

Evaluation of a Rectal Cancer Patient Decision Aid and the Factors Influencing its
Implementability in Clinical Practice

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Dr. Robert Wu is the principal author of the thesis, including the conception, design, data acquisition, analysis, and interpretation.

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Abbreviations

AHRQ: Agency for Healthcare Research and Quality

APR: Abdominoperineal resection

CAC: Cancer Assessment Center

CIHR: Canadian Institutes of Health Research

CSCRS: Canadian Society of Colon and Rectal Surgeons

DALI: Decision Aid Library Inventory

DCS: Decisional conflict scale

GRADE: Grading of Recommendations Assessment, Development and Evaluation

IPDAS: International Patient Decision Aid Standards

KtA: Knowledge to Action

LAR: Low anterior resection

ODSF: Ottawa Decision Support Framework

OHRI: Ottawa Hospital Research Institute

OHSN-REB: Ottawa Health Science Network Research Ethics Board

OPTION: Observer Patient Involvement in Decision Making

PtDA: Patient decision aid

QoL: Quality of life

SDM: Shared decision making

Thesis Abstract

A rectal cancer patient decision aid (PtDA) was developed to help patients consider the benefits and risks associated with two surgical treatment options. The current thesis evaluated the effect of the PtDA on patients and explored surgeons' perceived factors influencing the implementation of the PtDA in clinical practice.

Using a before and after study design, the PtDA was given to patients with rectal cancer at a cancer assessment center. Based on 28 patients recruited, the PtDA improved their knowledge, lowered decisional conflict, and patients rated it acceptable.

A cross-sectional survey was mailed to 105 Canadian colorectal surgeons and 49 responded (46.7% response rate). Commonly perceived barriers were time constraint, need for multiple visits, and additional personnel and facilitators were simplifying the decision aid, adding to content, and translating to other languages.

The PtDA improved patient decision making outcomes but requires interventions to overcome surgeon-identified barriers to use in clinical practice.

Chapter 1:

Introduction

This chapter provides the background and rationale for the two studies in the thesis, including a before and after evaluation of a rectal cancer decision aid and the survey exploring the facilitators of and barriers to its implementation. It also presents the overall purpose of the thesis and a brief outline of the chapters to follow.

1.1 Background and Rationale

Surgical options for rectal cancer: relevance of shared decision-making

Colorectal cancer is the third most common cancer accounting for 13% all new cancer diagnoses in Canada ¹. Rectal cancer comprises any tumor in the last 15 cm of the large intestine. The treatment of rectal cancer is especially challenging given the pelvic anatomy and the related muscles and nerves involved in sphincter control, as well as bladder and sexual functions. Two standard surgical therapies are widely adopted among surgeons: low anterior resection (LAR) with re-establishment of bowel continuity, and abdominoperineal resection (APR) with a permanent stoma. Each procedure presents a particular set of benefits and risks. While LAR is associated with higher risks of leakage at the intestinal re-connection and fecal incontinence; APR is associated with higher risks of stoma-related hernia, prolapse, skin damage, and surgery-related infections ². LAR combined with neoadjuvant therapy has become more common among surgical practices, given the non-inferior oncological outcomes in patient survival when compared to APR ². Although it was once believed that avoiding

a permanent stoma would improve quality of life, recent literature has questioned the validity of that claim ³⁻⁶.

A systematic review with meta-analysis identified APR as resulting in better global psychological and emotional scores among patients, while LAR was associated with better physical symptom and pain scores. However, results for overall quality of life (QoL), despite being measured by various validated instruments, were equivocal ⁷. Similarly, a recently updated Cochrane Review concluded that LAR did not lead to superior QoL ⁸. Given the equivalent survival outcomes, and the need to weigh QoL outcomes, the decision for rectal cancer surgery is therefore value-laden and requires a careful consideration of patient preferences.

Evidence suggests that patients have to date played a passive role in the decision making process regarding rectal cancer surgical options, with the decision traditionally influenced by three factors: 1) a patient's baseline functional status, 2) surgeon preference, and 3) tumour characteristics ⁷. Greater involvement of patients in shared decision making may lead to higher decisional quality, with a high-quality decision defined as one that is informed by the best available evidence and congruent with patient values ⁹.

Shared decision making & decision aids

Shared decision making (SDM) is an approach by which both the patient and his/her healthcare providers contribute to decisions about care ¹⁰. It encourages patients to play an active role in making decisions concerning their health, which is a goal of patient-centered care ¹¹. This approach to making clinical decisions has been endorsed by the Salzburg Declaration ¹², the US National Academy recommendations

on State and Federal SDM implementation ¹³, and the Patient Protection and Affordable Care Act of the American legislation ¹⁴. SDM can be facilitated by patient decision aids (PtDAs), which are defined as interventions designed to help people make specific and deliberative choices among options by providing information on the options and outcomes relevant to the patient's health status ¹⁵. The effectiveness of PtDAs has been demonstrated in multiple systematic reviews, including a comprehensive Cochrane review and specific reviews on cancer and surgery decision aids ¹⁵⁻¹⁸. PtDAs have been shown to improve patient knowledge, lower decisional conflict related to feeling uninformed and unclear about personal values, reduce the proportion of people who were passive in decision making, and improve agreement between patient values and the health care options chosen ¹⁹. Furthermore, exposure to decision aids can lead to a higher proportion of people with accurate risk perceptions ¹⁹. In 2003, consensus standards for PtDAs were established by the International Patient Decision Aid Standards (IPDAS) collaboration ⁹. Through a modified-Delphi method, the international collaboration involved over 100 major stakeholders representing patients, practitioners, researchers and policy makers to reach agreement on the criteria for the assessment of the quality of PtDAs. The IPDAS collaboration continues to play a major role in updating the syntheses of evidence and defining quality and effectiveness of PtDAs ²⁰.

The Patient Decision Aid Research Group at the Ottawa Hospital Research Institute (OHRI) leads the Cochrane review on PtDAs, hosts an A to Z Inventory of publically available PtDAs, and hosts the complete Decision Aid Library Inventory (DALI) containing PtDAs that are publically available, in development, or out-dated ²¹.

Prior to the development of the rectal cancer decision aid that prompted this thesis, a thorough search through these databases did not return any decision tools to engage rectal cancer patients in the decision-making process regarding surgical treatment options.

The rectal cancer decision aid

Adhering to quality criteria set by the IPDAS and using the Ottawa Decision Support Framework (ODSF) as a template, the rectal cancer PtDA was developed in paper-based and web-based formats (Appendix I). The ODSF is a decision making conceptual model informed by cognitive, socioeconomic, and organizational psychological theories that can be used to guide the development and evaluation of PtDAs ²². The ODSF has been used in the development of over 30 PtDAs, some of which were evaluated in 24 randomized controlled trials ²³. Three principal steps were followed in the rectal cancer PtDA development: 1) a systematic review to explore the long term side effects of rectal cancer surgeries; 2) decisional needs assessments with rectal cancer patients and colorectal surgeons; and 3) development and peer-review of the draft PtDA.

The systematic review identified that post-surgery bowel dysfunction after LAR (anastomosis) was high and associated with negative impacts on quality of life ²⁴. The needs assessments identified a lack of awareness of surgical options and potential outcomes among patients, as well as a general lack of patient involvement in the decision making process ²⁵. The decisional needs assessment also identified that

despite the surgeons expressing support to use a PtDA, their view of the population to which a PtDA could apply was limited. A conclusion from this work was that a rectal cancer PtDA would be valuable to help prepare patients for making shared decisions with their surgeon. A PtDA was then designed by integrating evidence knowledge on the benefits and risks associated with LAR and APR. The PtDA was formatted to be available both on paper and online (Appendix I). Since its development, the PtDA's content and presentation have been reviewed by a patient and a surgeon, but it had not been formally evaluated prior to this thesis. According to IPDAS and ODSF, higher quality PtDAs improve knowledge, clarify values for outcomes of options, and help guide the decision making process to achieve decisions that are informed and based on patient values ²⁶. These features are thus potential criteria for evaluating the rectal cancer surgery PtDA.

In summary, patients with mid to low rectal cancer often have two surgical options that have different impacts and may be associated with QoL. Typically patients are not involved in sharing this decision with surgeons. PtDAs have been demonstrated to be effective interventions in other areas, but the only available PtDA for rectal cancer surgery has not been evaluated. Therefore, the first phase of this thesis, informed by IPDAS and the ODSF, evaluated the impact of the PtDA among patients newly diagnosed with rectal cancer who were at the point of decision making ²⁷ using a before and after study design.

Implementation of the rectal cancer decision aid

Strong legislative and administrative support of PtDAs use can be found in the Affordable Care Act ¹⁴ and a white paper from the US National Academy for State Health Policy ²⁸. Several American states have implemented legislation for clinicians to demonstrate the use of SDM incorporating decision aids during the informed consent process ²⁹. Although PtDAs may foster SDM ^{30,31} and are supported via policies, use in clinical practice has not been widespread ³²⁻³⁴.

Ensuring the adoption of PtDAs goes beyond evaluating their effectiveness with patients. As decision-making within a healthcare environment is a process that involves both patients and healthcare professionals, the latter must also be involved in the evaluation of PtDAs. Patients' perceptions alone have not been sufficient to change clinical practice ^{35,36}. Significantly more effort is thus needed to understand the factors preventing the use of PtDAs from the perspective of clinicians ^{37,38}.

The Knowledge-to-Action (KtA) Cycle was chosen as the guiding framework to systematically consider implementation of the rectal cancer PtDA in clinical practice ^{39,40}. It is a framework endorsed by the Canadian Institutes of Health Research (CIHR) and is based on a review and analysis of over 30 planned action theories ⁴¹. According to the KtA, the first step in the action cycle is to identify a knowledge-practice gap (eg. a rectal cancer surgery patient decision aid is available but not being used in practice). The next steps are to: adapt the PtDA to the local context; identify potential barriers to its use in practice; design implementation strategies to overcome known barriers; monitor use of the PtDA; evaluate outcomes; and establish sustained knowledge use ³⁹.

Exploring factors likely to influence use of the rectal cancer PtDA from providers' perspectives may help to inform strategies for implementing it as part of the process of care. A systematic review of 38 studies identified that common barriers to PtDA implementation were related to attributes of the PtDA (e.g., clarity and balance of presentation), patient factors (e.g., psychosocial limitations), clinician factors (e.g., skepticism), and social and structural factors in the practice environment (e.g., limited resources) ^{42,43}. As such, the second study in this thesis explored barriers and facilitators to using the PtDA as perceived by surgeons specialized in treating patients with rectal cancer in Canada.

Summary

PtDAs can facilitate SDM and contribute to ensuring more patient-centred care. Following the guidelines of IPDAS and the ODSF, a rectal cancer surgery PtDA was previously developed. There is a gap in evidence on how well it helps patients prepare for the surgical consultation. We also need to understand the factors that may influence this PtDA being used by surgeons in practice.

1.2 Purpose of thesis

The overall aim of the thesis is to evaluate the effectiveness of a rectal cancer PtDA and determine factors that may influence its use in clinical practice. Specific objectives are: 1) To evaluate the effect of PtDA on patients' choices and decision-making processes, among rectal cancer patients who are considering LAR versus APR surgery; and

2) To explore surgeons' perceptions of the facilitators and barriers influencing implementation of the rectal cancer PtDA for this group of patients.

The thesis proposal was written *a priori* and published ⁴⁴. The PtDA evaluated in this study was developed prior to this thesis but had not been evaluated. Its development was not part of the thesis.

Chapter 2, entitled "Evaluation of the rectal cancer patient decision aid: a before and after study", addresses the first objective. It describes a study conducted with patients newly diagnosed with rectal cancer. Outcomes were measured before and after exposure to the rectal cancer PtDA.

Chapter 3, "Perceived facilitators and barriers influencing implementation of the rectal cancer decision aid: A Survey of Colorectal Surgeons in Canada", addresses the second objective. A survey was conducted with colorectal surgeons in Canada to determine commonly perceived factors that may facilitate or prevent the implementation of the decision aid as part of patient care.

Chapter 4 offers a summary of findings and integrated discussion. System, surgeon, and patient implications of evaluating and using the PtDA are discussed with suggestions for future research.

Chapter 2 examines the first objective of the thesis. It describes a before and after study looking at the effect of the rectal cancer PtDA on patients diagnosed with rectal cancer.

Chapter 2:

Evaluation of the Rectal Cancer Patient Decision Aid: A Before and After Study

This manuscript is formatted for: *Diseases of the Colon and Rectum* (not submitted)

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Introduction:

In rectal cancer surgery, low anterior resection and abdominoperineal resection have equivocal impact on overall quality of life. A rectal cancer decision aid was developed to help patients weigh features of options and share their preference.

Objective:

To evaluate the effect of a patient decision aid for mid to low rectal cancer surgery on the patients' choice and decision-making process.

Design:

A before and after study was conducted with adults having a biopsy confirmed rectal cancer at 10 cm or below from the anal verge. Consent and data collection occurred after surgeon confirmation of eligibility. Patients used the patient decision aid at home (online and/or paper-based formats) and completed post questionnaires on paper or online.

Main outcome measures:

Decisional conflict, knowledge, and preference for a surgical option.

Results:

Of 107 new rectal cancer patients referred to a tertiary care cancer center over 10 months, 37 (34.5%) were eligible, 32 (84.2%) of eligible patients consented to participate, and 28 completed surgery. Of 28 patients recruited, their mean age was 62.14 ± 9.73 years and tumor location was on average 7.11 ± 2.08 cm above the anal verge. At baseline, no patients preferred a permanent stoma, and after decision aid exposure, 2 patients (7.1%) preferred permanent stoma. Absolute knowledge score improved by 39.0% ($p < 0.0001$) and decisional conflict was reduced by 19.4%

($p=0.007$). Over 96% of participants would recommend the patient decision aid to others.

Limitations:

Unable to control for potential confounders and potential response bias.

Conclusion:

The patient decision aid reduced decisional conflict and improved patient knowledge.

Patients were willing to recommend it to other rectal cancer patients considering surgical treatment.

Introduction

Surgery is the only curative therapy for patients affected by rectal cancer. Rectal surgery is inherently challenging due to the sphincter muscles, pelvic bones, and nerves involved in sexual and urinary functions. Two surgical options are widely available for mid to low rectal cancers: low anterior resection (LAR) with a primary anastomosis and abdominoperineal resection (APR) with a permanent colostomy. Sphincter sparing surgery (LAR) coupled with neoadjuvant therapy now offers non-inferior oncological outcomes as compared to APR in selected patients ⁴⁵. This has led to the presumption that if possible, low rectum resection with primary anastomosis to avoid a permanent stoma is always the preferred option by patients. Indeed, the UK National Institute for Health and Care Excellence has recommended that sphincter preservation should be done whenever possible for patients ⁴⁶.

However, permanent colostomy is not always the most important factor that compromises quality of life (QoL) following rectal cancer surgery ⁴⁷. A Cochrane review showed that LAR does not lead to superior QoL ⁸. This point was further supported by a meta-analysis that identified APR as having better globally psychological and emotional scores, while LAR was associated with better physical symptoms and pain scores ⁷. The difference in overall QoL scores following the two surgeries was modest ⁷. Given that the comparable oncological and overall QoL outcomes between the two options creates equipoise, the patients are perhaps best positioned to weigh the risks and benefits of each surgical option.

Shared decision making (SDM) aims to include both patients and their healthcare providers in the decision making process and is the crux of patient centered

care ¹⁰. SDM may be facilitated by patient decision aids (PtDAs), which are tools designed to improve decision quality and to reduce possible unwarranted practice variation. A PtDA provides facts about conditions, options, outcomes and probabilities; clarifies patient values; and guides patients in the steps of decision making so that choice can be aligned with a patient's most important values ¹⁶. Multiple systematic reviews have shown that PtDAs improve knowledge and foster realistic expectations ^{15-17,48}. More specifically, a recent systematic review demonstrated the effectiveness of PtDA use with patients facing surgical treatment decisions ⁴⁸.

Guided by the Ottawa Decision Support Framework (ODSF) ⁴⁹, a formative decisional needs assessment identified a significant gap between physician expressed endorsement of SDM and their actual involvement of patients in decisions about rectal cancer surgery ²⁵. The rectal cancer patient decision aid was then developed to foster SDM in the process of rectal cancer treatment decision. The current study aims to formally evaluate the decision aid. We hypothesized that the decision aid would improve patient knowledge and reduce decisional conflict.

Materials & Methods:

Design

A before and after study was guided by the ODSF. Ethics approval was obtained from the Ottawa Health Sciences Network Research Ethics Board (OHSN-REB) (Appendix VII).

Setting and Participants

The study was conducted in an ambulatory cancer program at a tertiary care hospital serving a population of 1.3 million. Patients are referred to any of the five

surgeons specialized in colorectal cancer. The eligible participants were English-speaking adults with biopsy confirmed rectal cancer, located at a maximum of 10 cm proximal to the anal verge, and amenable to surgical resection. Those with existing or previous stoma and those who could only receive APR for technical reasons were excluded from the study.

Intervention

The self-administered rectal cancer PtDA was used in preparation for consultation with a surgeon⁵⁰. It is informed by the best available evidence on LAR and APR⁵⁰. It includes options and their associated benefits and harms based on systematic reviews; a value clarifying exercise for patients to indicate the level of importance of each option; and structured guidance on deliberation. The development of the PtDA was guided by the extensively validated ODSF⁵¹ and its content aligns with the International Patient Decision Aid Standards (IPDAS)¹⁵. The decision aid is available in both paper and web-based video formats (Appendix I).

Procedure

Patients were recruited at the first consultation appointment after their diagnosis was confirmed by the surgeon. Eligible patients signed the consent form (Appendix II) and were asked to complete baseline questions to assess their knowledge, decisional conflict, choice leaning, and demographics (Appendix III). They were then given the decision aid on paper and details on how to link to the online version to review at home within two weeks of the clinic visit (Appendix IV). After viewing the PtDA, patients completed a self-administered post-PtDA questionnaire. The post-PtDA questionnaire assessed knowledge, decision conflict, preferred choice,

preparation for decision-making, and acceptability of the tool (Appendix I). If the answers were not returned in the postage paid envelope, a phone call was made to troubleshoot technical issues with the use of the decision aid or completion of questions. There was no discussions around the disease or treatment options during the phone call.

Outcome Measures

The ODSF⁵¹ and IPDAS²⁶ were used to inform the selection of our outcome measures. The primary outcome was decisional conflict, measured by the decisional conflict scale (DCS), a validated 16 question, 5 response category instrument designed to indicate the amount of patient uncertainty related to a preferred choice⁵². It is robust in construct validity, has a Cronbach's alpha coefficient of 0.78, and was sensitive to change as a single construct⁵³. It is divided into five subscales including informed, value clarity, support, uncertainty, and effective decisions⁵². The DCS was converted to a total score of 100 in the analysis⁵⁴. A decisional conflict score of less than 25 is an indicator of less uncertainty and is associated with patients implementing their decisions^{53,54}.

Knowledge was a secondary outcome, assessed using a 4-item questionnaire about the benefits and risks of each option (Table 2.3). The knowledge questions separately addressed which of the surgical options: had the greatest likelihood of requiring a second surgery; was not reversible; had a higher chance of resulting in hernia/wound healing problems; and had a higher chance of incontinence. We calculated the percentage of respondents answering each question correctly before

versus after the PtDA; and we summed the number of correct responses for each participant before and after, as a crude total knowledge score.

The choice predisposition tool ⁵⁵ was used to determine patient's preferred option (permanent stoma, bowel hookup, or neutral) before and after the use of the decision aid. This tool is a 15 point scale ranging from 1 (towards bowel hookup) to 15 (towards permanent stoma) with a high test retest coefficient (0.90) and sensitivity to change ⁵⁵. When categorizing the choice predisposition tool, scores 1 to 5 were classified as bowel hookup, 6-10 as neutral, and 11-15 as permanent stoma ⁵⁵.

The preparation for decision making tool ⁵⁶ has 10 items evaluated on a 5 point scale that assess how prepared the patients are to engage in a discussion with surgeons after viewing the PtDA. It has a Cronbach's alpha coefficient of 0.92-0.96 and reliability of 0.95 ⁵⁶.

The acceptability tool ⁵⁷ consists of a 7 item scale that was used to understand how patients felt about the length, pace, amount and balance of presented information in the PtDA. This tool has face validity and was previously used in multiple PtDA studies ⁵⁷.

Analysis

Data were entered into an Excel database and data cleaning was performed to identify potential duplications and missing data. No missing data were identified. The analysis was done with SAS 9.2 statistical software. To compare outcomes among participants pre- versus post-PtDA, McNemar test was used for categorical data and the paired student t-test was used for continuous data.

Results

Patient characteristics

During study recruitment, there were 107 new rectal cancer patients who had a consultation with a surgeon (Figure 2.1). Of the 107, 37 patients (34.6%) were eligible and 70 ineligible (65.4%). Reasons for being ineligible were: tumours located higher than 10 cm, located too low where only APR could be offered, referred for trans-anal endoscopic microsurgery due to low risk features of the lesion, dysplasia associated lesion or mass in the setting of inflammatory bowel disease, extensive metastasis with no planned curative surgery, or patients who previously received or required intestinal surgery prior to curative surgery.

Of the remaining 37 (34.5%) who qualified for the study, 31 (83.8%) consented to participate. Reasons for not consenting were due to patient factors such as preferring not to receive additional information (n=2), preferring not to extend the visit to discuss the study (n=1), family advising patient against study (n=1); and physician factors such as patient indicating that the physician had framed LAR as the superior option (n=2). Of the 31 patients who consented to study, 28 (90.3%) completed the study and were included in the analysis. Reasons for not completing the study included a local excision was performed (n=1) or failing to complete the post-PtDA questions (n=2).

From November 2013 to July 2014, 28 patients were recruited to the study. The mean age of patients with rectal cancer was 62 years old, with 81% being male (Table 2.1). The location of the rectal tumour was on average 7.11 cm above the anal verge. Carcinogenic embryonic antigen (CEA) is a serum tumour marker that is

independently predictive of postoperative tumour recurrence and survival at an increased level of > 5 nanograms (ng)/milliter (mL) ⁵⁸. Within our study population, this level was below the threshold at 3.86 ng/mL. Most study participants had stage three rectal cancer (13/28).

Primary outcome: Decisional conflict

The mean decisional conflict score changed from 36.0 out of 100 at baseline to 16.6 after viewing the PtDA (Table 2.2). The reduction in decisional conflict of 19.4% was statistically significant (p=0.007). Among the decisional conflict subscales, patients expressed more certainty with being informed (p=0.0006) and making an effective decision (p=0.011), and more clarity about their values (p=0.002) after versus before viewing the PtDA. Sub-scores for feeling supported and uncertainty were not significantly changed after PtDA use.

Patient knowledge

The mean knowledge score increased from 48.5% before PtDA to 87.5% after PtDA use, resulting in a 39.0% change (p<0.0001). Proportion of patients with the correct answer significantly increased after PtDA use for questions 1 to 3 (Table 2.3).

Patients' preferred option

At baseline, no one (0%) preferred permanent stoma (APR), 17 patients (60.7%) preferred anastomosis (LAR), and 11 patients (39.3%) were neutral (Table 2.4). After decision aid use, 2 patients (7.1%) chose permanent stoma, 15 patients (53.6%) chose anastomosis, and 11 patients (39.3%) were neutral.

Of the 17 patients who preferred anastomosis before the PtDA, 6 changed their preference to “neutral” after viewing the PtDA (Table 2.5). Correspondingly, the average preference score in the pre-PtDA anastomosis group significantly shifted towards neutral ($p=0.034$) after PtDA use. Within the pre-PtDA neutral group (11/28), 5 participants remained neutral, 4 patients changed their preference to anastomosis, and 2 patients changed to a preference for permanent stoma after PtDA use. The change in mean preference score in the neutral group was not statistically significant ($p=0.25$).

Preparation for decision making

After viewing the PtDA, over 80% of participants reported that the PtDA helped them recognize a decision needs to be made, think about the pros and cons of each option, think about how involved they want to be in the decision, prepare them to talk to their physician about what matters most, and prepare them for a follow up visit with their physician (Table 2.6). Most participants also reported that the PtDA helped them think about which pros and cons are more important (75%), helped identify questions to ask a doctor (75%), and helped them organize their thoughts (68%).

Acceptability of the rectal cancer PtDA

Over 85% of participants agreed that the PtDA had good or excellent general information about surgical options, risks and benefits, and questions and answers (Table 2.7). Participants reported that they perceived the length of presentation to be just right (93%), but 29% reported that there was not enough information. Over 96% of patients stated that they would recommend the PtDA to other patients.

The presentation was rated by most participants as completely balanced (79%), with small minorities reported that they perceived it as slanted towards permanent stoma (1.8%), or slanted towards bowel hookup (3.6%). For patients who were undecided before viewing the DA (n=11), 8 patients (73%) rated the DA as completely balanced, 2 patients (18%) thought it was slanted towards the permanent stoma, and 1 patient (9.1%) found it slanted towards bowel hookup. Three of the five participants who reported that the PtDA was slanted towards permanent stoma had an *a priori* inclination towards the bowel hookup. Nine of the 28 participants (32%) reported that they preferred the web version of the decision aid, 12 (43%) preferred paper version, and 7 (25%) preferred both (Table 2.7).

Discussion

Our study represents the first evaluation of a decision aid looking at two surgical choices in the treatment of rectal cancer. The findings suggest that the rectal cancer PtDA improved patient knowledge and reduced decision conflict. However it did not lead to significant shifts of patients' preferred options. Overall, patients felt prepared to make a decision after using the PtDA and most found it acceptable.

Although the study did not reach the target sample size of 38 by the time of conclusion (sample size calculation was published *a priori* ⁴⁴), more than 80% of eligible candidates consented and completed the study, indicating the feasibility of recruiting patients to use the PtDA. There were statistically significant effects on patient outcomes, indicating that the study was adequately powered to measure the primary outcome, decisional conflict, as well as knowledge.

The reduced decisional conflict after compared with before exposure to the PtDA indicates that patients generally felt more certain with their choice preference and positive about the decision making process. Patient decision aids have been shown to reduce decisional conflict across studies in a range of areas of medicine, and our findings are consistent with evidence from randomized controlled trials ^{16,48}. In fact, patients' baseline decisional conflict (a score of 36.0) was lowered to 16.6 post-PtDA. Previous research showed that decisional conflict scores higher than 35 indicate significant uncertainty while the reduction to less than 25 suggests that patients would be more likely to proceed with a decision about their treatment ^{53,54}. The rectal cancer PtDA was associated with abating the feeling of being uninformed and reduced uncertainty about personal values in decision making; these are two key outcomes as per IPDAS. It is likely that decisional conflict would be reduced even further after the follow-up surgeon consult ⁵⁹.

The improved patient knowledge score is consistent with existing literature ¹⁶. The magnitude of knowledge change in our study (1.5/4 or 37.5%) was higher than published rates of 14-26% improvement in the PtDA arm in randomized controlled trials ^{60,61}, and comparable to other observational studies ⁶². Though the knowledge improvement itself demonstrates the potential value of the PtDA, patients' poor baseline knowledge regarding the choices of rectal cancer surgery is also concerning. That patients come into this health care decision with low knowledge supports the need to use interventions such as PtDA to enhance education about options to prepare patients for discussions with their surgeons and to prepare them to provide informed

consent to the surgical procedure. In fact, PtDAs have been described as perfecting the informed consent process ⁶³.

Our study showed that the PtDA did not significantly change the choice preference of patients. This finding is consistent with other clinical trials examining invasive surgeries on topics of prostate cancer, bariatric surgery, coronary angiography, and breast cancer, where preferred option is not altered by the use of PtDAs ⁶⁴⁻⁶⁷. This is not surprising, given that PtDAs are designed to raise decision quality where no clear benefit exists for one option over another. However, our findings revealed that the rectal PtDA may particularly impact those who preferred sphincter-sparing surgery at baseline. Patients who initially preferred anastomosis were shifting towards a more neutral position after viewing the PtDA, perhaps indicating their improved understanding of the complexity and trade-off in the treatment decision. However, the actual surgery performed needs to be measured to determine if patients achieved options they preferred.

Participants found the PtDA acceptable and were satisfied with its role in preparing them for decision-making. This result is supported by trials in the literature, where people exposed to a PtDA as compared to usual care or simpler form of information delivery have a higher satisfaction with decision making ^{68,69}. Although five patients found the PtDA slanted towards permanent stoma, three of those five had strong preferences for anastomosis before viewing the PtDA. This was likely a result of the PtDA differentially impacting individuals with different baseline views, and thus a perception of biased presentation ⁷⁰. As such, the IPDAS guidelines suggested

interpreting the results of balance relative to patient baseline predisposition ⁷¹. The user rating of PtDA balance ranged from 16-96% in ten different studies ⁷¹, thus our balance rating of 79% (22/28) lies in the upper range in comparison to other studies. Among the few neutral patients who found the DA “slanted”, bias was not consistently perceived towards a single option. Overall there was limited evidence to suggest our PtDA presentation was imbalanced.

This study has three important limitations. First, this study does not have a parallel control arm and thus it is difficult to determine the true magnitude of association between decision aid and quality of decision. Notably, we cannot exclude the potential influence of confounding factors, such as patients’ own independent research, that may have affected both knowledge and decision-making over the time period when they were exposed to the PtDA. The rectal PtDA development and this study were guided by the ODSF and adhered to the criteria set forth by the IPDAS ⁹. High level evidence with randomized controlled trials comparing similarly developed PtDAs to usual care have found PtDAs to be associated with improved choice and decision making process ¹⁶, supporting a potential causal interpretation for our findings. Second, the PtDA was introduced to a small number of patients for evaluation at a regional cancer center and thus the results may not be generalizable to other care settings. Third, although patient perception of the PtDA was evaluated in this study, the evaluation was conducted prior to the surgeon consultation; the views of the surgeons remains unknown but is important to the implementation of the PtDA in practice.

Conclusion

The rectal cancer PtDA was found to enhance patient knowledge and decrease decisional conflict, which satisfies the IPDAS evaluation criteria. Patients reported that they found it to be acceptable and felt better prepared for discussion with their surgeon. Evaluating the decision aid was a necessary step to determine its suitability for implementation in clinical practice. Future research should evaluate the influence of the PtDA on the surgical consultation and surgeons' perceptions of its usefulness. Also important will be to explore effects of the PtDA on patient-clinician dialogue.

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Table 2.1. Characteristics of participants and the tumour (N=28)

Characteristics	N (%)
Age, mean (years)	62.1 (9.7)
<50	2 (7.1)
50-59	8 (28.6)
60-69	14 (50.0)
70-79	3 (10.7)
>=80	1 (3.6)
Sex	
Male	20 (71.4)
Female	8 (28.6)
Stage	
I	9 (32.1)
II	5 (17.9)
III	13 (46.4)
IV	1 (3.6)
	Mean ± SD
CEA^a	3.86 ± 4.84
Location, above the anal verge (cm)	7.11 ± 2.08

a. Carcinoembryonic antigen

Table 2.2. Decisional conflict of patients before and after using the rectal cancer decision aid (N=28).

	Before PtDA Mean (SD)	After PtDA Mean (SD)	P value (before vs after)^a
Total score out of 100	36.0 (19.4)	16.6 (19.5)	0.007
Subscale (each out of 100)			
• Informed	35.7 (23.4)	20.2 (17.6)	0.0006
• Value Clarity	35.7 (25.2)	20.5 (17.1)	0.002
• Support	28.9 (17.2)	25.9 (23.8)	0.54
• Uncertainty	45.5 (26.0)	39.3 (29.6)	0.29
• Effective Decision	36.8 (22.3)	25.0 (21.6)	0.011

Score from 0 (no decisional conflict) to 100 (severe decisional conflict)

a. Paired student t-test.

Table 2.3. Knowledge of patients before and after using the PtDA (N=28).

	Before PtDA	After PtDA	P value
Number of questions answered correctly (Total of 4)	Mean (SD)	Mean (SD)	
	2.0 (1.1)	3.5 (0.9)	<0.0001 ^a
Number of patients with correct answer	N (%)	N (%)	
1. Which option has the highest chance of needing a second surgery	16 (57.1%)	24 (85.7%)	0.013 ^b
2. Which option cannot be reversed	15 (53.6%)	23 (82.1%)	0.013 ^b
3. Which option has the highest chance of hernia and wound healing problems	2 (7.1%)	21 (75.0%)	0.00004 ^b
4. Which option has the highest chance of incontinence (accidents) of stool or gas	21 (75.0%)	26 (92.9%)	0.074 ^b

Patients who answered “don’t know” were scored as incorrect.

a. Paired student t-test before and after using PtDA.

b. McNemar test based on association with using PtDA.

Table 2.4. Patient preference before and after using PtDA.

Preference	Pre-PtDA (n=28)	Post-PtDA (n=28)
Anastomosis ^a	17 (60.7%)	15 (53.6%)
Permanent stoma ^a	0 (0%)	2 (7.14%)
Neutral ^a	11 (39.3%)	11 (39.3%)

a. Continuous scale (out of 15) categorized as anastomosis (1-5), neutral (6-10), and permanent stoma (11-15)

Table 2.5. Change in preference after using PtDA.

Before PtDA preference	After PtDA preference	P value
Overall preference score out of 15		
4.0 (SD=3.5)	4.6 (SD=4.1)	0.48 ^b
Subgroups (n)		
Anastomosis 17	<ul style="list-style-type: none"> • Anastomosis 11 • Neutral 6 • Permanent stoma 0 	
Mean ^a : 1.33 SD: 1.00	Mean ^a : 5.00 SD: 4.13	0.034 ^b
Neutral 11	<ul style="list-style-type: none"> • Anastomosis 4 • Neutral 5 • Permanent stoma 2 	
Mean ^a : 8.09 SD=0.29	Mean ^a : 6.00 SD=4.46	0.246 ^b
Permanent stoma (0)		

a. Mean preference score out of 15.

b. Paired student t-test before and after using PtDA base on continuous preference scale out of 15.

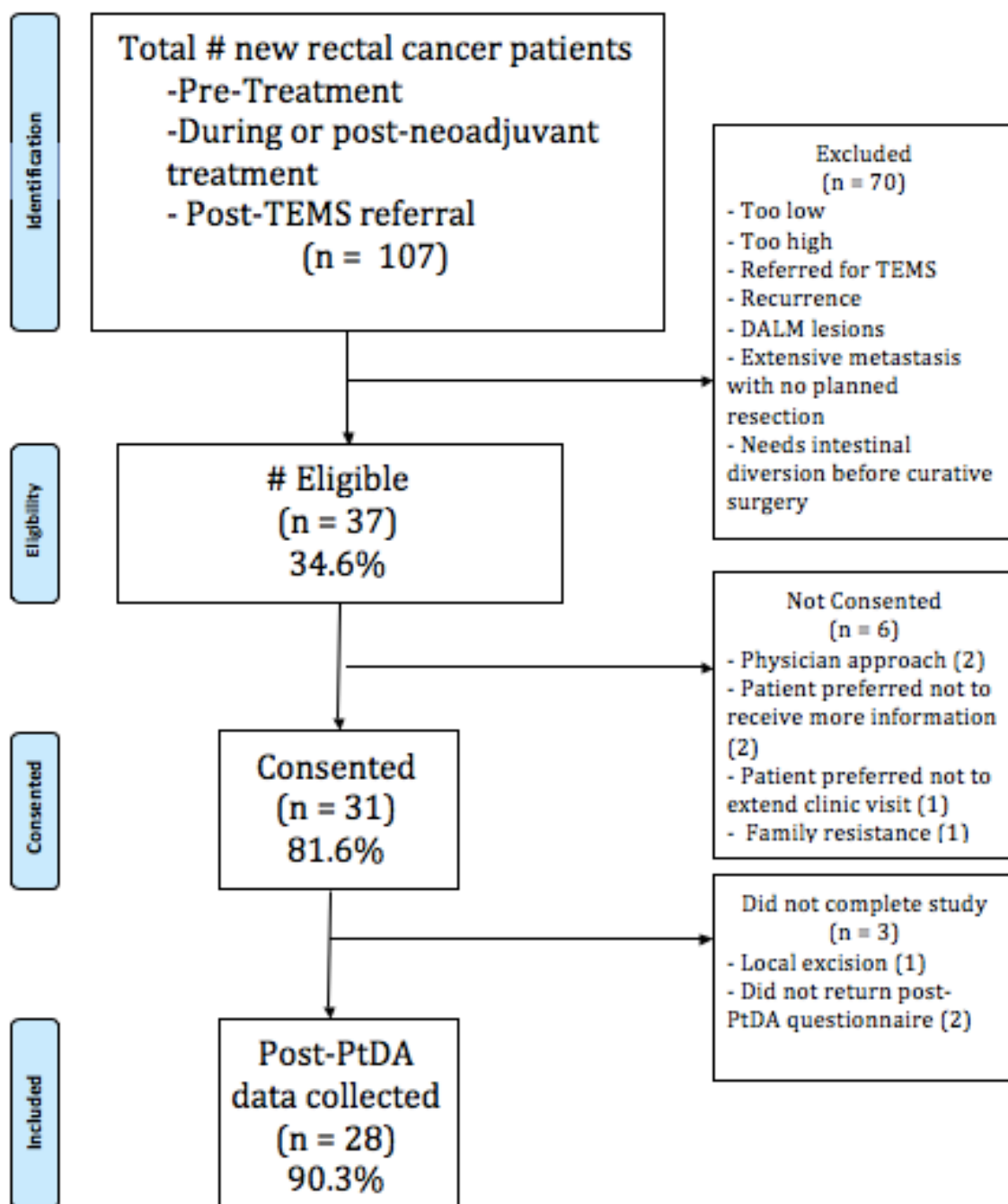
Table 2.6. Preparation for decision making after viewing the PtDA.

Did the decision aid... (N=28)	Quite a bit or A great deal	Some- what	Not at all or A Little
Help recognize a decision needs to be made?	24 (86%)	3 (11%)	1 (4%)
Help think about pros and cons of each option?	23 (82%)	4 (14%)	1 (4%)
Help think about which pros and cons are most important?	21 (75%)	6 (21%)	1 (4%)
Help organize your thoughts about the choice?	19 (68%)	6 (21%)	3 (11%)
Help think about how involved you want to be in this decision?	25 (89%)	2 (7%)	1 (4%)
Help you identify questions you want to ask your doctor?	21 (75%)	4 (14%)	3 (11%)
Prepare you to talk to your doctor about what matters most to you?	23 (82%)	4 (14%)	1 (4%)
Prepare you for a follow up visit with your doctor?	24 (86%)	2 (7%)	2(7%)

Table 2.7. Acceptability of the rectal cancer PtDA. N (%)

Information on (n=27)	Excellent	Good	Fair	Poor
• General information	10 (37)	16 (59)	1 (3.7)	0
• Surgical options	10 (37)	16 (59)	1 (3.7)	0
• Risks & benefits	10 (37)	14 (52)	3 (11)	0
• Questions & answers	8 (30)	15 (56)	4 (15)	0
Length of presentation (n=28)				
• Just right		26 (93)		
• Too short		2 (7)		
• Too long		0		
The amount of information (n=28)				
• Just right		20 (71)		
• Too little		8 (29)		
• Too much		0		
Balance of presentation (n=28)				
• Completely balanced		22 (79)		
• Slanted towards permanent stoma		5 (18)		
• Slanted towards bowel hookup		1 (4)		
Clarity of information in decision aid (n=27)				
• Everything was clear		10 (37)		
• Most things were clear		11 (41)		
• Some things were unclear		5 (19)		
• Many things were unclear		1 (4)		
Recommend this decision aid to others (n=28)				
• Definitely recommend		14 (50)		
• Probably recommend		13 (46)		
• Probably not recommend		1 (4)		
• Definitely not recommend		0		
Preferred format of PtDA (n=28)				
• Web		9 (32)		
• Paper		12 (43)		
• Both		7 (25)		

Figure 2.1. Flow diagram of patient participation.



TEMS: transanal endoscopic microsurgery.

DALM: Dysplasia associated lesion or mass in the setting of inflammatory bowel disease.

Too high: the tumour was higher than 10 cm above the anal verge.

Too low: the tumour was invading the rectal sphincter and not amenable to sphincter sparing surgery.

Although there is evidence to suggest that the rectal cancer PtDA may help patients, the opinion from surgeons should also be explored to facilitate implementation into clinical practice. Chapter 3 describes a cross-sectional survey study that explores the perceived factors influencing the implementation of the PtDA from surgeons' perspective.

Chapter 3:

Perceived Facilitators and Barriers Influencing Implementation of the Rectal Cancer Patient Decision Aid: A Survey of Colorectal Surgeons in Canada

This Manuscript is formatted for: *Diseases of Colon and Rectum* (not submitted)

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Abstract

Background:

A patient decision aid was associated with improved knowledge and decreased decision conflict in patients faced with low anterior resection or abdominoperineal resection for mid to low rectal cancer. Little is known about whether surgeons will use it with their patients in practice.

Objective:

To investigate surgeons' perceptions of barriers and facilitators to the implementation of a rectal cancer patient decision aid as part of clinical practice.

Design:

A cross-sectional survey was mailed to members of the Canadian Society of Colon and Rectal Surgeons. The procedure included a pre-notification, index survey, and three follow-ups to non-respondents with replacement surveys. We used descriptive analysis to identify barriers and facilitators, and univariable and multivariable analysis to identify factors associated with surgeons' perceived likelihood of using the decision aid.

Main outcome measures:

The outcomes were barriers and facilitators, and self-perceived likelihood of using the decision aid.

Results:

We received 60 responses from 105 mailed surveys (57.1%). Half of the respondents (51%) reported that they were either "very likely" or "likely" to use the decision aid. Respondents reported that the decision aid contained accurate information (90%), was

well developed (84%), and would be applicable to a sizeable proportion of patients (67%). Only 53% reported that it would be easy to incorporate in practice. The common barriers were time constraints and the need for multiple visits with dedicated personnel. The common facilitators were simplifying the decision aid, adding information to its content, and translating to other languages.

Limitations:

Although our response rate was good, non-response bias was possible, whereby non-responders may have had different views.

Conclusions:

Although surgeons found the decision aid well developed and beneficial for patients, only half intended to use it. Potential challenges from surgeons' perspectives related to the ease of implementation, and their own attitudes towards its use.

Introduction

Low anterior resection (LAR) with rectal sphincter sparing and a bowel anastomosis and abdominoperineal resection (APR) with a permanent colostomy, are two standard curative surgical therapies offered to patients in the treatment of rectal cancer. The common assumption that bowel continuity is always preferable to patients is challenged by equivalent oncological outcomes and reported quality of life ^{7,8}. Despite surgeons' recognition of the need for patient involvement in decision making, a lack of awareness of surgical options among patients was identified ⁷².

To improve shared decision-making in the surgical consent process, a rectal cancer patient decision aid (PtDA) was developed in accordance with the International Patient Decision Aid Standards (IPDAS) ⁹. Available on paper and web, the take home PtDA provides information on the risks and benefits of LAR versus APR, a values clarification exercise to identify strength of personal values associated with features of each option, and steps to guide patients towards a preference. Evaluation of the rectal cancer PtDA showed that it was associated with improved patient knowledge and reduced decisional conflict. Patients felt more prepared for decision-making after viewing the PtDA, and expressed satisfaction with its content, length, and presentation (chapter 2). These findings are consistent with the findings of multiple systematic reviews that decision aids are effective interventions to enhance patients' preparation for shared decision making with surgeons ^{16,48}.

Although there is evidence of effectiveness of patient decision aids on patient outcomes and legislation that supports their use ^{14,29,73}, their adoption into clinical practice has been isolated ³⁶. To increase the potential for uptake of new evidence in

practice, it is important to engage physicians prior to implementation to identify the potential barriers and facilitators to use. Knowledge of physicians' perceptions of factors influencing the use of a PtDA can be used for adapting it to different local contexts and for designing strategies to address barriers to implementation. Previous research found that failure to fully implement evidence may be related to adopter knowledge, lack of agreement on evidence and applicability to patients, and perception of a non-supportive environment ⁴⁰. Still, understanding of providers' perceived barriers to implementing PtDAs is relatively limited and targeted strategies have been relatively sparse compared to the abundant research on PtDA effectiveness with respect to patient outcomes.

Surgeons hold busy practices and may direct discussions with a patient to the proposed procedure of their preference and its related risks ⁷⁴⁻⁷⁶ and as a result may not present a balanced picture. Practice resource limitations may also interfere with implementation of PtDAs as physicians from other specialties have perceived PtDAs to require additional resources ⁷⁷. However, given that the rectal cancer PtDA has been developed as a take-home, non-directive tool to guide patients in decision making prior to meeting with the surgeon to make a final decision, it may actually enhance time sensitive consent processes by providing a full range of surgical benefits and risks, helping patients consider the options to determine the one that is most preferred.

The overall aim of this study was to evaluate Canadian colorectal surgeons' perceptions of the barriers to and facilitators of implementing a PtDA on rectal cancer surgery options.

Materials & Methods

We conducted a cross-sectional survey, guided by the Knowledge to Action (KtA) Cycle ⁴⁰. This framework, based on the analysis of 31 planned action theories ⁴¹, promotes the contextualization of a knowledge product and a structured process for its implementation ⁴⁰. A key step in the process of implementation, according to this framework, is the identification of perceived barriers and facilitators anticipated to influence its use such that implementation interventions can be designed to overcome known barriers. This study was approved by the Ottawa Health Science Network Research Ethics Board (OHSN-REB) and the Canadian Society of Colon and Rectal Surgeons (CSCRS).

Sample Participants & Setting

Canadian colorectal surgeons were identified using a regularly updated directory maintained by the Canadian Society of Colon and Rectal Surgeons. The membership is updated throughout the year. Staff surgeons, fellows, and residents are clearly identified along with their level of training. Once the study was approved by the CSCRS, we obtained a sampling frame containing the full roster of surgeons up to June 2013 with their email and postal mail addresses. Addresses were confirmed in public registries hosted by respective provincial College of Physicians and Surgeons. There are an estimated 114 colorectal surgeon registrants with the Society, of which 105 are listed as surgeons currently working in Canada. These 105 surgeons were the targeted sample and their final eligibility for the study (currently licensed and working with rectal cancer patients) was established by the screening question on our questionnaire: “Are you a board certified surgeon currently working with rectal cancer patients?”.

Procedure

We conducted the survey study by mail, following Dillman et al.'s tailored design method to maximize the response rate ⁷⁸. Specifically, we delivered a pre-notification, index mail, and three follow-ups.

A pre-notification letter was sent to all 105 surgeons to explain the study and alert them to expect to receive the questionnaire. One week later, the index mail included a cover letter, an upfront gift card of \$10 Canadian in value, a paper copy of the rectal cancer decision aid, a link to the online decision aid, the barriers and facilitators questionnaire, and a stamped return envelope. Follow-up reminders with a new paper copy of the PtDA and a replacement questionnaire were mailed at weeks two and five to non-responders. A final couriered mail ⁷⁹ with the same content was delivered on week seven to those who had still not responded.

The first question on the survey defined eligibility by asking the surgeon if he/she is currently treating rectal cancer patients. The second question asked the surgeon to confirm the viewing of the decision aid (on paper, online, or both). Instructions indicated that if they answered "yes" to the first two questions, they could proceed with the rest of the questions in the barriers and facilitators questionnaire (Appendix VI).

Outcome measures

All of the items on our questionnaire were based on a previously validated questionnaire, developed by Graham et al. in a PtDA study evaluating the perspectives of physicians in three different specialties ⁷⁷. A tailored version of the same

questionnaire was used in two additional studies to assess healthcare professionals' use of PtDAs^{80,81}.

This questionnaire includes a 41 item set of questions addressing barriers and facilitators to using the PtDA, divided into five main groups, including issues related to development of the PtDA, content and format of the PtDA, PtDA meeting patients' needs, physicians' clinical practice, and implementation (Appendix VI). Each question on the questionnaire is rated on a 5 point scale from 1 (strongly disagree) to 5 (strongly agree).

Additional questions, also drawn from Graham et al.⁷⁷ addressed surgeons' level of comfort in using the PtDA and their views on whether there is a need for a PtDA in clinical practice. The last closed-ended substantive question asked surgeons how likely they were to use the decision aid, categorized into "not at all", "very unlikely", "somewhat likely", "likely", and "very likely". Four open-ended questions at the end of the survey explored changes necessary for program specific adaptations of the PtDA, barriers to implementation, facilitators of using the PtDA, and general comments. Finally, the questionnaire closed with questions about demographic characteristics and practice characteristics.

The barriers and facilitators items used in the survey were previously demonstrated to have factorial validity in a principal components analysis, with items loaded onto four components including 1) quality and value for patients, 2) value for physicians, 3) PtDA content, and 4) issues related to implementation⁷⁷. For our study, we assumed relevance of these same components and, as per Graham et al., the mean

score of items within each of these principal components was calculated and used as a predictor variable in the multivariable logistic regression.

Analysis

Data from survey questions were independently entered twice into a Microsoft Excel database to ensure accuracy. Any missing data were treated by case-wise deletion. The overall response rate was determined based on the total number of returned surveys and the number of mail-outs. Descriptive statistics included proportions and means for individual variables.

Chi-squared tests were used for bivariate comparisons of those who were more likely (“very likely” and “likely”) versus less likely (“somewhat likely”, “very unlikely”, and “not at all”) to use the PtDA, by respondent demographics, each barrier/facilitator, questions on comfort, and need for PtDA. Univariable logistic regression analysis was performed to predict likelihood of use using principal component scores. Following univariable analysis, each principal component score was used to predict intent to use in a separate multivariable logistic regression model, adjusting for demographic characteristics (age, years in practice, annual patient volume). All statistical analysis was performed using SAS 9.3 software.

Barriers and facilitators generated from open-ended questions were examined and grouped into themes including PtDA issues, surgeons’ attitudes, patient issues, and resource issues. Frequency of appearance of each identified issue was counted.

Results

Survey Delivery

Of the 105 mailed surveys, 60 were returned (57.1%), and none were returned as unopened. The response rates based on initial mail and reminders were 27.6%, 13.3%, 7.6%, and 8.6%, respectively (Figure 3.1).

Surgeon Characteristics

Of the 60 respondents, 53 (88%) were eligible and 7 were ineligible (Figure 3.2). Four respondents of the 53 had missing data on one or more key items and were excluded from the analysis (Figure 3.2).

The 49 included participants were on average 46.6 years old, most were male (84%), and they had a mean clinical experience of 14.7 years in practice, with most practicing in affiliation with a university (88%) (Table 3.1). Of the 49 participants, 30% saw ≥ 40 patients a year, 43% saw 20-39 patients a year, and 27% saw < 20 patients a year. The non-respondents, based on publically accessible data, were similar with respect to gender (84% male) and clinical experience (mean 12.4 years).

Perceived likelihood of using Decision Aid

About half of participating surgeons indicated that they were “very likely” (32.6%) or “likely” (18.4%) to use the PtDA. The other half indicated that they were “somewhat likely” (36.7%), “very unlikely” (8.2%), or “not at all” likely (4.1%) to use the PtDA (Table 3.1). About 80% of participants reported being “comfortable” or “very comfortable” with using the PtDA (Table 3.1). While 67% of participants agreed that

there was a need for PtDA, 33% were unsure or did not perceive a need for it (Table 3.1).

On Decision Aid Development

More than 90% of respondents agreed that the developers of the PtDA were credible and the information provided in the PtDA was based on evidence (Table 3.2). 84% of respondents agreed that the PtDA was well developed and its development was not influenced by vested interest. A well-developed PtDA was associated ($p=0.002$) with surgeons reporting that they were likely to use the PtDA (Table 3.2).

Content and Format of the Decision Aid

Over 85% of participants agreed that the PtDA provided essential, accurate, up-to-date information to help the decision making process and found the combination of computer- and paper- based formats to be a good idea. Over 80% agreed that the information presented on the PtDA was balanced, unbiased, and described treatment choices in an organized fashion. 69% agreed that the PtDA presented probabilities in an understandable manner. Description of treatment choices ($p=0.011$), balanced information ($p=0.049$), availability of essential information ($p=0.0096$), understandable risks and benefits presentation ($p=0.024$), and accurate reflection of evidence ($p=0.022$) were associated with likelihood to use the PtDA (Table 3.2).

Clinical Relevance of the Decision Aid

Most surgeons agreed that the PtDA was compatible with how they think patients should be informed (86%) and that it would complement their usual approach (78%). Fewer surgeons agreed that the PtDA would improve their approach (45%),

help them understand patient issues (57%), or improve the quality of patient visits (53%).

Agreements on each item in this category were significantly associated with participants reported likelihood of using the PtDA. In particular, agreement with items indicating that the PtDA would improve a physician's usual approach, quality of patient visits, and provide observable benefits to patients were highly associated ($p \leq 0.0001$) with a greater perceived likelihood of using the PtDA (Table 3.2).

Patient Relevance of the Decision Aid

Although 71% of surgeons agreed that the PtDA would be acceptable to patients, 39% agreed it would be simple for patients, while 27% thought it would be too complex to use with patients. Over 65% of respondents agreed this tool would apply to a sizeable proportion of patients, explain benefits and risks of each surgery, and logically guide them through the decision making process. Over half of participants (59%) agreed that the PtDA would improve patient decision making. Surgeons who found the PtDA to be acceptable ($p=0.0011$) and those who agreed that the PtDA would guide patients ($p=0.019$), help patients understand benefits and risks ($p=0.005$), prepare them for decision making ($p=0.038$), help them reach a decision ($p=0.011$), allow patients to participate ($p=0.011$), and improve their decision making ($p=0.0025$) reported being more likely to use the PtDA. Agreeing that the PtDA would be simple to use ($p < 0.0001$) was strongly associated with a participant expressing that he or she was likely to use the PtDA (Table 3.2).

Implementation of the Decision Aid

Most respondents indicated clear direction existed within their cancer programs to support protocols and guidelines (69%) and that the PtDA would affect patient relationships in a positive way (61%). Approximately half agreed (53%) it would be easy to use, would not require major changes to discussion (53%), and would help tailor counseling to patient needs (53%). But only a minority agreed that sufficient time was available (47%) to use the PtDA, 27% agreed that it would be used by most of their colleagues, and 14% of surgeons agreed that the PtDA would save time.

Surgeons who have a clear direction to use guidelines ($p=0.024$), believed that there would be adequate time and the PtDA would save time ($p=0.062$), that the PtDA would positively affect the physician patient relationship ($p=0.0008$), and that it would be used by colleagues ($p=0.029$) were more likely to express that they were likely use the PtDA (Table 3.2). Agreeing that the PtDA would be easy to use and that using the PtDA would help tailor patient counseling ($p=0.0001$) seemed to be strongly associated with likelihood of use.

Factors Influencing Perceived Likelihood of Using the Decision Aid

Univariable analysis showed that each component score, including quality and value for patients, value for physicians, decision aid content, and implementation, was independently associated with participants' reported likelihood of using the PtDA (Table 3.3). When adjusted for participant age, years in practice, and annual patient volume, in multivariable logistic regression, factors related to implementation were no longer associated with likelihood of use but the other three components remained statistically significant. In the model consisting of all four principal components, while

adjusting for demographic variables, only surgeons who thought PtDA was valuable towards their clinical practice expressed a significantly higher likelihood to use the PtDA (odds ratio 17.1, Table 3.3).

Themes from open-ended questions

Barriers to Using PtDA

Themes indicating common barriers to PtDA use were grouped into factors related to resources, the PtDA itself, the surgeon, and the patient (Table 3.4). The most common resource issues were perceived needs for extra clinic time, multiple clinic visits, and additional supporting staff. Other resource barriers included alteration of clinic flow, inadequate referral structure, uncertainty in the timing of delivering the PtDA, costs, lack of administrative support, and space confinement.

Within PtDA related factors, the most common barrier was lack of translation into languages other than English, such as French, Chinese, Punjabi, and Hindi. Some were concerned about the length and complexity of the PtDA for patient use. A few participants noted a lack of input from healthcare professionals on PtDA content and evidence to show its effectiveness.

A number of surgeons cited behaviours of colleagues as a major barrier. Some felt that surgeons have an inherent bias towards LAR, while others worried there is a lack of consensus over the PtDA approach in general. Other surgeon related barriers were that the approach was “not individualized” enough to consider patient variation, that there was no need for a PtDA as physicians alone are seen as facilitators of decision making, and that the PtDA may actually “interfere with the physician-patient relationship rather than improving it”.

At the patient level, many surgeons predicted that low socioeconomic status, poor education, and older age would limit patient comprehension and thus reduce the applicability of the PtDA to the population. Another barrier was the perception that the PtDA had limited applicability for the overall rectal cancer population due to varying clinical scenarios and that it was an additional burden on patients.

Facilitators of Using PtDA and Changes Needed to Adapt the PtDA to the Local Context

Facilitators were identified at the level of the PtDA and the environment. Surgeons identified facilitators of the PtDA as its being a pertinent tool, high quality, and complementary to participants' practice (Table 3.4). While many surgeons identified a need to add more information, others suggested simplifying it. Other suggestions to improve the PtDA to facilitate its use included translation into other languages, additional diagrams, and more individualized content. Some urged improvement on clarity of presentation, while a few suggested specific content changes to sections of the PtDA. One recommendation was to "acknowledge stoma nurses" within the PtDA.

Environmental facilitators that participants believed would promote use of the PtDA included additional resources to support the need for more clinic time, personnel, and administrative support. Some surgeons suggested giving the PtDA to patients prior to a clinical visit. The necessity of Internet access was identified as a facilitator for using the online version of the PtDA. Some participating surgeons also felt that "reorganization of the clinic" would facilitate the implementation.

Discussion

Our study is the first large scale survey to explore the factors that influence the implementation of a PtDA as perceived by the surgical community. Given the limited number of existing surgical PtDAs ¹⁹, this study sheds light on the contextual factors that influence PtDA adoption in surgical practice.

At 57.1%, our study achieved a response rate comparable to other survey studies involving surgeons ⁸²⁻⁸⁴. Of those who responded, a majority of surgeons were involved in treating rectal cancer patients. Overall, our study demonstrated that although physicians endorse the PtDA's quality and agreed that patient decision aid is a good way to inform patient choices, they are more skeptical about its actual use into practice. This finding is consistent with a systematic review ^{36,77} that found physicians often cited competing demands, time pressure, and holding the view that patients would not want decisional responsibilities as main reasons for not incorporating PtDAs into practice ¹². As such, a seemingly favourable attitude towards this PtDA may not be sufficient to support a high rate of adoption in practice.

Most respondents agreed that the PtDA contained well-presented and evidence-based information that was developed by a credible source. However, our qualitative results showed that despite their general approval, surgeons have mixed opinions on the complexity and the amount of information on the PtDA. Some suggested adding information to the content and others suggested reduction of material. This is perhaps a reflection that the constellation of information physicians disclose to patients is highly variable ⁷⁶. While the rectal cancer PtDA was constructed to inform patients in

consultation with the surgeon, it was not intended to replace clinical discussion on the options but rather surgeons could tailor the consultation to suit varying patient needs.

Many surgeons believed that the PtDA would help patients understand the benefits and risks associated with each choice, and guide them through the decision making process. However, a number of surgeons were concerned that the PtDA may not be broadly applicable to patients due to psychosocial limitations (eg. older age, lower socioeconomic status). Some surgeons added that they were concerned with burdening patients with more work. These findings suggested a view among physicians that although the PtDA may be helpful, it would apply to a limited spectrum of patients. This indicates that healthcare providers may be selecting patients for shared decision making rather than broadly applying this approach, a concerning issue given that physicians may not accurately gauge patients' preferred involvement in decision making ⁸⁵. In addition, evidence suggests that patients of lower literacy and socioeconomic status may benefit more from a PtDA ⁸⁶, further highlighting the importance of broadly applying the PtDA.

With respect to their own clinical practice, many surgeons felt that the PtDA would complement the consulting process and improve their relationship with patients. However, few thought it would be easy to use in their own setting and even fewer could see their colleagues using the PtDA. Resource issues such as time, need for reorganization of the clinic, and specialized personnel were the most commonly described barriers. Proposed improvements to address these factors were seen as helpful to facilitate implementation. Other studies have also demonstrated that time constraint was viewed as the most important barrier to implementing PtDAs ^{32,87-89}.

Contrary to that perception, a Cochrane review of 115 clinical trials on PtDAs showed that PtDA use does not consistently lead to increased consultation time based on 10 trials that measured this outcome ¹⁶. However, the review authors concluded that further research with an a priori definition of consultation length and sufficiently powered sample sizes would be necessary to definitively address this controversy ¹⁶. The need for reorganization of clinic flow and specialized clinic personnel were seen as further stresses on limited resources. Although the upfront cost of PtDA delivery is likely unavoidable, downstream cost saving is far from certain ⁹⁰. The solution perhaps, is to consider PtDA as part of cost-effective healthcare delivery, where patient-physician encounters may be improved in exchange for an acceptable investment ⁹¹.

Strikingly, physicians themselves were seen as barriers by some respondents citing resistance to change and personal bias towards a specific procedure as main obstacles. This is consistent with the current rectal cancer surgery consultation where the evidence suggests that the surgical choice is often made based on a surgeon's perception of the patient baseline functional status, tumour factors, and surgeon expertise ⁷. Maintenance of the *status quo* is natural without interventions to change behavior ⁹². Despite the strong evidence demonstrating PtDAs' effectiveness in improving patient decision making, widespread clinical adoption lags behind. Supportive strategies to implement shared decision making and PtDAs are being explored, including training and policy change. Training programs for healthcare professionals and interprofessional approaches to shared decision making including use of PtDAs have demonstrated effectiveness in helping providers with patient engagement ⁹³. In 2010, US legislative support of SDM was featured in the Affordable

Care Act Section 3506 endorsing the development, evaluation, and use of PtDAs ¹⁴.

There is also an appeal to change the reimbursement scheme to reward the documentation of PtDA use in the process of consultation ⁹⁴. These legislative, administrative, and monetary interventions are likely to help increase the uptake of PtDAs ⁹⁵. The next steps are to study the effectiveness of different implementation strategies and the sustainability of using PtDAs to prepare patients for shared decision making.

The results of our study need to be interpreted in the context of several limitations. We used a Canadian organization that represents all surgeons working with rectal cancer in Canada. Although the membership likely captures most of the relevant surgeons, it is possible some were not reached. However, this society remains the best available repository in Canada to reach the colorectal surgeon community. Our response rate was reasonable at 57.1%. Although some demographic information regarding non-respondents was available and they appeared to be demographically similar, we had no data to evaluate the difference in perceptions of the PtDA between responders and non-respondents. The magnitude of non-response bias is often difficult to predict ⁹⁶ and therefore caution should be used when generalizing the results to all colorectal surgeons. In addition, although the response rate was good, the study population was small and therefore our sample size was small. Some analyses, especially the logistic regression, may be underpowered. As with other surveys, our data rely on self-reported answers and are susceptible to social desirability bias where a respondent may underreport the undesirable attributes and overstate their support for the PtDA ⁹⁷. Despite the aforementioned potential limitations, our survey

represents the best available evidence on the views of colorectal surgeons with respect to using PtDAs to prepare patients for SDM and our findings are consistent with published studies.

Conclusion

Although colorectal surgeons generally agreed with the approach to SDM, they perceived various obstacles to its implementation in their practice. Resource constraints and the lack of applicability to patients were among the most often perceived barriers. Those who perceived that the PtDA was valuable to their clinical practice were more likely to indicate willingness to use it. In an era where the use of PtDAs to facilitate shared decision making is gathering significant legislative support, surgeons' perceived concerns need to be addressed to better support their use of PtDAs. A multifaceted approach to involve surgeons in SDM delivery includes raising the awareness of surgeons and patients on availability of PtDAs, training in SDM and the use of PtDAs, organizational prioritization of patient centered care and investment to integrate PtDA into practice. Further research is required to define effective implementation strategies to overcome known barriers and ensure sustained adoption of PtDA among healthcare practitioners.

Table 3.1. Characteristics of participating surgeons and intention to use decision aid (N=49)

	Mean (SD)	N (%)
Age	46.63 (10.7)	
Groups		
<40		12 (24.5)
40-50		19 (38.8)
>50		18 (36.7)
Years in practice	14.67 (10.1)	
Groups		
<10 years		20 (40.8)
10-20 years		14 (29.6)
>20 years		15 (30.6)
Sex		
Male		41 (83.7)
Female		8 (16.3)
University affiliation		
Yes		43 (87.8)
No		6 (12.2)
Annual patient volume		
<20		13 (26.5)
20-39		21 (42.9)
>=40		15 (30.6)
Likely to use PtDA		
Yes		25 (51.0)
No		24 (49.0)
Comfortable offering PtDA		
Yes		39 (79.6)
No		10 (20.4)
Need for PtDA		
Yes		33 (67.3)
No		16 (32.7)

Table 3.2. Surgeons responding “agree” or “strongly agree” (on a five point scale) regarding their perceptions related to the use of rectal cancer patient decision aid by perceived likelihood of using the decision aid. (N=49)

Characteristics	Agree or strongly agree among all respondents	Agree or strongly agree among those who are likely to use PtDA	Agree or strongly agree among those who are unlikely to use PtDA	P (Likely to use vs. unlikely to use)	Principal Component ^a
	Total n=49 (%)	Total n=25 (%)	Total n=24 (%)		
Development of DA...					
Developers of the DA are credible	46 (94)	24 (96)	22 (92)	0.53	3
Info provided within DA is supported by evidence	47 (96)	25 (100)	22 (92)	0.23	3
DA is well developed	41 (84)	25 (100)	16 (67)	0.002 ^b	3
Development of the DA not influenced by vested interests	41 (84)	23 (92)	18 (75)	0.14	3
Content and Format...					
Info provided on treatment choices is balanced	42 (86)	24 (96)	18 (75)	0.049 ^b	3
DA contains essential info to help the decision making process	43 (88)	25 (100)	18 (75)	0.0096 ^b	3
DA well organized	39 (80)	22 (88)	17 (71)	0.17	1
DA describes treatment choices	40 (82)	24 (96)	16 (67)	0.011 ^b	3
Evidence reflects my understanding of the data	44 (90)	25 (100)	19 (79)	0.022 ^b	3
Evidence presented in unbiased manner	43 (88)	24 (96)	19 (79)	0.098	3
Evidence is up-to-date	43 (88)	23 (92)	20 (83)	0.42	3
DA presents probabilities of benefits/risks in understandable manner	34 (69)	21 (84)	13 (54)	0.024 ^b	1
Combination of internet & paper format a good method of presenting info	43 (88)	24 (96)	19 (79)	0.098	1

For Patients, this DA will...

Be acceptable	35 (71)	23 (92)	12 (50)	0.0011 ^b	1
Be simple to use	19 (39)	17 (68)	2 (8.3)	<0.0001 ^b	1
Be too complex to use	13 (27)	3 (12)	10 (42)	0.019 ^b	4
Guide patients through the decision making process in logical fashion	32 (65)	21 (84)	11 (46)	0.005 ^b	1
Help patients understand benefits/risks of surgical choice	37 (76)	22 (88)	15 (62)	0.038 ^b	1
Prepare patients for the decision making process	33 (67)	21 (84)	12 (50)	0.011 ^b	1
Help patients in reaching decision about surgical choice	33 (67)	21 (84)	12 (50)	0.011 ^b	1
Allow patients to participate as they wish in the decision making process	35 (71)	22 (88)	13 (54)	0.0088 ^b	1
Improve patient decision making	29 (59)	20 (80)	9 (38)	0.0025 ^b	1
Apply to a sizeable proportion of them	33 (67)	19 (76)	14 (58)	0.18	1

Clinically, this DA will...

Is compatible with how I think patients should be informed about choices	42 (86)	25 (100)	17 (71)	0.0035 ^b	3
Will complement my usual approach	38 (78)	24 (96)	14 (58)	0.0016 ^b	2
Will improve my usual approach	22 (45)	18 (72)	4 (17)	<0.0001 ^b	2
Is a reliable tool for helping patients make decisions	26 (53)	18 (72)	8 (33)	0.0067 ^b	2
Will help me to more fully understand those issues of importance to patients	28 (57)	20 (80)	8 (33)	0.001 ^b	2
Will increase patients' satisfaction with my help	30 (61)	21 (84)	9 (38)	0.0008 ^b	2
Will improve the quality of patient visits	26 (53)	20 (80)	6 (25)	0.0001 ^b	2
Will provide easily observable benefits to the patients	22 (45)	18 (72)	4 (17)	<0.0001*	2

Issues related to implementation, This DA will...

DA will be easy to use in our rectal cancer program	26 (53)	20 (80)	6 (25)	0.0001 ^b	4
DA will save time	7 (14)	7 (28)	0 (0)	0.0096 ^b	2
Clear direction within our rectal cancer program that we need to provide support using protocols/guidelines	34 (69)	21 (84)	13 (54)	0.024 ^b	4
There is adequate time to use the DA	23 (47)	15 (60)	8 (33)	0.062 ^b	2
Using DA will require reorganization of practice setting	18 (37)	9 (36)	9 (36)	0.91	4
Using the DA will not require major changes to the way I currently discuss topic with patients	31 (63)	17 (68)	14 (58)	0.48	4
Using DA will help me tailor my counseling to patients' needs	26 (53)	20 (80)	6 (24)	0.0001 ^b	2
Using DA will affect my relationship with patients in a positive way	30 (61)	21 (84)	9 (38)	0.0008 ^b	2
DA will be easy to experiment with before deciding to adopt them in our rectal cancer program	32 (65)	19 (76)	13 (54)	0.108	4
DA likely to be used by most of my colleagues	13 (27)	10 (40)	3 (12)	0.029 ^b	4

a. Principal components:

Component 1: Quality and value for patients; Component 2: Value for physicians;

Component 3: Decision aid Content; Component 4: Implementation

b. Statistically significant

Table 3.3. Factors influencing the use of rectal cancer decision aid.

Independent Variables	Unadjusted Odds Ratio (95% CI ^a)	Odds Ratio Adjusted For Demographics ^c (95% CI ^a)	Odds Ratio Adjusted for Demographics ^c and other components (95% CI ^a)
Principal components ^b			
Quality and value for patients	21.2 (2.7-164.1) ^d	33.9 (2.8-410.3) ^d	3.34 (0.2-71.0)
Value for physicians	30.1 (4.1-222.9) ^d	28.3 (3.3-240.2) ^d	17.1(1.2-254.1) ^d
Decision aid content	17.7 (2.9-107.9) ^d	14.6 (2.3-94.8) ^d	2.4 (0.2-25.1)
Implementation	5.4 (1.0-28.6) ^d	5.8 (0.8-40.6)	0.6 (0.0-11.4)

a. CI=Confidence interval

b. Derived from principal component analysis and verimax rotation by Graham et al ⁷⁷.

c. Adjusted for age, years in practice, and annual patient volume

d. Statistically significant at p<0.05

Table 3.4. Themes from open-ended questions on the perception of barriers and facilitators to using the decision aid.

Theme	Frequency
Barriers	
PtDA Issues	
Not available in other languages	6
Lack of evidence	4
Too long	3
Too complex	3
More input from other professionals	2
Surgeon Attitude	
Surgeon bias towards LAR	4
Lack of surgeons consensus with PtDA approach	3
No need for PtDA as physician already practices it	2
Others (ie. approach not individualized, physicians resistance to change)	2
Resource Issues	
Time	17
Requires multiple visit	7
Requires more clinic personnel	7
Requires reorganization of clinic or referral	4
Challenge with timing of delivery	4
Others (ie. difficulty in independent practice, lack of electronic equipment, cost of using tool, lack of administrative support, general availability to patients, space confinement)	6
Patient Issues	
Patient environmental factors affecting comprehension (ie. SES a, education, age)	7
A burden on patients during consult	3
Lack of applicability to patient population	2
Facilitators	
PtDA Content	
Simplify/shorten PtDA	20
Additional information	12
Translation into other languages	8
Clarify wording	6
Reorganize presentation	4
Larger or additional diagrams	2

Others (ie. clarify choices, content needs to be individualized, improve value questions, stoma nurse acknowledgement) 4

Resource adjustment/Reorganization

Dedicated personnel 9

Give to patients before consultation 6

Reorganize/standardize patient flow 4

Administration support 2

Others (ie. more clinic time, access to computer/ipad) 2

a. SES – Socioeconomic status

Figure 3.1. Survey response rate by sequence of mail-out and cumulative response.

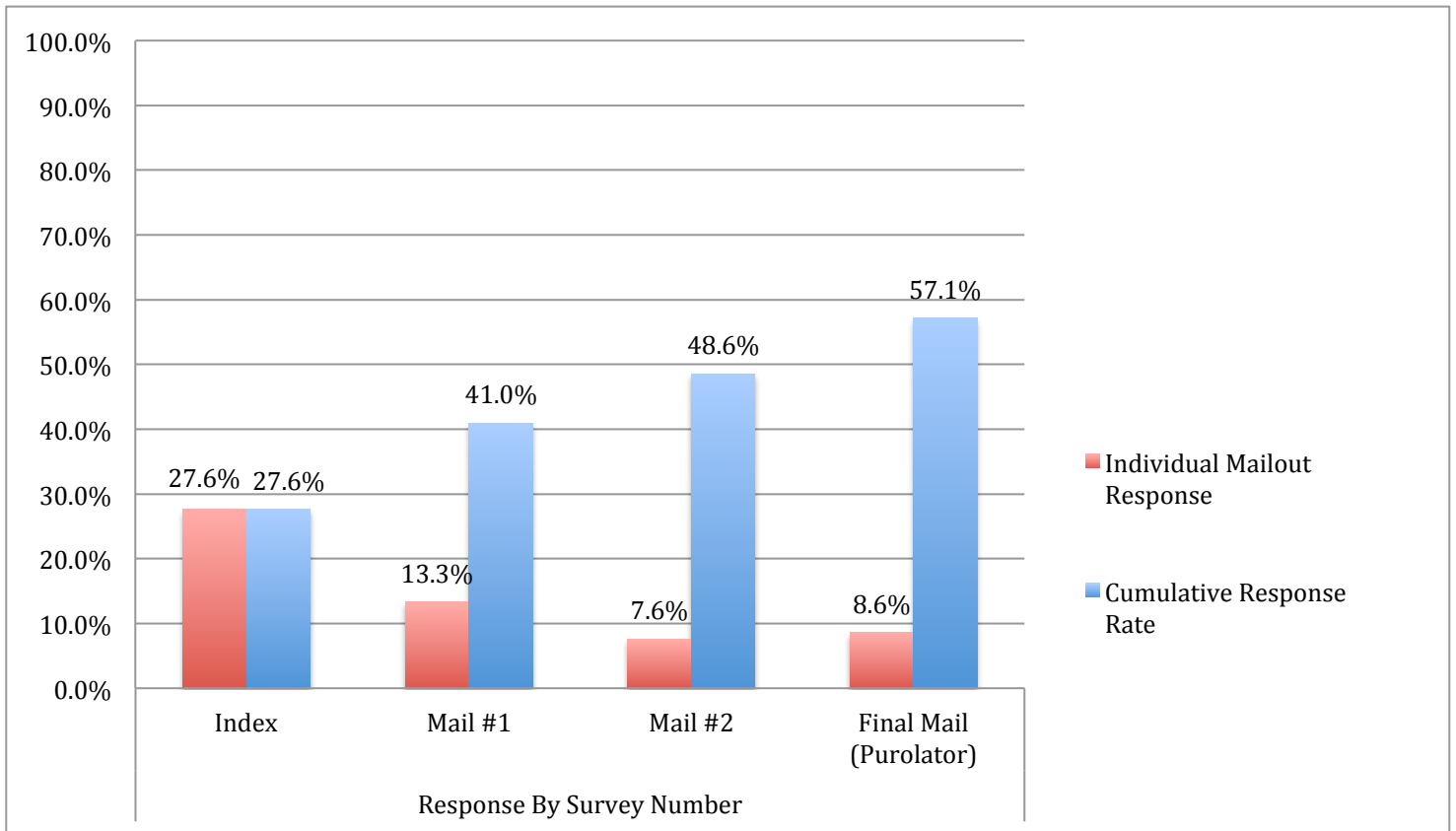
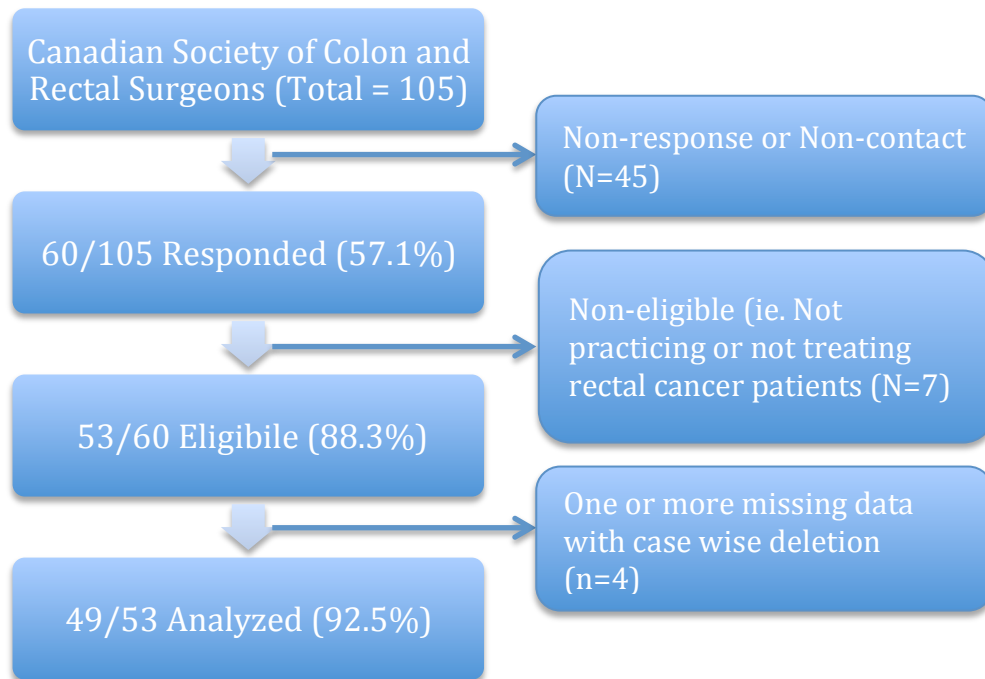


Figure 3.2. Survey respondent data flow.



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Chapter 4 is an integrative chapter that summarizes the previous three chapters and provides a discussion around the study findings.

Chapter 4

Integrated Discussion

Guided by the ODSF ⁴⁹ and the Knowledge to Action Framework ⁴⁰, this thesis involved a before and after study to evaluate the rectal cancer patient decision aid and a survey study to examine the potential factors that may impact the patient decision aid implementation as perceived by surgeons. These two studies are important for informing the process of patient decision aid adoption in clinical practice.

The purpose of this chapter is to provide a summary of the findings and an integrated discussion with implications for future research.

Patient Decision Aid Evaluation and Implementation

Overall results and literature support

Our before and after study of 28 patients newly diagnosed with rectal cancer supported the effectiveness of the rectal cancer patient decision aid in reducing patients' decisional conflict, improving their knowledge, and preparing them for discussion with surgeons (chapter 2). In addition, patients rated it as acceptable with a willingness to recommend it to others. The study of Canadian colorectal surgeons (N=49, chapter 3) showed that while surgeons agreed with the content and balanced presentation of surgical options in the patient decision aid, and agreed with a shared decision making approach, they perceived many barriers to its actual use in practice (e.g. time constraint, need for multiple visits, and dedicated personnel). Collectively, our findings are promising with respect to positive outcomes for patients, but the mismatch between surgeons' expressed support and their perception of barriers is likely to influence adoption of the patient decision aid in clinical practice.

Our before and after study results were consistent with a recently updated Cochrane review ¹⁶ of 115 trials supporting the effectiveness of patient decision aids, which found good quality evidence indicating, among patients, there was improved knowledge, reduced decisional conflict related to feeling uninformed and unclear about personal values, a more active role in decision making, and more accurate risk perception ¹⁶. Other systematic reviews on patient decision aids, including one specifically focused on surgical topics, have found similar effects ^{17,48,86}. Despite overwhelmingly positive data to support the use of patient decision aids, their adoption by healthcare professionals has been slow in Canada and US ^{73,94}. Common barriers to implementation identified in a systematic review included: 1) time constraint, and lack of applicability due to 2) patient characteristics and 3) the clinical situation ⁴². Similar views were expressed by Canadian colorectal surgeons in our survey study (Chapter 3). Four major issues that may stimulate the use of patient decision aids are establishing a patient empowerment approach, addressing surgeons' concerns, ensuring organizational supports, and considering healthy policy drivers.

Using patient decision aids within a patient empowerment approach

Patients' improvement in knowledge is necessary but not sufficient to achieve shared decision making ^{32,38,98,99}. In our study, the patient decision aid was associated with improved knowledge but it is unclear if it was adequate to stimulate SDM within the surgical consultation. Based on the surgeons' perspectives reported in our survey, we suggest that the improved patient knowledge we identified is unlikely to result in SDM without additional supports. Enabling patients to learn about their disease and treatment options is key to facilitate their inclusion in medical decisions but patients

may still face systematic barriers in playing a fully active role in the decisions ¹⁰⁰. Unless expectations and opportunities for patients to contribute their personal preferences are normalized within surgeons' practice, an asymmetry of power between patients and surgeons could persist to restrict their involvement ⁹⁹. Empowering patients to participate in clinical decisions to the extent that they prefer should therefore include a dual purpose, one to improve patients' knowledge of the condition and their treatment options, and second to encourage them in the consult to ask questions and share their preferences ¹⁰⁰. Initiatives to promote patient involvement in SDM are underway in the US, where the Agency for Healthcare Research and Quality (AHRQ) started the Questions Are the Answer campaign ¹⁰¹ to help normalize patient engagement through asking questions about their treatment. A randomized controlled trial in Australia showed that using simulated patients to ask three questions (e.g., other options, benefits and risks of options, likelihood of benefits and risks) facilitated greater involvement of patients by physicians ¹⁰². Increased use of such strategies may help remove the patient-physician power differential and create an expectation to use patient decision aids and share patient preferences ¹⁰³.

Addressing surgeons' perceptions influencing patient decision aid adoption

Our survey findings showed that physicians may be susceptible to misdiagnosis of patient preferences and selective use of a patient decision aid ¹⁰⁴. The survey found that surgeons assumed some patients prefer a passive role in decision making and that the patient decision aid would overburden them or that they would not be able to comprehend its content. These assumptions are concerning as a significant proportion of patients would prefer active involvement in decision making ¹⁰⁵ and physicians often

do not accurately predict patient preference ¹⁰⁶. In our before and after study, 82% of eligible patients agreed to participate and a majority reported the amount of information in the decision aid was just right and balanced (chapter 2). Patients did not report information overload. Interventions may be needed to encourage surgeons to use the patient decision aid and engage patients in shared decision making more broadly without *a priori* assumptions that patients do not want to be involved.

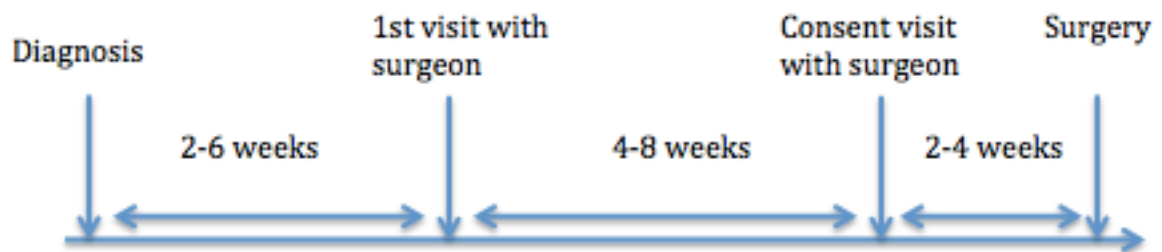
Anecdotally, we found that surgeons were sometimes apprehensive about their patients participating in the before and after study at the beginning of our work, but they became more motivated when they observed firsthand the impact of the patient decision aid on their patients' knowledge and comfort with choices. As a result, all five surgeons in our study setting informed eligible patients of the study. In planning an implementation strategy for the patient decision aid, it will be important to ensure that surgeons observe the impact of the patient decision aid on their patients' preparation for the discussion in the consultation. A systematic review found that interventions activating both the patients and physicians could lead to increases in patient involvement in shared decision making ³⁵. The next challenge will be to effectively evaluate surgeons' behaviours, and design ways to monitor and sustain the use of the patient decision aid beyond our before and after study ⁴¹. One strategy to monitor use could be to document its use during the patient dialogue ⁹⁴, but such a strategy would need to be endorsed by the organization and requires further consideration.

Ensuring organizational supports to implement patient decision aid

Delivering a patient decision aid as part of the process of patient care also requires an implementation intervention targeting the organization ⁹⁵. At the Cancer Assessment Center (CAC), all surgical patient are referred to a nurse-organized perioperative education session ¹⁰⁷ to orient patients around the general aspects of surgery and recovery. Patients with rectal cancer are also scheduled with a stoma nurse to review self-management of a stoma. These supportive educational sessions can complement the rectal cancer patient decision aid. Therefore, an important element to a patient decision aid implementation strategy may be to integrate it as part of an existing educational program ⁹⁵.

Second, the patient decision aid should be integrated into the clinical pathway. In the Ottawa Hospital, each patient is scheduled to see a surgeon at least twice before surgery (figure 4.1).

Figure 4.1. Pathway for patient care in the Ottawa Colorectal Cancer Assessment Center.



The first visit often involves completing the staging workup, making a plan for treatment, and having preliminary discussions about the surgery options. The second

visit focuses on the surgical consent. The time interval between the two visits would give patients the opportunity to view the patient decision aid at their own pace. This clinical pathway is ideal but specific to the institution where the study was conducted and may be different elsewhere ¹⁰⁸. As identified by our survey study, many institutions face logistic challenges where surgeons see a patient only once before surgery. Hence, the patient decision aid delivery would need to precede the first visit with a surgeon for consent. Two main roadblocks arise from such a pre-encounter delivery. Firstly, the rectal cancer patient decision aid applies to a subset of mid to low rectal cancers so that its applicability can be accurately assessed only by a specialist surgeon ¹⁰⁹. In addition, a subset of low-risk tumours may be amenable to undergo local excision ¹¹⁰ (ie. Trans-anal endoscopic microsurgery or endoscopic excision); whereas metastatic late-stage tumours may not be resectable ¹¹¹. Without surgeons differentiating potential candidates, it is challenging to predict appropriate patients and there is a risk of over-distributing the patient decision aid and potentially leading to unnecessary worries in the patients. To overcome the issue where multiple visits with the surgeon are not possible, a surgeon or advanced nurse practitioner could screen with the available medical records to decide on tumour location and the likelihood of needing formal resection before patient's visit ¹¹². Alternatively, the patient decision aid could be used within a consultation by a surgeon or the nurse, and subsequently provided to the patient to review at home.

Health policy drivers to endorse use of patient decision aid

Patient decision aid implementation may be further promoted by health policy changes. Policy level support for patient decision aids was reflected in the US Affordable Care Act ¹⁴ , multiple US state legislations ²⁹, UK health policy ¹¹³, and the province of Saskatchewan ⁷³. For example, the UK National Health Service has publically endorsed shared decision making, including the accessibility of decision aids to enable choice of treatment ¹¹⁴. Many US states, such as Washington, Minnesota, and Vermont have legislative support to facilitate the implementation of patient decision aid and shared decision making practice ¹³. Furthermore, funding for patient decision aid implementation is becoming available ^{14,94,113}. Such government policies and new investments may be important strategies to overcome known resource barriers, such as time constraint and dedicated personnel, as cited by the surgeons (chapter 3). It is conceivable that as governments shift attention and investment towards implementing these new health policies, the adoption of patient decision aids to facilitate shared decision making should evolve into the standard of practice.

Implications of Research Methodologies Used

Is before and after evaluation enough for patient decision aid evaluation?

The before and after study contributed important evidence toward evaluating the effect of the rectal cancer patient decision aid on patient choices and decision making processes ²⁷. It was strongly and statistically significantly associated with improved knowledge and reduced decisional conflict with the magnitude of effect being consistent with results from randomized controlled clinical trials ¹⁶. Our rectal cancer

patient decision aid followed a rigorous developmental process, guided by the ODSF ⁴⁹, and using quality criteria outlined by the IPDAS ²⁶. The comprehensive process ³⁷ included a study to identify the decision-making needs of patients and practitioners ²⁵, a systematic review to identify evidence on benefits and harms of surgical options ¹¹⁵, and a peer review with patients and practitioners who have made the decision ⁵⁰. The evaluation process of the current thesis focused on both its impact on the end users (patients), and the potential barriers and facilitators as perceived by the adopters (surgeons).

Although a direct impact on patient knowledge and decisional conflict was supported by the results of our before and after study, this non-randomized study could not adjust for any potential confounders and this leaves open the possibility that the associations we observed are not causal ¹¹⁶. Possible confounders include other experiences and interventions to which participants were exposed between the pre- and post-PtDA assessments and that might have influenced the study outcomes. For example, this includes educational materials other than the PtDA that are provided in the clinic, teaching sessions organized by nurses, Internet based information, and consultation with friends and/or family. Another potential threat to the validity of our observed association is measurement bias, where participants may have felt pressured to overstate their level of certainty with decision after patient decision aid use ¹¹⁶.

With respect to evidence from randomized controlled trials, of the 115 trials in the Cochrane Review, there are over 20 patient decision aids based on the ODSF that followed a similar process of development as our rectal cancer surgical patient decision aid and the overall findings are highly consistent with our study. The Grading of

Recommendations Assessment, Development and Evaluation (GRADE) group ¹¹⁷ has suggested that if there are large and consistent estimates of a treatment effect, it may be appropriate to accept the apparent benefit of the same treatment despite the potential methodological flaws in study design ¹¹⁸. Therefore, while recognizing the methodological limitations of our before and after study, we believe that confounding is unlikely to explain all of the observed benefits of the rectal cancer patient decision aid ¹¹⁸.

The most important evidence gap in this literature is understanding and addressing the poor uptake of patient decision aids in routine clinical practice despite evidence of their effectiveness with regards to patient outcomes ^{36,38,119}. Given that the rectal cancer decision aid now has some evidence to indicate improved knowledge and lowered decisional conflict, the next logical step is a clinical trial to evaluate interventions to implement it in a range of surgical practice settings ³⁶. For example, a clustered randomized trial assessing whether systematic identification and distribution of the patient decision aid to patients before a clinic visit could lead to shared decision making and raise the decision quality during a consultation with surgeon would be a pertinent study to assess an implementation strategy.

Strategies to enhance survey response rates

Obtaining good response rates in survey studies is challenging ¹²⁰. Our survey response rate was 57% which may be considered moderate, although there is no definitive standard for such judgements ⁸²⁻⁸⁴ and response rates should be interpreted in the context of other aspects of survey methodology ^{121,122}. A higher response rate would reduce the magnitude of non-response bias ¹²³, which results when non-

respondents are different in their perceptions of the patient decision aid relative to respondents. Given that survey responders may have been particularly interested in reviewing the patient decision aid, the study may have overestimated the perceived likelihood of its use, surgeons' levels of comfort in offering it, or their perceptions about the need for a patient decision aid. However, we hypothesize that the barriers and facilitators perceived as most important were less likely to have been affected by non-response bias, which is supported by evidence that these were consistent with other studies ⁴².

To enhance the survey response rate in our study, six key approaches were used based on Dillman's method and multiple literature reviews ^{120,124,125}. First, a postal mailed survey was chosen due to the comparatively higher response rates for mailed versus web surveys among clinicians ^{126,127}. Second, the survey length was restricted to four pages formatted to fit on two sheets of Legal size paper. Length of survey has been shown to impact response ¹²⁷. Third, a non-contingent monetary incentive of gift cards (\$10 Canadian) was included with the index mail-out. There is evidence that including an incentive upfront can increase response rate ¹²⁸. Fourth, the survey invitation was signed by a surgeon considered to be an opinion leader (Dr. Robin Boushey) and the study was endorsed by the Canadian Society of Colon and Rectal Surgeons. In addition, the initiation of the survey study was announced in the Canadian Society of Colon and Rectal Surgeons monthly e-newsletter. Although the addition of an opinion leader alone may not always increase response rate among physicians ¹²⁹, when coupled with the endorsement of the association ¹³⁰ it may have contributed to the response rate. Fifth, we obtained the membership list from the Canadian Society of Colon and Rectal

Surgeons and used the publically accessible registration information from the respective provincial College of Physicians and Surgeons to obtain their official work addresses. In addition to enabling us to verify accuracy of mailing addresses, this allowed us to provide personalized follow-up messages to non-respondents. Furthermore, we could track errors in addresses and determine a reasonable denominator for the calculation of the response rate. Personalized reminders have been shown in the literature to positively affect the response rate ¹³¹. Sixth, the final follow-up reminder was sent via courier mail, which has been previously shown to increase response rates among physicians. ^{79,132}

All of the six approaches were integrated into the design and conduct of the survey to achieve a reasonable response rate in a historically challenging population ¹³³. Given that practitioners are inundated with surveys, further research is required to continue to determine the effectiveness of strategies to increase response rates.

Implications for future research

Two main research gaps are prominent for the rectal cancer patient decision aid. Firstly, although many clinical trials have demonstrated positive effects on patients, uncertainties exist as to how the patient experience translates to patient involvement at the moment of surgeon encounter ^{16,134,135}. Of 115 trials, only 5 trials rigorously measured the effect of a patient decision aid on patient-physician communication using analysis of audio-recordings; none of these involved surgeons ¹⁶. Using the OPTION Scale or the Decision Making Observer Instrument, these 5 trials all reported statistically significantly improved patient-physician communication. The main

challenge associated with evaluating the interaction is the lack of reliable instruments. Instruments such as collaboRATE^{136,137} and Observer Patient Involvement in Decision Making (OPTION) scale¹³⁸ are being developed but each has its drawbacks. The collaboRATE scale uses patient reported measures that do not address the physician aspect of the encounter^{136,137} and the OPTION scale measures physician behavior without patient considerations¹³⁸. A dyadic OPTION scale, theoretically founded on assessing both physicians and patients but no psychometric properties have been reported¹³⁹. At the moment, any planned studies may need to include both instruments (eg. collaboRATE and OPTION) to evaluate the process and to avoid overly simplistic unidimensional measures.

The second important research gap is lack of evidence on effective interventions for implementing patient decision aids³⁶. Although our studies evaluated the rectal cancer patient decision aid at the patient level and assessed the perceived contextual challenges associated with surgeons' use, these study results do not guarantee that addressing the identified barriers would ensure integration of the patient decision aid into clinical practice³⁶. It is also unknown whether physician endorsement of a patient decision aid throughout the before and after study is sustainable without the pressure of study recruitment and the presence of a research assistant³⁶.

For the next steps of implementation, we plan to continue to follow the KtA framework by refining the rectal cancer patient decision aid and applying implementation interventions targeting surgeons and the organization⁴⁰. The patient decision aid should be revised based on surgeon and patient feedback collected in both

of our studies. Given the Canadian context, we plan to translate it to French as per surgeons' recommendation (chapter 3), and we will consider inserting suggestions for other readings in the patient decision aid. For surgeons to achieve comfort with patient decision aids, interactive educational workshops may be useful, focused on developing their knowledge and skills on patient decision aids and shared decision making ¹⁴⁰. Such training could also include others within the interprofessional team who can also support patients in using patient decision aids ¹⁴¹. Examples of such training programs can be found in the UK ¹⁴², Germany ¹⁴³, Canada ¹⁴⁴, with some beneficial effects on increasing patient participation ^{145,146}. Organizational interventions to facilitate patient decision aid implementation may include administrative support, using patient decision aids as a quality indicator, orienting care pathways to facilitate the use of patient decision aid, and improving access to patient decision aid to surgeons and patients ³⁸. These interventions should be delivered and evaluated as a multifaceted intervention to reach maximum effectiveness ¹⁴⁷.

Conclusion

The rectal cancer patient decision aid may improve patient knowledge and reduce decisional conflict for patients diagnosed with mid to low rectal cancer. Even though surgeons are receptive to the patient decision aid, perceived barriers are likely to impede its wide adoption. The patient decision aid has the potential to overcome patient barriers to shared decision making (eg. lack of knowledge, decision conflict) but requires targeted interventions to overcome surgeon identified barriers to use the patient decision aid in clinical practice (eg. time demands, additional personnel). Subsequent research should focus on evaluating an implementation strategy that is

tailored to address the identified barriers from surgeons' survey, and aim to have sustained use of rectal cancer patient decision aid in everyday practice. In addition, further research should evaluate the patient decision aid impact on the patient-physician dialogue.

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Name: _____

Should I have my bowels “hooked up” (anastomosis) when removing my rectal cancer?

A decision aid for patients with rectal cancer

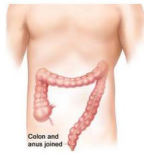
This decision aid is for you if:

- You have rectal cancer treatable by surgery
- Your surgeon has suggested having your bowels hooked back up at surgery

What is rectal cancer?

- Rectal cancer is a tumour located in the last 15 cm of the intestine.
- It is a difficult cancer to treat as it grows close to the muscles involved in the control of bowel movements and gas.
- The first goal of treatment is to remove all of the tumour for the best chance of survival.
- The second goal of treatment is to achieve acceptable bowel function.
- Although having your bowels hooked up is commonly recommended there is another option of having a permanent stoma (bag). These options are described next.

What are your options to remove the tumor?



Bowel hook up (Anterior Resection): The rectum is removed and the two healthy ends of bowel are reconnected. Your surgeon may need to create a temporary stoma (bag) to allow the hook up to heal. This temporary stoma produces more liquid stool with little odour. After 4-6 months the temporary stoma is reversed. After recovery, bowel movements are likely to be less predictable, more frequent, including at night, and urgent. Most people are able to manage this change. Some patients have poor control and have another operation for a permanent stoma. Patients who have radiation are more likely to experience changes in their bowel habits.



Permanent stoma (Abdominoperineal Resection): The rectum and anus are removed. The area of the anus is permanently closed and the bowel is not hooked up. The bowel is brought out to the skin and a stoma bag is attached. Following recovery, bowel movements will become more regular and predictable (e.g. morning and night). The bag controls smells and release of gas. Daily stoma care is necessary such as cleaning the area, changing the bag and applying creams. The costs of these materials may be covered. Most people resume their normal activities.

Name: _____

What other health factors may affect your choice? Check any that apply.



Do you currently have bowel problems?

	Never	Once a week	More than once a week	Daily
1.1 Accidental leaks of gas?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.2 Accidental leaks of liquid stool?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.3 Accidental leaks of solid stool?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.4 Wear a pad because of accidental leaks of liquid or solid stool?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> None of these apply to me				



Do you have problems getting to the bathroom?





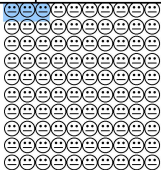
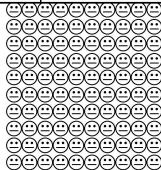
	Yes	No
1.5 Difficulty walking?	<input type="checkbox"/>	<input type="checkbox"/>
1.6 Use a wheelchair?	<input type="checkbox"/>	<input type="checkbox"/>
1.7 Job/lifestyle limits easy access to bathrooms? (eg. Outdoors)	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> None of these apply to me		

Name: _____




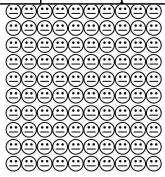
Step 1: What are the benefits and harms of each option?

What does the research show?

Blocks of 100 faces show a 'best estimate' of what happens to **100 people** after surgery and up to 4 years after who have their bowels reconnected or a permanent colostomy. Each face(☹) stands for one person. The shaded areas show the number of people affected. There is no way of knowing in advance if you will be one of those affected. You should discuss with your surgeon if you have any risk factors for these outcomes.

		
Benefits	Bowel hook up	Permanent stoma
85 fewer people have a permanent stoma if they have their bowels reconnected.	12 get a permanent stoma	100 get a permanent stoma
By avoiding a permanent stoma you also avoid the complications of a permanent stoma such as:	85 avoid a permanent stoma	0 avoids a permanent stoma
<ul style="list-style-type: none"> • hernia of the stoma • bowel sliding out through the stoma • skin irritation around the stoma • problems with healing or infection where the anus was closed 		
Risks		
3 more people who have their bowels reconnected with a temporary stoma return to the operating room (OR) because of a life-threatening leak at the connection site. This may mean extra treatments, longer hospital stay and a longer recovery. You may need to be treated in the intensive care unit.	3 return to the OR	0 return to the OR
This number is higher for people who do not have a temporary stoma when their bowels are reconnected. In this case, 11 more people will return to the OR.	97 avoid this	100 avoid this
		

Name: _____

		
Risks continued	Bowel hook up	Permanent stoma
<p>35 more people will complain of some form of incontinence following bowel hook up. The majority has minor incontinence (accidents) to gas and liquid stool. 14 people (out of 100) experience major incontinence to solid stool.</p> <p>All of these people choose to wear a protective pad in their underwear.</p>	<p>35 wear a pad</p>	<p>0 wear a pad</p>
	<p>65 avoid a pad</p> 	<p>100 avoid a pad</p> 
	<p>Problems from either surgery:</p> <p>Some people who have either surgery report worsening of their urinary or sexual function. The number of people who report this problem is the same for both surgeries.</p> <p>Urinary problems include difficulty emptying the bladder. There may also be problems of leaking urine, which is more common in women.</p> <p>For men, sexual problems may include impotence or ejaculation problems. For women, sexual problems may include vaginal dryness, pain during intercourse, problems with arousal or achieving orgasm.</p>	

Name: _____

Step 2. Which reasons to choose each option matter most to you?

Common reasons to choose each option are listed below.

Mark ✓ how much each reason matter to you on a scale from 0 to 5.

'0' means it is not important to you. '5' means it is very important to you.



Reasons to...
Choose to have your bowels hooked up

		Not Important		Somewhat Important		Very Important	
		[0]	[1]	[2]	[3]	[4]	[5]
2.1	How important is it for you to have bowel movements the usual way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2	How important is it to you to avoid the inconvenience of caring for a stoma? (e.g. emptying the bag, cleaning the area, applying creams and buying bags)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.3	How important is it for you to avoid the complications of a permanent stoma? (including wound healing problems, stoma hernias, and skin irritations)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Reasons to ...
Choose a permanent stoma

		Not Important		Somewhat Important		Very Important	
		[0]	[1]	[2]	[3]	[4]	[5]
2.4	How important is it that your bowel movements are more predictable, less frequent and less urgent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.5	How important is it for you to avoid incontinence (leaking) of stool or gas?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.6	How important is it to for you to avoid having multiple surgeries?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Name: _____

List other reasons that are important

List other reasons that are important

Now, thinking about the reasons that are most important to you...

If you definitely prefer a permanent stoma, check the box far to the right.

If you definitely prefer a bowel hook up, check the box far to the left.

3.1 If you are uncertain, check the centre box

Bowel hook up	Uncertain		Permanent stoma

Choice predisposition © AM O'Connor 1996

Step 3: What else do you need to prepare for decision-making?

KNOWLEDGE



Find out how well this decision aid helped you learn the key facts.

Check the best answer.

Bowel hook up Permanent stoma Don't know

- | | | | | |
|------|---|--------------------------|--|---------------------------------------|
| 4.1. | Which option has the <u>highest</u> chance of needing a second surgery? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.2. | Which option cannot be reversed? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.3. | Which option has the <u>highest</u> chance of hernia and wound healing problems? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.4. | Which option has the <u>highest</u> chance of incontinence (accidents) of stool or gas? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.5. | Do you know enough about the benefits and side effects of each option? | | Yes
<input type="checkbox"/> | No
<input type="checkbox"/> |

Check your answers at the bottom of the page

Name: _____

DECISIONAL CONFLICT



Find out if you have uncertainties.

		Strongly agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
		[0]	[1]	[2]	[3]	[4]
5.1	I know which options are available to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2	I know the benefits of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.3	I know the risks and side effects of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.4	I am clear about which benefits matter most to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.5	I am clear about which risks and side effects matter most to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.6	I am clear about which is more important to me (the benefits or the risks and side effects).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.7	I have enough support from others to make a choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.8	I am choosing without pressure from others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.9	I have enough advice to make a choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.10	I am clear about the best choice for me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.11	I feel sure about what to choose.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.12	This decision is easy for me to make.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Name: _____

	Strongly agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
	[0]	[1]	[2]	[3]	[4]
5.13 I feel I have made an informed choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.14 My decision shows what is important to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.15 I expect to stick with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.16 I am satisfied with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Decisional conflict scale © AM O'Connor 2005

The information is not intended to replace the advice of a healthcare provider.
A final decision can only be achieved through discussion with a healthcare provider.

Step 4. What are the next steps?

PREPARATION FOR DECISION MAKING



Find out if you are ready to communicate with the doctor.

Did this educational material ...	Not at all	A little	Some-what	Quite a bit	A great deal
6.1 Help you recognize that a decision needs to be made	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2 Help you think about the pros and cons of each option?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.3 Help you think about which pros and cons are most important?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.4 Help you organize your own thoughts about the choices?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.5 Help you think about how involved you want to be in this decision?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.6 Help you identify questions you want to ask your doctor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.7 Prepare you to talk to your doctor about what matters most to you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.8 Prepare you for a follow-up visit with your doctor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Name: _____

Preparation for Decision Making Scale © Graham & O'Connor 1995

This information is not intended to replace the advice of a health care provider.

Answers for the key facts: 1. Bowel hook up 2. Permanent stoma 3. Permanent stoma 4. Bowel reconnection

Content editors: AS Scheer, RC Wu, RP Boushey, PL Roberts

Funded in part by: PSI, ASCRS. All Authors have declared no conflict of interest.

Format based on the Ottawa Personal Decision Guide © 2000, A O'Connor, D Stacey, University of Ottawa, Canada.

Readability: FK Grade level 8.

References:

1. Matthiessen P, Hallbook O, Rutegard J, Simert G, Sjødahl R. Defunctioning stoma reduces symptomatic anastomotic leakage after low anterior resection of the rectum for cancer: A randomized multicenter trial. *Ann Surg* 2007; 246: 207 - 214.
2. Carne PWG, Robertson GM, Frizelle FA. Parastomal hernia. *British Journal of Surgery* 2003; 90: 784-793.
3. Salvadalena G. Incidence of complications of the stoma and peristomal skin among individuals with colostomy, ileostomy, and urostomy: A systematic review. *Journal of wound, ostomy, and continence* 2008; 35 (6): 596-607.
4. Tan WS, Tang CL, Shi L, Eu KW. Meta-analysis of defunctioning stomas in low anterior resection for rectal cancer. *British J of Surg* 2009; 96(5): 462 - 472.
5. Scheer AS, Boushey RP, Liang S, Doucette S, O'Connor AM, Moher D. The long-term gastrointestinal functional outcomes following anterior resection for rectal cancer: A systematic review, meta-analysis and meta-regression. Submitted for publication.
6. Lange MM, Mass CP, Marijnen CAM, Wiggers T, Rutten HJ, Klein Kranenberg E, van de Velde CJH, cooperative clinical investigators of the Dutch Total Mesorectal Excision Trial. Urinary dysfunction after rectal cancer treatment is mainly caused by surgery. *British J Surg* 2008; 95: 1020 - 1028.
7. Lange MM et al. Risk factors for sexual dysfunction after rectal cancer treatment. *Eur J Cancer* 2009; 45(9): 1578 - 88.

Appendix II. Consent forms



The Ottawa Hospital | L'Hôpital
d'Ottawa

Participant Information Sheet and Consent Form

Title of study: Impact of the rectal cancer decision aid on patient shared decision making.

OHSN-REB Protocol Number: 20130634-01H

Principal Investigator (PI): Dr. Robert Wu

Co-Investigators: Dr. Robin Boushey, Dr. Dawn Stacey, and Dr. Elizabeth Potter

Funding source: None.

Introduction

You are being asked to participate in the current study because you have recently been diagnosed with rectal cancer and you have had your first visit with a surgeon at the Cancer Assessment Centre (CAC).

A decision aid for patients with cancer in the rectum has been developed to help patients with more than one option for surgery. You are being asked to participate in this research study to test and give feedback on a new decision aid.

Participation in this study is voluntary. Please read this Participant Information Sheet and Consent Form carefully and ask the study doctor and study team as many questions as you like before deciding whether to participate in this research study. You may also discuss your options with family, friends, or your healthcare team.

Background, Purpose and Design of the Study

A decision aid helps patients make decisions on their future treatment by looking at benefits, harms, and scientific uncertainty. The purpose of the study is to test a new decision aid for patients with rectal cancer and find if it helps patients talk to their surgeon about the decision. This study is for patients who have learned they have rectal cancer and who need to think about options for surgery at the Ottawa Hospital. The result of the study will be used to make any needed changes to the decision aid and the decision aid may then be used in other cancer programs in Canada.

This study is taking place at the Ottawa Hospital Cancer Assessment Clinic (CAC). We plan to enroll 38 people in the study.

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General Campus Général
501 chemin Smyth Road
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Riverside Campus Riverside
1967 prom. Riverside Drive
Ottawa, Ontario K1H 7W9

Study Duration

You participation in the study will last about 2 months. Over this time, you will not have any extra visits to the CAC.

Study Procedures

You will be asked to complete two sets of questions, one at your first visit, and one when you are home, after you have viewed the decision aid. The questions will help us learn how the decision aid helps you with thinking about your options for surgery. We will also ask your opinion on the decision aid. Each set of questions will take about 15-20 min to complete. You may skip any questions that make you feel uncomfortable or that you do not wish to answer.

Responsibilities of the Participant

It is important that you remember the following things during this study:

- Ask if you have any questions or concerns about the study.
- You will be asked to sign a consent form and then answer a set of questions.
- Then, you will be given the decision aid to review at home and you may share it with family or friends. The decision aid is on a password protected Internet site and you will also get a paper copy. You may choose to review both formats.
- As part of the decision aid, you will be asked to answer a few questions. This can be done on the computer or on the paper copy. If you answer the questions online, they go directly to the investigator's office. If you answer on the paper copy, then please bring it with you to the next clinic visit.
- A CAC nurse will call in two weeks, to ask you if you have any questions and if you had any problems with the decision aid. You may be asked if you want another call a week later to answer any questions.

Potential Risks and Discomforts

You might not like all the questions that you are asked. You do not have to answer any question that makes you feel uncomfortable.

Potential Benefits

Decision aids used with other participants have been shown to help participants talk to their doctor about their preferred choice and what is important to them in the decision. The potential benefit from this study is that you may learn more about rectal cancer, types of surgery, and think about what is important to you in this decision.

Alternative Treatment Available

You do not have to participate in this research study. You will also receive the usual information that all participants receive in the Cancer Assessment Centre.

Withdrawal from the Study

You may withdraw from the study at any time without any impact on your current or future care at the Ottawa Hospital Cancer Assessment Centre. If you decide to withdraw you should contact the investigator or the study team, before you withdraw, so that they can discuss any issues involved in discontinuing this study.

If you choose to also withdraw your consent, the study team will no longer use your personal health information for research purposes, unless it is necessary to preserve the scientific integrity.

You have the right to check your study records and request changes if the information is not correct. However, to ensure the scientific integrity of the study, some of your records may be available until after the study has been completed.

Study Costs/Coverage

You will not be paid to take part in this research study.

Conflict of Interest

This study is being conducted at the Ottawa Hospital. We do not have any funding for the study and the investigators will not benefit financially from the study.

Possibility of Commercialization

If the rectal cancer decision aid is proven effective, it may be approved for use and available free of cost to other organizations. The investigators and the Ottawa Hospital will not benefit from this development.

Confidentiality

Personal health information that identifies you may be used or shared for the purposes of the study. This section of the consent form describes how your information will be used and shared in this study, as well as the ways the CAC will safeguard your privacy and confidentiality.

All personal health information will be kept confidential, unless ~~release is required by law~~. For audit purposes only, representatives of government agencies (such as Health Canada), the Ottawa Health Science Network Research Ethics Board (OHSN-REB) and the Ottawa Hospital, may review your original medical records under the supervision of the Investigator's staff.

Results should be shared, to ensure patients are always provided with the best possible care. Therefore, results from this study may be presented at scientific

conferences and/or published journals but you will not be identifiable in any publications or presentations.

Your name, full date of birth, sex, medical record number, phone number, and email address will be collected, however, no identifiable information will leave the Ottawa Hospital Cancer Assessment Clinic. All information that leaves the CAC will be coded with an independent study number. The Master List which links your name and the independent study number will only be accessible by the Investigator and/or his staff. The link and study files will be stored separately and securely.

All paper records will be stored in a locked filing cabinet. All electronic records, including the Master List, will be stored in a secure internal hospital server and password protected, again only accessible by the Investigator and his staff. No identifiable information will be stored in any mobile devices (laptops, USB keys, CDs, DVDs, etc.). Research files will be kept for a period of 10 years after the study has been completed, as required by law. At 10 years, all paper records will be disposed of in confidential waste for shredding and all electronic records will be securely deleted.

Voluntary Participation

Your participation in this study is completely voluntary. You may decide not to be in this study, or to be in study now, and then change your mind later. Your decision will not affect the care you receive at this institution now or in the future, and will not result in any loss of benefits that you are otherwise entitled.

You will be told of any new findings during the study that could affect your willingness to continue the study. You may be asked to sign a new consent form.

Study Contacts

If you have any questions about the study, please page Robert Wu

The Ottawa Health Science Network Research Ethics Boards (OHSN-REB) has reviewed this protocol. The Board considers the ethics aspects of all research studies involving human participants at the Ottawa Hospital. If you have any questions about your rights as a study participant, you may contact the Chairperson



Impact of the rectal cancer decision aid on patient shared ~~decision making~~.

OHSN-REB #20130634-01H

Consent to Participate in Research

I understand that I am being asked to participate in a research study about rectal cancer patient decision aid implementation. This study has been explained to me by _____

I have read, or have had it read to me, this five-page Participant Information Sheet and Consent Form. All of my questions have been answered to my satisfaction. If I later decide that I would like to withdraw from my participation and/or consent from the study, I know that I can do so at any time. I voluntarily agree to participate in this study.

A copy of the Participant Information Sheet and Consent Form will be provided to me.

Signatures

Participant's Name (Please Print)

Participant's Signature

___/___/___
Date

Investigator Statement (or Person Explaining the Consent)

I have carefully explained the study to the study participant. To the best of my knowledge, the study participant signing this consent form understands the nature, demands, risks and benefits involved in taking part in this study. I acknowledge my responsibility for the care and well being of the above study participant, to respect the rights and wishes of the study participant, and to conduct the study according to applicable Good Clinical Practice guidelines and regulations.

Name of Investigator/delegate Name (Please Print)

Investigator/delegate Signature

___/___/___
Date

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Appendix III. Pre-decision aid questionnaire

**The Rectal Cancer Decision Aid Study-
Pre-Decision Aid Questionnaire**

Questions to answer before decision aid viewing.
Please complete the following questions to the best of your ability.

KNOWLEDGE



Find out how well this decision aid helped you learn the key facts.

Check the best answer.

Bowel hook up

Permanent stoma

Don't know

- | | | | | |
|----|---|--------------------------|--|---------------------------------------|
| 1. | Which option has the <u>highest</u> chance of needing a second surgery? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. | Which option cannot be reversed? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. | Which option has the <u>highest</u> chance of hernia and wound healing problems? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. | Which option has the <u>highest</u> chance of incontinence (accidents) of stool or gas? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. | Do you know enough about the benefits and side effects of each option? | | Yes
<input type="checkbox"/> | No
<input type="checkbox"/> |

CHOICE PREDISPOSITION




Any choice you are leaning to?

If you definitely prefer a permanent stoma, check the box far to the right.
 If you definitely prefer a bowel hook up, check the box far to the left.
 If you are uncertain, check the centre box

6.

Permanent Stoma					Uncertain					Bowel hook up				



DECISIONAL CONFLICT

Find out if you have uncertainties.

		Strongly agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
		[0]	[1]	[2]	[3]	[4]
7.	I know which options are available to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	I know the benefits of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	I know the risks and side effects of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	I am clear about which benefits matter most to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	I am clear about which risks and side effects matter most to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.	I am clear about which is more important to me (the benefits or the risks and side effects).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13.	I have enough support from others to make a choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

14.	I am choosing without pressure from others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15.	I have enough advice to make a choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16.	I am clear about the best choice for me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Strongly agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
		[0]	[1]	[2]	[3]	[4]
17.	I feel sure about what to choose.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18.	This decision is easy for me to make.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19.	I feel I have made an informed choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20.	My decision shows what is important to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21.	I expect to stick with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22.	I am satisfied with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Content editors: AS Scheer, RC Wu, RP Boushey, PL Roberts

Funded in part by: PSI, ASCRS. All Authors have declared no conflict of interest.

Format based on the Ottawa Personal Decision Guide © 2000, A O'Connor, D Stacey, University of Ottawa, Canada.

Readability: FK Grade level 8.

References:

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3. Salvadalena G. Incidence of complications of the stoma and peristomal skin among individuals with colostomy, ileostomy, and urostomy: A systematic review. *Journal of wound, ostomy, and continence* 2008; 35 (6): 596-607.
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5. Scheer AS, Boushey RP, Liang S, Doucette S, O'Connor AM, Moher D. The long-term gastrointestinal

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6. Lange MM, Mass CP, Marijnen CAM, Wiggers T, Rutten HJ, Klein Kranenberg E, van de Velde CJH, cooperative clinical investigators of the Dutch Total Mesorectal Excision Trial. Urinary dysfunction after rectal cancer treatment is mainly caused by surgery. *British J Surg* 2008; 95: 1020 – 1028.

7. Lange MM et al. Risk factors for sexual dysfunction after rectal cancer treatment. *Eur J Cancer* 2009; 45(9): 1578 – 88.

Appendix IV. Key instructions for patients in before and after study.

**KEY INSTRUCTIONS
for Rectal Cancer Decision Aid Study**

Please find the following in your package:

- Two identical paper copies of the Rectal Cancer Patient Decision Aid & Questionnaire (one copy to keep; one to send back)
- Envelope to mail your questionnaire back if you decide to answer the questions on paper

Email

You will get an email to access the online decision aid to you. Please look for an email entitled “Rectal Cancer Decision Tool Login Account”. To access the online decision aid, please use the username and password provided to you in the email.

Procedure

1. Please look at the decision aid and answer the questions attached. You can use the paper version, online version, or both. You only need to answer one set of questions.
2. Return the completed questions

2.1) Online version:

- If you answer the questionnaire online, all your answers will reach us directly after you push the “submit” button. No further action required.

2.2) Paper version:

- If you answer the questionnaire on paper, please mail us the copy containing all your answers. You may keep the other copy as a reference.

A member of the study team will contact you in 2 weeks to see if you have any questions. If you have questions, don't hesitate to contact the study investigator Robert Wu.

Thank you for participating in this study.

Dr. Robert Wu, Study Investigator
The Ottawa Hospital Cancer Assessment Centre
Ottawa, Ontario



The Ottawa Hospital | L'Hôpital
d'Ottawa

Rectal Cancer Surgery



A Decision Aid to Help Your Decision

We are doing a **research study** for those participants who are faced with two possible alternatives in rectal cancer surgical treatment. If you decide to participate, you will be asked to use a **rectal cancer decision aid** tool, developed at the Ottawa Hospital. This decision aid was created to provide knowledge, help you with your decision making process, and align your values with your preferred choice of surgery. Your study doctor/delegate will provide you with the information package for you to decide on whether you would like to participate in this study.

You must be able to read and understand English in order to participate in this research study.

If you have any questions about the study, at any time, please **feel free to ask the investigator or clinic nursing staff.**

If you decide to participate, you will be asked to answer a questionnaire over the next 20-30 minutes, and then you will be given an information package related to the decision aid.

If you decide not to participate, your care will not be affected in any way.

Thank you in advance for your consideration.

This research study has been approved by the Ottawa Health Science Network Research Ethics Board.

Version Date: Oct 9, 2013

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Appendix VI. Colorectal surgeon survey

Survey of Factors Influencing Colorectal Surgeons Using Rectal Cancer Decision Aid

Instructions:

- 1) Two formats are available; you may choose to view one or both formats
 - a. Paper format is attached
 - b. Online format by using the following access:

- 2) Complete the survey AFTER you've seen the decision aid, you are welcome to revisit it any time
- 3) Return the completed survey in the enclosed envelop

r. Are you a board certified surgeon CURRENTLY working with rectal cancer patients?

- Yes No

If no, please check "no" and return the survey in the enclosed envelope
 If yes, please view the decision aid AND complete the survey

z. Have you reviewed the rectal cancer decision aid?

- Yes No

If no, view decision aid before proceeding further (open attached paper version OR visit online version)
 If yes, continue to the next question

3. Is there a need for a decision aid on this topic?

- Yes No Unsure

Please tell us how much to you agree or disagree with the following statements. (Choose one answer)

<i>Factors influencing colorectal surgeons using rectal cancer decision aid</i>	Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
Issues related to the development of the symptom protocols					
4.01 The developers of the DA are credible	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.02 The information provided within the DA is supported by evidence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.03 The DA is well developed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.04 The development of the DA was not influenced by vested interests	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Issues related to the content and format					
4.05 The information provided on treatment choices is balanced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.06 The DA contains essential information to help the decision making process	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.07 The DA is well-organized	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.08 The DA clearly describes treatment choices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.09 The evidence described in the DA reflects my understanding of the data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.10 The evidence is presented in an unbiased manner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.11 The evidence is up-to-date	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<i>Factors influencing colorectal surgeons using rectal cancer decision aid</i>	Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
4.12 The DA presents the probabilities of benefits/risks in an understandable manner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.13 The combination of internet and paper format is a good method of presenting information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
For patients making this decision, the Decision Aid will					
4.14 Be acceptable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.15 Be simple to use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.16 Be too complex to use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.17 Guide patients through the decision making process in a logical fashion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.18 Help patients understand the benefits/risks of the surgical choice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.19 Prepare patients for the decision making process	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.20 Help patients in reaching their decision about surgical choice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.21 Allow patients to participate as they wish in the decision making process	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.22 Improve patient decision making	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.23 Apply to a sizeable proportion of them	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Issues related to my clinical perspective, the Decision Aid					
4.24 Is compatible with how I think patients should be informed about choices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.25 Will complement my usual approach	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.26 Will improve my usual approach	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.27 Is a reliable tool for helping patients make decisions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.28 Will help me to more fully understand those issues of importance to patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.29 Will increase patients' satisfaction with my help	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.30 Will improve the quality of patient visits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.31 Will provide easily observable benefits to the patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Issues about implementation; from my perspective					
4.32 The decision aid will be easy to use in our rectal cancer program	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.33 The DA will save time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.34 There is clear direction within our rectal cancer program that we need to provide support using protocols/guidelines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.35 There is adequate time to use the DA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.36 Using the DA will require reorganization of my practice setting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.37 Using the DA will <u>not require</u> major changes to the way I currently discuss the topic with patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.38 Using this DA will help me tailor my counseling to patients' needs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.39 Using this DA will affect my relationship with patients in a positive way	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<i>Factors influencing colorectal surgeons using rectal cancer decision aid</i>	Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
4.40 The DA will be easy to experiment with before deciding to adopt them in our rectal cancer program	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.41 The DA is likely to be used by most of my colleagues.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. How comfortable would you be offering the DA to patients?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Very uncomfortable	Uncomfortable	Neutral	Comfortable	Very Comfortable

6. How likely are you to use this DA?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not at all	Very Unlikely	Somewhat likely	Likely	Very likely

7. What CHANGES need to be made to the DA to make it more relevant to your rectal cancer practice?

8. What are three barriers interfering with your center using the DA for patients undergoing rectal cancer surgery (please list them from first priority to third highest priority)?

1st priority _____

2nd highest priority _____

3rd highest priority _____

9. What are two to three factors that would make it easier for your center to use the DA for patients undergoing rectal cancer surgery (please list them in order of importance, starting with the most important)?

Most important _____

2nd highest _____

3rd highest _____

10. Do you have any further comments, questions or suggestions?

21. How many rectal cancer patients did you see in the CALENDAR YEAR of 2013?

- ≤10
- 10-19
- 20-29
- 30-39
- ≥40

22. Including 2013, how many years have you been in practice?

_____ Years

23. What's your age as of Dec 31, 2013.

I am _____ years old as of Dec 31, 2013

24. What's your sex?

- Male
- Female
- Prefer not to say

25. Do you practice in a university-affiliated hospital?

- Yes
- No

Appendix VII. Ethics approval



Ottawa Hospital Research Ethics Boards / Conseils d'éthique en recherches

725 Parkdale Avenue, Box 411, Ottawa, Ontario K1Y 4E9 613-796-5555 ext. 14902 Fax: 613-761-4311
<http://www.ohri.ca/ohreb>

October 11, 2013

Dr. Robert Wu
Ottawa Hospital - General Campus
Department of Surgery
Division of General Surgery
501 Smyth Road
Ottawa, ON K1H 8L6

Dear Dr. Wu:

Re: Protocol # 20130634-01H Effect of a rectal cancer decision aid on patient choice and decision making process: a pre- and post- study

Protocol approval valid until - October 10, 2014

I am pleased to inform you that your Application for Chart Review underwent delegated review by the Ottawa Health Science Network Research Ethics Board (OHSN-REB) and is approved to recruit only English-speaking participants. No changes, amendments or addenda may be made to the protocol without the OHSN-REB's review and approval.

Approval is for the following documentation:

- Protocol (version 1) dated August 17, 2013
- English Poster dated October 9, 2013
- English Participant Information Sheet and Consent Form (version 2) dated October 11, 2013
- English Decision Aid & Post Decision Aid Questionnaire (version 1) received September 2, 2013
- English Pre-Decision Aid Questionnaire (version 1) received September 2, 2013

The OHSN-REB no longer requires a "valid until" date at the bottom of all approved informed consent forms. The consent form currently approved for use by the OHSN-REB is listed above.

If the study is to continue beyond the expiry date noted above, a Renewal Form should be submitted to the OHSN-REB approximately six weeks prior to the current expiry date. If the study has been completed by this date, a Termination Report should be submitted.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) was created by the merger of both the Ottawa Hospital Research Ethics Board (OHREB) and the Human Research Ethics Board (HREB) for meetings held at the University of Ottawa Heart Institute.

OHSN-REB complies with the membership requirements and operates in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization - Good Clinical Practice: Consolidated Guideline; and the provisions of the Personal Health Information Protection Act 2004.

Yours sincerely,

Raphael Saginur, M.D.
Chairman
Ottawa Health Science Network Research Ethics Board



Ottawa Hospital Research Ethics Boards / Conseils d'éthique en recherches

725 Parkdale Avenue, Box 411, Ottawa, Ontario K1Y 4E9 613-798-5555 ext. 14902 Fax: 613-761-4311
http://www.ohri.ca/ohreb

January 19, 2014

Dr. Robert Wu
Ottawa Hospital - General Campus
Department of Surgery
Division of General Surgery
501 Smyth Road
Ottawa, ON K1H 8L6

Dear Dr. Wu:

Re: Protocol # 20130777-01H Exploring the facilitators and barriers of rectal cancer decision aid implementation: a web-based survey on surgeons and nurses

Protocol approval valid until - January 18, 2015

I am pleased to inform you that this protocol underwent expedited review by the Ottawa Health Science Network Research Ethics Board (OHSN-REB) and is approved. No changes, amendments or addenda may be made to the protocol or the consent forms without the OHSN-REB's review and approval.

Approval is for the following documents:

- Protocol (version 1) dated October 6, 2013
- English Survey uploaded December 12, 2013
- English electronic consent to participate in study (version 2) dated January 15, 2014
- English participant information sheet and consent form (paper format) (version 2) dated January 15, 2014
- English e-mail recruitment text uploaded January 15, 2014

We acknowledge receipt of the English Rectal Cancer Decision Aid (version 1) uploaded January 15, 2014.

The OHSN-REB is no longer adding the 'valid until' date on all informed consent forms. Therefore, the consent forms currently approved by the OHSN-REB are listed above.

If the study is to continue beyond the expiry date noted above, a Renewal Form should be submitted to the OHREB approximately six weeks prior to the current expiry date. If the study has been completed by this date, a Termination Report should be submitted.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) was created by the merger of both the Ottawa Hospital Research Ethics Board (OHREB) and the Human Research Ethics Board (HREB) for meetings held at the University of Ottawa Heart Institute.

OHSN-REB complies with the membership requirements and operates in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization - Good Clinical Practice: Consolidated Guideline; and the provisions of the Personal Health Information Protection Act 2004.

Yours sincerely,

Francine F-A. Sarazin, Ph.D., C.Psych.
Vice-Chairperson
Ottawa Health Science Network Research Ethics Board

/cb