Centre universitaire de santé McGill | McGill University Health Centre

RESEARCH PROTOCOL

Study Title: The Impact of a Patient Education Tool on Parental Anxiety and Productivity: A Prospective Cohort Study

Principal Investigator: Sherif Emil, MD,CM, Professor & Director; Harvey E. Beardmore Division of Pediatric Surgery, The Montreal Children's Hospital, McGill University Health Centre

Co-investigators:
Hussein Wissanji, MD, MPH, Assistant Professor and Staff Surgeon; Harvey E. Beardmore Division of Pediatric Surgery, Montreal Children's Hospital, McGill University Health Centre

Julia Loyola, MD, Harvey E. Beardmore Division of Pediatric Surgery, Montreal Children's Hospital, McGill University

Nadia Safa, MD,CM, Resident, General Surgery, McGill University Health Centre

Study Coordinator: Elena Guadagno, Harvey E. Beardmore Division of Pediatric Surgery, Montreal Children's Hospital, McGill University Health Centre

1 BACKGROUND AND STUDY RATIONALE

1.1 Background

Terminology regarding how to measure the patient and family experience when a child receives medical or surgical care varies and includes patient-reported outcome measures (PROMs), patient-reported experience measures, and patient satisfaction.[1,2] Preoperative patient education and postoperative patient participation are key components of the multimodal enhanced recovery after surgery (ERAS) protocols, which are gaining force in elective surgical procedures and impact both surgical outcomes and patient-reported outcomes.[3-5] However, ERAS protocols and standardized care pathways have rarely been adopted in pediatric populations, and there exists a paucity of high-quality literature examining outcomes associated with implementation of enhanced recovery programs (ERPs) in children.[6,7] Pediatric ERAS implementation has been met with many hurdles, including accounting for physiological differences between adults and children, the divergence of specific disease incidences between adults and children, and bridging the knowledge from adult pathways to pediatric-specific diseases which have no adult analogs.[8] Therefore, specific pediatric preoperative patient/family education and postoperative patient/family participation needs to be developed to achieve reliable pediatric ERAS protocols. Medical procedures are considered especially stressful for children and parents[9]. From over 5 million children that undergo elective surgery in North America each year, almost 75% of them experience considerable anxiety[9]. Child anxiety is associated with many problems beginning with less cooperation with the anesthetic procedure, higher needs for analgesic usage, post-operative pain, slower recovery, delays in hospital discharge, and changes in behavior during the post-operative period. Also, preoperative anxiety can affect children's future interactions with medical personnel representing a long-term consequence. A major risk factor for children's distress is parental anxiety, which is also linked to physical and mental health problems for parents themselves[9]. Based on these findings, different interventions have been studied in an attempt to reduce the burden for families. Audiovisual interventions for parents whose children were undergoing elective surgery had positive effects on both parental and children's preoperative anxiety[9]. However, there has been no study on interventions to reduce parental anxiety during a child's surgical emergency.

Moreover, there has been little research, both in adults and in children, on the applicability and effectiveness of these same ERAS protocols for patients undergoing emergency surgery.[10] Many of the limitations in acute care surgery come from the unpredictability of the timing for surgery and the variability of preoperative care, making it difficult to standardize postoperative care and offer perioperative counseling.

Although there are high numbers of surgical procedures performed in children, the impact on caregivers and families is poorly described. In the context of transitioning to same-day or early post-operative discharges, parents are facing the responsibility of having to care for their child early in the recovery process. This can lead to significant indirect costs associated with loss in productivity at work and at home, and increase caregiver anxiety and caregiver demands. The

magnitude of these indirect costs and loss in productivity has never been measured in a pediatric surgical setting. In reference to the ERAS guidelines, specifically the pillar of preoperative counseling and education, our aim in this research study is to implement an education tool, developed in collaboration with the McGill University Health Center Patient Education Office, for patients and caregivers in both elective and emergency surgical contexts and report its impact on indirect costs and caregiver productivity during the post-operative period. We hypothesize that by providing consistent and accessible information to patients and caregivers we may minimize anxiety, maximize satisfaction, and mitigate caregiver productivity loss during the post-operative recovery period, specifically within 2 weeks of discharge from the hospital.

We aim to examine the impact of a patient education tool in both the emergency and elective surgical settings:

1.1.1 Emergency Surgery - Appendectomies

We have chosen appendectomies for acute appendicitis as the emergency surgical setting given that appendicitis is one of the most common causes of acute abdominal pain, with a lifetime risk of 8.6% in males and 6.7% in females and has the highest incidence in children aged 10-19 years old. [10,11] Laparoscopic appendectomy performed within the first 24 hours of diagnosis is the standard treatment for acute appendicitis, and hospital admission varies based on whether or not the appendix has perforated, with patients with simple appendicitis going home the same day or the day following operation.[12,13] Around 25-30% of appendicitis presents with perforation and those patients require a longer hospital admission.[14,15] At the Montreal Children's Hospital (MCH) we perform approximately 300 appendectomies for acute appendicitis per year.

1.1.2 Elective Surgery – Inguinal and Umbilical Hernias

For the elective surgical setting, we have chosen to target patients with umbilical and inguinal hernias who are booked for elective surgical repairs. Inguinal hernias occur in approximately 3-5% of term infants and 13% of infants born at less than 33 weeks gestational age.[16] Inguinal hernias are commonly repaired to avoid incarceration of the hernia, and at the MCH we perform approximately 240 inguinal hernia repairs per year. Umbilical hernias are also one of the more common pediatric conditions, occurring in approximately 1 in every 6 children.[17] However, they are more likely to close spontaneously and resolve without surgery than inguinal hernias. Nevertheless, some umbilical hernias do cause symptoms and may also fail to regress, thus necessitating surgical repair. At the MCH, we perform approximately 140 umbilical hernia repairs per year.

We hope that by testing the impact of education tools on such a large sample of patients, we will demonstrate an accurate measure of our primary outcome and continue to improve our patient-centered care practices in the realm of pediatric surgery. Furthermore, we believe that this study will serve as further evidence in support of a movement towards ERAS protocols and standardized care pathways in pediatric surgical centers.

2 OBJECTIVES, HYPOTHESIS AND STUDY QUESTIONS

2.1 Objectives

- Create education tools for patients and caregivers to educate them on the diagnosis, surgical management, and post-operative recovery process for acute appendicitis, umbilical hernias, and inguinal hernias.

- Test whether the education tool reduces parental anxiety and improves satisfaction with care during a child's surgical illness.

- Test whether the education tools impact caregiver productivity loss in the immediate post-operative period, specifically 10-14 days post-discharge.

2.2 Hypothesis

We hypothesize that implementing an education tool for patients and caregivers will decrease parental anxiety, improve satisfaction, and mitigate productivity loss among caregivers after hospital discharge.

2.3 Study Question

Does the implementation of an education tool for patients and caregivers decrease preoperative parental anxiety and caregiver productivity loss in the post-operative period in the realm of pediatric surgery?

3 STUDY METHODS

This study is a collaboration between the Harvey E. Beardmore Division of Pediatric Surgery and the Patient Education Office, with whom we have developed a plain-language patient education tool for appendectomies.

This study has several phases, which will be similar for all three surgical procedures. For convenience, the phases have been described in relation to the first surgical procedure that will be examined, namely appendectomy:
This study has several phases:

1. Pilot Phase (2-3 weeks) – Validation of Questionnaire
    - A convenience sample of 5 patients with acute appendicitis and their families will be selected during their routine postoperative visits to provide input on the questionnaire. The preliminary questionnaire is attached, and was developed by the authors based on the Amsterdam Preoperative Anxiety and Information Scale (APAIS), Productivity and Disease Questionnaire (PRODISQ), the Health and Labor Questionnaire (HLQ), and a literature review.[18-21]
    - A convenience sample of 5 surgeons and 5 nurses will also be solicited to provide feedback.
    - The questionnaire will be adapted based on qualitative feedback from the participants listed above.

2. Pre-Implementation Phase (100 patient/approx. 6 months)
    - All patients with acute appendicitis who undergo appendectomies will be eligible to participate, and families will be consented prior to surgery. The parental anxiety assessment will be done only before surgery with the Amsterdam Preoperative Anxiety and Information Scale (APAIS). In addition, the email of one of the primary caregivers will be collected, and the caregiver will receive an email with a link to the post-operative questionnaire 10 days post-discharge. At 14 days post-discharge, they will receive a reminder email with the link to the questionnaire. All responses to the questionnaire are voluntary and anonymous.

Before Surgery	Obtain Consent
	Amsterdam Preoperative Anxiety and Information Scale (APAIS)
	Collection of email of primary caregiver
10 days Post-operative	Link to Parental Productivity Survey will be sent
14 days Post-discharge	Reminder email with link to the questionnaire will be sent.

3. Post-Implementation Phase (100 patient/approx. 6 months)
    - The education tool will be distributed to families whose child is undergoing an appendectomy. The parental anxiety assessment will be done in the same way as above, only before surgery with the Amsterdam Preoperative Anxiety and Information Scale (APAIS). In addition, the email of one of the primary caregivers will be collected, and the caregiver will receive an email with a link to the post-operative questionnaire 10 days post-discharge. At 14 days post-discharge, they will receive a reminder email with the link to the questionnaire. All responses to the questionnaire are voluntary and anonymous.

Before Surgery	Obtain Consent
	Amsterdam Preoperative Anxiety and Information Scale (APAIS)
	Collection of email of primary caregiver
10 days Post-operative	Link to Parental Productivity Survey will be sent & Link to Patient Education Tool Survey will be sent
14 days Post-discharge	Reminder email with links to the questionnaires will be sent.

3.1 Study Population

3.1.1 Inclusion criteria:

- Primary caregivers of all pediatric patients (0-17 years old) with **acute appendicitis**, including both perforated and non-perforated appendicitis cases, who have undergone an **urgent** appendectomy.
- Primary caregivers of all pediatric patients (0-17 years old) with **umbilical** or **inguinal hernias** who have undergone an **elective** surgical repair.

3.1.2 Exclusion criteria:

- Patient or family does not understand English or French (education material available in only these two languages).
- Patient presenting for an elective interval appendectomy.
- Patient presenting with an incarcerated or strangulated hernia requiring emergency surgical repair.

3.2 Period studied

We anticipate a period of enrollment of approximately 6 months for each surgical procedure, as specified above in Section 3. We will aim to have 100 patients for the Pre-Implementation Phase & 100 patients for the Post-Implementation Phase.

3.3 Description of data being retrieved

For each patient, we plan to collect answers from the circulated questionnaires, which will include questions related to the child and caregiver. This survey will not collect any identifiable information. However, we will collect some patient/parent information including:

- Age of the child and caregiver
- Relation of the caregiver to the child
- Caregiver's education level
- Caregiver's yearly income
- Caregiver's work hours

To assess indirect resource use (productivity losses) we will collect the following information:

- Hours absence from paid or unpaid job
- Loss of leisure time and sleep
- Access to compensated or uncompensated help at home
- Number of follow ups with medical personnel during the child's recovery
- Utility of education tool

3.4 Duration of the study

The study is expected to last approximately 12-24 months, depending on recruitment.

4 DATA ANALYSIS

The primary outcome that will be assessed is the loss of parental productivity measured in hours of paid or unpaid work missed due to caring for a child in the post-operative recovery period in caregivers who received the education tool compared to those who did not. Secondary outcomes that will be assessed include: household income (dollar amount) lost due to indirect productivity losses, hours of sleep lost, hours of leisure time lost, number of times that medical assistance is sought in the post-operative period, and need for compensated or non-compensated help at home.

Bivariate analysis will be performed using 2 sample t-tests for dichotomous predictor variables, Fisher's exact test or one-way ANOVA for categorical predictor variables, and Pearson correlation for continuous predictors where appropriate. A p-value of < 0.05 will be deemed statistically significant.

5 ETHICAL CONSIDERATIONS

5.1 Oversight

This study will be conducted in accord with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2018), as well as in respect of the requirements set out in the applicable standard operation procedures of the Research Institute of the McGill University Health Centre Research Institute and of the McGill University Health Centre Research Ethics Board. The McGill University Health Centre Research Ethics Board will review this study and will be responsible for monitoring it at all participating institutions in the health and social services network in Québec.

5.2 Confidentiality

Only data relevant to this study as outlined in this protocol will be collected by the research team. All the information collected during the research project will remain confidential to the extent required and provided by law.

The data collected from the online surveys will be stored in a digital file on a password protected computer behind the MUHC firewall for 7 years following the completion of the study. The data will then be destroyed. No personal or identifiable information will be collected from patients.

We foresee no ethical issues that would prevent the conduct of this study. The patient education tool is being implemented as part of a continuous process for ongoing improvement in our pediatric surgery division, with the ultimate goal of providing the highest quality of patient- and family-centered care. Survey participation is voluntary and anonymous, with no negative impact from non-participation. This study does not change the current clinical practice guidelines for appendicitis.

5.3 Informed consent

All patients and their families who undergo an operation for acute appendicitis, umbilical hernia, and inguinal hernia will be eligible for the research study and invited to complete the anxiety scale and to take the survey 10 days after discharge from the hospital. Informed consent will be obtained prior to surgery. The primary caregiver will be asked to provide us with their email address.

They will be emailed a link to an online questionnaire(s) 10 days after their discharge. They will be emailed a reminder email and link to the online questionnaire 14 days after discharge.

The answers collected from questionnaire will be anonymous, and no patient identifiable information will be collected. However, we will be collecting some sensitive information about the caregiver, including their average annual income. Furthermore, we require their email addresses to facilitate the distribution of the online surveys one week post-discharge of the child. Therefore, we will obtain informed consent from the patient and caregiver during the patient's hospitalization.

Participation in the survey is anonymous. This means that although emails will be obtained to facilitate the distribution of the surveys, the answers will not be linked to the patient or caregiver's emails and therefore the research team will not be able to trace the answers back to the patients or caregivers. This ensures patient and caregiver anonymity.

6 DISSEMINATION PLANS

The results of this study will be used for publication. It will also be used to improve the educational materials and culture of patient and family-centered care at our hospital. Results are also projected to be available to present at relevant conferences.

7 REFERENCES

1. Frank L, Basch E, Selby JV, Patient-Centered Outcomes Research I. The PCORI perspective on patient-centered outcomes research. *JAMA.* Oct 15 2014;312(15):1513-1514.
2. Martin NE, Massey L, Stowell C, et al. Defining a standard set of patient-centered outcomes for men with localized prostate cancer. *Eur Urol.* Mar 2015;67(3):460-467.
3. Thiele RH, Rea KM, Turrentine FE, et al. Standardization of care: impact of an enhanced recovery protocol on length of stay, complications, and direct costs after colorectal surgery. *J Am Coll Surg.* Apr 2015;220(4):430-443.
4. Lv L, Shao YF, Zhou YB. The enhanced recovery after surgery (ERAS) pathway for patients undergoing colorectal surgery: an update of meta-analysis of randomized controlled trials. Int J Colorectal Dis 2012; 27: 1549-54.
5. Spanjersberg WR, Reurings J, Keus F, van Laarhoven CJ. Fast track surgery versus conventional recovery strategies for colorectal surgery. Cochrane Database Syst Rev 2011; 2: CD007635.
6. Leeds IL, Boss EF, George JA, Strockbine V, Wick EC, Jelin EB. Preparing enhanced recovery after surgery for implementation in pediatric populations. *J Pediatr Sur*. 2016; 51: 2126-2129.
7. Shinnick JK, Short HL, Heiss KF, et al. Enhancing recovery in pediatric surgery: a review of the literature. J Surg Res 2016;202(1):165–76.
8. Short HL, Heiss KF, Burch K, Travers C, Edney J, Venable C, Raval MV. Implementation of an enhanced recovery protocol in pediatric colorectal surgery. J Pediatr Surg. 2018; 53: 688-692.
9. CHOW ET AL. Impact of AV on Parental Preoperative Anxiety: A Systematic Review and Meta-Analysis. Health Psychology, 2018, Vol. 37, No. 8, 746–758.
10. Paduraru M, Ponchietti L, Casas IM, Svenningsen P, Zago M. Enhanced Recovery after Emergency Surgery: A Systematic Review. *Bull Emerg Trauma*. 2017; 5(2): 70-78.
11. Buckius MT, McGrath B, Monk J, Grim R, Bell T, Ahuja V. Changing epidemiology of acute appendicitis in the United States: study period 1993-2008. *J Surg Res.* Jun 15 2012;175(2):185-190.
12. Al-Omran M, Mamdani MM, McLeod RS. Epidemiologic features of acute appendicitis in Ontatio. *Canada. Can J Surg.* 2003; 46: 263.
13. Aguayo P, Alemayehu H, Desai AA, Fraser JD, St Peter SD. Initial experience with same day discharge after laparoscopic appendectomy for nonperforated appendicitis. *J Surg Res.* Jul 2014;190(1):93-97.
14. Cameron DB, Williams R, Geng Y, et al. Time to appendectomy for acute appendicitis: A systematic review. *J Pediatr Surg.* Nov 20 2017.
15. Cheong LH, Emil S. Determinants of appendicitis outcomes in Canadian children. *J Pediatr Surg.* May 2014;49(5):777-781.
16. Cheong LH, Emil S. Outcomes of pediatric appendicitis: an international comparison of the United States and Canada. *JAMA Surg.* Jan 2014;149(1):50-55.
17. Wang KS, Committee on Fetus and Newborn, Section on Surgery. Assessment and Management of Inguinal Hernia in Infants. Pediatrics. Oct 2012; 130(4): 768-773.

18. Katz D. Evaluation and Management of Inguinal and Umbilical Hernias. *Pediatric Annals*. Dec 2001; 30(12): 729-735.
19. Koopmanschap MA. PRODISQ: a modular questionnaire on productivity and disease for economic evaluation studies. Expert Rev Pharmacoeconomics Out- comes Res 2005;5(1):23–8.
20. Van Roijen L, Essink-Bot ML, Koopmanschap MA, Bonsel G, Rutten FFH. Labour and health status in economic evaluation of health care: the Health and Labour Questionnaire. Int J Technol Assess Health Care 1996;12:405–15.
21. Wolleswinkel-van den Bosch JH, Stolk EA, Francois M, Gasparini R, Brosa M. The health care burden and societal impact of acute otitis media in seven European countries: Results of an Internet Survey. *Vaccine*. 2010; 28S: G39-G52.
22. Wolleswinkel-van den Bosch JH, Speets AM, Rümke HC, Gumbs PD, Fortanier SC. The burden of varicella from a parent's perspective and its societal impact in the Netherlands: an Internet survey. *BMC Infectious Diseases*. 2011; 11:320.
23. Moerman et al. The Amsterdam Preoperative Anxiety and Information Scale (APAIS). 1996 Anesth Analg 1996; 82:445-51