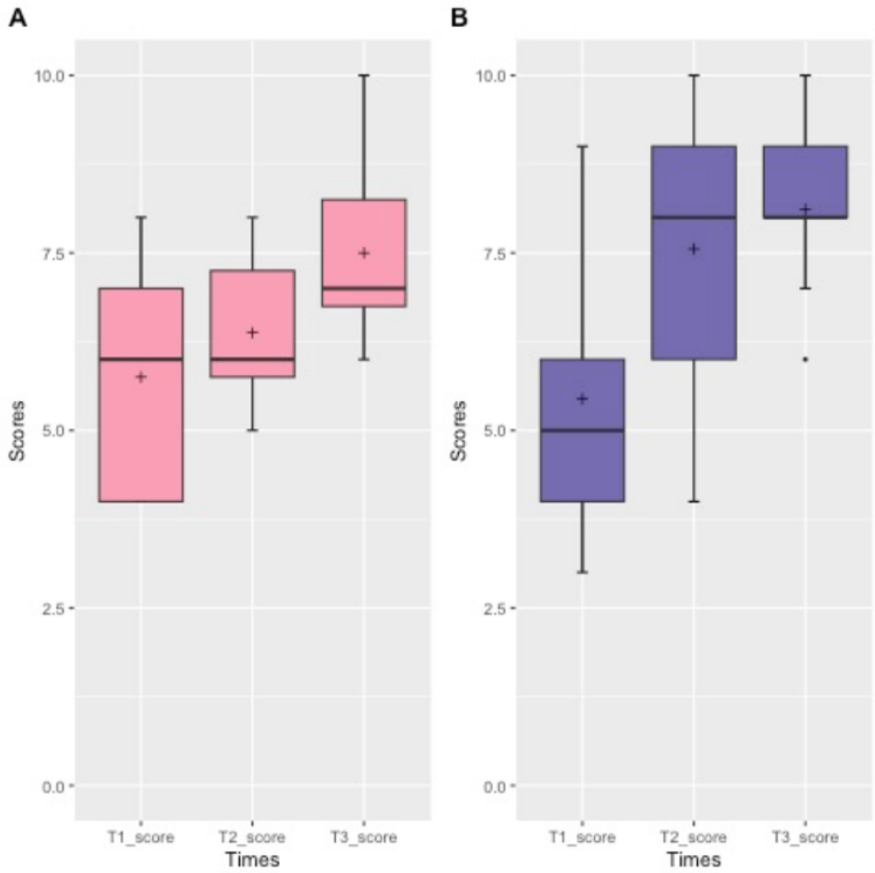
Analysis of Variance, ANOVA

Table 2 and Figure 12 illustrate the results found from the repeated measures ANOVA. The analysis of variance revealed that the main effect of "Pathway" was not statistically significant ($p>0.05$), suggesting that the observed differences order of intervention implemented in each pathway were not pronounced. However, the main effect of "Times" presented a significant result ($p<0.05$), indicating a substantial temporal progression on the outcome (knowledge acquisition over time). Moreover, the interaction between "Pathway" and "Times" was not statistically significant ($p<0.05$), supporting the notion that knowledge acquisition over time was consistent independent of the different order of intervention implemented in each pathway.

Table 2: Repeated measures ANOVA results for the effect of "Pathway" and "Times", and their interaction					
Effect	**DFn**	**DFd**	**F**	***p-value***	**ges**
Pathway	1	15	0.56	0.466	0.024
Times	2	30	15.356	0.0000256*	0.252
Pathway:Times	2	30	1.737	0.193	0.037

*Statistically significant ($p<0.05$)

Figure 12: Box plots representing the statistical analysis of questionnaire results for Pathway A and B at T1, T2 and T3.



Paired t-test

In order to evaluate further the possible dynamics of different times within each pathway, a paired t-test was conducted, as well as the Bonferroni method to adjust p-value and to help mitigate the chances of finding significant results by chance alone (Type 1 error) when conducting multiple tests. The results obtained are displayed on Table 3.

Table 3: Results from paired t-test (adjusted for Type 1 error with the use of Bonferroni method) regarding score differences in "Times" for Pathway A and B

Pathway	Time score	Time score	t-value	df	p-value	p-value adjusted
A	T1	T2	-2.37595	7	0.049	0.148
A	T1	T3	-4.78191	7	0.002	0.006*
A	T2	T3	-2.82594	7	0.026	0.077
B	T1	T2	-2.46317	8	0.039	0.117
B	T1	T3	-3.57771	8	0.007	0.022*
B	T2	T3	-1.47442	8	0.179	0.537

*Statistically significant ($p<0.05$)

Table 3 presents statistically significant improvement in score from T1 to T3 for both Pathway A and B when looking into the adjusted p-value (Bonferroni method), meaning that there was significant knowledge acquisition overtime, independently of the Pathway followed (A- baseline knowledge, followed by nursing teaching, augmented with the video tool; or B- baseline knowledge, followed by the video tool, augmented with the nursing teaching).

Comparisons within Pathway A

Non-significant knowledge improvements can be observed when comparing the score obtained from T1 to T2 (adjusted p-value= 0.148) and from T2 to T3 (adjusted p-value= 0.077). It is important to observe the effect of the Bonferroni method, particularly in the comparison between T1 and T2. Initially, a statistically significant p-value of 0.049 ($p<0.05$) was observed, but this significance was attenuated in the adjusted p-value, which increased to 0.148, indicating a lack of statistical significance. However, the comparison scores from T1 to T3 demonstrates a significant difference (adjusted p=0.006), aligning with the significant main effect of "Times" observed during the ANOVA test.

Comparisons within Pathway B

Similar non-significant results were observed when examining knowledge improvement between T1 and T2 (adjusted p-value= 0.117) and between T2 and T3 (adjusted p-value =0.537) on Pathway B. As was observed on Pathway A, the improvement in scores from T1 to T3 was significant (adjusted p-value= 0.022), supporting the results of improvement over time seen on the ANOVA analysis.

Overall, the pairwise comparisons presented above complemented the ANOVA test results, reinforcing the impact of multiple interventions through time on the final knowledge acquisition for both pathways.

Guardian's Perceived Understanding Results

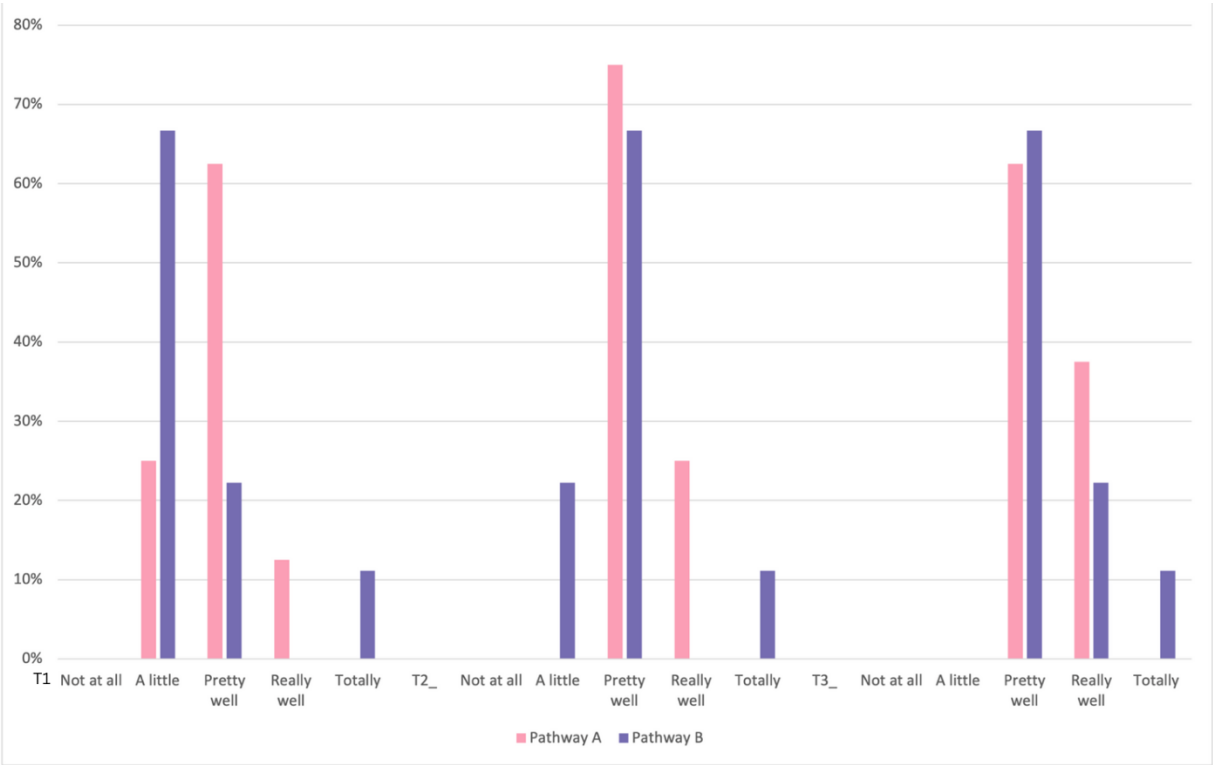
As outlined earlier in this thesis, the validated Theologis questionnaire, administered to the study participants, included one multiple-choice question aiming to look at the guardian's

perceived understanding after each intervention. Participants could choose their level of understanding from options including “not at all”, “a little”, “pretty well”, “really well”, and “totally”, and the results obtained are detailed in Table 4 and Graph 1 below:

Table 4: Frequency of answers seen from guardian’s perceived understanding between Pathway A and B, when asked about their perceived understanding of the content included in the surgical discussion at T1, T2 and T3 N(%)

Pathway	A			B		
Variable	T1	T2	T3	T1	T2	T3
Not at all	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
A Little	2 (25%)	0 (0%)	0 (0%)	6 (66.6%)	2 (22.2%)	0 (0%)
Pretty well	5(62.5%)	6 (75%)	5 (62.5%)	2 (22.2%)	6 (66.6%)	6 (66.6%)
Really well	1 (12.5%)	2 (25%)	3 (37.5%)	0 (0%)	0 (0%)	2 (22.2%)
Totally	0 (0%)	0 (0%)	0 (0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)

Graph 1: Guardian's perceived understanding of the content included in the surgical discussion at T1, T2 and T3, for Pathway A and B.



When looking into the Graph 1, a particular focus can be given on the pattern and trends observed in guardians' responses across different time points (T1, T2 and T3) for both Pathway A and B.

Results within Pathway A

Participants enrolled in Pathway A displayed a positive trend with sustained improvement in their perceived understanding over time. This can be noticed as their answers progressed from some feelings of "a little" understanding at T1 to the total number of participants shifting their perception to "pretty well" and "really well" at T2. These answers were

sustained at T3, with a higher number of guardians moving to “really well” at this time. The trends seen in this pathway suggest not only improvement, but also an evolving sense of confidence and assurance acquired over time.

Results within Pathway B

Answers from participants in Pathway B also demonstrate an upward favorable trend, with a visible transition from a majority answering “a little” at T1 to “pretty well” at T2. The subsequent shift to exclusively “pretty well” and “really well” suggest a sense of progress and confidence.

5.1.2 Public and Patient Engagement Evaluation Tool (PPEET) Results from Patient Partners, Staff Members and Research Team

A total of five members participated in the survey evaluation. Out of those participants two were patient partners, two were staff members directly involved in the patient engagement strategy, and one was the primary researcher (thesis candidate). The results obtained from this survey will be analyzed in two separate sections: 1) this first section will investigate the results from statements where the participants were asked to rate their level of agreement in response to a specific declaration (quantitative); 2) this second section will provide details of the thematic analysis performed for the open-ended questions requesting participants for comments or feedback (Section 5.2 – qualitative analysis).

5.1.2.1 Survey Results

Table 5 summarize and illustrate the level of agreeability participants had to specific statements.

Table 5: Results from Patient Engagement Evaluation Survey, indicating participants' level of agreeability to specific statements N(%)					
PPEET statements	Response options				
	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
I had a clear understanding of the purpose of this project	5 (100%)	-	-	-	-
The support I needed to participate were available	5 (100%)	-	-	-	-
I had enough information to contribute to the topic being discussed	5 (100%)	-	-	-	-
I was able to express my views freely	5 (100%)	-	-	-	-
I feel that my views were heard	3 (60%)	2 (40%)	-	-	-
A wide range of views on the topics discussed was shared	3 (60%)	1 (20%)	-	-	-

The individuals participating in this project represented a broad range of perspectives on the topic	2 (40%)	-	2 (40%)	-	-
I think that this project achieved its objectives	4 (80%)	-	-	-	-
I am confident the input provided through this initiative will be used by the research team	4 (80%)	1 (20%)	-	-	-
I think the input provided through this activity will make a difference to the work of the organization	4 (80%)	1 (20%)	-	-	-
As a result of my participation, I am better informed about the current efforts the Orthopedic Pediatric Spine team is making to improve their practices	4 (80%)	1 (20%)	-	-	-
Overall, I was satisfied with this engagement initiative	3 (60%)	2 (40%)	-	-	-
This engagement initiative was a good use of my time	4 (80%)	1 (20%)	-	-	-

The responses provided in the above table offer valuable insights from the members involved in this engagement initiative, shedding a light on key aspects such as understanding, support, opportunity to express their views, diversity of perspectives, achievements from this initiative, and the perceived impact of their contributions.

Understanding and support

Participants unanimously (100% strongly agree) expressed a clear understanding of the purpose and idea behind this project, as well as the availability of support offered during their contribution.

Information and freedom of expression

All participants felt like they had sufficient information to allow their contribution during the video creation process. Moreover, they all strongly agreed to the statement "I was able to express my views freely", and continued to demonstrate positive answers when asked if their views were heard (60% strongly agree and 40% somewhat agree).

Diversity

The topic of diversity showed a split opinion, where half of the participants that answered this question (n=4) felt the absolute presence (strongly agree) of individuals with a diverse range of perspective in this topic, and the other half neither agreeing nor disagreeing to this statement.

Impact

The groups demonstrate confidence in the impact brought by this project, with the majority (80%) believing their input will be used by the research team and that this project will make a difference to AHS. Likewise, participants felt that this project also shows the efforts from the Pediatric Orthopedic Spine team in improving their practices.

Satisfaction

Every participant demonstrated positive sentiments regarding their satisfaction with this initiative, with 60% strongly agreeing and 40% somewhat agreeing. Additionally, the majority (80%) strongly agreed that their engagement was a good use of their time.

5.2 Qualitative Results

5.2.1 Thematic Analysis

The thematic analysis performed identified, collected, and analysed the common data originated from this specific dataset. The guidelines recommended from Braun and Clarke (2008) were implemented during this analysis.

The data obtained from six open ended questions were coded, followed by the identification of 4 main themes: (1) Importance of support, (2) patient involvement and engagement, (3) project impact, and (4) feedback and suggestions for improvement.

Importance of support

This theme demonstrated how the research environment was supportive, which assisted member and partners to share their thought on the research project and their own life experiences: *"I was comfortable sharing my thoughts with other members of the research team"*

and *"made it easier for myself, as a previous scoliosis patient, to voice my personal opinions regarding the video and to reflect on my previous care experiences"*.

Accessibility was also found as an important support component in this strategy, involving consideration and accommodation of partners' preferences in their collaboration *"I was able to share my views from the comfort of my own home and was given time to compile my thoughts and communicate them in a way that I was happy with".*

Patient involvement and engagement

The transparency and thoughtfulness of the team members during the strategy implementation was appreciated and appears as a facilitator of patient involvement and engagement *"incredibly personable and transparent about the project"*, "*Without her kindness, I think I would have been more reluctant to think back to a more intimidating/daunting point in my pediatric patient journey"*, and *"I received support and great feedback from different members of the team".*

Survey participants also highlighted how they felt valued during their participation in the project *"(the team) desire to get patient input was palpable", "made me feel like my role in this project mattered and that this was a good use of my time"*, and *"My feedback was always received well"*.

Project impact

Participants were very vocal on how they believe this project is creating an important and significant tool *"I think this project has created a valuable tool for patients and families preparing for what might be their first major surgery", "This video provides patients and families a valuable resource to repeatedly reference when preparing for surgery day"*, and

"Having a video for families to watch would be very beneficial for learning and retaining all of the information families need to know".

Multiple comments and feedback on the project strengths were provided throughout the survey *"biggest strength of the video was (the) utilization of patient voices to colour the information presented and ensure that the information that is prioritized in the video reflects that actual care priorities of the patients", "The inclusion of patients voice ensures that the content of the surgical discussion includes what is meaningful and important to the patients and their families, and not only to doctors", "Used a variety of teaching techniques: audio, written and visual",* and *"Good information. Clear and well put together"*.

One participant also commented on the impact of including patient engagement in health research *"patient engagement and partnership always improves research quality"*.

Feedback and suggestions for improvement

One important piece obtained from this survey and encouraged in this initiative was the possibility for all members to provide their final thoughts regarding their participation, as well as ideas for future improvement. Participants discussed their experience as being part of the team and their interaction with each other *"This was my first time being a part of a research team that included patient partners and I am very happy I had the chance to participate in this project and collaborate with them"* and *"(The research members were) very knowledgeable and easy to communicate with"*, as well as their feeling of working on this project *"Was great to be a part of the project"*.

Suggestions were made for improvement regarding further clarification on how their voice was incorporated *"I am not sure how my thoughts were incorporated into the tool"* and to

keep them more frequently posted about the modifications performed in the video tool *"provide patients with each iteration of the video as it was coming together".* Other participant also mentioned the will to connect further with other members during the research process "*If this project was not conducted during COVID, it would have been nice to offer in person meeting and joint discussion sessions during the script and video creation".*

When looking into next steps, their hopes for this project were also mentioned *"I hope this project can be expanded to other surgical specialties, allowing more patients and families to receive meaningful information about their own surgical procedure".*

Overall, this chapter provided a comprehensive analysis of the results obtained in this study (including knowledge acquisition over time, guardians' perceived knowledge, and data from the patient evaluation tool), respecting the particularities and distinct characteristics seen and applied in each methodological approach (quantitative and qualitative).

Chapter Six relates the impact of the Covid-19 pandemic, and how it directly affected some aspects of the study. Then, the study's findings are examined in detailed and discussed. Specifically, the study's limitations, potential implications, and applications to current medical practice, as well as recommendations for future research are reviewed. Dissemination, knowledge translation considerations, and a conclusion is also present in this final chapter.

Chapter Six

DISCUSSION AND CONCLUSIONS

This chapter begins by revising the broader context established by the pandemic and its direct effects on certain aspects of this research, as described in detail in Chapter Three. Subsequently, a detailed examination and discussion of the study's findings presented through Chapter Five unfold. Furthermore, this chapter also includes recommendations for future research, considerations for dissemination and knowledge translation, and concludes with a synthesis of key insights and contributions this thesis brings to the field.

6.1 Discussion of the COVID-19 context and its direct implications in this research

Overall, the impact of the COVID-19 pandemic in health care research was described in detail through Chapter Three. This project was significantly influenced by several factors, that directly impacted participant recruitment, data collection and the patient engagement strategy, including a substantial reduction in the availability of clinical and surgical services for non-urgent cases, limitations on the number of guardians accompanying children for consultations and medical procedures, hospital-imposed restrictions on elective surgeries, the redeployment of medical and nursing staff to frontline roles, a decline in patient and guardian confidence in the healthcare system, increased reluctance among patients and parents to attend non-urgent medical appointments, and a notable rise in burnout and mental health issues among medical professionals.

Over the period of approximately 45 months (since the establishment of the COVID-19 as a global pandemic by the WHO in March 2020 until the present day – December 2023), a

substantial accumulated backlog of surgical procedures was noticed in Alberta, including pediatric surgeries and consequently PSIF to manage scoliosis. As previously outlined in this thesis, the direct impact on participant availability significantly influenced recruitment, ultimately leading to the analysis of a relatively small sample size (17 participants), despite achieving a high adherence rate of 94.4% during the recruitment phase. This adherence rate was lower than 100% because one participant requested to be removed during the research conduction, citing a lack of available time to complete all necessary steps to provide accurate and measurable data.

In regard to the COVID-19 pandemic implications on the patient engagement strategy, its effects were seen especially due to the restrictions of in-person interactions. As presented in section 5.2.1, if it were not for COVID-19 health restrictions, patient partners would have appreciated the opportunity to engage in joint, in-person discussions with each other during the video co-design process. This desire demonstrates a preference for direct collaboration with fellow patient partners rather than solely communicating with research members without sharing their thoughts among themselves. Patient partners also express a desire for more frequent updates from the research team regarding each video modification performed. This wish for continuous and frequent communication could potentially have been addressed through scheduled in-person joint meetings if they were a viable and allowed option at that time.

6.2 Discussion of Findings

6.2.1 Quantitative Findings

The results displayed through section 5.1 of this thesis allow the discussion of the impact of different intervention pathways (A or B) on the outcome “knowledge acquisition over time”.

The ANOVA results showed that the difference between Pathway A and B was not statistically significant, indicating that the order of interventions applied in Pathway A (C at T2 and I at T3) presented similar results as Pathway B (I at T2, followed by C at T3), suggesting that one order of interventions was not superior to the other. However, the significant effect of "Times" demonstrates the temporal progression in knowledge acquisition in this study, independently of the pathway followed. Furthermore, the absence of significance in exploring the relationship between "Pathway" and "Times" strengthens the conclusion that the influence of multiple "Times" on knowledge acquisition occurred independently of the Pathway used. This implies that exposure to repeated teaching methods consistently yielded positive and significant results, regardless of the order of their implementation.

Additionally, the effect size included in Table 2 provides further information on the significance of the described findings. In the case of the "Pathway" variable and the interaction between "Pathway" and "Time", the small effect size presented in both results can indicate the minimal impact that each specific "Pathway" had on the outcome, as well as the limited impact that the described interaction had on the final results, reinforcing the non-significant differences presented. However, when looking into the variable "Times", the effect size is large, showing a more substantial impact of this variable on the outcome.

The paired t-test comparisons presented non-significant differences between questionnaire scores obtained from T1 to T2 and T2 to T3 for both Pathway A and B. However, when looking into improvement between T1 and T3, significant enhancement was noticed in both pathways, reinforcing the findings obtained from the ANOVA analysis that suggests the accumulated temporal aspect of subsequent interventions has a more significant influence on knowledge acquisition than the specific intervention pathway chosen.

Overall, the results presented above suggested that repeated teaching opportunities can provide positive outcomes regarding knowledge acquisition over time.

When comparing the results presented in this project to the ones described in Chapter Two (Literature Review), a considerable improvement can be noticed. Theologis et al. (2016) assessed children and guardian's understanding of the traditional (verbal) surgical consent for Adolescent Idiopathic Scoliosis by applying the same validated questionnaire used in this thesis. Their study concluded that patients and guardians only understood approximately 60% of the content presented in the surgical consent, while on this pilot project, after the implementation of both interventions (conventional – oral and multimedia - video), participants from Pathway A improved their questionnaire score from 57.5% at T1 to 75% at T3, while participants from Pathway B presented even better results going from 54.4% at T1 to 81.1% at T3. These findings underscore the potential for improvement in understanding of the pre-operative surgical consent by the introduction of the proposed intervention to the conventional pre-operative process.

The guardian's perceived understanding findings can reinforce the results presented above. In Pathway A, a positive trend was observed, indicating a significant temporal progression in their perceived knowledge acquisition over time. Higher improvement of perceived understanding was noticed specially between T1 and T3, reinforcing the idea of significant temporal progression observed in the statistical analysis. Similarly, in Pathway B, the shift from a majority answering "a little" at T1 to exclusively "pretty well" and "really well" at T3 underscores the perceive progress in knowledge acquisition overtime, once again reinforcing the significant findings regarding temporal progression noted through the analysis.

6.2.1.1 Quantitative Methodology Considerations

As described earlier, this project was conducted during the limitations imposed by the COVID-19 global pandemic, resulting in a recruited sample size of 17 participants for data collection. The small sample size warrants careful consideration of the findings discussed above. Smaller sample sizes can restrict the generalizability of the study findings due to the possibility of limited statistical power. Despite the efforts to minimize Type I error, such as applying the Bonferroni method, the presented results may be more susceptible to random variations.

6.2.2 Qualitative findings

The results obtained from the PPEET survey demonstrate the close alignment that this study had with the four CIHR guiding principles of patient engagement in healthcare research.

The PPEET has its questions strategically divided in four parts, that are also directly aligned with the CIHR guiding principles: Part A- Communication and Supports for participants, Part B- Sharing your views and perspectives, Part C- Impact and influence of the engagement initiative, and Part D- Final thoughts.

Examples of positive results reinforcing the four principles of inclusiveness, support, mutual respect, and co-building were extensively described and highlighted during the survey results review and thematic analysis presented in the fifth chapter of this thesis.

As discussed in the Literature Review, the significance and relevance of patient engagement approaches in healthcare research can directly influence critical outcomes, including the quality of care (Marzban et al. 2022). The central pilar of this thesis lies in the co-creation of an intervention tool with the aim of improving the pre-surgical discussion process, thereby enhancing patient safety and overall quality of care. The close alignment between the patient

engagement strategy employed in this study and the principles outlined by the CIHR is of paramount importance. This alignment ensures the development of a reliable, patient-centered, co-developed tool, reinforcing the dedicated efforts invested in conducting meaningful research throughout this project.

6.2.2.1 Qualitative Methodology Considerations

The study's patient engagement strategy limitations include the COVID-19 restrictions discussed earlier in this chapter, as well as the suggestions for improvement in their participation and possible continuous contribution into the next steps of this project (such as knowledge translation plan and implementation). These suggestions demonstrate that even during patient engagement initiatives that seem to be fully aligned with the CIHR four guiding principles, there is often room for improvement, and perhaps having patient partners also involved in the early stages of the patient engagement strategy could have mitigated those issues.

6.3 Implication of the Results

6.3.1 For Research

Several literature gaps were identified and presented in the second chapter of this thesis, and this research project was envisioned with the goal of bridging those gaps while contributing to the existing knowledge on the subject in several keyways.

This project presents the assessment of the creation of an educational video tool, aimed to advance the understanding and the improvement of the informed consent process in pediatric spinal surgery setting.

The video tool co-developed directly address the key elements that should be presented clearly on the surgical consent process (including the risk, benefits, alternative treatments, and general information about a specific surgical procedure), as well as facilitate its adequate understanding to deem the consent as valid. By assessing the comprehension and knowledge acquire after the application of this new intervention, this project offered valuable insights into possible patient- and guardian-friendly ways to improve the pre-operative surgical discussion process.

Moreover, failure to provide sufficient information and obtain a valid consent can jeopardize patients' autonomy, safety, and can be considered medical negligence. In this context, the co-creation of the multimedia video tool through a partnership with patient partners was seen as an effective communication strategy, particularly for pediatric patients and their guardians, ensuring the informed consent process aligns with the ethical and legal standards discussed earlier in this thesis.

The literature review emphasized the need for further evaluation on understanding of surgical consent in vulnerable populations, including pediatric patients. This project directly addresses this gap by focusing on pediatric patients undergoing PSIF to manage scoliosis, providing valuable insights into the comprehension levels and factors that influence informed consent in this specific context.

Furthermore, it is clear there is a gap in the literature comparing guardians' understanding of surgical consent using different information delivery methods, specially in the population studied in this project. The introduction of multimedia resources, such as video, was evaluated, providing comparative data and subsequent analysis of the potential benefits of utilizing multiple communication methods during this process.

The results presented in this study align with the existing literature findings that demonstrate significant improvement in patients' and guardians' perceived comprehension and satisfaction with the introduction of multimedia resources. These results assist with the recognition and validation of the impact of implementing multimedia tools to enhance understanding of the surgical consent, as well as its importance in optimizing and improving the informed consent process.

Additionally, the recognition that individuals may need repetition of information, including receiving more than one teaching opportunity for better comprehension and higher satisfaction, is a notable contribution of this project. These findings can inform the design the delivery of future interventions to accommodate multiple learning styles and preferences.

Next, the study addresses the gap in the literature by exploring the use of multimedia tools to improve the informed consent process specifically for pediatric spine patients undergoing PSIF. This project enriches the existing knowledge on the subject by focusing on a specific context and population, promoting improved approaches to effectively deliver information for pediatric spine patients and their guardians.

Lastly, the application of a patient-engagement strategy in this study aligns with the growing emphasis on patient- and family-centered care. This initiative promotes patient autonomy and shared-decision making, recognizing the importance of involving patients and their families in the co-development of tools and research that directly impact their care.

In addition, this project recently received the support from the Charlie Fischer fellowship in advancing patient- and family-oriented research, which will allow the further expansion of introducing multimedia tools into pediatric patient care settings, as well as continue to explore the findings obtained from this thesis.

6.3.2 For Clinical Practices

The results obtained in this project can also affect current clinical practices. This study revealed that most guardians start the pre-operative surgical discussion process with baseline knowledge level ranging from 54% to 57%. Following a single teaching module (either conventional – oral or multimedia -video), an improvement is seen, with comprehension levels reaching 63% to 75%. These numbers are slightly better than the ones described in the literature (Theologis et al. 2016), which were typically deemed at around 60%. Notably, a second educational session on the subject provided further knowledge acquisition, resulting in a significant rise (in comparison to the baseline values) in knowledge rates between 75% to 81%.

In today's medical setting, marked by limited appointment availability and persistent backlog of surgical procedures, the option to offer educational, user-friendly educational videos appears as an effective and valuable tool for enhancing knowledge and comprehension. These videos could be watched outside the hospital setting, allowing patients and guardians to view them at their own time and pace and as many times as needed. This would potentially not add to clinical appointment time or create a burden to the clinical schedule, potentially improving the preoperative surgical process with minimal to no downsides.

6.4 Dissemination of Results

The findings described in this thesis, such as the literature review, patient engagement strategies and results, are currently either already submitted for publication (Chapter Two) or are in the editing process to be submitted. Some findings described in this project were already presented in multiple conferences, (Canadian Spine Society Annual Conferences, Global Spine,

and ISOQOL), reaching a diverse target population (from orthopedic spinal surgeons to individuals involved in patient engagement strategies and patient partners).

6.5 Knowledge Translation Plan

One great advantage of this project is that this tool's creation and co-development included members of the Pediatric Orthopedic Spine team, who are the end users of this instrument. With that being said, the knowledge translation strategy would include uploading the video tool to a free online platform that could be easy accessed by patients and guardians currently on the waitlist for PSIF to manage scoliosis. The Pediatric Orthopedic Spine clinic could also have this video available on a tablet, that could be used by patients and guardians that do not have access to computer or smartphone devices to access its content while waiting for their appointment in the clinic waiting room.

Professional training workshops and peer-to-peer education will be encouraged, promoting continuous application of this tool into the Pediatric Orthopedic Clinical assessment by residents, fellows and medical students during their rotations in this service.

The dissemination on the existence of this tool could be done via posters in the clinic, as a QR code applied to the current clinical contact information given to patients, through AHS social media accounts and website, and with the help of patient partners to disseminate this information in other ways that they might see fit (such as Patient and Guardians Advocacy Groups).

Patient partners will also be consulted prior to the implementation of any knowledge translation activities, to ensure appropriateness of ideas and strategies.

Further efforts will also be done to translate the content of this video and to have it available in multiple languages and with subtitles, promoting a fair and inclusive access to its content to all populations of patients that are currently treated in the Pediatric Orthopedic Spine clinic.

6.6 Future Initiatives

The results and findings obtained in this study can be directly followed by opportunities for various future research and clinical initiatives.

6.6.1 For Research

The continuous implementation of this tool, as well as long term follow-up on the impact of this project can provide continuous information on understanding, satisfaction, and outcomes. Future research could investigate the effects that this tool could have on patients' and guardians' post-operative routine and adherence to processes, as well as patient reported outcomes and possible knowledge retention after a specific amount of time has passed from the educational sessions.

The improvement of the tool itself could also be done via technological advancements and software tools available. The current possibility of incorporating interactive elements, virtual reality, and tailored content (such as personal avatars) could improve further the benefits noticed in this pilot project.

A health economic analysis could also be conducted in the future, to evaluate the possible cost-effectiveness of implementing this educational video in the pre-operative discussion process. This assessment could investigate savings in terms of reduced medical and nursing

appointment times, improved patient, and guardian pre-operative preparation, and a decrease in medical-legal expenses related to possible medical negligence and enhanced outcomes.

6.6.2 For Clinical Practices

The idea of creating an animated video tool could be expanded to other pediatric orthopedic patient populations, as well as other medical specialties and adult sites. The beneficial aspects and positive feedback received during this study (by research subjects, patient partners, and other research members) is encouraging and demonstrates the possibility of improvement that could be expanded to other medical settings and surgical specialties.

Moreover, a multicentric collaboration would allow further evaluation of the impact of this tool in different settings, including rural areas, other provinces in Canada, and even other countries.

6.7 Conclusions

The results and findings provided by this thesis demonstrate the efforts of this project in co-developing a tool to improve the pre-operative surgical discussion process and to bridge existing gaps in the literature on this subject.

This project presented limited but optimistic results, representing the positive aspects of introducing a secondary educational opportunity to guardians and pediatric patients undergoing PSIF to manage scoliosis. Further research is recommended to more thoroughly assess and distinguish whether the positive outcomes resulted from repeated teaching opportunities, different teaching methods, or a combination of both.

The limitations regarding patient sample, influenced by the context in which this project was conducted, do not invalidate the results obtained, but rather encourage careful consideration of the findings presented in this thesis.

On a reflexive note, this project's approach concerning patient engagement, and the incorporation of patient partners throughout research projects to produce meaningful research, strengthens the concept of including patient's voice to improve healthcare system. The inclusion of these concepts in training and through continuous medical education could encourage more frequent use of similar approaches in health research conducted by physicians.

It is hoped that this project was the first of many educational initiatives to improve patient care and safety through patient-centered and share-decision making approaches.

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Appendix 1: The validated multiple-choice Theologis questionnaire

Age:
Gender:
Ethnicity:

What is your educational level?

1. What is the chance of injuring your child's nerves during the operation?
    a. 100%
    b. 50%
    c. 5%
    d. About 0.5%
    e. I do not remember hearing this information

2. Which of the following might be a reason for a second operation on your child's spine?
    a. The bones in his/her spine might not stick together
    b. Wound infection
    c. The metal rods may break or pull off his/her spine
    d. A, b and c
    e. I do not remember hearing this information

3. The chance of infection after your child's operation is?
    a. 100%
    b. 50%
    c. 10%
    d. 1-2%
    e. I do not remember hearing this information

4. All of the following are supposed to happen after your child's operation EXCEPT?
    a. The bones in his/her spine that are stuck together (or "fused") will not curve any more
    b. He/she will not be able to move where the bones in his/her spine are stuck together
    c. The fused part of the spine will not grow
    d. His/her bones could break easily and he/she can't play sports
    e. I do not remember hearing this information

5. During your child's operation
    a. He/she may get blood that came from someone else
    b. He/she may get bone that came from someone else
    c. Both a and b
    d. Neither a or b
    e. I do not remember hearing this information

6. After your child's operation
    a. He/she will have pain
    b. He/she will get pain medications
    c. His/her pain won't be that bad, and he/she probably will not need pain medications
    d. Both a and b
    e. I do not remember hearing this information

7. After your child's operation
    a. Someone (such as my nurse or a physical therapist) will help my child get out of bed on the next day
    b. He/she can walk right away
    c. He/she has to stay in bed the whole time in the hospital
    d. both a and b
    e. I do not remember hearing this information

8. After your child's operation
    a. He/she will have a tube (known as an "IV") in his/her arm
    b. He/she will have a tube (known as a "catheter") so he/she can pee
    c. He/she may be given oxygen to breathe
    d. He/she may have a tube (known as a "drain") in his/her wound
    e. All of the above

9. The rods in your child's back
    a. Help his/her bones stick together
    b. Help make his/her spine straighter
    c. Have to be taken out in a second operation later
    d. Both a and b
    e. I do not remember hearing this information

10. By the time your child becomes an adult
    a. There is a possibility that he/she may need another operation for his/her spine
    b. There is a possibility that he/she may have some pain in his/her back
    c. Her operation will not bother her when she has children
    d. Girls - a, b and c; boys - both a and b
    e. I do not remember hearing this information

11. How well do you think you understand the risks, benefits and expected results of your child scoliosis surgery?
    a. Not at all
    b. A little
    c. Pretty well
    d. Really well

Appendix 2: Public and Patient Engagement Evaluation Tool (PPEET)

Public and Patient Engagement Evaluation Tool (PPEET)

Version 2.0
August 2018

PUBLIC AND PATIENT ENGAGEMENT COLLABORATIVE

McMaster University

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The PPEET instruments are generic tools designed primarily to help organizations assess their engagement activities. The authors do not take responsibility for the improper use of the PPEET instruments.

Module A. One-time Engagement Activities

We are interested in your feedback about your participation during the creation of the animated video to assist with the surgical discussion process for scoliosis patients and their guardians.
The questionnaire includes 21 statements or questions – some questions ask you to rate your level of agreement in response to a statement and others ask for you to provide your comments and feedback. You are encouraged to share your experiences and any information you feel is relevant and will help us to improve our engagement processes.
We appreciate your feedback. It is critical to helping us improve our engagement processes. Please be aware that all of the information you provide will be confidential. Should you have any questions about this questionnaire, please contact

Thank you for your participation!

Background Information

1. What perspective did you bring to this project?
   - ☐ Patient/patient advisor/patient partner
   - ☐ Family member/caregiver
   - ☐ Staff member
   - ☐ Community member
   - ☐ Community partner
   - ☐ Others, please specify:

2. How long have you been working with AHS/University of Calgary as an employee or patient/family/community advisor?
   - ☐ Less than 6 months
   - ☐ 6 – 12 months
   - ☐ 1 – 2 years
   - ☐ 3 – 4 years
   - ☐ 5 years or more

Part A. Communication and Supports for Participation

Please indicate your level of agreement with each of the statements below.

3. I had a clear understanding of the purpose of this project:

☐ Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree

4. The supports I needed to participate were available (e.g., travel, childcare, etc.)

☐ Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree

5. I had enough information to contribute to the topic being discussed.

☐ Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree

6. What else would you like us to know about how your participation in this project was supported?

Part B. Sharing Your Views and Perspectives

7. I was able to express my views freely.

☐ Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree

8. I feel that my views were heard.

☐ Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree

9. A wide range of views on the topics discussed was shared.

☐ Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree

10. The individuals participating in this project represented a broad range of perspectives on the topic.

☐ Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree

11. What else would you like us to know about how you were able to share your views?

Part C. Impacts and Influence of the Engagement Initiative

12. I think that this project achieved its objectives.

☐ Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree

13. I am confident the input provided through this initiative will be used by the research team.

☐ Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree

14. I think the input provided through this activity will make a difference to the work of the organization.

☐ Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree

15. What else would you like us to know about the influence you think this project will have?

Part D. Final Thoughts

16. As a result of my participation, I am better informed about the current efforts the Orthopedic team I making to improve their practices.

☐ Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree

17. Overall, I was satisfied with this engagement initiative.

☐ Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree

18. This engagement initiative was a good use of my time.

☐ Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree

19. What were the strengths of the creation of this video?

20. What could be improved about this project approach?

21. What else would you like us to know about your experience with this research team/ research coordinator?

Thank you for your participation. If you would like to connect with a member of the organization to discuss your experience with this activity further, please contact

_____

Appendix 3: Results from ANOVA and Mixed Effect Model analysis performed in R demonstrating virtually identical results

```
> get_anova_table(res.aov)
ANOVA Table (type III tests)

       Effect DFn DFd      F        p p<.05   ges
1       Group   1  15  0.560 4.66e-01       0.024
2       Times   2  30 15.356 2.56e-05     * 0.252
3 Group:Times   2  30  1.737 1.93e-01       0.037
>
Analysis of Variance of Aligned Rank Transformed Data

Table Type: Analysis of Deviance Table (Type III Wald F tests with Kenward-Roger df)
Model: Mixed Effects (lmer)
Response: art(Scores)

                                                  F Df Df.res    Pr(>F)
1 factor(long_df$Group)                     0.39233  1     15   0.54049
2 factor(long_df$Times)                    15.37975  2     30 2.527e-05 ***
3 factor(long_df$Group):factor(long_df$Times)  1.98681  2     30   0.15477
---
Signif. codes:   0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
>
```