

THE DEVELOPMENT OF A RECTAL CANCER TREATMENT DECISION AID

**THE DEVELOPMENT OF THE ONTARIO DECISION AID IN RECTAL CANCER
FOR STAGE II OR III PATIENTS (ODARC)**

By

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A Thesis

Submitted to the School of Graduate Studies

in Partial Fulfilment of the Requirements

for the Degree

Master of Science

McMaster University

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MASTER OF SCIENCE (2013)

McMaster University

Health Research Methodology

Hamilton, Ontario

TITLE:

The Development of the Ontario
Decision Aid in Rectal Cancer for
Stage II or III Patients (ODARC)

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NUMBER OF PAGES:

vii, 106

ACKNOWLEDGEMENTS

To put it lightly, my experience as a Master's thesis student has certainly been a roller coaster ride – and a fantastic one at that! Full of expected (and sometimes unexpected) 'highs' and 'lows', moments of panic and uncertainty punctuated with flashes of delight, but *always* an adrenaline rush! Intimating as it could be time to time, somehow I managed to hold on, keep calm and carry on...but luckily, I was never alone.

My dear family and friends – you have voluntarily boarded this rollercoaster with me, experiencing the very same sensations yet have consistently remained by my side – supporting me, encouraging me, inspiring me. My parents (Baba & Ma) and brother (Dada), I thank you for your enormous patience, undivided cooperation and unconditional love – three things which are often most difficult to provide yet most important to a person's success...and the three things which were indispensable in my journey. To the rest of my family, those near and far and to the cherished few that have departed this universe – at one point or another, you have all been my best advisors, cheerleaders and most importantly, a shoulder to lean on. I am always thankful and grateful to have you in my life.

To Tina, you have been an incredible source of guidance, wisdom and inspiration. I truly value our sisterly bond and friendship – thank you for always being there for me. Somewhere along this incredible journey, I also connected with a special HRM peer who has become my closest confidante, most honest critic and my ultimate rock - always through 'thick and thin' Jason!

To all my well-wishers who have constantly encouraged me along this academic and in a large sense, personal journey and never failed to remind me to "keep the faith" in myself and in my work - your words and actions were always appreciated.

Throughout my life, I have been fortunate to have received education from an outstanding group of teachers who have influenced the way I think, act, approach and overcome challenges, do work and essentially, view the world. My educators, both past and present, have shaped the student I am today. Through the Health Research Methodology program at McMaster University and Hamilton Health Sciences, I have been able to apply my interests and cultivate my knowledge and capabilities as a budding healthcare investigator – an opportunity for which I am deeply grateful.

First, I would like to acknowledge my supervisor Dr. Marko Simunovic, without whom, this life-changing journey would have never existed. Marko – thank you very much for ongoing mentorship, commitment and support, and for introducing me to a compelling field of health research. When we first met you encouraged me to take on a thesis-based Masters stating it would be more “torture” but well worth it in the end. I am happy to say, you were exactly right and I am glad I followed your advice.

To my thesis committee members – Drs. Amiram Gafni, Cathy Charles and Erin Kennedy - thank you for sharing your invaluable expertise, critical insights and for conducting an honest appraisal of my work. Your comments have helped shape my thesis into a better product and I have learned immensely from this iterative process. I would also like to thank Dr. Mary Ann O’Brien for attending my thesis oral presentation and thoughtfully contributing her insights and recommendations during the final revision process.

Thank you to all my HRM course instructors – for enlivening each class with your unique personalities and life stories and to all the ‘Key Contact People’ of the HRM program: Lorraine Carroll, Kristina Vulkelic, Kristine Leadbetter and Steve Hanna – many, many thanks for your attention and assistance in ensuring the successful completion of my degree and for considerably easing my stress during challenging times!

This roller-coaster ride has finally come to an end. What lingers now is a feeling of liberation, a deep sense of accomplishment and a thought that I am stepping off with much, much more than a graduate degree...

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Preface

Statement of the Problem

A report from Statistics Canada states that there were 23 000 new cases of colorectal cancer diagnosed in Canada in the year 2012, and over 90% of cases are more than 50 years old.^{1,2} Every day on average nearly 61 Canadians are diagnosed with colorectal cancer and 24 succumb to the disease.³ Surgery is the cornerstone of therapy offered to patients diagnosed with rectal cancer.^{4,5} Following treatment for rectal cancer, patients may experience negative clinical outcomes such as local recurrence which is characterized by return of the tumour in the pelvic region, or death.⁴ Combining radiation therapy with surgery has been demonstrated to decrease the risk of local recurrence among patients with stage II or III disease.^{1,6-8}

In medical decision-making, the communication of relevant clinical information from the physician to patient is a priority.⁹⁻¹² Some research has demonstrated challenges with treatment decision-making in the cancer field primarily due to problems with information-transfer during a medical consultation.⁹⁻¹² Patients often report desiring more detailed information on treatment options and associated benefits and risks, and research demonstrates that often final decisions are incongruous with patient preferences/values.¹³⁻¹⁵ Researchers also report poor patient recall with respect to information on important outcomes and side effects, such as expected survival benefits of treatment and potential bowel and sexual dysfunction.¹² Decision aids (DAs) are educational tools that can help inform patients on available treatment options and related outcomes specific to their medical condition, and help patients reach a deliberate decision that is congruent with their preferences and values.¹⁶ Thus DAs may facilitate improved decision-making among patients facing complex decisions related to cancer treatments.

Ontario treatment guidelines recommend the use of preoperative RT and chemotherapy only for patients diagnosed with Stage II or III rectal cancer.^{17,18} When compared to surgery alone, combining preoperative RT with surgery can result in an approximate 50% relative risk reduction in rates of local recurrence, though there is no associated survival advantage.^{1,2,7,19,20} But radiation therapy also increases the risk of debilitating long-term side effects such as bowel and sexual function which may adversely impact patient quality of life.²¹⁻²³ Thus patients with stage II and III rectal cancer must effectively balance information on the potential associated benefits (decreased chances of local recurrence) and risks (chronic side effects) in deciding whether or not to consent to the use of preoperative RT with surgery. We suggest that for patients in Ontario with stage II or III rectal cancer there is an opportunity to improve the transfer of relevant information from physicians to patients through development of a DA.

Focus of Thesis

This thesis focuses on the initial stages of developing the *Ontario Decision Aid in Rectal Cancer for Stage II and III patients* (ODARC). The ODARC is a DA meant to facilitate relevant information exchange among physicians and patients. Such a tool should enhance patient knowledge and accuracy of treatment expectations by effectively conveying to patients relevant information on treatment options and associated benefits and risks. The ODARC is designed for use during a physician-patient consultation. The ODARC prototype development was guided by a workbook on developing & evaluating patient DAs published by O'Connor & Jacobsen (for efficiency we will call this the *Workbook*).²⁴ This latter document provides detailed instructions for a 7-step DA development process including: 1) assess patient and provider need 2) assess DA feasibility 3) define objectives of the DA 4) identify the framework to guide DA development 5) select tailored methods of decision support to be used in the DA 6) select the designs and measures to evaluate the aid and, 7) plan dissemination.²⁴ In this thesis we have created a prototype ODARC as informed by Steps 1 to 5 of the *Workbook*. The last two steps covering evaluation and dissemination are beyond the scope and available resources of this current research effort, and can be considered as future research endeavours. This will be reviewed in the final chapter.

What to Expect in Upcoming Chapters

In Chapter I, we present an overview of DAs in clinical decision-making. We also present a model of decision-making known as shared decision making, which has been used in a number of clinical fields.²⁵⁻²⁷ This model also informs the design of the ODARC. In Chapter I, we also elaborate on the essential components of a decision aid, variations in delivery, acceptable risk formatting strategies, and describe some measures used to evaluate DA impact. In Chapter II we focus on the first two steps of the *Workbook*, which are to assess need and feasibility of a rectal cancer information-transfer tool. We also provide a summary of pertinent clinical issues related to rectal cancer surgery with/without preoperative RT and present a review of relevant randomized trials with data on main clinical outcomes (i.e., local recurrence and overall 5-year survival) and side effects (i.e., bowel and sexual dysfunction) experienced with each option. These data are the key data points displayed on the ODARC. In Chapter III we provide a detailed report of the ODARC methodology – or Steps 3 to 5 of the *Workbook* - which focuses on defining research objective(s), selecting a theoretical model to guide DA development, and outlining risk communication and delivery strategies. Finally, in Chapter IV we discuss potential future directions of the ODARC including short and long-term goals and dissemination plans.

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Chapter I The History and Development of the Decision Aid & Clinical Practice Applications

What are Patient Decision Aids?

Often medical treatment decision-making is based on the physician's assessment of a patient's signs and symptoms, with resulting recommendations made with minimal input from the patient.^{1,2,3} There is growing interest in facilitating increased patient engagement with medical decision-making.^{4,5,6} Some have suggested this is due to rising rates of chronic diseases which are often associated with multiple treatment options and complex treatment trade-offs.^{1,4} In such situations, patients require accurate information to better understand offered treatment choices and the probabilistic outcomes of related treatment benefits and risks. A lack of effective communication regarding treatment decision-making between the patient and physician is often reported.^{6,7} In deciding if physicians should dedicate more effort into the decision-making process with patients, time constraint is often cited as the main barrier.^{6,7}

Decision-making in the cancer context may be especially difficult. Clinicians managing cancer patients are often oblivious to patient informational needs, and patient understanding of medical content is rarely assessed.⁹⁻¹² Studies evaluating knowledge levels among patients of cancer treatments often demonstrate major gaps.⁹⁻¹² Cancer therapies often involve more than one treatment modality, such as surgery, radiation or chemotherapy.¹³ This augments the complexity of disease management and treatment choices.^{14,15} Patients must understand medical information to ultimately balance potential treatment benefits, such as improved local recurrence rates, with specific risks, such as adverse treatment side effects, while struggling with a recent diagnosis of a serious medical condition.^{4,16,17}

Physicians dealing with cancer patients may also struggle with disclosing poor prognoses and discussing treatment impact in a sensitive, yet patient-friendly manner that adequately covers important information for decision-making.^{9,18-20} Research shows that physician recommendations and patient preferences are often incongruous, which may result in subsequent patient regret with regards to cancer treatment decisions.^{11,21-23} These findings encourage the development of better mechanisms of information-giving during medical consultations.^{11,21,22}

Decision aids (DAs) may be a solution to some of the communication problems that persist with regards to information-transfer during medical consultations.^{7,24-26} *O'Connor et al* defines DAs as educational tools that can help inform patients on available treatment options and related outcomes specific to

their medical condition, and help reach a specific and deliberate decision.²⁷ Researchers emphasize that DAs should supplement and not replace the main patient-physician consultation.^{17,28,29,30,31} The increased interest in decision aids in North America is likely in response to several factors: a shift from informed consent to informed choice among patients; the greater emphasis on evidence-based practice; and, the development of patient-centred approaches to treatment decision making.^{4,29,32} Published decision aids have covered an assortment of topics such as adjuvant therapy options for breast cancer patients, hormone therapy (HRT) for post-menopausal women, and statin use for diabetes management.^{30,33} Decision-making in such clinical areas can involve treatment trade-offs between competing risks and benefits and are defined by some researchers and clinicians as “preference-sensitive decisions which will ideally will involve patient input.”^{34,35} There is no “right” or “wrong” choice with such decisions and DAs may help facilitate decision making.^{28,34,35}

Some General Goals of Decision Aids

Researchers often cite three main potential goals of a DA: information provision and resulting knowledge improvement; clarifying patient values and treatment preferences; and, improving patient participation in decision-making.³⁶⁻³⁸ *Charles et al* suggest that decision aid goals must be rationally reflected on and clearly defined prior to pursuing subsequent steps in development, evaluation and implementation.^{8,39,40} This will allow the overall development process to be well-tailored to the target audience and given decision-making context.^{8,39-41}

Elwyn and colleagues suggest that to enable good decision support, a DA should allow patients to consider the medical choice to be made either independently or jointly with others.³⁶ In its basic form, the DA is a medium of translating treatment information for patient deliberation.^{3,36,42} The DA should present relevant information on available treatment options and related functional outcomes which impact a patient’s daily life.³⁶ With this knowledge, patients are potentially better prepared to understand implications of treatment choices, and to make a final decision which is fitting to their individual case.³⁶ Thus, a fundamental goal of decision aids is the conveying to patients of information on multiple treatment options and associated benefits and risks.³ In the breast cancer context, findings from one systematic review revealed that surgical decision aids significantly improved patient knowledge for women with early-stage breast cancer.⁴³ The majority of patients reported that their awareness and understanding of surgical and adjuvant therapy options (such as radiation therapy) were enhanced with DA use.⁴³ The review also noted that patients considered DAs an important adjunct to the informed consent process, and that they also assisted surgeons with information provision and addressing points of

patient uncertainty.⁴³ Strikingly, approximately 98% of female patients in one study indicated they would recommend the use of a breast cancer decision aid to a fellow peer in the same position.⁴²

Aside from provision of information, DAs may also work to clarify values and preferences and help patients reach an individualized health decision.^{7,37} Some decision aids integrate available treatment information with benefit-to-risk trade-off exercises to help delineate which treatment option is most valued by the patient.^{7,37} For example, during the review of a decision aid for long-term hormone therapy (HRT), post-menopausal women completed a personal worksheet to objectively assess which treatment course was right for them (i.e., receive or not receive HRT).^{7,33} The worksheet guided the patient through important decision-making considerations such as, current practices in preserving bone, breast and heart health, a review of menstrual history and menopausal symptoms, and, a personalized risk assessment for developing estrogen-based diseases (e.g., coronary heart disease, breast cancer).³³ Finally, to help patients rate which benefits and risks were most important to them, a “weigh scale” exercise was used and provided patients insight to their preferred, value-driven treatment option.^{7,33,7} In another study, a DA outlining different vascular access options (i.e., radial vs. femoral artery access) was developed for patients undergoing a coronary angiography.⁴⁴ The developers of the aid included a values assessment section to help patients personalize the information to be more aligned with their treatment values and preferences.⁴⁴ In evaluation, patients who were counseled with the DA (i.e., intervention arm) prior to the procedure reported greater value congruence with their chosen vascular access option relative to patients counseled without a DA (47% vs. 26%, $p < 0.01$).⁴⁴

These study findings suggest that when used as adjuncts to medical consultations, DAs can assist patients deliberate complex preference-sensitive treatment decisions.

Decision aids can also be incorporated into clinical practice to increase patient participation in the decision-making process.⁴⁵ In a study by *Whelan et al*, patients deliberating breast irradiation post-lumpectomy were randomized to receive standard consultation with an oncologist, or consultation and a decision board conveying treatment and quality-of-life information related to adjuvant radiation.²⁴ Patients in the standard consultation group versus the decision board group were less likely to feel that they were extended a treatment choice (70% vs. 97%, $p < 0.05$).²⁴ Importantly, the use of a decision board motivated patients to voice their concerns and seek answers to their inquiries regarding the use of radiation therapy.^{26,42}

In one colorectal cancer screening study, more than 60% of the healthcare providers (physicians and nurse practitioners) felt that the DA had a positive influence on patient decision-making with respect to enhancing patient participation, and willingness to get screened.⁴⁶ Patient screening intentions with

scores ranging from 0 to 5 ('not sure at all' to 'completely sure') were evaluated post-consultation, and compared to patients not consulted with a decision aid (control arm).⁴⁶ When asked, 'How sure are you that you will complete a colorectal screening test?' the intervention group (receipt of DA) had higher mean scores versus the control arm, respectively (4.3 vs. 3.9, $p < 0.001$).⁴⁶

Finally, in one DA trial, the level of patient participation was quantified using the OPTION scale (observing patient involvement) which measures the extent a physician involves patients in the decision-making process.⁴⁷ A DA titled *The Chest Pain Choice* DA was designed to facilitate collaborative discussion between the clinician and patient on the decision to be admitted and tested for cardiac stress in an emergency unit, or to follow-up with the clinician within a specified timeframe.⁴⁷ Patients randomized to the usual care group (with no use of DA) were observed to be less engaged in decision-making compared to patients who participated in decision-making using a DA, as reflected by the higher OPTION score (26.6 vs. 7.0, 95% CI 1.6 – 21.6).⁴⁷

With the exception of the first goal discussed in the above section, clarifying patient values and treatment preferences and increasing patient participation in the decision-making process are not intended objectives of the current DA prototype. However, such goals may be adapted into future iterations of the DA as the study evolves depending on feedback to be obtained from the target patient demographic and involved clinicians.

A Theoretical Model That May Inform Patient Decision-Making

A commonly-cited theoretical model which has been previously linked to various clinical decision-making encounters is the shared decision-making model (SDM) conceptualized by *Charles et al.*^{3,48-50}

This model was derived from work with patients with early-stage breast cancer, where multiple treatment options can be used with varying clinical outcomes and treatment side effects.³ The developers of the shared decision-making model identify three "pure" models of treatment decision-making: paternalistic, informed and shared.³ For each of these pure models there are three analytical stages of decision-making including information-exchange, deliberation and decision implementation.³ In the paternalistic model, there is no sharing of information during the information-exchange stage – the transfer of information is strictly unidirectional from physician to patient.^{2,3} The physician also assumes full decision-making control and does not elicit patient input or preferences for treatment.^{2,3} There is no deliberation of treatment options by the patient; the physician makes the final decision (alone or in conjunction with other physicians) and communicates this to the patient.^{2,3}

In the pure informed decision-making approach, transfer of information also occurs one-way from the physician to the patient.^{2,3} The physician provides

medical and scientific information to the patient including, details on various treatments and related benefits and risks of each choice to enable informed patient decision-making.^{2,3}, the patient assumes control of decision-making and is able to deliberate and discuss treatment options (alone or with significant others), and decide on which treatment he/she prefers without any physician input.^{2,3}

In contrast to the paternalistic and informed models, the essential characteristic of the shared decision-making model is its interactional nature between physician and patient in all-stages of the decision making process.^{2,3} Bidirectional flow of information during the information-exchange stage includes a discussion of the medical condition, available treatment options and their potential effects which is conveyed by the physician (i.e., technical expert) to the patient.³ Patients communicate to the physician personal information such as their medical background, lifestyle factors, values and treatment preferences during this exchange.³ Both the physician and patient collaborate during the deliberation stage and express their thoughts and preferences on possible treatment options.³ The underlying assumption is that both parties have a legitimate investment in the treatment decision to be made.^{2,3} Hence, both parties declare treatment preferences and their reasons for selection, and then try to arrive at a consensus on the most appropriate decision.^{2,3} For shared decision-making to occur, both physician and patient must adhere to the role expectations set out in the *Charles et al* approach to shared decision making for each stage of the decision-making process.³ According to *Charles et al*, treatment decision-making should be seen as a dynamic process, and the approach taken can change both over time and within any given consultation.³ Moreover, these authors argue that there are many in-between approaches to treatment decision-making and that it is likely that these in-between approaches are more common in practice than the pure-type approaches.³

Some Examples of Developmental Approaches for Decision Aids

The development of a decision aid is usually an iterative collaborative process conducted by stakeholders such as researchers, healthcare providers, patients or policymakers.⁵¹ Properly documenting the developmental process will allow non-developers to ascertain the steps undertaken and thus the credibility of the tool.⁵¹

There are strengths and limitations to any approach used to develop a decision aid. The updated *International Patient Decision Aids Standards* (IPDAS) document outlines six different systematic approaches to DA development.⁵¹ The first, from *Cardiff University* researchers, was originally created for internet-based decision aids.⁵¹ The developers of this approach recommend a “process map” consisting of three integral steps: gathering necessary clinical evidence on the risks and benefits of available treatments reviewed by patients and clinicians; an

iterative process of design and ‘trial-and-error’ usability testing; and, field testing with patients and their treating clinicians.⁵¹ The “process map” is a joint endeavour involving a range of stakeholders including patients, clinicians and policy makers.⁵¹ However, the application of web-based decision support tools is not well evaluated in the literature and requires greater elucidation in design concepts and implementation.⁵¹ In a recent Cochrane review of treatment patient decision aids, of the 86 studies reviewed, only two utilized web-based formats delivered on the Internet.²⁸ The authors of this approach acknowledge that further work is needed to test ease of use and applicability.⁵¹

Decision aid developers from the *Dutch Institute for Healthcare Improvement* base DA development on available clinical practice guidelines.⁵¹ The approach focuses on developing DAs that elicit patient values to treatment choices.⁵¹ The four key steps include: topic(s) selection and criteria setting; gauging patient informational needs via review of the literature and focus groups; prototype drafting with involved stakeholders; and, DA endorsement to verify developer responsibility for content maintenance of both the decision tool and the reference guideline(s).⁵¹ This group notes that their DA development approach needs to be further evaluated for impact within the Dutch healthcare system.⁵¹

The *Informed Medical Decisions Foundation (IMDF)* develops DAs for both research and commercial use.⁵¹ The development process begins with content specification and literature reviews which is supplemented by patient focus groups to explore specific needs and preferences to treatment information.⁵¹ In the subsequent prototype development and evaluation phase, both clinicians and patients are involved in assessing DA content accuracy, balance and relevance of information and general acceptability.⁵¹ The IMDF also conducts periodic content review every six months to account for emerging clinical evidence, and every two years, a second full-scale evaluation is completed to document any changes in DA impact using specified outcome measures.⁵¹ Finally, the entire course of DA evaluation and timely review/updates is facilitated by a medical editor and various panels of involved healthcare providers and patients.⁵¹ However, the time to final product release is considered relatively lengthy.⁵¹

The DA developer group from the *Mayo Clinic* also focuses on decision-making in the clinical encounter.⁵¹ Initial prototype design processes are influenced by real-life physician-patient interactions during medical consultations.⁵¹ These observations influence downstream DA evaluative steps. The *Mayo Clinic* group does not specify a step-by-step approach as some of the other examples. Decision aid development is a collaborative creative process between target users (i.e., patients) and providers (i.e., clinicians) and based exclusively on direct observations from the clinical encounter.⁵¹ This approach is appropriate for developers conducting a needs assessment segment of what patients and physicians desire in a patient decision aid, prior to assembly of prototype components.⁵¹

The *Healthwise* approach is most commonly utilized in developing decision aids for commercial use.⁵¹ The four main steps of development are labelled as planning, research, writing and review.⁵¹ Similar to the IMDF approach, the users of this approach also perform a periodic review step in which patient and other user input is sought to update DA design and content.⁵¹ *Healthwise* DAs have not been formally evaluated in any trial, and the group does not widely circulate explicit details of their development process.⁵¹

The *Ottawa Decision Support Framework (ODSF)* originates from the Ottawa Health Research Institute (OHRI) Patient Decision Aids Group.⁵¹ The *ODSF* is particularly well-suited for preference-sensitive decisions in which a considerable amount of information on potential treatment risks and benefits is involved.⁵¹ It includes three main components to DA development and evaluation.⁵¹ First, developers should assess specific determinants of healthcare decisions as perceived by patients and practitioners in a given clinical context.⁵¹ Modifiable determinants may be grouped into i) perceptions of the decision (e.g., low knowledge, unrealistic expectations, decisional conflict); ii) perceptions of others (e.g., roles in decision-making, peer support) and iii) personal and external decision-making resources (e.g., information support, limited decision-making skills).⁵¹ Second, developers should create tailored decision support tools which incorporate characteristics of involved patients and practitioners and also help address selected problematic determinants.⁵¹ In the final step, the DA is evaluated in terms of improving decisional quality and outcomes in relation to the determinants identified in the first step.⁵¹ However, the *ODSF* does not include explicit directions on how to review and synthesize relevant data from the literature.⁵¹ Also, compared to some of the approaches described above, instructions on how to periodically monitor and maintain DA content or how to implement a DA apart from research use are also not specified.⁵¹

“Workbook on Developing and Evaluating Patient Decision Aids” – A Systematic Approach to Decision Aid Development

O’Connor and Jacobsen provide a seven-step approach to DA development. The approach is informed greatly by the above referenced Ottawa Decision Support Framework, and is titled the *“Workbook on Developing and Evaluating Patient Decision Aids”*.⁴⁵ This structured approach to DA needs-assessment, development and evaluation will be utilized in this thesis. The *workbook* is well-suited for the development of a DA prototype based on several factors. First, the *Workbook* is a 22-page descriptive document that is available online for interested DA developers and researchers.⁴⁵ Second, its instructions are easily understood and presented in a systematic and practical 7-step process addressing key considerations to DA development and evaluation including: 1) assess patient and provider need 2) assess DA feasibility 3) define objectives of the DA 4) identify the framework to guide DA development 5) select tailored

methods of decision support to be used in the DA 6) select the designs and measures to evaluate the aid and, 7) plan dissemination.⁴⁵ Each step includes multiple meaningful question prompts which help guide nascent DA developers such as, “*Is there enough evidence of benefits and risks to incorporate into a decision aid?*”⁴⁵ Thirdly, the *Workbook* is specifically targeted for DA use in an actual physician-patient consultation rather than an Internet-based or audio/video DA.⁴⁵ This parallels the planned information-transfer tool proposed in this thesis. Finally, the *Workbook* has a proven track-record to facilitate the development of consultation-based DAs such as the ‘Decision Aid for Postmenopausal Hormone Replacement Therapy’ (O’Connor et al, 1998) and the ‘Breast Cancer Prevention Treatment Decision Aid’ (Stacey et al, 2003).⁴⁵

The *Workbook* is well-suited to help design DAs that assist patients with decisions usually involving multiple treatment options, uncertain clinical outcomes, and benefit-to-risk trade-offs that often pose difficulties for patient decision-making.⁴⁵ As further discussed in the upcoming chapter, the decision to combine preoperative RT in addition to rectal cancer surgery is one such decision. Recent clinical evidence presents well-documented benefits and risks associated with each option and prior to making a decision, patients will need to review and process key comparative information on treatment choices.

Methodological Considerations in Developing Decision Aids

Common Elements of Decision Aids

There is ongoing discussion on what constitutes standard elements of a decision aid in the literature, and a definitive list has not been established as DA design is largely influenced by developer and user preferences.^{36,38,52} In general, for a given health condition or treatment decision, DAs must provide information on treatment options, and on associated clinical outcomes and side effects with each option.^{17,45,52,53} A DA should also provide a synopsis of method and duration of delivery of treatment options.^{17,45,52,53} Relevant associated outcomes and side effects following each treatment option should be adequately defined.^{17,45,52,53} Where appropriate, descriptions should outline how a given outcome or side effect derived from aggregate-level averages from selected RCTs may impact patient function either physically, emotionally or socially on a day-to-day basis.^{17,45,52,53} In consulting a decision aid, patients need to be able to judge the importance of specific outcomes and side effects.^{10,17,36,45,54} Information must be collected from high quality studies and should represent the latest clinical evidence on that particular topic.^{17,29,32,52} The language in a DA must follow credible standards of risk communication to facilitate realistic and accurate risk expectations.^{38,45,54-56} A quantitative representation of outcome or side effect probabilities is most frequently recommended.^{29,54-56} Outcomes or side effects can be framed in both positive and negative terms, or by the number of patients

affected and not affected.^{53,54,57,58} Finally, supplementary sections of a decision aid may include additional information on the disease condition, explicit values clarification exercises, and patient anecdotes on treatment choices.^{45,59} However, these components are not considered mandatory.^{38,45,52}

Variations in Formats and Methods of DA Delivery

Decision aid delivery can vary according to developer preference, available resources and the medical condition of interest.^{29,34,60} Previously developed DA delivery layouts have included audiotape with booklet, decision workbook, videodisc, decision board, and computer-based versions of all of these.^{29,60} Decision aids can be individually customized to facilitate comprehension and knowledge uptake in a target patient group.^{29,34,60} However, the method or physical structure of delivery is an important consideration.^{26,38,54,60} It is recommended that DA developers communicate decision-making material in a compact and focused manner, covering only essential patient information needs.^{26,38,54,60}

Elwyn et al classifies use of decision support interventions into three distinct categories.³⁶ The first class of DAs is designed for use by a healthcare provider and patient during a clinical encounter.³⁶ Most often available at the point of decision-making, such DAs help engage both the provider and patient in discussion of treatment information and corresponding preferences.³⁶ The second category of DAs are used away from a clinical encounter and are designed for independent patient use.³⁶ Self-administered DAs are gaining popularity due to the advent of web-based tools. Such tools can be used prior to or following a medical consultation to improve patient preparedness for decision-making or reinforce important discussion items.³⁶ In the third category, patients may also reach out to other patients using social media platforms such as, Twitter, Facebook, blogs or websites. The “*Patients Like Me*” website facilitates peer-to-peer guidance and advice exchange on best courses of treatment.³⁶ Additionally, such latter tools can be used in conjunction with clinicians. For example, a nurse trained in use of a decision support tool can provide decision-coaching over the phone with patients who seek this service.^{1,35}

Stacey et al notes that most currently available DAs are self-administered and can be paper-based or digital, (i.e., computer-based) or sometimes both.¹ Such tools are easily accessible and may be routinely updated with new clinical content at a relatively low cost.^{1,36} Some research suggests a digital interface may not be as effective as an actual physician-patient consultation.^{24,31,53,61,62} *Schenker et al* found that DA formats which increased face-to-face discussion time between physician and patient were more likely to promote patient understanding.⁶² Additionally, a highly technical computerized DA format may not be appropriate for advanced-age patients, due to a likely lack of operational knowledge and technical familiarity.^{31,53,63} This is especially relevant in the

proposed decision-making context discussed in this thesis as the median age of rectal cancer patients is 70 years of age.

In a recent study on the use of decision-support tools in rectal cancer treatment, decision boards ranked superior to computer-based and interactive software-based DAs in terms of usefulness during consultations as adjudicated by colorectal surgeons.³¹ Approximately 50% of participating surgeons in a focus group viewed the board format as 'extremely useful', with special importance placed on its use of diagrams, charts, and pictures compared to the digital DA formats.³¹ Most participants found the decision board to be patient-friendly, easy to use, and ranked highest with regards to surgeon preference for use in practice, and for future research initiatives.³¹ The board format is conducive to facilitating face-to-face time which allows the physician and patient to collaboratively discuss the medical information during a counselling session.^{31,48,53} The healthcare provider will guide the patient through the decision options which may promote greater discussion about the accompanying risks and benefits and other related concerns.^{26,31,48,53} This quality is valued by many patients, but most notably with those diagnosed with cancer where emotional stressors induced by fear, embarrassment, helplessness or isolation may be overwhelming.^{26,31,48,64}

Risk Communication Formats & Framing Strategies

Researchers and clinicians stress that the proper presentation in DAs of relevant probabilistic information on treatment benefits and harms is crucial for patient decision-making.^{45,54}

In a study on screening and treatment decision aids, *Stacey et al* reported that people who reviewed decision aids with descriptions for treatment outcomes and associated probabilities were significantly more likely to have accurate and realistic risk perceptions versus patients who did not view this information in a decision aid, or who received standard counselling alone (i.e., overestimated or underestimated benefits and risks).^{28,45} Some researchers advise using numbers to depict realistic probabilities compared to text formats which may be interpreted in multiple ways.⁴⁵ There is evidence to suggest that textual representation of outcomes using descriptive terms such as, "moderate risk", "low risk" or "high risk" may be incorrectly interpreted by patients with varying levels of magnitude.^{45,54,65} This recommendation is also echoed by findings from a large systematic review which concluded that DAs that depict treatment outcomes using numerical probabilities with accompanying descriptions facilitated enhanced accurate risk perception compared to DAs that did not provide information in this form (RR = 1.74; 95% CI 1.46 to 2.08).²⁸ Specifically, the pooled relative risk for effective probability information using numbers was 1.93 (95% CI 1.58 to 2.37) versus RR = 1.27 for probabilities reported as text (95% CI 1.09 to 1.48).²⁸ However, quantitatively communicating risk may be perceived as confusing by some patients who do not possess a high fluency in technical language and interpretation.^{38,66,67} This is especially true for bar graphs

and pie charts which fall short in meeting optimal accuracy and comprehension standards.^{38,54,55,58,68} In particular, bar graphs are perceived as difficult to understand by an older patient demographic (i.e., majority of rectal cancer population).^{58,69} With pie charts, errors with interpretation often occur due to difficulties in delineating between small differences in outcome probabilities (e.g., 30% versus 40%).^{37,45,55,68,53,54,57,58}

In response, researchers suggest that the best way to accurately depict gross and detail-level information is via pictographs - a matrix of icons (e.g., 10 by 10) with a certain portion filled in to convey a given statistic.^{29,57,66,70,71} Pictographs can visually depict a frequency (e.g., 60 out of 100 patients affected, 40 out of 100 patients not affected) and as such are easier to analyze and interpret by patients.^{38,54,58,69} Incorporating helpful visual statistical aids in a decision support tool may help patients place potential treatment risks in context, which ultimately facilitates improved patient understanding.⁶⁵ Of note, horizontally placed icon arrays are interpreted more quickly and accurately as opposed to vertically-oriented displays.⁶⁷ This is explained by researchers as the influence of Western teaching, where text is typically presented and read in a left to right direction, in contrast to some Eastern written material.^{38,66}

Framing a risk event by establishing a clear denominator (i.e., out of 100) has also been found to help avoid the problem of “denominator neglect.” This is when not providing a reference base number leads to unclear patient assessments of outcome events.^{65,71,72} To illustrate, a sample of 57 older non-patient adults (median age of 68 years old) succumbed to “denominator neglect” when probabilities between two treatment options were presented numerically (i.e., absolute risk) without considering a reference number of patients (i.e. out of 100).⁷¹ This condition was more apparent in older adults compared to younger adults.⁷¹ As well, maintaining the same denominator across all treatment outcomes and side effects is an accurate way to communicate risk in context to patients of all educational levels.⁶⁵

The Ottawa group prefers setting a consistent denominator with a “100 faces” format with shaded faces representing the number of patients likely to experience an outcome.^{7,45} Human icons were perceived as more effective in communicating risk compared to bar graphs or histograms.^{38,45,54,58,68} The “100 faces” variation or icon arrays using denominators of 100 has been applied in numerous decision aids.^{30,57,70} In one study, 100 facial icons were used to depict risk of developing stroke and major haemorrhage as a result of atrial fibrillation.⁷⁰ The visual matrix used sad and happy faces to represent the occurrence and non-occurrence of an adverse outcome, respectively.⁷⁰ Additionally, probability statements such as, “8 in 100 chance of having a stroke” also accompanied the graphical displays.⁷⁰ The DA developers reported that this method of risk framing had several advantages. Primarily, patients had a clearer visual image and understanding of outcome probabilities.^{70,73} Explicit probability statements also facilitated greater understanding of outcome events.⁷⁰ A similar risk format was also incorporated in another study in which the authors used 100 faces to

quantitatively express the likelihood of outcome events in breast cancer surgery.⁷³ The formatting choice was positively received by the target patient audience as reported in a needs-assessment focus group session.⁷³ Moreover, graphical or visual depictions of quantitative information are easier to process by patients, especially if language barriers are a concern.^{38,54,55,58,68,69,74}

Decision aids may also use the concepts 'Number Needed to Treat' (NNT) and 'Number Needed to Harm' (NNH) to convey risk to users.^{17,75} The NNT indicates the average number of patients a physician would need to treat to prevent one additional patient from experiencing an adverse outcome.^{17,75} This value is calculated from the inverse of the absolute risk reduction (i.e., risk in control group – risk in treatment group) between two treatment options.^{17,75} As such, the more effective an intervention treatment is in reducing an adverse outcome the lower the NNT value (i.e., towards one).

The NNH value is also calculated in a similar fashion, but is the inverse of the absolute risk increase, that is the event rate is higher in the treatment group.⁷⁵ It indicates the number of patients a physician would need to treat for one patient to experience a negative outcome.⁷⁵ If used in a DA, NNT and NNH calculations should be derived from high quality randomized controlled trials where potential differences in risks of outcomes or side effects observed between treatment groups is unlikely to be due to bias or confounding.⁷² NNT/NNH statements are a useful method of concisely and quantitatively summarizing treatment benefits and risks.^{17,75} This statistical presentation may be combined with other tailored risk communication strategies to assist clinicians help improve patients' ability to assess and understand treatment risk.⁷⁶

In a study involving older patients and screening tests for cancer, temporal risk data was a key motivating factor for undergoing screening tests or receiving treatments.⁷⁷ In the study, patients were more interested in immediate (year 0) and endpoint (year 5) data, versus data from intermediate years (years 2 to 4).^{54,77} In general, studies report that older patients prefer receiving risk information on long-term or chronic outcomes compared to short-term risks, since these are interpreted as more meaningful to overall quality of life.^{19,68,77} It was also noted that comparison of different treatment options and text comprehension was most improved with a side-by-side layout as opposed to information being presented sequentially over a number of separate pages.^{38,66,71} Similarly, other research on DA text presentation shows that displaying treatment information for all available options simultaneously has advantages compared to introducing relevant information sequentially and separately over a number of pages.^{38,66} In particular, research evidence has shown that patient assimilation of relevant knowledge for multiple treatment choices is improved.^{38,66}

Many patients experience difficulty in processing medical information, and this problem is further augmented when numbers are introduced.⁵⁴ Therefore, to promote greater understanding during treatment decision-making, patient educational tools such as decision aids must incorporate effective risk formatting

strategies to ensure patients understand the benefits and risks of each treatment option.^{54,58,78}

Methodological Considerations in Evaluating Decision Aids

Evidence from systematic reviews demonstrates that compared to standard care (with no DA use), decision aids help improve patient knowledge on treatment options and associated outcomes/side effects, facilitate patient involvement in the decision-making process, reduce decisional conflict, and potentially improve patient satisfaction.^{9,37,28} Collectively, such features of DAs or outcomes may be used to evaluate the impact of a DA.^{9,37,28} Limitations of using such measures to assess DA impact will also be discussed below.

Patient Knowledge in Treatment Information

Reviewed research demonstrates that patient use of a DA increases knowledge of treatment options, and accuracy of perceptions of treatment outcomes and side effects, compared to care with no DA consultation.^{28,37,48,79} Knowledge assessments are typically conducted with standardized tests and generally reported as percentages ranging from 0% (no correct response) to 100% (perfect and complete responses).⁴⁸ Results from a large systematic review by *Stacey et al* on decision aids for people facing health treatment and screening decisions reported that patients who consulted with decision aids had better performances on knowledge tests relative to patients who received usual care alone.²⁸ On average, the DA group scored 14% higher (95% CI 11.40 to 16.5) resulting in a statistically significant improvement in knowledge of decision-making material.²⁸ A previous version by *O'Connor et al* reported similar results, showing that compared to usual care patient knowledge of treatment options and outcomes (particularly in an oncology setting) improved with DA consultation, with patients scoring 19% higher (95% CI 14 to 25).³⁷

Cancer-specific DAs also appear to improve average patient knowledge scores when used in consultation compared to usual care with no DA, with a weighted mean difference of 13.7% (95% CI 9.0 – 18.5) favouring the DA intervention.²⁸ O'Brien and colleagues also reviewed the effectiveness of cancer-related decision aids.⁹ Consistent with the above findings, the authors found a significant increase in patient knowledge following counselling with DAs compared to usual care (with no DA) in cancer screening and treatments, respectively, with weighted average effect sizes (ES) reported as 0.67 (95% CI 0.40 – 0.94) and 0.50 (95% CI 0.31 – 0.70), favouring the DA interventions.⁹

Patient Involvement in Decision-Making

O'Brien et al also showed that cancer-related DAs promoted discussion on treatment options and related outcomes.⁹ With DA use, a patient's satisfaction with role in decision making was improved, most notably with breast and prostate cancer treatment areas.⁹ Similarly, *Stacey et al* reported a pooled relative risk for the proportion of patients indicating that their physician made a cancer treatment decision on their behalf as 0.50 (95% CI 0.3 – 0.8), indicating a 50% reduction in solely practitioner-controlled decision-making.²⁸ This suggests that use of a DA helps patients exercise greater involvement in decision-making.^{28,37,43} For example, after reviewing a decision aid compared to usual care without a decision aid, patients were less likely to opt for major elective surgeries (e.g., mastectomy versus lumpectomy for breast cancer surgery) (RR = 0.80; 95% CI 0.64 to 1.00).²⁸ *Whelan et al* demonstrated that patients who reviewed treatment options and risk information via a DA with their surgeon versus standard consultation were more likely to opt for breast-conserving treatment relative to patients who underwent counselling alone (94% vs. 76%, $p = 0.03$).⁸⁰ Another study reported that breast cancer patients with early-stage tumours who did versus did not consult with a DA were less willing to undergo adjuvant chemotherapy (58% vs. 87%, $p < 0.01$).⁸¹

Decisional Conflict

The use of a DA in medical consultations can also result in reduced decisional conflict among patients making a medical choice.^{28,9,82} Evaluation of decisional conflict can be done using a validated instrument known as the Decisional Conflict Scale (DCS).^{28,37} This scale can be administered to determine specific factors that influence levels of patient uncertainty regarding the healthcare decision.²⁸ Similar to knowledge tests, DCS scores are standardized from zero to 100 points, indicating no decisional conflict to high degrees of decisional conflict.²⁸ When comparing intervention (i.e., DA) and control (i.e., no DA) groups, a negative DCS score represents a decrease in decisional conflict in favour of the intervention group.²⁸ In a review of 19 studies by *Stacey et al* that evaluated decisional conflict among patients using decision aids in comparison to usual care, DCS scores had a mean difference of -5.66 out of 100 points (95% CI -7.68 to -3.64).²⁸ In particular, fewer patients reported feelings of indecisiveness regarding their treatment choice after consulting a decision aid (RR = 0.57; 95% CI 0.44 to 0.74), and this finding was noted in a wide variety of decision contexts.²⁸ In one study, prior to consulting with a breast cancer treatment DA, 10 out of 17 (65%) patients were undecided on their use of the drug tamoxifen.⁸³ Following consultation with a DA, only 2 out of 17 patients (12%) were left undecided about their treatment decision.⁸³ Undecided patients primarily cited the need for more information via physician counselling on treatment side effects to enable decision-making.⁸³ Findings by *O'Brien et al* also suggest that DA use

(compared to usual care) appears to reduce decisional conflict among patients making cancer screening or prevention/treatment related decisions.⁹

Patient Satisfaction

One would expect lowered decisional conflict to correlate with greater patient satisfaction in the decision-making process and final decision reached. However, findings with use of DAs and patient satisfaction remain inconclusive.²⁸ A report by *Stacey et al*, reviewed studies that rated patient satisfaction on a scale from 0 to 100 using satisfaction questionnaires among patients who did and did not use a DA.²⁸ Only three out of ten studies in the review reported that patients had significantly higher levels of satisfaction with the decision choice reached after consulting a decision aid compared to patients who received usual care alone.²⁸ The involved researchers suggest that their findings may be expected since satisfaction with the decision-making process and decision reached is largely influenced by the nature of the physician-patient relationship and baseline levels of satisfaction (i.e. with usual care) which are well-established prior to use of a DA.²⁸ Regardless, many researchers in this field consider patient satisfaction in the final decision reached as an important attribute to consider when evaluating the impact of decision aids in patient decision-making.^{19,28,32,34,84}

Evaluating Decision Aid Impact – Conceptual Problems

As mentioned previously, decision aid goals need to be determined prior to evaluating decision aid impact. Outcome measures used to evaluate DA impact can be varied, and what constitutes an appropriate measurement variable for each stage of decision-making is at times debatable.

For example, an assessment of patient knowledge of treatment options and outcomes might be relevant to evaluating impact of a DA with the goal of information-transfer.^{26,70} However, knowledge and understanding, though considered as synonymous terms by some DA developers, are two different concepts.^{8,39} Assessment of patient knowledge acquisition can be made by checking if patients recall specific details presented on a DA such as the probability of side effects for a given treatment.^{8,39,40} This may be easily accomplished via a ‘recall of information’ patient questionnaire post DA consultation. Conversely, true understanding is not revealed simply by recalling numbers, but by demonstrating a grasp of the implications of presented statistic(s).^{8,39,40} For example, outcome probabilities presented in DAs are derived from group-based estimates from RCT results that are not individualized to each patient case.^{8,39} To elaborate, a patient cannot predict in advance if he/she will belong to the cohort that survives compared to the cohort that does not survive post-treatment.³⁹ Most importantly, if increased knowledge does not help create a more informed patient and this latter feature is a goal for a given DA, then an evaluation would indicate that the DA did not accomplish its pre-determined goal.

In another example, the outcome of reduced decisional conflict might be reflective of the psychological impact of a DA in patient decision-making.^{33,85} In the literature, decisional conflict is defined as, *'the aspect of regret stemming from the knowledge that the treatment choice made was non-optimal...'* yet the term, "non-optimal" used in the definition is elusive.^{39,85} This measure might be influenced by the "regret" patients may experience with non-optimal health outcomes (i.e., late side effects of treatment) following DA use.^{39,85} The Decisional Conflict Scale (DCS) evaluates the degree to which patients felt like they made the "right" decision, and is not designed to evaluate regret related to post-decision health-related outcomes.^{39,85}

There are often inconsistencies with outcomes measures incorporated in cancer-related DA studies to evaluate their impact or effectiveness.⁹ As noted by *O'Brien et al*, decisional conflict was measured in approximately half of the 19 trials on cancer screening DAs, and patient knowledge was measured in only three of the nine trials on cancer treatment DAs.⁹

Examples of Decision Aids in Clinical Practice

The DA trials described below were referenced from other relevant articles discussing an aspect of DA development or evaluation such as, developmental approaches, review of the clinical evidence, risk formatting and presentation strategies or DA evaluative criteria. All articles were retrieved from *PubMed* and cover a broad range of decision-making contexts.

For patients diagnosed with an aneurysm of the abdominal aorta (AAA) *Ubbink et al* developed a DA (2008) to facilitate surgeon and patient shared decision-making (Academic Medical Center, Amsterdam, Netherlands).⁵⁷ An AAA is an asymptomatic condition which is usually discovered by chance but may result in rupture and death.⁵⁷ Patients and treating physicians must consider the up-front risks of surgery (i.e., invasive option) against the risk of rupture associated with watchful waiting (i.e., non-invasive option).⁵⁷ Developers utilized a 5-stage systematic approach to plan, develop, test and evaluate the instrument.⁵⁷ A specific model was not consulted in the DA design.⁵⁷ A multidisciplinary clinical advisory team was assembled to review DA content and functional requirements and collect relevant data from the current evidence base on survival and risk estimates attributed to each treatment option.⁵⁷ In the design and creation stage, DA developers used various graphical images to visually represent treatment risks and benefits and also opted for a digital DA delivery format which would automatically record information in patient log files.⁵⁷ To evaluate measures of comprehensibility and user-friendliness, the DA was pilot-tested with 15 previously diagnosed AAA patients in the final stage of the study.⁵⁷ The majority of patients considered the DA user-friendly (median score = 75 out

of 100, IQR 53-86), easy to understand (median score = 86 out of 100, IQR 80-90) and perceived it to be a useful addition to their decision-making.⁵⁷

Many patients have difficulty adhering to statin drug use to lower cholesterol despite high quality evidence and clinical guidelines recommending such use, especially among patients with diabetes and high risk of a cardiovascular event.³⁰ Inadequate use of statin use is often attributed to poor quality of information-transfer on treatment benefits and risks and a lack of patient involvement in decision-making.³⁰ A DA titled *Statin Choice* (2007) was created to promote quality information-transfer on statin drug use between physicians and patients with Type 2 diabetes.³⁰ The one-page decision aid was intended for use during medical consultation and was developed using a framework created by researchers from the Mayo Clinic.³⁰ Using “100 faces” pictographs and absolute risk reductions from statin use, the estimated 10-year risk of experiencing a heart attack based on various cardiovascular risk factors are graphically and numerically presented.³⁰ In addition, common treatment side effects with statin use (e.g. muscle aching/stiffness, nausea, diarrhea) are presented as probability statements.³⁰ Using *Statin Choice*, patients expressed improved knowledge of treatment options and associated benefits and harms.³⁰ Seventy-five percent of patients felt that using *Statin Choice* helped clarify treatment decision choices, and information on risk of heart attack (10-year risk).³⁰ Common treatment side effects were also more accurately perceived with DA use (OR = 6.7; 95% CI 2.2 to 19.7).³⁰ This effect was typically enhanced when clinicians guided patients through the various DA components.³⁰ Finally, patients responded well to DA acceptability (OR = 2.8; 95% CI 1.2 to 6.9) and 74% of patients would recommend the DA to others compared to 53% of patients who received the pamphlet alone (OR = 2.6; 95% CI 0.6 – 3.8).³⁰

Clinical practice guidelines on use of hormone therapy (HRT) suggest patients consider treatment only after personally assessing the long-term benefits and risks.³³ However, decisional difficulty exists due to the uncertainty surrounding potential outcomes, treatment benefit-to-risk trade-offs, and variation in treatment preferences among physicians and patients.³³ O'Connor *et al* created a self-administered audiotape DA (1998) with accompanying illustrated handbook for women to consider long-term hormone therapy (HRT) in the post-menopausal setting.³³ The effects of HRT (benefits and risks) on coronary heart disease, osteoporosis, menopausal symptoms, endometrial and breast cancer were outlined.³³ Illustrative icons were used (i.e., 100 faces pictograph) to depict risk information on potential HRT clinical outcomes as a proportion (e.g., 10 out of 100).³³ As well, numerical estimates of treatment outcomes over a defined timeframe were provided.³³ With the HRT DA (compared to no DA use), patients were more certain and informed on their decision-making process.³³ For patients who did and did not consult the DA, 50% and 32% ($p = 0.001$), respectively, had accurate risk perception of treatment outcomes.³³ This is clinically important since

women often misperceive the risks of HRT use such as heart disease (underestimated) or breast cancer (overestimated).³³ Overall, when the DA was prescribed, women felt better prepared to make a well-informed and personalized treatment decision on HRT.³³

In the cancer treatment decision-making context, patients are often faced with an abundance of complex information even while they are in a mentally vulnerable position (e.g., increased anxiety, fear and depression).^{9,33,82} This can make any decision-making task onerous.^{9,33,82} Patients diagnosed with cancer need to understand important clinical outcomes such as the potential for disease spread (e.g., local or distant tumour recurrence) and risk of adverse side effects associated with different treatment options.^{9,10,29}

A DA in colorectal cancer treatment was developed (2011) to help patients with advanced-stage tumours consider palliative therapy with or without chemotherapy and to help improve patient understanding of prognostic information.⁷⁹ In the study, patients were randomized to receive a standard medical oncology consultation or a consultation with a DA.⁷⁹ The DA was a take-home booklet with accompanying audiotape.⁷⁹ Content on treatment options and probable benefits and toxicities was summarized from relevant RCTs.⁷⁹ Probabilistic information was depicted using graphical formats, numeric estimates and illustrations which were reviewed by the patient and treating clinician during consultation.⁷⁹ The results demonstrated that relative to the control group, patients randomized to receive the intervention reported significantly increased levels of patient understanding of risks and benefits (median score 11.6 vs. 9.6 out of 16, $p < 0.01$). Use of the DA was also associated with greater certainty in choosing a treatment option. Moreover, use of the DA did not increase anxiety or decrease satisfaction with the decision-making process.⁷⁹

The DA studies mentioned above underscore the importance of incorporating tailored patient education tools within medical consultations to encourage improved methods of treatment information-exchange during decision-making. This practice is especially important in cancer care settings where therapies such as chemotherapy and radiotherapy often present complex risk/benefit trade-offs which patients must be able to effectively balance to make sound decisions.

Chapter Summary – Use of Decision Aids in Clinical Practice and the Introduction of “*The Ontario Decision Aid in Rectal Cancer for Stage II and III Patients*” (ODARC)

The use of DAs by patients making important treatment decisions has been shown to improve patient knowledge and recall of clinical information, to help clarify patient treatment preferences, and, to enhance patient participation in

decision making. Decision aid goals must be judiciously determined in the early phases of DA development, since selected goals will influence eventual DA implementation and evaluation. Based on defined DA goals, developers must also decide how to best arrange content using specific risk communication strategies and delivery formats. There are several acceptable standards suggested in the literature, but inconclusive evidence on which method is superior. As well, outcome measures to assess DA impact should be appropriately selected since results need to reflect pre-determined goals.

We wish to develop a treatment information-transfer tool to help address challenges faced by physicians and patients in the area of rectal cancer. It is anticipated that this tool, the *Ontario Decision Aid in Rectal Cancer for Stage II and III Patients* (ODARC), will be used during a consultation with treating physicians, and will help convey relevant treatment information on rectal cancer surgery with or without preoperative RT among patients with stage II or III tumours.

We will use the 7-step *Workbook* as outlined above to direct development of the ODARC. In this thesis, we concentrate on steps 1 through 5 of the *workbook* to develop an ODARC prototype. The remaining two steps which are outside the scope of this thesis are addressed in Chapter IV as future research considerations. The shared decision-making model proposed by *Charles et al* will inform the development of the ODARC.

The ODARC will hopefully encourage a two-way flow of information among patients and physicians, rather than a one-way flow (i.e., paternalistic or informed models). The physician may help communicate technical information presented on the ODARC combined with their professional expertise, and the patient may engage in the dialogue by asking questions, seeking clarification and presenting preferences.

In this chapter we provided a review of decision aids in clinical practice and outlined key developmental considerations to be addressed by DA developers. In the next chapter, we present clinical information and evidence on radiation therapy and rectal cancer surgery, and address the first two steps of the *Workbook*, which include assessing DA need and DA feasibility.

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Chapter II

Clinical Management of Rectal Cancer & Need for the ODARC

This chapter will cover Step 1 (assessing the need for a DA) and Step 2 (feasibility of developing a DA) of the O'Connor/Jacobsen 7-step *workbook*, introduced in Chapter I. Determining need may be achieved by considering the number of individuals affected with the medical condition, variation in the utilization of outlined treatment(s), nature of decision difficulty due to clinical trade-offs, challenges in decision-making practices, and the availability or implementation of related decision aids. The purpose of assessing DA feasibility is to ensure that there are adequate resources for DA development, compelling evidence justifying the need for a DA, and that DA delivery is accessible and acceptable to target users. We first provide a background on the clinical management of rectal cancer to illustrate the need for a treatment DA in this clinical field.

Step 1 - Assess Need for a Decision Aid

Epidemiological Background of the Disease

Cancers of the colon and rectum pose a significant challenge in the Canadian healthcare system.^{1,2} Approximately 23 000 Canadians were diagnosed with colorectal cancer in 2012 alone, and of this number 9 000 will succumb to their disease.³ In 2012, colorectal cancer was the second most commonly diagnosed cancer and second leading cause of cancer deaths in Canada.¹ Provincially, Ontario ranks at the top for the highest number of incident colorectal cancer cases in the country (8 700 in 2012) and colorectal cancer deaths (3 450 in 2012).^{1,3,4} Therefore, it is important to build on the current knowledge base of effective treatment modalities, and assess the current perceptions of treatment caregivers and patients to facilitate effective management of colon and rectal cancer care.

Anatomy and Staging System of Rectal Cancer

Anatomically, the rectum is situated at the distal end of the bowel system and is approximately 12-20 cm in length. Its main function is to act as a reservoir for material to be excreted via the anus.^{2,5,6} The rectum consists of a muscular tube surrounded by mesorectum.⁵ The mesorectum is complete except for the top half of the anterior surface of the muscular tube.⁵ The mesorectum contains the draining lymph nodes of the rectum proper and is encapsulated in a defined layer of connective tissue which marks the mesorectal margin.⁵⁻⁷ Nearly all rectal

cancers form in the mucosal lining of the rectal tube, and then can grow locally in a radial pattern into the rectal wall, or through the rectal wall into the mesorectum, or through the mesorectum into other surrounding pelvic or abdominal structures.⁵⁻⁷ Cancer cells from the main tumour can also leave the main tumour through lymphatic or blood vessel channels and grow in other areas – a concept known as metastatic spread.⁵⁻⁷ Lymph nodes in the mesorectum are the most common site of metastatic spread.⁵⁻⁷ But rectal cancer can also go to organs and sites outside the pelvis such as the liver or lungs.⁵⁻⁷

The most commonly utilized system of rectal cancer staging is the Tumour Node Metastasis (TNM) system outlined in the American Joint Committee on Cancer (AJCC) Guidelines (See Table 1 at back). Using this approach, cancer of the rectum is classified into four main stages, based on T, N and M categories.⁸⁻¹⁰ The T category represents the depth of tumour invasion through the rectal wall.^{8,10} The N category indicates the absence (negative) or presence (positive) of cancer cells in the mesorectal lymph nodes.^{8,10} The M category identifies the absence or presence of cancer metastasis outside the rectum or mesorectum such as in the liver or lungs.^{8,10} The four stages include (See Figure 1 at back):

Stage I (T1 or T2, N0, M0) – The main tumour has invaded into the submucosa (T1) or muscle layer (T2) of the bowel wall but there are no cancer cells in mesorectal lymph nodes or elsewhere.

Stage II (T3 or T4, N0, M0) – The main tumour has penetrated into the mesorectum (T3) or surrounding organs or structures (T4) but there are no cancer cells in mesorectal lymph nodes or elsewhere.

Stage III (any T, N1-2, M0) – Cancerous cells have spread to the mesorectal lymph nodes.

Stage IV (any T, any N, M1) – Cancerous cells have spread to distant organs or sites outside the true rectum.

Accurate identification of tumour stage at the time of disease presentation is imperative to determine the most appropriate treatment plan and to help prognosticate for patients.¹¹⁻¹³ Patients with stage IV colorectal cancer have only a 5% chance of cure at 5 years, while this increase to 90% for patients with stage I disease.^{11,14} Such information will greatly influence the provision and acceptance of treatment options.

More recently in an effort to better prognosticate for patients, in addition to T, N, and M categories, clinicians are encouraged to note the status of the mesorectal margin.^{7,9,11,14} As mentioned, the mesorectal margin is defined by a connective tissue layer which encapsulates the mesorectal lymph nodes and fat which in turn surround the muscular rectal tube.^{7,9,11,14} A positive margin is determined by observing cancer cells within 1 mm of the mesorectal margin.^{7,9,11,14} The presence of such cells greatly increases the chance for negative patient outcomes, as will be further described below.^{7,11}

Rectal Cancer Surgery

For most patients diagnosed with Stage I, II or III rectal cancer, the cornerstone of curative therapy is surgery.⁵ Following curative rectal cancer surgery, patients may experience immediate complications that lead to post-operative death.² However, this is very unusual.² Of greater concern is local or distant tumour recurrence.^{15,16} Local recurrence is defined as tumour recurrence in the pelvis near the original site of operation.^{11,15,16} It is especially feared since it typically results in poorly controlled pain and inevitably leads to patient death.^{8,16} The return of the tumour outside the pelvic area is termed a distant recurrence.⁵ Similar to local recurrence, distant recurrence almost always contributes to a shortened expectation of long-term overall survival.⁵ Overall survival is usually forecast over 5 years and is another key patient outcome.¹⁵

Other important long-term morbidities or negative outcomes associated with rectal cancer surgery include problems with bowel function and sexual function.¹⁷⁻²⁰ Features of bowel dysfunction can include fecal incontinence, urgency requiring rapid visits to a washroom, and incomplete emptying leading to numerous visits to a washroom over a time period that may last hours.^{18,21} Such difficulties may lead to a severe impairment in activities of normal living, and lead to patients being afraid to leave their homes.^{18,21} Sexual dysfunction among women may include painful intercourse due to dryness of mucous membranes. Sexual dysfunction among men can include an inability to achieve erection or ejaculation. Prior to surgery it is important to determine a patient's baseline bowel and sexual function to best determine the causes of poor function post-operatively.

If a patient has a tumour very low or very near the anus, it is unlikely bowel continuity can be restored.⁵ The operating surgeon will remove the rectum and anus and the patient will require a permanent colostomy, also known as a stoma for waste excretion.^{2,5,14} Such a procedure is known as an abdominoperineal resection (APR).² If the tumour is higher in the rectum the appropriate section of rectal tube and surrounding mesorectal lymph nodes and fat is removed, and the bowel continuity restored through the use of surgical stapling devices. Such a procedure is known as a low-anterior resection (LAR).²

Radiation Therapy in Rectal Cancer Treatment – Local Recurrence & Overall 5-year Survival

Over the last three decades, treatment of rectal cancer has undergone many considerations and changes. In an effort to decrease the risks of local and distant recurrence and improve survival, investigators have trialed and developed various additions to surgery including the use of radiation therapy (RT) and chemotherapy.^{9,22,23} Such additional treatments can be given after surgery (i.e., adjuvant treatments) or before surgery (i.e., neoadjuvant treatments).^{9,22,23} As

discussed previously, the risk of negative patient outcomes such as local recurrence increases with higher tumour stage.⁸ Clinical trials in North America have found that patients diagnosed with stage II or III rectal cancer are the most suitable candidates to receive adjuvant or neoadjuvant treatments.^{22,23}

In North America, the Gastrointestinal Tumor Study Group (GITSG) in 1986 demonstrated a decreased LR rate with the use of radiation among patients with stage II and III rectal cancer.²⁴ Combined patients from both stages who received postoperative RT and CT compared to surgery alone experienced a significant decline in overall recurrence, from 55% to 33% ($p = 0.009$), and in local recurrence, from 21% to 6% ($p < 0.009$).²⁴ The dose of chemotherapy used in the trial was designed to augment the effects of RT in reducing rates of local recurrence which could lead to an improvement in overall survival.^{14,15,22,24} Overall five-year survival rates in the same treatment groups discussed above trended to improvement at 64% and 44%, respectively ($p = 0.07$).²⁴

Shortly after in 1991, the North Central Cancer Treatment Group (NCCTG) reported a study for stage II and III rectal cancer patients which compared patients receiving adjuvant RT alone versus RT combined with chemotherapy.²⁵ For these arms respectively, the local recurrence rates were 25% and 13.5% ($p = 0.036$), the overall recurrence rate was 63% and 42% ($p = 0.0025$), and the five-year overall survival was 49% and 62% ($p = 0.043$).²⁵ Based on these studies, in 1991 the National Institutes of Health (NIH) issued a consensus document advocating for the use of combined postoperative RT and chemotherapy for all patients with stage II or III rectal cancer.¹⁵ A recent guideline produced in Ontario continues to endorse this treatment regimen of chemoradiation for patients with stage II or III rectal cancer.²²

In a 1993 Swedish study led by *Frykholm et al*, tested a different adjuvant RT approach than the one promoted by the 1991 NIH consensus document.²⁶ In the study, local recurrence and overall 5-year survival were assessed with patients randomized to short-course preoperative RT or long-course postoperative RT in addition to surgery.²⁶ In the trial, no significant difference in overall survival was detected between the two groups, but a marked improvement in local recurrence rates was observed in the group treated preoperatively (13% vs. 22%, $p = 0.02$).²⁶ A few years later in 1997, the Swedish Rectal Cancer Trial published its report on patients randomized to receive preoperative short- course RT or no RT (surgery alone).²⁷ The results demonstrated superior rates of local recurrence for irradiated patients (11% vs. 27%, $p < 0.001$).²⁷ This latter trial showed a beneficial effect of RT on overall 5-year survival, with a 10% absolute risk improvement in the group treated with preoperative RT (58% and 48%, $p = 0.004$).²⁷

Of note, the rates of local recurrence in many western jurisdictions in the 1970's and 1980's were in the range of 25-40%, though rates are much lower today.^{24,25,28} For example, recent data from the provinces of British Columbia and Manitoba report local recurrence rates of approximately 15% while a recent study from Ontario found rates of approximately 7%.^{12,29,30}

Radiation Therapy in Rectal Cancer Treatment – Chronic Side Effects

Combining RT with surgery for rectal cancer does come at a cost.^{18,31,32,26,27,24,25} Patients receiving RT may have increased risks of long-term bowel and sexual dysfunction.^{18,31,32} Years following surgery, patients receiving RT may also have greater rates of bowel obstruction and hip fractures.³³ It is postulated that RT may damage the internal and external sphincters which help maintain bowel continence, or the pliancy of the bowel wall which may prevent the rectum from acting as a reservoir.²¹

In the GITSG study, patients who had undergone combined-modality treatment suffered most from severe nonhematologic side effects (35%), including enteritis with diarrhea.²⁴ In comparison, patients treated with either chemotherapy or radiation alone experienced such toxic reactions at approximately half that value, 15% and 16%, respectively.²⁴ Severe gastrointestinal complications involving severe radiation enteritis occurred in 5% (96 in total) of the patients administered combined-modality therapy or radiation alone, and two patients died from radiation-induced complications.²⁴ Similarly, in the NCCTG trial approximately 7% of all patients (204 in total) who received radiation alone or combined with chemotherapy experienced severe delayed reactions.²⁵ Of note, an acute reaction with severe diarrhea was more pronounced in the combined group (20%) compared to patients who were simply irradiated (5%).²⁵

Frykholm et al reported that chronic side effects were more common in the postoperative versus preoperative RT group.²⁶ To illustrate, in the postoperative group 15% and 6% of patients experienced morbidities with bowel and bladder, respectively.²⁶ In contrast, in the preoperative group corresponding side effects occurred in 11% and 2% of patients, respectively.²⁶

Finally, *Dahlberg et al* using data from the Swedish Rectal Cancer Trial showed that preoperative RT increased the risk of bowel dysfunction and impaired patient social life.²¹ Among patients in the no preoperative RT versus preoperative RT groups, 10% and 30% ($p < 0.01$) experienced severe impairment with activities of daily living due to bowel problems.²¹

Forms of Radiation Therapy – Short vs. Long-course Regimens, Pre- vs. Postoperative Regimens and the Inaccuracy of Preoperative Staging

Radiation therapy may be delivered using short or long-course regimens. These regimens are biologically equivalent with regard to radiation effect. Short-course RT is delivered over five daily treatments or fractions, and each radiation dose per fraction is 5Gy.³⁴ In contrast, long-course RT is provided in 25 smaller radiation doses of 1.8 – 2.0Gy over a 5-week span.³⁴ Many European jurisdictions use preoperative short-course RT for nearly all patients with rectal cancer.³⁵

Most North American treatment guidelines do not support the use of short-course preoperative RT, but prefer long-course RT combined with chemotherapy for patients with Stage II or III tumours.^{9,36} This is despite one trial demonstrating similar local recurrence and overall survival rates for patients treated with long-course postoperative RT and chemotherapy versus short-course preoperative RT.³⁷ More recently, following the publication of an important trial by *Sauer et al*, most North American guidelines, including the Ontario guidelines, now encourage the use of preoperative long-course RT and chemotherapy for patients with stage II or III rectal cancer.¹³ In the *Sauer et al* trial patients with presumed stage II or III rectal cancer were randomized to pre- or postoperative long-course chemotherapy and RT.¹³ There was no survival advantage for the preoperative arm, but the risk of local recurrence was superior (6% vs. 13%, $p = 0.006$).¹³ In contrast to postoperative RT, it is hypothesized that irradiation of the tumour prior to surgery is more effective since the tumour is better oxygenated (radiation kills cancer cells through the production of oxygen free radicals from oxygenated tissues), isolated cancer cells do not have the potential protection from radiation of hypoxic environments created by post-surgical scar tissue, and patients are more likely to complete full treatment courses since they are not recovering from major surgery.⁸

As also demonstrated in the *Sauer et al* trial, inaccuracies with tumour staging pre-treatment may lead to unsuitable provision of adjuvant RT.¹³ To illustrate, only patients diagnosed with stage II and III rectal cancer were eligible for participation in the *Sauer et al* trial. However, 18% of patients in the post-operative treatment arm were found to have stage I tumours, and were thus not eligible for post-operative long-course chemotherapy and RT.¹³ A recent Ontario guideline summarizing the accuracy of staging tests for rectal cancer also demonstrated a 20% rate of inaccuracy in rectal cancer staging with the use of pelvic magnetic resonance imaging or computed tomography.⁹ Thus in Ontario, it is likely that some patients with stage I tumours receive preoperative RT, and some patients with stage II and III tumours receive less effective postoperative RT.^{9,38} As well, despite guidelines recommending preoperative RT for all stage II and III rectal cancer patients, or at least postoperative RT for such patients, in

Ontario only 43% of patients diagnosed with stage II/III cancer receive RT, and the great majority of RT is delivered in the postoperative setting.^{11,39}

In summary, North American guidelines, including guidelines in Ontario, suggest that patients with Stage II or III rectal cancer should receive preoperative RT and chemotherapy in an effort to decrease risk of local recurrence. However, many patients in Ontario with stage II or III rectal cancer do not receive RT, and it is likely some patients with stage I cancer do receive RT.

Evolving Standards of Surgical Treatment – Total Mesorectal Excision (TME) Procedure

Traditionally, surgeons removed rectal tumours from the pelvis using blunt or hand dissection.⁴⁰⁻⁴² It is now known that blunt dissection can easily disrupt the mesorectal fascia resulting in an incomplete removal of lymphatic, nervous and blood vessel tissues, any of which may harbor cancer cells, leading to local recurrence rates as high as 20 - 45%.^{23,40,41,40-42} The reduction of local recurrence rates to approximately 13% with the use of RT described above in the NCCTG and Swedish Rectal Cancer studies were considered important advances in treatment.^{25,27,43} A surgical technique known as total mesorectal excision (TME) is now accepted as the “gold standard” for rectal cancer surgery and is associated with local recurrence rates in the single digits even without the use of RT.^{23,40,41} Total mesorectal excision involves sharp dissection under direct vision in the mesorectal plane, or the plane just outside the mesorectal fascia (See Figure 2 at back).⁴⁰ This latter fascia encloses the rectum proper and all the regional or mesorectal lymph nodes, which are usually the first site of metastatic spread from the main tumour.⁴⁰

In Stockholm, Sweden starting in 1994 surgeons were trained in total mesorectal excision techniques through workshops, live surgery demonstrations, and histopathology sessions on specimen evaluation.^{23,42} A report from Stockholm with 2-year follow-up found that the local recurrence rate was 9% in patients treated with total mesorectal excision surgery alone and 15% in patients who received non-total mesorectal excision surgery ($p < 0.0001$).⁴² Since that time, numerous single rectal cancer treatment centers have reported local recurrence rates as low as 1% - 5% with the adoption of total mesorectal excision techniques.^{7,41,44} Based on these encouraging results, there has been a drive to establish effective total mesorectal excision training programs for multidisciplinary clinical care teams worldwide.^{7,28,30,45}

Practice Variation in the Utilization of RT Treatment

As mentioned, there are marked variations in the regimens used to deliver RT for patients with rectal cancer, in jurisdictions around the world. In North America, RT is usually delivered postoperatively in a long-course schedule - over 5 weeks in relatively small daily fractions and in combination with chemotherapy, and ideally only for patients with stage II or III tumours.^{22,46} This was the form of RT used in the GITSG and NCCTG studies outlined above. In most European nations, such as Sweden, Poland and the Netherlands, there is less concern with stage I patients receiving RT in addition to patients with stage II or III tumours, and the standard treatment regimen is 25 Gray given in equal doses over five consecutive days and with no chemotherapy, and only a few days prior to surgery.^{37,43,47} In contrast, in Norway radiation therapy is reserved for the minority of patients where tumour cells threaten the mesorectal margin of the rectum, or the potential surgical plane of resection.⁴⁸

In Ontario guidelines recommend preoperative CRT for patients with Stage II or III rectal cancer.²² But a recent study by *Francescutti et al* showed that only 43% of Ontario patients diagnosed with stage II or III rectal cancer received RT, and the great majority of RT was delivered in the postoperative setting.³⁹ Thus, there are marked variations in how RT is delivered around the world, and a lack of fidelity in Ontario with recommendations from relevant treatment guidelines.

Re-evaluating the Role of Radiation Therapy in Rectal Cancer Treatment

With improvements in patient outcomes with total mesorectal excision surgery there is a need to re-evaluate the risks (side effects) and benefits (improved rates of local recurrence and survival) of RT in rectal cancer. Evidence of marked variations among countries in the application of RT in rectal cancer increases the need for such a re-evaluation.

As discussed previously, initial trials from North America and Europe demonstrated that combining RT with surgery for patients with rectal cancer – especially patients with stage II and III tumours – was associated with clinically and statistically significant improvements in patient rates of local tumour recurrence and overall survival. But the use of RT also results in serious patient side effects such as bowel and sexual dysfunction, and the over-treatment of some patients with early stage I rectal cancer.

Improving surgical standards represented by the total mesorectal excision technique significantly lowers the risk of local recurrence, a main negative patient outcome following rectal cancer surgery. This result highlights the importance of implementing a standardized surgical approach utilizing total mesorectal excision before considering any form of adjuvant RT therapy, and encourages a

reassessment of the way the risks and benefits of RT are presented to patients with rectal cancer.^{23,31,42,49}

Challenges with Treatment Decision-Making in Rectal Cancer

The percentage of Ontario patients with rectal cancer that present with stage II or III tumours – and thus are eligible to receive preoperative RT - is 59%.⁴ Such patients are faced with the decision of balancing the risks and benefits of RT therapy in concert with major surgery. The use of a structured decision support tool as an adjunct to a standard physician consultation may be a helpful way of allowing patients to consider recent new knowledge on the benefits and risks associated with RT. Such a tool may help physicians effectively communicate appropriate medical knowledge to help improve patient awareness and understanding of treatment choices and their associated outcomes, and may help patients communicate preferences back to their physicians. Some studies show that patients seek detailed prognostic information and this is often misinterpreted by physicians who believe that providing explicit details on treatment risks (i.e., adverse side effects) may further raise patient anxiety levels and distress.⁵⁰⁻⁵² But improved information-giving during consultation has been shown to help patients cope with their diagnosis and address quality-of-life concerns.⁵³⁻⁵⁵

Braddock and colleagues suggest that to ensure information ‘completeness’, following full information disclosure on the clinical decision to be made, including a balanced presentation of treatment risks and benefits and alternative therapies, healthcare providers should assess patient understanding.⁵⁴ In a related evaluation of consultation ‘completeness’, *Braddock et al* noted that only 15% of consultations for complex issues such as cancer treatment were considered complete. Of note, physicians rarely assessed patient understanding of treatment information (only 7%) checking.⁵⁴ The majority of patients (84%) engaged in complex decision-making received information on standard treatment modalities, but information on alternative therapies, disclosure of treatment risks and benefits, and uncertainties associated with the clinical decision were provided less frequently at 30%, 26% and 17% ($p < 0.001$), respectively.⁵⁴

Of note, older adults, a group which comprises the majority of rectal cancer patients, also desire completeness of treatment information during medical consultations.⁵⁶ In a study by *Flynn et al*, of 5199 older-adult participants, 60% “agreed strongly” that discussion with their healthcare providers on relevant treatment information was important.⁵⁶ But several studies have shown that cancer patients are not adequately informed of treatment procedures.^{52,55,57,58} *Scheer et al* evaluated thirty patients diagnosed with advanced-stage rectal cancer who had undergone surgery.⁵⁵ With regard to surgical outcomes, the majority of patient participants (67%) had a vague understanding of survival with

no knowledge of specifics related to surgical benefit.⁵⁵ Side effects of treatment such as bowel and sexual dysfunction were also poorly recalled with 47% of patients having no awareness of any potential postoperative risks.⁵⁵ Researchers have also shown that patients receiving radiotherapy or chemotherapy are overly optimistic of potential benefits, and generally misinformed of potential treatment side effects.^{59,60}

There is evidence that many patients with locally advanced rectal cancer would defer preoperative chemotherapy and RT and accept the increased risk of local tumour recurrence in exchange for improvements in functional outcomes.⁶¹ In a study by *Kennedy et al*, patients were presented with a threshold task on accepting the risk of local recurrence with two treatment options: preoperative chemotherapy and RT with total mesorectal excision surgery or total mesorectal excision surgery alone. Initially, the risk of local recurrence for both groups was set at 15%.⁶¹ The risk of local recurrence for the RT option was systematically decreased by 1% (from 15%) until the participant indicated their preferred threshold value for accepting the risk of RT side effects to decrease the chances of local recurrence.⁶¹ Approximately 54% (27 out of 50) identified a threshold value of 5% (from original baseline 15%) to consider switching from surgery alone to preoperative chemotherapy and RT with surgery.⁶¹ That is, the risk of local recurrence would have to be equal or less than 5% (an absolute decrease of at least 10% from the baseline 15%) with the use of preoperative chemotherapy and RT prior to patients accepting this treatment.⁶¹ But this risk is much lower than the quoted risks in most jurisdictions among patients with Stage II or III rectal cancer. If these findings are generalizable to the population of patients with stage II or III rectal cancer, and there is no reason to think otherwise, the results suggest that many patients would not accept preoperative RT. That is, patients may be willing to accept a higher risk of local recurrence from surgery alone and avoid RT and its associated side effects.⁶¹ Participants of this study also felt that a threshold task exercise would be useful in helping all patients reach a treatment decision regarding preoperative RT in treatment of rectal cancer.⁶¹

The above findings underscore the need for improving methods of information-transfer for complex decision-making scenarios (i.e., rectal cancer) with regards to available treatment options and their related benefits and risks.^{50,51,55,56,62} A decision support tool may facilitate information-exchange between patient and physician. In a related study, *Harrison et al* demonstrated that colorectal cancer surgeons were concerned with the ability of patients to comprehend 'complex' DA content.⁶³ Specifically, surgeons felt that most patients would experience difficulty understanding group-based outcome averages derived from the literature.⁶³ Some also expressed that the application of a DA would detract from the physician-patient relationship; although this thought was mostly targeted to the use of computer-based decision-support tools.⁶³ However, surgeons also felt that a DA was a 'worthwhile' mechanism to help improve patient understanding of probabilistic outcomes of treatment benefits and risks.⁶³

Many also felt that the use of a DA functioned as a 'good checklist' to ensure surgeons discussed with patients all key aspects of treatment.⁶³

Other Rectal Cancer Treatment Decision Aids

The Cochrane Inventory of Decision Aids houses over 400 decision aids, but none are specifically designed for stage II and III rectal cancer patients considering the use of preoperative RT in addition to surgery.⁶⁴ There is one decision aid related to the medical scenario relevant to the *Ontario Decision Aid in Rectal Cancer* (ODARC).⁶⁵

In 2004, Australian researchers constructed a computer-based and take-home booklet version of a DA titled "*Making Choices – Deciding whether to have radiotherapy and/or chemotherapy*" for use by patients with locally advanced rectal cancer.⁶⁵ For the purposes of this thesis we refer to this DA as the, "Australian Decision Aid." This DA outlines four different treatment options: surgery alone, surgery with preoperative radiotherapy (RT) alone, surgery with postoperative chemotherapy alone, and, surgery with preoperative chemoradiotherapy.⁶⁵ The computerized component was constructed for interactive use during a patient's consultation with their treating physician, while the DA booklet was provided to patients to take home following consultation.^{65,66} The key outcomes were local and distant tumour recurrence 5 years post-surgery.⁶⁵ Long-term side effects related to bowel and sexual function were also considered.⁶⁵ The chance of developing outcomes or treatment side effects was presented probabilistically via pie charts and text formats.⁶⁵

The Australian Decision Aid (2004) was designed to act as an effective DA for patients considering the use of RT in addition to rectal cancer surgery. However, content and methodological weaknesses of the Australian Decision Aid make it of little use to Ontario patients. For example, the Australian Decision Aid does not incorporate recent data on improved outcomes in rectal cancer surgery with TME surgery, does not accurately and comprehensively convey information on potential side effects with RT, does not distinguish patients with stage II or III rectal cancer versus patients with stage I rectal cancer (only the former are eligible to receive RT in Ontario), and does not embody current improved standards of risk communication and presentation strategies. It has also not undergone a formal evaluation to assess its impact on decision-making with actual patients in a pilot or randomized clinical trial setting.

The ODARC varies in three substantive ways from the Australian Decision Aid. First, the decision-making content presented on the ODARC is synthesized from data published in recent randomized controlled trials on rectal cancer total mesorectal excision surgery and the use of RT. This is important since the evidence showcased on DAs must be accurate, routinely updated and monitored.^{67,68} Second, the ODARC utilizes commonly accepted

recommendations on DA methodology such as appropriate risk formatting of probabilistic information. The strategies employed in the ODARC should more accurately convey the risks and benefits associated with relevant treatment options. Lastly, the ODARC is designed specifically for patients with stage II or III rectal cancer and thus complements current Ontario treatment guidelines.

To summarize, related to rectal cancer surgery in Ontario and elsewhere, we have presented information on improved standards of surgical care which has significantly changed the risk-to-benefit ratio for RT. Additionally, we have demonstrated there is no universal protocol on the use of RT and marked variations in RT utilization exist both internationally and in the province of Ontario. With regard to treatment decision making in rectal cancer, there is evidence that patients often do not fully understand the implications of their cancer treatments, and that many patients would forego the use of RT in clinical scenarios where RT would currently be recommended. Finally, we identified a related DA published by an Australian group, but the content of this DA is obsolete in light of updated clinical and methodological knowledge. Thus, with regards to RT and rectal cancer surgery there is an imperative to improve strategies of information-transfer between physicians and patients during treatment decision-making.

Step 2 - Assess Feasibility to Develop the Decision Aid

Availability of Adequate Resources

Designing and constructing the ODARC commenced in August 2012 and is the thesis component of my Master's degree. This continues to be done in collaboration with my thesis committee. My supervisor, Dr. Marko Simunovic, is a surgical oncologist sited at the Juravinski Cancer Centre. His clinical practice is centred on patients with colorectal cancer. As such, he has direct access to other clinicians treating such patients, including radiation oncologists and potential access to patients for DA development purposes.

Other members of the thesis supervisory team have extensive expertise and experience in the DA development process including Drs Gafni, Charles and Kennedy. Dr. Gafni is a health economist and adds valuable insight to the development of the ODARC prototype, specifically with regards to risk framing strategies and methods of decision analysis. As an expert in qualitative research methods, Dr. Charles also provides key methodological and conceptual insights into the DA developmental process. Both Drs Gafni and Charles are affiliated with the Centre for Health Economics and Policy Analysis (CHEPA) located at McMaster University in Hamilton. They have published collaboratively and separately on various aspects of patient-physician decision-making in the clinical encounter. Their contributions to evidence-based literature have included the development and evaluation of decision aids, specifically in an oncology

setting⁶⁹⁻⁷² as well as, theoretical models of decision-making.⁷³⁻⁷⁶ Finally, Dr. Erin Kennedy, an external reviewer, is a clinician-scientist who specializes in colorectal cancer care and is also highly knowledgeable on shared-decision making research using patient decision aids.

Availability of Sufficient Evidence on Benefits & Risks for Decision Aid Content

A key step in feasibility assessment as defined in the *Workbook* is to ensure the availability of sufficient evidence of treatment benefits and risks to incorporate into the DA. Evidence is retrieved from recent clinical trials, systematic overviews, and discussion with clinical experts.

Synthesis of Key Trials for ODARC Clinical Content: Dutch TME & MRC-CR07 Trials

We were interested in reassessing the role of RT in the era of total mesorectal excision surgery for treatment of rectal cancer for patients diagnosed with stage II and III tumours. We searched the following electronic databases: Medline (2001 – 2011); OVID (2001 - 2011); Cochrane Controlled Trial Register (2001-2011) and UpToDate (2001 - 2011). We applied MeSH (Medical Subject Headings) terms including, ***radiation therapy and rectal cancer, local recurrence, overall survival, treatment side effects, long-term and acute.***

We used several eligibility criteria in our review to ensure we identified appropriate data for our purposes. First, we restricted our search to randomized controlled trials (RCTs), and to studies published after 2001. This optimized the chances that surgical trials would utilize total mesorectal excision surgery which came into effect internationally only in the mid-1990's. Related to this first parameter, we also insisted that included trials utilized some form of quality assurance to ensure the appropriate use of total mesorectal excision surgery. Second, patients had to be randomized to some form of preoperative RT and surgery versus surgery alone. Research demonstrates that preoperative RT is more effective at improving patient outcomes, such as local tumour recurrence than postoperative RT.^{13,21,28,31,32,34,35} Third, trials included in the literature review had to have the study endpoints of local tumour recurrence and 5-year overall survival. Fourth, study data had to allow us to differentiate patients with stage II or stage III tumours as our review is ultimately directed to assist decision-making in a North American context – where RT is reserved for patients with stage II and III rectal cancer.

We reviewed a total of 8 studies and 6 randomized trials outlining the effects of RT in rectal cancer surgery when total mesorectal excision surgical principles are used (See Table 2 at back). Only two RCTs met our study eligibility criteria and were thus included in our review to determine the effects of surgery

with/without preoperative RT on important clinical outcomes (local recurrence and survival) and the risk of important side effects (sexual and bowel dysfunction). These include the Dutch total mesorectal excision (TME) Trial and the MRC-CR07 trials.

The Dutch TME Trial

The Dutch TME trial initiated in the mid 1990's and published in 2007 investigated the value of preoperative short-course RT combined with TME surgery.⁴⁹ Patients were randomized to receive RT and surgery or surgery alone.⁴⁹ The primary endpoints were local recurrence and 5-year overall survival.⁴⁹ Bowel and sexual function data were also collected.⁴⁹ The eligibility criteria mandated that patients had resectable adenocarcinoma of the rectum without any evidence of distant metastasis.⁴⁹ The Dutch TME trial strived to implement quality surgical guidelines to promote the gold standard of total mesorectal excision in surgery.⁴⁹ Workshops and video instruction were used to train surgeons on optimal total mesorectal excision surgery.⁴⁹ As well, a surgeon-instructor was present at each study site to supervise the first five operations of individual surgeons.^{49,77} In terms of histopathological analysis of the surgical specimen, a standardized inspection protocol (Quirke protocol) was adopted, and a panel of expert pathologists was created to review results of each evaluation as part of quality assurance.⁴⁹

One thousand eight hundred and sixty-one patients were recruited between 1996 and 1999.⁴⁹ The great majority of patients were recruited from the Netherlands; however, there were some Swedish and Canadian patients. For the main outcome of local tumour recurrence, a 49% relative risk reduction was observed in the surgery and RT group vs. the surgery alone group, consistent with previous studies on RT in rectal cancer.⁴⁹ In a six year follow-up study and for these same arms respectively, among all study patients the local recurrence rate was 5.6% and 10.9% ($p < 0.001$), while for stage II and III patients the LR rate was 8% and 15% ($p < 0.001$).⁴⁹

Patients who received preoperative RT also had higher rates of bowel dysfunction.⁴⁹ The most common forms of impaired bowel function were fecal incontinence, urgency and emptying difficulties.^{17,49} Of the 600 patients assessed in a chronic side-effects sub-study, 34% of RT patients experienced severe restrictions with daily activities secondary to bowel dysfunction compared to 22% of surgery-alone patients ($p = 0.001$).¹⁷ The study authors also assessed sexual function.¹⁷ At two years post-treatment, there were declines in sexual function among patients sexually active prior to surgery.¹⁷ In the surgery alone and the surgery and RT groups, respectively, 24% and 33% of male patients ($p < 0.001$) and 10% and 28% of the female patients were no longer sexually active ($p < 0.001$).¹⁷ The main problems described among men were erectile and ejaculation dysfunction, and among women were vaginal dryness and pain during intercourse.^{17,19}

Of interest, while efforts were taken to ensure high standards of surgical and pathology practice in the Dutch TME trial, a sub-study of the trial found that only 27% of surgeries were high-quality total mesorectal excision type procedures.⁷⁸ This may explain why the positive radial margin rate was relatively high at 23%.⁷⁸ While the results of the Dutch TME trial reinforce the ability of preoperative RT to greatly decrease the risk of local recurrence, it is possible that the relatively low rates of local recurrence for both treatment arms observed in the trial would have been even lower with better quality surgery.⁷⁸

The Medical Research Council (MRC) - CRO7 Trial

The MRC-CR07 study was a large multicentre trial conducted between 1998 and 2005 and published in 2009.³¹ Patients were randomized to receive either short-course preoperative RT followed by surgery (intervention) or selective postoperative chemo-radiotherapy after initial surgery (control).³¹ The latter treatment was provided to patients with a positive circumferential radial margin following surgery.³¹ The main purpose of the trial was to determine if in a clinical setting of optimal total mesorectal excision surgery, RT could be reserved for patients with a positive radial margin, and thus delivered only in the postoperative setting.³¹ In the trial, only 12% of patients had a positive radial margin and were eligible to receive postoperative RT.³¹ Similar to the Dutch TME trial, the primary endpoints of the trial were local recurrence and 5-year overall survival.³¹ As well, patient quality of life (i.e., sexual function) was also evaluated.¹⁹ In the MRC-CR07 trial, approximately 1300 patients with operable adenocarcinoma of the rectum with no evidence of distant metastasis were recruited from 80 centres across the United Kingdom, Canada, South Africa and New Zealand.³¹

In the trial, at five years there was a 61% relative risk reduction in recurrence among patients treated with preoperative RT and surgery compared to patients treated with surgery and selective postoperative RT for patients with a positive radial margin.³¹ The local recurrence rate in the preoperative RT and surgery group versus the selective RT group, respectively, was 4.4% and 10.6% ($p < 0.0001$), while for stage II and III patients only it was 5.1% and 11.4% ($p < 0.0001$).³¹ There was no survival advantage with the use of preoperative RT for all study patients, or for stage II and III patients.³¹ Finally, patients in the preoperative RT group versus patients in the control group experienced worsened sexual quality of life.¹⁹ Based on a 38-item treatment outcomes questionnaire, intervention and control patients scored 65 out of 100 and 56 out of 100 points, respectively ($p < 0.0001$).¹⁹ A higher score indicated a worse functional quality of life and this trend continued at 6 months and 2 years post-treatment.¹⁹

Of note, the quality of surgery in the MRC-CR07 trial was likely superior to that in the Dutch TME Trial, though there were still quality gaps.³¹ The percentage of patients with a positive radial margin was only 12% in comparison

to the 23% rate observed in the Dutch TME study.^{31,49,78} Pathology assessment found that only 52% of patients received optimal total mesorectal excision surgery, though this was better than the rate of 27% in the Dutch TME Trial.^{7,78} It is likely that rates of local recurrence would have been even lower in both groups if all patients in the trial received optimal total mesorectal excision-type surgery.

Relevant data from the Dutch TME and MRC-CR07 trials are outlined in Table 3 (see below). Radiation therapy did confer a significant improvement in local recurrence rates for both stage II and III patients, with an approximately 50% relative risk reduction compared to surgery alone.^{31,49} However, RT did not lead to improvements in overall survival, with 5-year survival rates in control and intervention groups of approximately 65%.^{31,49} Finally, patients receiving preoperative RT were more likely to experience bowel and sexual dysfunction.^{31,49}

Table 3: Summary of Main Clinical Outcomes & Treatment Side Effects from Clinical Trials in Rectal Cancer – Stage II and III Patients Only

Study & Accrual Years			Local Recurrence		Overall 5-year Survival		Treatment Side Effects			
	INT (n)	CTRL (n)	INT	CTRL	INT	CTRL	Sexual Dysfunction ^{+/^}		Bowel Dysfunction ⁺	
							INT	CTRL	INT	CTRL
<i>Dutch TME Trial (6-year follow-up study)</i> Peeters et al., 2007 1996 to 1999	Short-course preop RT + surgery n = 897	Surgery alone n = 908	8% [†]	15% [†]	64%	63%	Males = 33% [†] Females = 28% [†]	Males = 24% [†] Females = 10% [†]	34% [†]	22% [†]
<i>MRC-CRO7 Trial</i> Sebag-Montefiore et al, 2009 1998 to 2005	Short-course preop RT + surgery n = 674	Surgery with postop CRT for patients with positive CRM n = 676	5% [†]	11% [†]	70%	68%	Score [¥] on QOL questionnaire Males = 66 [†]	Score [¥] on QOL questionnaire Males = 57 [†]	n/a	

NB: Abbreviations include intervention (INT), control (CTRL), radiotherapy (RT), chemoradiotherapy (CRT), circumferential radial margin (CRM), preoperative (preop), postoperative (postop)

¥ Only reported for Male Sexual Dysfunction (MSD) – higher score indicates more chronic problems

† Indicates statistical significance ($p < 0.05$)

Sexual Dysfunction Description

+ Dutch TME – Erection/ejaculation disorders in males and vaginal dryness/pain during intercourse in females affecting postoperative sexual activity

^ MRC-CR07 – Erection/ejaculation difficulty affecting postoperative sexual function in males

Bowel Dysfunction Description

+ Dutch TME – Fecal incontinence, urgency and emptying difficulties causing impairments in daily activities

Acceptability and Accessibility of DA Delivery

The third aspect of feasibility as defined in the *Workbook* is consideration of acceptability and accessibility of the decision support tool delivery. Assessments of acceptability and accessibility DA delivery can be elicited with focus groups or market surveys with target users.⁶⁸ We were unable to respond to this criterion in the current thesis but it will be discussed in next research steps as further outlined in Future Directions – Chapter IV.

Chapter II Summary

This chapter addressed Step 1 (assessing the need for a DA) and Step 2 (assessing the feasibility of a DA) of the O'Connor/Jacobsen 7-step *Workbook*. The presented information and evidence suggest there is a definite need for a DA related to the use of RT in patients with stage II or III rectal cancer, and developing such a DA is feasible. Rectal cancer is a major source of morbidity and mortality for patients around the world.^{1,10,15} Early studies showed improvements in local tumour recurrence and overall survival with the use of RT. However, with improved standards of surgical technique (e.g., total mesorectal excision techniques), RT no longer confers a survival advantage for patients, and local recurrence rates without RT are decreased greatly. This increases the number of patients that must be treated with RT to avoid one local recurrence. Radiation therapy also increases the risk of important negative patient side effects such as bowel and sexual dysfunction. There is a consensus that RT should be delivered prior to surgery, though the preferred length and dose of RT (e.g., long-course versus short-course RT) varies in North America and European jurisdictions. Ontario patients diagnosed with stage II or III rectal cancer are eligible to receive preoperative RT.

To help patients improve their awareness and understanding during a medical consultation of treatment options (i.e., surgery with/without preoperative RT), and the potential benefits and risks of each option, we have designed a prototype information-transfer tool called the *Ontario Decision Aid in Rectal Cancer for Stage II and III patients* (ODARC). Chapter III provides data and information on Steps 3, 4, and 5 of the O'Connor/Jacobsen 7-step *Workbook*.

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Chapter III

Development of the ODARC – Content, Format and other Methodological Considerations

The content of this chapter is focused on Steps 3 through 5 of the O'Connor & Jacobsen 7-step *Workbook*. Specifically, we will identify the objectives of the proposed ODARC, we will discuss the decision-making model to guide development, and we will present the design and layout features as informed by current methodological standards of DA development. The ODARC improves on a related Australian rectal cancer DA which was introduced in Chapter II, but which has major content and methodological limitations because new clinical information has become available since the former DA was developed.

Step 3 - Objectives of the Ontario Decision Aid in Rectal Cancer for Stage II and III Patients (ODARC) – To Consider Surgery with/without Preoperative RT

As discussed in Chapter II, surgery is the cornerstone of curative efforts for patients with stage I, II, or III rectal cancer, while in Ontario patients with stage II or III tumours are candidates for pre- or post-operative RT, though RT is more effective in the pre- versus post-operative setting.^{1,2} Chemotherapy is not provided in the preoperative setting unless it is given in conjunction with RT to enhance the effectiveness of this latter treatment.^{1,2} Thus, the key decision patients in Ontario with stage II or III rectal cancer must make prior to surgery is the potential use of preoperative RT. The ODARC presents two treatment options: surgery with or without preoperative RT. Other modalities of care are not reviewed in the ODARC such as no surgery, chemotherapy, or RT after surgery. An important primary step in DA development is to establish a focused and measurable objective(s).^{3,4} This is important as the chosen DA objective influences succeeding steps of the developmental process such as selecting risk communication strategies and methods of evaluating DA impact.^{3,4} Accepted potential goals of DAs include the provision of clinical information (e.g., treatment options, associated clinical outcomes/side effects) to help improve patient knowledge; assistance with clarification of treatment preferences; and, improved patient participation in decision-making. Most researchers suggest that the key goal of any DA is to provide information on treatment benefits and risks to help patients better understand their available options.³⁻⁵ Proper information-transfer from the physician to patient is thus an important prerequisite to medical decision-making and the overall informed consent process.

The main objective of the proposed ODARC is the following:

- For patients with stage II or III rectal cancer, to improve knowledge on treatment options, main clinical outcomes and chronic side effects related to surgery with/without preoperative RT.

When incorporated in a medical consultation with a clinician, the ODARC should be able to act as an information-transfer tool to help convey up-to-date clinical evidence on relevant benefits and risks associated with outlined treatment options. Identifying measures to demonstrate success with our main objective will be discussed in Chapter IV of this thesis - 'Future Directions'.

Step 4 – Theoretical Foundation to Guide ODARC Development

Step 4 of the *Workbook* involves the selection of a conceptual framework(s) which can be used by developers to inform DA development.⁶ The *Workbook* provides several examples of conceptual frameworks. For the ODARC we have selected the shared decision-making model - as previously introduced in Chapter I - described by *Charles et al* to help guide development of our DA.⁷ An essential characteristic of the *Charles et al* model of shared decision-making model is its interactional nature between the physician and patient in all decision-making stages, including the three key steps of information-exchange, deliberation and final decision implementation.⁷ The selection of this conceptual approach was facilitated by thesis committee members at the outset of the development process based on the thesis focus and defined DA objective. In particular, the framework illustrates in detail different approaches to treatment decision-making in a clinical encounter, and the ODARC is intended for use in this context as an adjunct to consultation with a healthcare provider.⁷ Additionally, the *Charles et al* framework helps distinguish features of the shared decision-making model from paternalistic and informed decision-making models.⁷ The former approach has been previously linked to treatment decision-making in the acute care context involving newly diagnosed breast cancer patients considering alternative surgical options, and in another study, considering adjuvant chemotherapy in addition to surgery.^{7,8}

The shared decision-making model emphasizes communication between healthcare providers and patients, as highlighted by the two-way flow of communication in the information-exchange stage.⁷ Importantly, for shared decision-making to occur, patients need to be well-informed on treatment options and related benefits and risks to enable subsequent deliberation and final decision implementation with their healthcare provider.⁷ This approach complements the overall purpose of the proposed DA. The ODARC presents relevant information on potential clinical outcomes (i.e., local recurrence and overall 5-year survival) and chronic side effects (i.e., bowel and sexual dysfunction) for stage II or III rectal cancer patients undergoing surgery with or

without preoperative RT. The technical content is based on a literature review of recent and relevant randomized controlled trials. The Dutch TME and MRC-CR07 trials presented in Chapter II provide best available data on the benefits and risks of preoperative RT in addition to surgery for stage II and III patients in the era of TME. It is expected the ODARC will facilitate the transfer of the relevant information from physicians to patients and help improve patient knowledge on the use of preoperative RT in addition to routine surgery. As such, the current design and delivery of the ODARC focuses on information-transfer and not deliberation and actual decision-making in a physician-patient encounter. Therefore, we concentrate on the first of the three shared decision-making stages (i.e., information-exchange). According to the shared decision making model, the treating physician is the main source of technical decision-making knowledge and communicates this information to patients.⁷ The patient conveys to the physician his/her treatment preferences, personal beliefs and lifestyle needs that will be taken into consideration when discussing which treatment plan to implement.⁷ However, medical information may also be accessed by patients from alternate sources (e.g., social network, media, printed materials, Internet resources).^{9,10} Decision aids may be especially suited to facilitate the exchange of complex medical information and ensuing questions between a patient and their physician in a medical encounter.^{10,11}

The first prototype of the ODARC will be designed as a decision board information-transfer tool to supplement a medical consultation. The information-exchange stage provides relevant context to guide selection of appropriate outcome measures for DA evaluation (i.e., Step 6 of *Workbook*). The ODARC is designed as an information-transfer tool to help communicate treatment information; therefore, assessment of patient knowledge would be a fitting measure to evaluate DA impact and not measures related to decision-making or decision made.^{4,7}

The latter two stages of shared decision making - deliberation and decision implementation - are beyond the scope and objective of this current thesis, but may be integrated as research goals continue to evolve. Following assessment of the ODARC face validity via focus group discussions and via initial pilot-testing, the purpose of the ODARC may expand beyond initial information-transfer.

Step 5 - Methodological Considerations to Support ODARC Objectives

The Delivery Layout of the ODARC

The ODARC is designed as a decision board. There are numerous reasons we selected this format. Compared to other decision aid formats, a decision board can be easily supplied as a take-home copy for further patient

deliberation, is inexpensive to produce, and can be distributed at low cost.^{5,8} A decision board format has the added advantage of being easily revised and updated to incorporate new clinical findings or new information on DA methodology.^{8,12} As one of the earliest DA prototypes, the decision board layout was created to facilitate information-transfer and guide physician-patient communication during a decision-making encounter.⁸ The decision board developed by Whelan and colleagues was positively received by early-stage breast cancer patients deliberating treatment with or without adjuvant chemotherapy.⁸ At the point of decision-making, 98% (out of 175) of patients indicated that the presented information was 'easy to understand' and 81% of patients expressed that the decision board helped them arrive at a final treatment decision.⁸ The study also illustrated that the application of a decision board was best suited in a consultation setting.⁸ Surgeons used the board as a guide to convey important treatment information to their patients, and the majority of patients (57%) made a treatment decision during the consultation and many (86%) also preferred to make a collaborative decision with their treating surgeon.⁸ Results from one study found that individuals from both high and low literacy levels indicated that DA content should be presented in a concise and direct manner, void of excess reading to maximize retention of health information by patients.¹³ A decision board delivery displays all relevant risk information on one compact space which helps reduce the cognitive burden placed on patients to analyze and comprehend vast amounts of decision-making text.^{8,14,12,15,16} In this arrangement, only information most relevant to a patient's medical condition (i.e., treatment options and associated clinical outcomes/side effects) is presented and some researchers contend that simpler and focused DA presentation is an effective way to communicate risk information.^{13-15,17}

In comparison, the take-home booklet version of the Australian Decision Aid uses 39 pages to deliver key clinical content on treatment options, outcomes and side effects.¹⁸ The Australian Decision Aid is thus text-dense with a large quantity of information for patients to absorb and understand before arriving at a decision.¹⁸ Reviewing a computerized-based component or booklet version of a DA may be viewed as a cumbersome and technologically complex exercise for rectal cancer patients, who are typically advanced in age (median age of diagnosis in Ontario is 70).^{19,20} A decision board format would likely be more appropriate for this patient group which embodies more of a "show-and-tell" quality.²⁰ Researchers also suggest patients derive greater benefit in reviewing a decision support tool in-person with their healthcare provider.^{8,12,21,16,20}

The ODARC decision board would be utilized in conjunction with a healthcare provider involved in the patient's care during a medical consultation. As such, it should not interfere with vital patient-provider relationship, which involves engaging in discussion about the condition of interest, information-exchange on treatment options, answering questions and clarifying misconceptions.^{8,12,20,22,23} To allow for a more customized and gender-specific approach to understanding the information presented on the ODARC, we will

create male and female versions of the prototype. Treatment outcomes and bowel dysfunction side effects are similar in these two groups, but sexual dysfunction side effects are not. The ODARC prototype presented in this thesis is printed on poster paper with foam backing to ensure durability and mobility. This composition focuses on a “show-and-tell” feel and thus is conducive to use during a treatment decision-making consultation with a clinician. The ODARC has a physical dimension of 70 cm by 80 cm (length x width) to ensure adequate space for the inclusion of all pertinent text and visuals. In contrast to a multi-page booklet, this facilitates patient movement among text and visuals on presented treatment options, outcomes and side effects, and facilitates subsequent questions and requests for clarification.

ODARC Information on the Clinical Condition, Options and Outcomes

A preface or patient guide describing the clinical situation, available healthcare options and relevant outcomes is typically the first section patients will encounter when consulting a decision board.⁶ The guide will provide patients with a “snapshot” of the essential content presented on the ODARC. This is provided to help prepare the patient to review complex DA information such as probabilistic information on clinical outcomes/side effects and to help focus the user’s attention.^{6,14,24-26} For example, to facilitate user understanding of the graphical risk format utilized in the ODARC, a sample visual of the “100 people picture” with a description box on how to interpret the numbers is included in this section (See Appendix Ai at back). By initially reviewing the patient guide section, the patient will be better oriented on how to review the ODARC and proceed through the various sections systematically in collaboration with a clinician during consultation.

The main treatment options are found on the leftmost side of the ODARC. The first option is for surgery alone and directly below this is the second option of preoperative RT and surgery (See Appendix Aii at back). As discussed above, the key decision faced by Ontario patients with stage II or III rectal cancer is whether to accept or reject the use of preoperative RT. Surgery is always recommended if the patient is medically fit for surgery, and preoperative chemotherapy is only provided in concert with RT.^{19,27} Of note, The Australian Decision Aid is designed for use by patients with ‘advanced’ rectal cancer.¹⁸ But the term “advanced” is nebulous. In Ontario only patients with stage II and III rectal cancer are presented with the option of pre- or postoperative RT.^{1,2} The term ‘advanced cancer’ is not specific and undermines the generalizability of the decision-making content in the Australian Decision Aid for Ontario patients with rectal cancer.

Local recurrence is the first main clinical outcome presented on the ODARC and is defined as, “state of tumour returning in the pelvic area.” The second clinical outcome, overall 5-year survival is referred to as “state of being alive.” Bowel dysfunction is first of the two chronic side effects presented on the ODARC. It is defined as the state of having such poor bowel function (e.g., incontinence, frequency, urgency) that it leads to severe daily social restrictions in household and work-related activities. Lastly, sexual dysfunction (for both male and female patients) is defined as the state of having no sexual activity at 2 years following treatment among patients who were sexually active in the six-month period prior to surgery. Citations of the evidence-based literature referenced for the ODARC clinical content is also provided on the decision board. There is some research to show that providing transparency on how and where the information was derived is favourably received by DA users.^{21,25} This also helps healthcare providers and patients assess the credibility of a decision support tool.^{15,28}

The Australian Decision Aid presents information on four treatment choices for patients including surgery alone, surgery with preoperative radiotherapy alone, surgery with postoperative chemotherapy alone, and, surgery with preoperative chemoradiotherapy.¹⁸ Information on main clinical outcomes (i.e., local recurrence) and side effects is categorized under each treatment option and distributed over multiple pages. It is recommended by many DA developers to avoid presenting large volumes of text which inevitably increases the complexity level to be processed by a patient.^{13-15,17}

Main Clinical Outcomes – Local Recurrence and Overall 5-year Survival

For patients diagnosed with stage II and III rectal cancer, our updated review of the literature demonstrated that the range for risk of local recurrence with surgery alone was 11% to 15% ($p < 0.01$) (See Appendix iii at back).^{29,30} In the Australian Decision Aid, the 5-year risk of local recurrence (LR) for patients with locally advanced rectal cancer with surgery alone is reported as 21%.¹⁸ This risk of local recurrence for the surgery-alone arm is over-inflated. As well, the Australian local recurrence statistic is inclusive of patients with stages I to III rectal cancer. If patients with stage I disease had been excluded from the Australian Decision Aid, the reported risk of local recurrence with surgery alone would be even higher than 21%. Patients with stage I rectal cancer are not eligible for RT in Ontario and thus data from such patients does not inform the content presented in the ODARC.^{1,31} The Australian Decision Aid also reports a 10% chance of local recurrence for patients who undergo preoperative RT and surgery.¹⁸ Again this rate among RT patients would be even higher if patients with stage I tumours were excluded. More importantly, this rate is higher than recent evidence demonstrating a local recurrence risk of 5% to 8% when RT is added to surgery.^{29,30} These absolute changes for patients receiving and not receiving preoperative RT have a substantive impact on the number of patients

needed to be treated prior to one patient benefiting from RT. One of the main considerations in the developmental process of DAs is ongoing renewal of the medical content.^{28,32-34} The decision-making content of the Australian Decision Aid has not been updated since its creation in 2004 and thus does not reflect new relevant clinical evidence, especially in the key area of local recurrence risk.^{18,35} The second main clinical outcome users of the ODARC will review is overall survival. Defined as the state of being alive at 5 years, this outcome is absent from the Australian version of the decision aid. But overall survival has been long considered a key patient outcome in cancer care.³⁶ Older age patients especially prefer to receive information on long-term events influenced (or not influenced) by treatment.^{37,38} Recent evidence shows that the overall survival range for patients opting for direct to surgery is 63% to 68%.^{29,30} The use of preoperative RT with surgery results in a statistically similar survival range of 64% to 70% (See Appendix Aiv at back).^{29,30}

Treatment Side Effects – Bowel and Sexual Dysfunction

After being guided through the two main clinical outcomes, patients will review risks of developing two important long-term treatment side effects associated with preoperative RT and surgery or surgery alone – bowel and sexual dysfunction. As outlined above, bowel dysfunction is defined as the state of having such poor bowel function that it leads to severe daily social restrictions in household and work-related activities. Similarly, sexual dysfunction is defined as the state of having no sexual activity at 2 years following treatment among patients who were sexually active in the six-month period prior to surgery. We did not incorporate short-term RT side effects such as skin burning or fatigue associated with treatment visits since these are rarely long-term issues. We did not present other long-term side effects such as hip fracture or bowel obstruction associated with RT since their occurrence is very rare and thus differentiating risk differences for patients between the outlined treatment options is problematic.

With preoperative RT, 34% of patients will experience bowel dysfunction compared to 22% of patients who receive surgery alone ($p = 0.01$).³⁹ This evidence is reflective of the current randomized controlled trials demonstrating the effect of rectal cancer surgery (with/without preoperative RT) on long-term side effects (See Appendix Av at back).^{30,39} In contrast, the side effects reported in the Australian Decision Aid are poorly defined and their rate of occurrence does not reflect the latest evidence. For example, the Australian version defines bowel difficulty as ‘more than 4 bowel movements a day’.¹⁸ The likelihood with surgery alone of experiencing bowel dysfunction is displayed as “*sometimes*” or approximately “5 to 10 out of 100” patients.¹⁸ This underestimates the numeric risk of bowel dysfunction, and underestimates the impact of bowel dysfunction on patient quality of life. Similarly, the likelihood of experiencing ‘more than 4 bowel movements a day’ as a result of preoperative RT and surgery is described as

“*sometimes*” or “10 to 30 out of 100” patients.¹⁸ Again, such terms and framing underestimates the severity of bowel dysfunction, and provides a range of risks that are non-specific and inaccurate.^{3,14,39}

We have created separate versions of the ODARC for male and female patients to account for gender-specific risk differences in the side effect category of sexual dysfunction. In the surgery alone group, the ODARC reports that 24% of male and 10% of female patients can be expected to experience sexual dysfunction.³⁹ In the preoperative RT and surgery group, the ODARC reports that 33% of male and 28% of female patients will experience sexual dysfunction.³⁹ These differences among male and female patients are all significantly different ($p < 0.001$) (See Appendix A vii at back).^{39,40} In the Australian Decision Aid, sexual dysfunction is defined for males as erectile difficulty and for females as vaginal discomfort.¹⁸ Risk information is presented the same for male and female patients and defined as “*sometimes*” or approximately “5 to 10 out of 100” patients in the surgery alone arm, and “*sometimes*”, or “10 to 30 out of 100” patients in the preoperative RT and surgery arm.¹⁸ Similar to the section on bowel dysfunction, the Australian Decision Aid presents sexual dysfunction risks that are not reflective of data from recent clinical trials, and in a format that is ambiguous, inaccurate and likely difficult to interpret by most patients.

Values Clarification Exercise

During the deliberation stage of the shared decision-making process, patients are able to voice their values, concerns and preferences regarding available treatment options.⁷ A values clarification exercise (e.g., weigh scale) is sometimes incorporated as a DA component to help patients evaluate available options and related outcomes to identify which option best fits with their needs and expectations.⁴¹ However, there is inconclusive evidence on the benefit of such exercises in patient decision-making.^{6,41} In the updated IPDAS chapter on ‘Clarifying and Expressing Patient Values’ a review of 13 trials that compared DAs which incorporated values clarification methods (VCMs) to DAs without any VCMs revealed mixed results with regards to impact of VCMs on the overall decision-making process.⁴¹ Of note, findings indicated that VCMs required stronger theoretical and empirical justification to support use in DAs.⁴¹ Studies evaluating VCMs in DAs need to provide adequate detail on the development process to facilitate comparison across findings including, i) a design rationale with reference to an underlying theory; ii) number of members involved in the design process; and, iii) input from key informant groups via focus group feedback or pilot testing.⁴¹

Since the ODARC prototype proposed in this thesis focuses only on information-transfer, a values clarification component will not be added at this time but may be considered for future study endeavours.

Presenting Probabilities of ODARC Outcomes & Side Effects

The ODARC presents probabilistic information on treatment benefit and risks using risk communication strategies that are widely-recognized in the literature and commonly recommended. These include, a graphical representation of risk depicting natural frequencies titled, the “100 people picture”, and accompanying probability statements depicting percentage ranges and information on number needed to treat/harm (NNT/NNH). These risk formats are intended to help communicate group-based average statistics from recent randomized controlled trials for the clinical outcomes and side effects associated with each treatment choice outlined in the ODARC.

Graphical Risk Visuals

Certain risk presentation formats influence how accurately information is processed by physicians and patients^{3,5,25,37} However, as described in Chapter I, research shows that graphical visuals (i.e., pictographs) rank superior in improving patient comprehension compared to other graph types (e.g., pie and bar graphs).^{14,15,42,43}

For example, ODARC data on the main clinical outcomes (local recurrence and overall 5-year survival) and long-term treatment side effects (bowel and sexual dysfunction) are presented as a natural frequency through the “100 people picture”; or the number of people out of 100 who are likely to experience the outcome or side effect depending on whether they receive or do not receive RT prior to surgery. Compared to percentages, which possess a quality some patients find intimidating, frequencies or proportions are easier to conceptualize, comprehend and are the most commonly recommended method to present probabilities.^{3,14,44} Importantly, to allow for effective comparisons of treatment outcomes/side effects between the two outlined treatment options, a consistent denominator is recommended. Specifically, frequencies based on denominators of 10 or 100 were preferred by patients to estimate the magnitude of risk compared to larger numbers (i.e., 1000).^{3,14,37,44} The ODARC “100 person picture” also maintains a constant base reference number (i.e., out of 100) across all presented main clinical outcomes and side effects.

In reviewing the ODARC, patients also need to differentiate between baseline risk of outcomes and side effects (i.e., surgery alone) and risks associated with the intervention treatment (i.e. surgery with preoperative RT). Pictograph formats are proven effective methods to depict incremental risk associated with the treatment intervention from baseline risk.^{3,11,45} For example, on the ODARC, outcomes and side are sequentially presented. The “100 people picture” would be a useful method of showcasing probabilities with surgery alone or surgery with preoperative RT as the shaded portion of the two “100 people pictures” would reflect the number of patients experiencing the given outcome/side effect and thus highlight the incremental risk difference.^{3,11,45}

Number Needed to Treat/Harm Information

In addition to visual representations of risk, the ODARC also presents both NNT (number needed to treat) and NNH (number needed to harm) values for local recurrence and bowel/sexual dysfunction, respectively. This risk format can be used to present changes in numeric outcomes resulting from surgery with or without preoperative RT.³ For example, in rectal cancer, the improvements in surgical technique and commensurate decreases in local recurrence risk lead to an increase in the number of patients that must be treated with RT to avoid one local recurrence.^{29-31,46-49}

In essence, the NNH value highlights the safety profile of the treatment and provides insight to the treatment effect on potential morbidities.⁵⁰ It indicates the number of patients a physician would need to treat for one patient to experience a negative outcome.⁵¹ Both NNT and NNH calculations should be derived from high quality randomized controlled trials where potential differences in risks of outcomes or side effects observed between treatment groups is unlikely to be due to bias or confounding.⁵⁰

When presented in isolation, NNT/NNH information may be difficult to interpret by some patients, and thus should be used to supplement other risk framing formats.^{3,52} Although not a focus of the current thesis, understanding patient preferences with regards to risk communication formats and its potential usefulness in improving patient knowledge is an important consideration to designing DAs that will be addressed in future research steps.

Risk Formatting & Presentation

An optimal method(s) of communicating risk with decision aids has not been identified in the literature. However, researchers suggest that patient interpretation and understanding of probabilistic information is not exclusively based on specific risk formats, but also influenced by the context in which the risk information is conveyed.^{3,26,45} *Visschers et al* suggest that factors such as, time, motivation and cognitive capacity also affect patient risk perception.²⁶ The ODARC decision board is specifically designed for use during a medical consultation with a treating clinician. The “100 person picture” portraying frequencies is the main method of risk presentation on the ODARC. In addition, accompanying statements to enhance patient understanding of risk are provided including percentage range estimates and NNT/NNH. During treatment information-exchange, the clinician can assist patients in reviewing the various ODARC risk information sections, thus keeping patients on track and potentially minimizing cognitive burden. Attending clinicians can also assess patient understanding of the various risk messages associated with ODARC outcomes and side effects.

To facilitate counselling, the main sections (described above) of the ODARC are visually presented under distinct section headings. This design

feature is based on research findings suggesting that patients feel that section headings on a DA are highly useful and direct readers' attention to specific areas of interest.^{14,21} Outcomes and side effects are arranged from left to right and presented in a side-by-side manner on the ODARC. Some research shows that patient understanding is substantially improved with a side-by-side presentation of DA information.^{25,14,43,45} As well, the likelihood of experiencing a main outcome or side effect (in either treatment group) is depicted horizontally with shaded person icons, while the un-shaded icons represent the likelihood of not being affected (See Appendix Aiii for example). To further facilitate patient comparison between treatment options, the ODARC frames risk information on local recurrence and overall survival using a 5-year time reference. Bowel and sexual dysfunctions are also presented using long-term treatment morbidity data.

It is important to stress that the outcome probabilities presented in the ODARC are based on group-based averages derived from high-quality randomized controlled trials. As such, it is difficult to ascertain what will happen at the individual level since each patient is different and substantial variation exists in single event rates for each patient.^{4,53,54} Therefore, a disclaimer will be inserted in the 'patient guide section' on the ODARC decision board indicating to patients that there is always uncertainty associated with probabilistic information – treatment outcomes will be experienced differently from person to person since only group-based estimates can be reported.⁵⁴

The ODARC incorporates numerous improvements over the Australian Decision Aid, which is the only other DA available designed to assist patients deciding on the use of RT with rectal cancer surgery.¹⁸ In addition to the use of outdated clinical content, methodological and design features of the Australian Decision Aid model do not reflect currently accepted risk communication techniques. Primarily, the Australian Decision Aid utilizes a combination of pie charts and written probability statements, which do not follow current DA recommendations on conveying detailed and gross-level knowledge on treatment benefits and harms.^{15,42-44,55-56} Reviewing probabilistic information formatted as descriptions may be viewed as less intimidating by some patients, however they fall short of accurately conveying treatment risks which may distort patient understanding.³ For example, treatment morbidities on the Australian version are qualitatively framed using statements such as, "*often*" (30 to 50 out of 100) "*sometimes*" (5 to 10 out of 100) and "*rarely*" (less than 5 out of 100) to convey differentiation across treatment choices.¹⁸ These probability definitions also vary among the four outlined treatment options. For example, "*sometimes*" for bowel dysfunction in the preoperative RT plus surgery arm is defined as "10 to 30 out of 100" patients, but in the surgery alone arm is defined as "5 to 10 out of 100" patients.¹⁸ As well, the section on main clinical outcomes (e.g., local recurrence) is primarily illustrated with pie charts and accompanying statements, with the absence of qualitative statements.¹⁸ As such, the incongruent methods of risk communication presented in the Australian Decision Aid may further hinder

patient comprehension and accuracy of risk perception of treatment risks and benefits.

Patient understanding of probabilistic uncertainty is an important aspect of making a well-informed treatment decision. Still, this area of risk communication is relatively unexplored in the literature and methods to appropriately convey uncertainty in medical decision-making are currently being evaluated. Literacy is a related factor in this area. A study by *Smith et al* evaluated comprehension levels of adults with varying literacy ability to inform the development of a colorectal cancer (CRC) screening decision aid tailored for adults with low literacy.²¹ Participants with low literacy skills were recruited from an adult literacy class and high literacy participants were defined as possessing a University education.²¹ It was demonstrated that the use of medical terminology such as colonoscopy, bowel cancer and sigmoidoscopy confused many participants with lower literacy levels.²¹ However, including a glossary of definitions appeared to help ameliorate this problem.²¹ Many researchers have argued that the written material of decision aids must be formulated at the reading level of the general study population; and that simplification of content, both numerical and descriptive, is desirable as most patients are unfamiliar in processing complex technical language.^{34,50,57} This finding is particularly noted in Canadian seniors aged 65 and over.^{21,58,59} Of note, older patients tend to experience greater difficulty in processing complex technical language and making statistical inferences.^{25,37,45,56,21,58,59} The risk formatting and presentation techniques employed in the ODARC aim to foster adequate risk comprehension for such patients, which is a critical step to processing health information.^{21,59-61}

The ODARC conveys risk information on treatment clinical outcomes and side effects using a number of quantitative methods that are currently accepted and proven effective in the literature.^{14,15,56,57,62} Collectively, the methods of risk presentation presented in the ODARC were selected to fulfill a set DA objective, which is to improve patient knowledge of benefits and risks associated with outlined treatment options. As such, the presentation and risk formatting techniques incorporated in the ODARC decision board should be evaluated in light of this main objective.

Chapter III Summary

The development of a DA is an iterative process. To date, our ODARC developmental process covers the first five steps outlined in the '*Workbook on the Development and Evaluation of Patient Decision Aids.*' The final two steps outlined in the *Workbook* are discussed in the next chapter where we review considerations that need to be addressed prior to integration of the ODARC in routine practice or with patients at the point of care.

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Chapter IV

Study Discussion & Future Directions of the ODARC Research Process

Study Contributions to Current Research

We have established the groundwork for the development of a rectal cancer treatment information-transfer tool known as the ODARC. We presented clinical evidence on the use of surgery and radiation therapy in rectal cancer and reviewed relevant randomized trials. We limited our review to trials published after 2001 to ensure the inclusion of studies where surgical standards incorporated the principles of total mesorectal excision – an improved method of rectal cancer surgery. Data on key outcomes including local recurrence and overall 5-year survival, and key side effects including bowel and sexual dysfunction, were abstracted from trials that met our eligibility criteria. The data in the ODARC are presented using accepted methodologies on data and risk presentation. The strengths and weakness of a related 2004 Australian Decision Aid created by *Butow et al* helped inform the design of the ODARC.¹

The course of development for this early ODARC prototype was guided by a panel of researchers and clinicians who are opinion leaders with expertise on rectal cancer management and decision aid methodology (Drs. Simunovic, Gafni, Charles and Kennedy). The iterative process entailed a series of feedback, draft revisions and recommendations which was incorporated to refine the ODARC prototype and plan for future validity work.

Findings generated from this thesis should help inform subsequent stages of ODARC development and evaluation such as focus group sessions with clinicians and with patients not at the point of decision-making; a pilot study with rectal cancer patients at the point of decision-making; and, finally, a randomized controlled trial to assess the impact of the ODARC on patients during routine treatment decision-making with healthcare providers.

Step 6 - Design and Measures to Develop the Decision Aid

Step 6 in the '*Workbook for Developing and Evaluating Patient Decision Aids*' focuses on the designs and measures which will be employed to assess a decision support tool.² The evaluation component is largely dependent on pre-defined research objectives of the tool.² The key objective of the ODARC decision board is to improve patient knowledge of the outlined treatment options which include surgery with or without preoperative RT, and the main clinical outcomes and long-term side effects related to each option. We anticipate that future research considerations will help elucidate the impact of a rectal cancer treatment information-transfer tool in routine care as evaluated by target healthcare providers and patients.^{2,3}

Next Steps in the Development & Testing of the ODARC – Short-term Research Goals

The next steps of the development process should involve focus groups with a multidisciplinary clinical care team of surgeons, oncologists, and oncology nurses, and, patients not at the point of decision-making. Focus groups are often implemented to find out what motivates patients and clinicians to use specific health products (i.e., ODARC decision board) or to adopt better healthcare practices in clinical settings.⁴ Focus groups are a qualitative research method that involves bringing small groups of people together for a guided discussion with a moderator.^{5,6} The moderator is responsible for continually encouraging participants to express their opinions and provide personalized input during discussions.^{5,6} With this method, the moderator is able to efficiently elicit a wide range of participant perspectives, including commonalities and differences with topics of interest.⁷ Importantly, focus group feedback can be useful for hypotheses generation in a research area where existing knowledge is inadequate or limited.^{7,8} For example, the construction of a relevant measurement tool (e.g., patient knowledge questionnaire) can be better informed and refined with feedback incorporated from target respondents.^{7,8}

Compared to one-to-one interview techniques, an advantage of the focus group method is that group processes can help participants explore and clarify their views in ways that would be less accessible in the former method.^{6,7,9} This can be very valuable and provide access to consensus/diversity of experiences on a given topic.^{6,7,9} As well, through indication with non-verbal cues (e.g., nodding in agreement or disapproval) in response to generated discussion, a focus group can also help elicit contributions from individuals who are reluctant to voice their thoughts or deemed unresponsive.^{6,7,9}

A focus group would be first held with a multidisciplinary clinical care team to gather their perception(s) of the ODARC. The literature suggests including six to eight participants in a focus group to optimally acquire adequate coverage of varied perspectives.^{10,11} Hamilton Health Sciences' (HHS) surgeons, medical and radiation oncologists and nurses who are collaboratively involved in providing clinical care to patients with resectable stage II or III rectal cancer at the Juravinski Cancer Centre (JCC) in Hamilton would be ideal participants for such a focus group. Two participants from each clinical discipline could be recruited to fulfill the minimum requirement of eight focus group members. An interview guide consisting of open-ended questions would encourage clinicians to comment on the accuracy, completeness and clarity of factual information, and the feasibility of implementation during consultation with a patient. Potential barriers and facilitators to use of the ODARC would be identified and explored.

Importantly, as the ODARC is designed for patient use during a medical consultation, gathering initial patient perspectives on the decision board is

essential. A focus group would also be conducted with patients who are not at the point of decision-making. In this focus group, acceptability of the ODARC would be explored via open-ended questions that prompt on content clarity and comprehension, acceptability and accessibility of delivery methods, risk formatting preferences, and expected usefulness of the ODARC to better understand the benefits/risks of outlined treatment options. Patient recommendations for improving the content and format would be noted and addressed in future iterations of the ODARC. The inclusion criteria for the patients to participate in the focus group will be: to have undergone surgery for stage II or III rectal cancer, with or without RT, and should be at a minimum of one year but less than two years from the point of surgery. Such patients are similar to potential users of the ODARC, and should be in an optimal position to comment on their related experiences with minimal recall or memory lapse. Additionally, as determined by their physician, recruited patient participants should not have local or distant tumour recurrence, and should not have experienced any debilitating treatment morbidities. This should help ensure the discussion is focused on the potential usefulness of the ODARC.

Findings generated from this stage will offer insights on clinician and patient perceptions on the need for, feasibility, and acceptability of the ODARC information-transfer tool. Feedback generated from focus groups will likely identify minor or even major issues or weaknesses of the ODARC prototype.^{12,13} The design and evaluation of a decision support tool should be an iterative process, and thus the ODARC content, format and method of delivery will be appropriately monitored and evaluated, and adapted to meet the needs of patients and providers.

A background of rectal cancer management presented in Chapter II of this thesis highlights the patient numbers affected in Canada, the variation in local and international practice of RT in rectal cancer treatment, the nature and complexity of the decision to incorporate RT, challenges with technical information-transfer during a medical consultation, and, the limited availability of rectal cancer treatment decision support tools. These observations provide a preliminary rationale for developing a tool such as the ODARC.^{3,13-16} But it is also important to understand the specific needs of target users and providers in a given clinical context.^{3,13-16} A recommended strategy to ensure the incorporation of such preferences and expectations is to create a core prototype which is flexible in design, and then seek patient feedback to modify components accordingly.³

During the future needs-assessment stage of the study involving focus groups, the ODARC prototype would be first presented to the multidisciplinary clinical care team. Feedback received during this focus group would be used to make modifications to the ODARC. The adjusted prototype would then be presented to the patient focus group and a similar editing process will follow. These steps would be labelled as 'Focus Group Iteration I'. A second iteration may be

considered (clinicians or patients or both) if changes made to the ODARC following the first iteration are substantive.

Ethical Considerations for Future Needs-Assessment Step

Ethical considerations were not directly relevant for the first five steps of ODARC development outlined in this thesis. For the focus groups with a multidisciplinary clinical care team and patients not at the point of decision-making, ethics approval should be sought from an appropriate body, such as the joint McMaster Faculty of Health Sciences/Hamilton Health Sciences Research Ethics Board (FHS/HHS REB) in Hamilton, Ontario. Relevant documents submitted for approval would include: a study protocol, two versions of informed consent forms and focus group scripts (clinicians and patients), telephone/e-mail reminder scripts, and a template of the ODARC prototype.

Strict confidentiality and security measures as outlined by the HHS/FHS REB should be followed during focus groups with clinicians and patients not at the point of decision-making. Prior to study enrolment, a trained ODARC research associate could explain the study goals and objectives to all participants and written informed consent could then be obtained. Research progress will be closely monitored by the study supervisor and local principal investigator (Dr. M. Simunovic, who plans to continue validation work on the ODARC). Following recruitment, participants should not be offered incentives of any kind and will have the option to withdraw from the study at any point without incurring any consequences to their future treatment. Data collected from focus groups would be safely stored in the supervisor's research offices at the Juravinski Cancer Centre in Hamilton. The information would be password-protected on a secure office computer and all study participant identifiers would be removed to preserve anonymity.

Next Steps in the Further Development and Testing of the ODARC – Long-term Research Goals

ODARC Pilot Study

As the ODARC study evolves, it will be necessary to conduct a pilot study in a 'real-world' clinical encounter with patients at the point of decision-making. A pilot study with stage II and III patients at the point of decision-making will provide insight on the feasibility of an information-transfer tool and initial impact of the ODARC in improving patient knowledge of treatment information related to the use of preoperative RT in addition to standard surgery.¹⁷⁻¹⁹ The interaction between the healthcare provider and the patient in an actual decision-making encounter can be observed which brings to light other factors such as

interpersonal perceptions of the ODARC which may shape members' acceptability of the tool.¹⁷⁻¹⁹ Additionally, feedback generated from the pilot study may also be used to further revise the ODARC prototype.²⁰

A post-test pilot study design using a knowledge scale with items corresponding to the content of the ODARC may be applied to assess the impact of the tool in improving patient knowledge of treatment information.^{2,20} Following review of the ODARC with a healthcare provider during consultation, patients would be requested to complete a knowledge test with a pre-set criteria of success (e.g., 75% of correct responses). In addition, qualitative feedback from the pilot study patient participants would help document first impressions of the ODARC in an actual clinical encounter.^{2,20} *Sawka et al* adopted a similar quantitative/qualitative approach in an initial pilot study to assess the impact of a DA for early-stage breast cancer patients contemplating different surgical treatment options.² After consulting the DA with their treating surgeon, patient participants offered general and specific feedback to questions such as, '*Did the decision aid help clarify information given by your doctor?*' and '*How could the decision aid be better presented?*'² Collectively, comments were useful to help identify components that worked well (i.e., visuals were helpful in decision-making) and areas that required further improvement (i.e., patients sought detailed information on adjuvant systemic therapy options).²

We recommend that pilot testing occur in the Local Health Integration Network 4 (LHIN 4) region of Ontario. This region provides an excellent environment to pilot test the ODARC. First, the volume of rectal cancer surgery is the highest among the 14 Ontario LHINs.²¹ As well, all radiation therapy services provided to LHIN 4 patients with rectal cancer are provided at the Juravinski Cancer Centre.²¹ This centralization of care and the relatively high volumes of relevant therapy should optimize the chances of appropriate patient enrolment and study follow-through. The Juravinski Cancer Centre is also where the ODARC was developed, and where initial pilot-testing will occur with clinicians and with patients at the point of decision-making.

In preparation for a large multi-centered trial, such pilot-testing should also help clarify methodological issues such as participant inclusion/exclusion criteria and sampling procedures.^{17,22} Observing and analyzing participation rates from surgeon and patient groups should also provide insight on the barriers and facilitators to participant recruitment.^{19,22} This is an important issue to address to ensure adequate statistical power in an eventual randomized trial.²² In addition, the pilot study phase should also provide insight to selecting appropriate variables of interest and measurement tools for subsequent evaluative steps.^{2,20,23} Broadly, study findings from the ODARC pilot phase will help determine if a rectal cancer treatment information-transfer tool is feasible in the proposed clinical context and acceptable to patients (target users) at the point of decision-making.²² Lessons learned from the ODARC pilot study will be used to

improve the overall design and execution of a subsequent randomized controlled trial, which will require considerable funding, resources and time investment.^{12,19,22}

ODARC Randomized Controlled Trial (RCT)

Results from well-designed randomized controlled trials (RCTs) are considered the “gold standard” of the health research evidence hierarchy.^{2,23,24} A RCT could help assess the efficacy of the ODARC, or help detect clinically-meaningful differences in patient knowledge on the use of preoperative RT, including creating realistic expectations of the main clinical outcomes and accurate risk perceptions of chronic side effects. Since the ODARC is designed as a medium of information-transfer during a clinical consultation with a healthcare provider, evaluation of these relevant aspects of patient knowledge would help elucidate key points of difference between an intervention (ODARC) and control arm (standard practice without the ODARC).^{24,25} We suggest such a trial could be done in LHIN 4 hospitals. Multi-centre trials help satisfy the expected large sample size requirements and need for establishing the generalizability of a new information-transfer tool.^{24,25}

There is a growing body of evidence supporting the use of decision aids in routine medical practice.^{24,26-28} As illustrated in Chapter I, after consulting a DA, patients had improved knowledge of treatment options and outcomes/side effects.^{24,26-28} To measure the ability of the ODARC to increase patient knowledge, a before-after study consisting of pre- and post-intervention questionnaires on knowledge could be utilized.^{17,29-32} The items contained in the questionnaire would help evaluate patient knowledge on the use of surgery with or without RT.^{17,29-32} For this purpose, questions could be adapted from an appropriate assessment scale such as the validated Breast Cancer Information Test (BCIT) - a short and clinically useful knowledge test which was applied in several breast cancer DA evaluation studies.^{20,33,34} Individual test items would be customized and re-formatted to the given clinical context and based on the content presented in the ODARC. Prior to use with patients at the point of decision-making, key measurement properties of the test would need to be established. First, content validity which is a report on the accuracy, relevancy and appropriateness of item word arrangement can be assessed by a group of experts knowledgeable with the medical condition.^{34,35} A multidisciplinary clinical care team can review individual test items to ensure the range of important domains relevant to patient knowledge is adequately covered in instrument. Similarly, construct validity helps determine if questionnaire items capture respondent knowledge on the clinical condition, treatment options and related risks and benefits.^{34,35} This property is tested with groups expected to differ in knowledge scores.^{34,35} For example, construct validity of the BCIT was conducted with undergraduate nursing students, practicing nurses, and women diagnosed

with breast cancer.³⁴ Tests for homogeneity of variance showed that patient respondents, who lack specific clinical knowledge, had more variable test scores than nurses or students, and nurses (i.e., clinical experts) performed better than students.³⁴ Thus, the BCIT helped discriminate knowledge between different groups and established good construct validity.³⁴

Patient perception of a given outcome or side effect is considered accurate and realistic when knowledge complements the current evidence on group-based outcome data.^{29,36} The ability to interpret and understand presented risk information is critical to differentiating between possible treatment choices and eventual decision-making.^{20,23,36}

Patients participating in an ODARC trial could complete a 'realistic expectations' test prior to and succeeding consultation with or without use of the ODARC. For the purpose, a commonly used measurement tool created by the researchers at the Ottawa Health Research Institute (OHRI) Patient Decision Aids group could be appropriate since the risk framing matches closely to that used in the ODARC.³⁷ In the OHRI sample tool, patient respondents identify chances of developing fracture with/without use of various osteoporosis treatment modalities.³⁷ Responses (i.e., expectations) are framed as, *'51- 75 women out of 100 women will be protected from broken hips'* which presents the outcome as a natural frequency.³⁷ In the ODARC this is depicted as the "100 people picture" for all main clinical outcomes and side effects. The OHRI measurement tool could be adapted to the given clinical context and patients could report their expectations on risk of developing a local recurrence, 5-year overall survival and experiencing chronic bowel or sexual dysfunction attributed to surgery with or without preoperative RT. Responses to questionnaire items would be rated as 'accurate', 'risk underestimated' or 'risk overestimated' and analyzed to determine patient perception of outcomes/side effects pre and post-consultation.³⁷ A report of this analysis would help elucidate the potential impact of the ODARC in improving patients' realistic expectations of treatment information.^{23,29}

A test on recall of information of DA content (i.e., OHRI sample tool)³⁷ is commonly used to assess patient knowledge or understanding.^{3,16,38,39} However, some research suggests that such a test may not fully capture true patient understanding of outcome/side effect probabilities.^{3,16,38,39} To illustrate, statistical uncertainty is always inherent at the patient-level since risk information is derived from group-based results presented in RCTs.^{3,16,38,39} Group-based estimates cannot determine individual patient risk.^{3,16,38,39} Although the ODARC decision board has a related disclaimer on this issue, probabilistic uncertainty surrounding outcome/side effect information should always be highlighted by the treating clinician during counselling sessions and in follow-up discussions.^{16,36} In this way, patient understanding of risk assessment may be enhanced through discussion on their condition, associated treatment benefits and risks and the corresponding probabilistic uncertainty.^{16,36} Currently there is no standardized method of

objectively evaluating patient understanding of risk information and the area of conveying risk uncertainty via DAs requires further research.^{16,40}

Study Strengths and Limitations & Opportunities for Improvement

The purpose of the current study was to develop a prototype information-transfer tool to be used in medical consultations for the treatment of rectal cancer (i.e., ODARC). However, there were some study limitations.

First, to overcome the content and formatting weaknesses in the Australian Decision Aid, the ODARC incorporated clinical data from recent trials to build its content. Despite our comprehensive search strategy, the evidence-base from which the ODARC clinical content was abstracted consists of only two randomized controlled trials. Although several trials were screened during the review process, only two trials matched our outlined inclusion criteria established for the ODARC. But in many ways these two trials perfectly fit the information needs of the ODARC. Specifically the trials were of good quality, tested the efficacy of pre-operative RT versus no-RT in the setting of TME surgery, and assessed important outcomes such as local recurrence and survival, and, important treatment side effects such as bowel and sexual dysfunction. Both the Dutch TME and MRC-CR07 trials were large, well-designed and well-executed randomized trial that involved numerous sites and surgeons. Thus there is good generalizability of trial findings. Given the difficulties of performing RCTs, especially RCTs in surgery, it is fortunate that results from these trials were available for use in the ODARC. It is also important to note that the Ontario guidelines recommending preoperative RT for all patients diagnosed with stage II and III cancer is currently under review. While we were not able to account for this recent update in the current thesis, emerging guidelines on the use of preoperative RT may provide further justification to support the need for a DA to help stage II and III patients understand use of RT and its associated benefits and risks.

Second, an abbreviated study timeline was a limiting factor, which led to the exclusion of an evaluation and dissemination component for the ODARC. This presents a knowledge gap in the design and development of the ODARC. Gathering feedback on the ODARC from healthcare professionals responsible for providing medical care to patients diagnosed with stage II and III rectal cancer, and, more importantly, from patients is critical to understanding relevant perceptions and preferences of this DA, and will ultimately help shape an improved ODARC.

As well, the lack of a literacy testing aspect was another study limitation. The methods of risk presentation presented in the ODARC were selected to fulfill a set DA objective, which is to improve patient knowledge of treatment benefits

and risks. Health literacy assessments (i.e., objective, subjective numeracy and graph literacy) can help DA developers design content and layout features tailored to target users who possess a specific skillset.⁴¹ The written material of DAs must be formulated at the reading level of the general study population and simplification of content, both numerical and descriptive is strongly desirable.⁴¹⁻⁴³ This assessment was not included in the initial phase of DA development as presented in this thesis, but literacy tests of the ODARC decision board will be addressed as part of next research steps. Content and format adjustments on future iterations would also follow from focus group discussions with patients not at the point of decision-making and the clinical care team.

Step 7 – Dissemination Considerations

The final step outlined in the *Workbook* is focused on targeted distribution and promotion of the developed DA.² There are likely many barriers to the uptake in routine clinical practice of any DA, including the ODARC. First, physicians are constantly inundated with the latest information on best practices of care and as such, the uptake of a novel DA intervention may be problematic.⁴⁴ Second, physicians may be agreeable to new initiatives, but the clinical environment in which they practice may not be conducive to transformation.⁴⁴ Therefore, dissemination strategies must be personalized to the environment and culture of a particular healthcare institution and target audience in order to promote acceptability and uptake.⁴⁴

Effective knowledge exchange and translation strategies can help close the gap between research production and its translation into evidence-based clinical practice.⁴⁵ The ODARC can be considered a research product that will hopefully improve patient and physician information needs related to the use of RT in rectal cancer. Methods of ODARC dissemination may involve scholarly publications in peer-reviewed journals, or the presentations of study findings at clinical, research or policy-focused events.⁴⁶ Additionally, hosting training workshops for members of rectal cancer multidisciplinary clinical teams should provide an opportunity to showcase the ODARC and educate professionals and opinion leaders on the value of a treatment DA in the management of rectal cancer.⁴⁶ The ability to spark “actionable messages” across assorted target groups is also important.^{44,45} Informing other relevant stakeholder groups such as rectal cancer patient advocacy groups, government health organizations (e.g., Cancer Care Ontario) and other health organizations (e.g., Canadian Society of Surgical Oncology) may also contribute to the uptake of the ODARC.

Lessons learned from each phase of the ODARC development should add to a growing body of literature highlighting the importance of patient DAs in cancer care. Currently in its preliminary stages of development, the ODARC will

continue to evolve and should ultimately become a tool that can effectively transfer research knowledge to key stakeholders (e.g., patients, patient groups, health professionals, administrators, research teams, policy makers).

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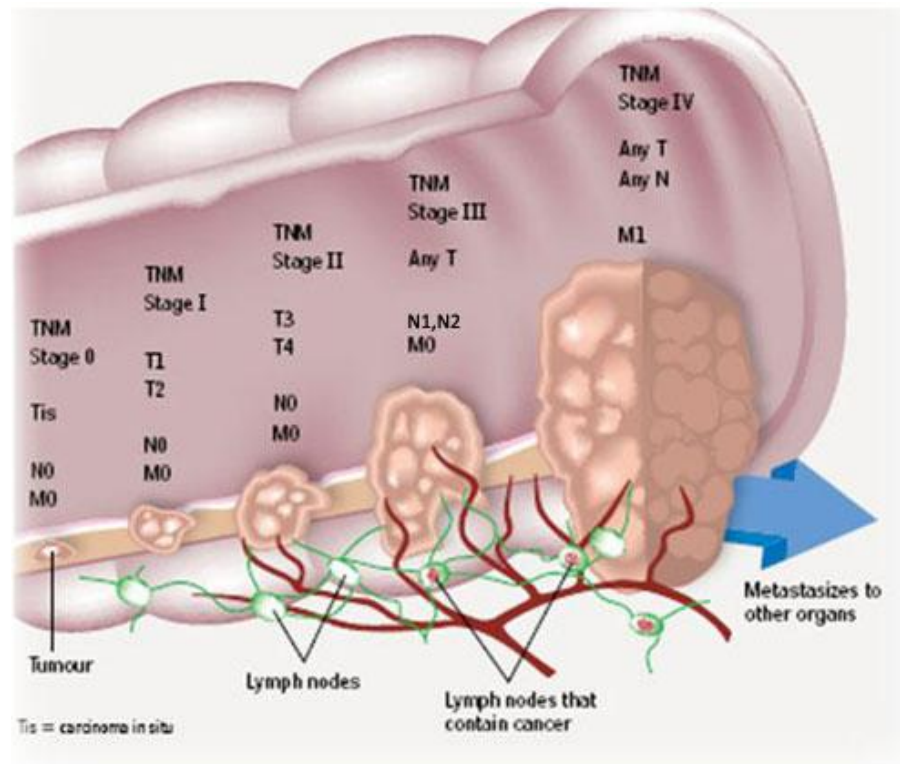
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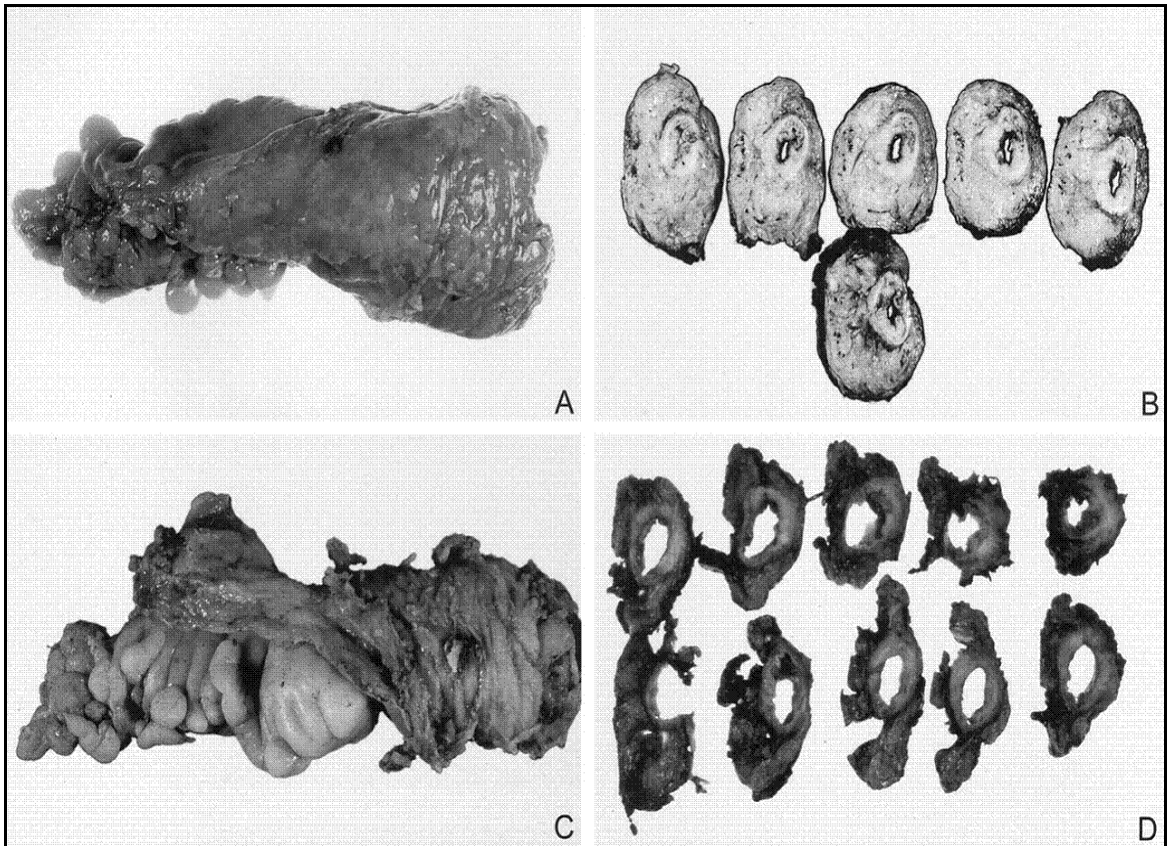
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Figure1: Anatomic Visual of Rectal Cancer Tumour Stages (I-IV)



(Source: from Colorectal Cancer Association of Canada website – <http://www.colorectal-cancer.ca>)

Figure 2: Anatomic Visual of Total Mesorectal Excision (TME) Resection



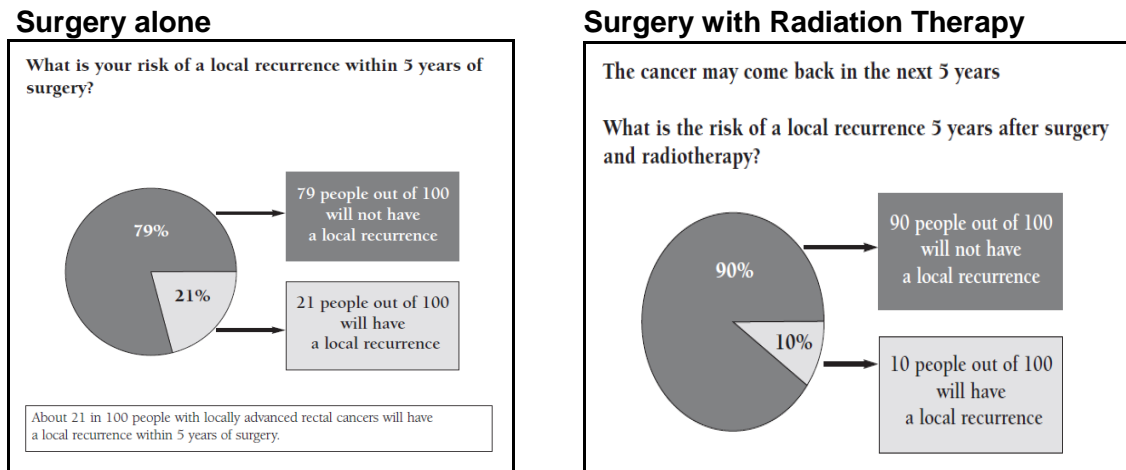
A/B - Resected TME specimen

C/D - Resected non-TME specimen

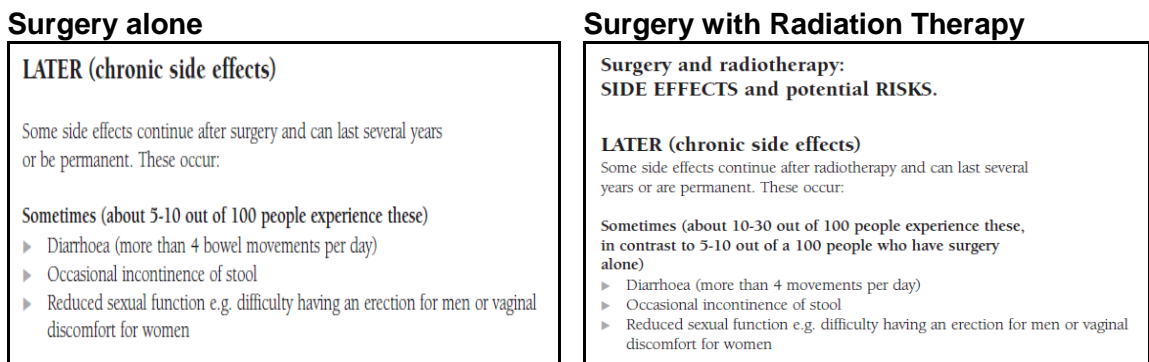
(Source: Figure from Nagtegaal, ID, et al. Macroscopic evaluation of rectal cancer resection specimen: clinical significance of the pathologist in quality control. *J Clin Oncol.* 2002; 20: 1729 - 1734)

Figure 3: Sample Presentation of Local Recurrence and Chronic Side Effects in the Australian Decision Aid

3a. Local Recurrence

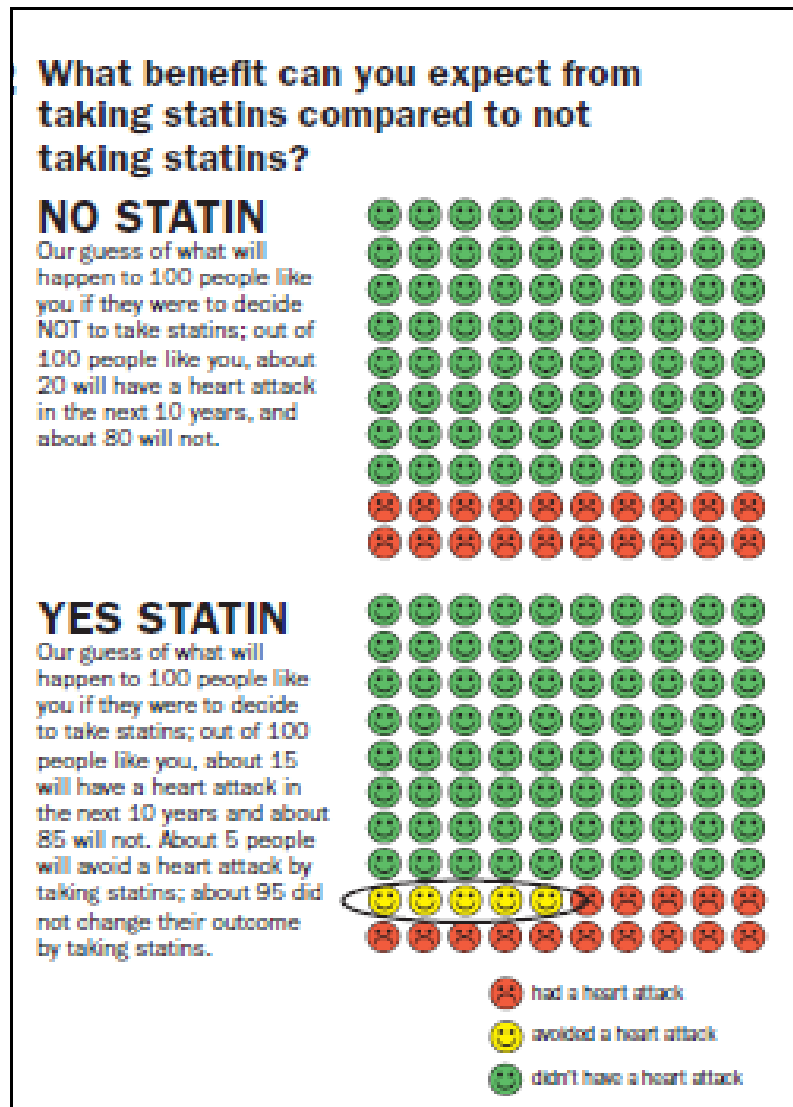


3b. Chronic Side Effects



(Source: "Making Choices – Deciding Whether to Have Radiotherapy and/or Chemotherapy" Decision Aid booklet by Butow et al, 2004)

Figure 4: Graphical Representation of Risk – The 100 Faces Pictograph



(Source: Figure from Weymiller AJ et al. Helping patients with type 2 diabetes mellitus make treatment decisions. Arch Intern Med. 2007; 167: 1076 – 1082)

Table 1: Rectal Cancer Tumour Staging using the Tumour/Node/Metastasis (TNM) Classification System

TNM Classification			
Tis	The cancer is confined to innermost layer of the colon or rectum	N0	There is no spread to lymph nodes
T1	The cancer has grown through the first few layers of the colon or rectum	N1	Cancer is found in 1-3 lymph nodes
T2	The cancer has grown into the thick muscular layer of the colon or rectum	N2	Cancer is found in four or more lymph nodes
T3	The cancer has grown through the entire colon or rectum wall	M0	There is no spread of cancer to distant organ(s)
T4	The cancer has grown through the entire colon or rectum wall and into nearby tissue or organs	M1	Cancer is found in distant organ(s)

(Source: from Colorectal Cancer Association of Canada website – <http://www.colorectal-cancer.ca>)

Table 2: Summary of Main Clinical Outcomes from all Reviewed Clinical Trials in Rectal Cancer

Study & Accrual Years	Stage & Number of Patients (x)	Intervention (Experiment Treatment)	Control (Routine Treatment)	Local Recurrence		Overall Survival at 5 years	
				Intervention	Control	Intervention	Control
<i>Dutch TME Trial</i> Kapiteijn et al 2001, NEJM 1996 –1999	Stage 0 - IV patients x = 1748 (eligible)	Short-course preop RT + surgery	Surgery alone	2.4%* At 2 years	8.2%* At 2 years	82% At 2 years	81.8% At 2 years
<i>The German CAO/ARO/AIO-94 Trial</i> Sauer et al, 2004, NEJM 1995 – 2002	Stage II and III patients x = 799 (eligible)	1) Preop CRT 2) Postop CRT	n/a	Preop CRT = 6%* Postop CRT = 13%*	n/a	Preop CRT = 76% Postop CRT = 74%	n/a
<i>The Swedish Rectal Cancer Trial (13 year follow-up)</i> Folkesson et al, 2005, Journal of Clinical Oncology 1987 - 1990	Stage I – III patients x = 908 (eligible)	Short-course preop RT	Surgery alone	6%* Stage II and III only	22%* Stage II and III only	29% Stage II and III only	23% Stage II and III only

*Indicates statistical significance ($p < 0.05$)

(Key Terms: **RT** – radiotherapy, **CRT** – chemoradiotherapy, **CT** – chemotherapy, **preop** - preoperative, **postop** – postoperative)

Table 2 (Continued): Summary of Main Clinical Outcomes from all Reviewed Clinical Trials in Rectal Cancer

Study & Accrual Years	Stage & Number of Patients (x)	Intervention (Experiment Treatment)	Control (Routine Treatment)	Local Recurrence		Overall Survival at 5 years	
				Intervention	Control	Intervention	Control
Gerard et al, 2006, Journal of Clinical Oncology 1993 –2003	Stages II and III x = 713 (eligible)	Long-course preop CRT + surgery with adjuvant CT	Long-course preop RT + surgery with adjuvant CT	8.1%*	16.5%*	68%	67%
Bujko et al, 2006, British Journal of Surgery 1999 – 2002	Stage II and III patients x = 312 (eligible)	Short-course preop RT followed by surgery within 1 week	Preop long- course CRT followed by surgery within 4-6 weeks (Optional postop CT)	9%*	14.2%*	67.2%	66.2%
<i>Dutch TME Trial (6 year follow-up)</i> Peeters et al, 2007, Annals of Surgery 1996 –1999	Stage 0 - IV patients x = 1748 (eligible)	Short-course preop RT + surgery	Surgery alone	8.2%*	15%*	64.2%	63.5%

***Indicates statistical significance ($p < 0.05$)**

(Key Terms: RT – radiotherapy, CRT – chemoradiotherapy, CT – chemotherapy, *preop* - preoperative, *postop* - postoperative)

Table 2 (Continued): Summary of Main Clinical Outcomes from all Reviewed Clinical Trials in Rectal Cancer

Study & Accrual Years	Stage & Number of Patients (x)	Intervention (Experiment Treatment)	Control (Routine Treatment)	Local Recurrence		Overall Survival at 5 years	
				Intervention	Control	Intervention	Control
<p><i>MRC-CR07 Trial</i></p> <p>Sebag - Montefiore et al, 2009, Lancet</p> <p>1998 - 2005</p>	<p>Stages I – IV</p> <p>x = 1350 (eligible)</p>	<p>Short-course preop RT followed by surgery to take place within 1 week</p>	<p>Initial surgery with selective postop CRT</p>	<p>5.1%*</p> <p>Stages II and III only</p>	<p>11.4%*</p>	<p>70.3%</p>	<p>67.9%</p>
<p><i>Dutch TME Trial (12 year follow-up)</i></p> <p>Gijn et al, 2011, Lancet</p> <p>1996 - 1999</p>	<p>Stage 0 - IV patients</p> <p>x = 1805 (eligible)</p>	<p>Short-course preop RT followed by surgery within 1 week</p>	<p>Surgery alone</p>	<p>7.2%*</p> <p>At 10 years – Stages II and III only</p>	<p>14.3%*</p>	<p>44%</p> <p>At 10 years - Stages II and III only</p>	<p>45%</p>

***Indicates statistical significance ($p < 0.05$)**

(Key Terms: RT – radiotherapy, CRT – chemoradiotherapy, CT – chemotherapy, preop - preoperative, postop - postoperative)

Table 3: Summary of Main Clinical Outcomes & Treatment Side Effects from Clinical Trials in Rectal Cancer – Stage II and III Patients Only

Study & Accrual Years			Local Recurrence		Overall 5-year Survival		Treatment Side Effects			
	INT (n)	CTRL (n)	INT	CTRL	INT	CTRL	Sexual Dysfunction ^{+/^}		Bowel Dysfunction ⁺	
							INT	CTRL	INT	CTRL
<p><i>Dutch TME trial (6-year follow-up study)</i></p> <p>Peeters et al., 2007</p> <p>1996 to 1999</p>	<p>Short-course preop RT + surgery</p> <p>n = 897</p>	<p>Surgery alone</p> <p>n = 908</p>	<p>8%[†]</p>	<p>15%[†]</p>	<p>64%</p>	<p>63%</p>	<p>Males = 33%[†]</p> <p>Females = 28%[†]</p>	<p>Males = 24%[†]</p> <p>Females = 10%[†]</p>	<p>34%[†]</p>	<p>22%[†]</p>
<p><i>MRC-CRO7 Trial</i></p> <p>Sebag-Montefiore et al, 2009</p> <p>1998 to 2005</p>	<p>Short-course preop RT + surgery</p> <p>n = 674</p>	<p>Surgery with postop CRT for patients with positive CRM</p> <p>n = 676</p>	<p>5%[†]</p>	<p>11%[†]</p>	<p>70%</p>	<p>68%</p>	<p>Score[¥] on QOL questionnaire</p> <p>Males = 66[†]</p>	<p>Score[¥] on QOL questionnaire</p> <p>Males = 57[†]</p>	<p>n/a</p>	

NB: Abbreviations include intervention (INT), control (CTRL), radiotherapy (RT), chemoradiotherapy (CRT), circumferential radial margin (CRM), preoperative (preop), postoperative (postop)

¥ Only reported for Male Sexual Dysfunction (MSD) – higher score indicates more chronic problems

† Indicates statistical significance ($p < 0.05$)

Sexual Dysfunction Description

+ Dutch TME – Erection/ejaculation disorders in males and vaginal dryness/pain during intercourse in females affecting postoperative sexual activity


^ MRC-CRO7 – Erection/ejaculation difficulty affecting postoperative sexual function in males

Bowel Dysfunction Description


+ Dutch TME – Fecal incontinence, urgency and emptying difficulties causing impairments in daily activities

Appendix A: Seven Components of the ODARC Prototype

- 1 - Introduction Section – Patient Guide to using the ODARC
- 2 - Treatment Options Section
- 3 - Main Clinical Outcomes Section - Local Recurrence
- 4 - Main Clinical Outcomes Section - Overall 5-year Survival
- 5 - Treatment Side Effects Section - Bowel Dysfunction
- 6 - Treatment Side Effects Section - Sexual Dysfunction
- 7 - References Cited on the ODARC Prototype



How to Use the Ontario Decision Aid in Rectal Cancer (ODARC) for Stage II & III Patients



1 You have been diagnosed with either **Stage II or III rectal cancer**. Together with your surgeon you have decided to proceed with surgery to remove your cancer. People with stage II or III rectal cancer are sometimes treated with radiation therapy prior to surgery – this is known as pre-operative radiation therapy or PRT. PRT is given by a radiation doctor and uses high energy x-ray beams to shrink and destroy cancer cells.

Any treatment choice has associated risks and benefits. This **decision aid** is designed to help you make a decision on the use of radiation therapy before surgery. The ODARC will help communicate relevant research information on **2 treatment options**:

1) **Direct to surgery with no PRT** 2) **Surgery with PRT**

We hope the use of this decision aid will help you make an informed decision about whether or not you wish to receive PRT as part of your treatment plan.

Important Points to Consider

On the ODARC, we present probability information on clinical outcomes and side effects for each treatment option using a **100 people picture**. The shaded people represent the percentage of patients, or the number of patients out of 100, likely to experience the outcome/side effect. Here is an **example** to help you visualize this concept:

The image on the right shows that **4 out of 10 people** are shaded and **6 out of 10 people** are not shaded. This means that **40%** or **4 out of 10 people**, will likely experience the presented outcome or side effect, and **60%** or **6 out of 10 people** will likely not experience the outcome or side effect.

We also present probability information using **Number Needed to Treat (NNT)** and **Number Needed to Harm (NNH)** – these are ways of summarizing the effect of a treatment choice (direct to surgery with/without PRT) on patient outcomes or side effects.

The probabilities we present are based on results from recent research studies* which provide averages for a group of people who are diagnosed with the same disease as you and have received surgery alone or with PRT – there is always uncertainty with the probability of an outcome for an individual patient.

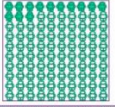
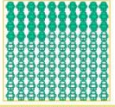
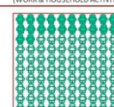

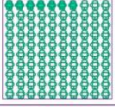
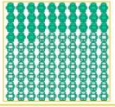
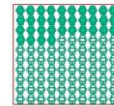
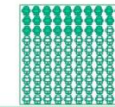
As you are guided through the ODARC please remember that both choices involve certain risks and benefits – **there is no right or wrong choice**. Your doctors are able to speak with you about any questions or issues that arise as you review this decision aid.

2

TREATMENT OPTIONS

MAIN CLINICAL OUTCOMES

TREATMENT SIDE EFFECTS

<div style="border: 1px solid black; border-radius: 10px; padding: 5px; text-align: center; margin-bottom: 10px;"> DIRECT TO SURGERY WITHOUT PREOPERATIVE RADIATION (PRT) </div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px; text-align: center;"> DIRECT TO SURGERY WITH PREOPERATIVE RADIATION (PRT) </div>	3	4	5	6	3	4	5	
								
	PERCENTAGE RANGE FOR LOCAL RECURRENCE IS 11% to 15%	PERCENTAGE RANGE FOR BEING ALIVE AT 5 YEARS IS 63% to 68%	PERCENTAGE FOR BOWEL DYSFUNCTION IS 22%	PERCENTAGE FOR SEXUAL DYSFUNCTION IS 10%	PERCENTAGE RANGE FOR LOCAL RECURRENCE IS 5% to 8%	PERCENTAGE RANGE FOR BEING ALIVE AT 5 YEARS IS 64% to 70%	PERCENTAGE FOR BOWEL DYSFUNCTION IS 34%	PERCENTAGE FOR SEXUAL DYSFUNCTION IS 28%
	NUMBER NEEDED TO TREAT (NNT) FOR EVERY 17 PATIENTS TREATED WITH PREOPERATIVE RT, 8 PATIENTS WILL AVOID A LOCAL RECURRENCE.	NO NNT STATEMENT SINCE TREATMENT WITH PRT DOES NOT IMPROVE CHANCES OF OVERALL SURVIVAL AT 5 YEARS	NUMBER NEEDED TO HARM (NNH) FOR EVERY 8 PATIENTS TREATED WITH PREOPERATIVE RT, 1 PATIENT WILL EXPERIENCE BOWEL DYSFUNCTION THAT LEADS TO DAILY RESTRICTIONS IN HOUSEHOLD WORK ACTIVITIES	NUMBER NEEDED TO HARM (NNH) FOR EVERY 6 PATIENTS TREATED WITH PREOPERATIVE RT, 3 PATIENTS WILL EXPERIENCE SEXUAL DYSFUNCTION THAT LEADS TO NO SEXUAL ACTIVITY AT 2 YEARS	SURGERY WITH PREOPERATIVE RT SIGNIFICANTLY DECREASES THE RISK OF A LOCAL RECURRENCE	SURGERY WITH PREOPERATIVE RT DOES NOT IMPROVE CHANCES OF BEING ALIVE AT 5 YEARS	SURGERY WITH PREOPERATIVE RT SIGNIFICANTLY INCREASES THE RISK OF BOWEL DYSFUNCTION	SURGERY WITH PREOPERATIVE RT SIGNIFICANTLY INCREASES THE RISK OF FEMALE SEXUAL DYSFUNCTION

7

*Petersen K, Alderman C, Hoopmann J, Eisenberg EJ, Patzer R, Higgins B, Kattan M, Robinson L, Colwell B, Leppink J, van de Velde CJH. The TIME trial: a randomised trial of radiotherapy versus postoperative chemotherapy in patients with rectal cancer (MRK COX7 and NCC-C103): a multicentre, randomised trial. *Lancet*. 2009; 373: 822-30.
 *Kang H, Martelaro G, Stephens RJ, Davis B, Aboum J, Green R, Thomas S, Quirk P, Cantore J, de Melo C, Bhatia AL, Bennett G, Griffiths G, Thompson JC, Palmer M. Preoperative & postoperative local control but no survival benefit in irradiated patients with resectable rectal carcinoma. *Ann Surg*. 2007; 246: 692-701.

Appendix Ai: ODARC Introductory Section (Patient Guide)



How to Use the Ontario Decision Aid in Rectal Cancer (ODARC) for Stage II & III Patients



You have been diagnosed with either **Stage II or III rectal cancer**. Together with your surgeon you have decided to proceed with surgery to remove your cancer. People with stage II or III rectal cancer are sometimes treated with radiation therapy prior to surgery – this is known as pre-operative radiation therapy or PRT. PRT is given by a radiation doctor and uses high energy x-ray beams to shrink and destroy cancer cells.

Any treatment choice has associated risks and benefits. This **decision aid** is designed to help you make a decision on the use of radiation therapy before surgery. The ODARC will help communicate relevant research information on **2 treatment options**:

1) Direct to surgery with no PRT 2) Surgery with PRT

We hope the use of this decision aid will help you make an informed decision about whether or not you wish to receive PRT as part of your treatment plan

Important Points to Consider

On the ODARC, we present probability information on clinical outcomes and side effects for each treatment option using a **100 people picture**. The shaded people represent the percentage of patients, or the number of patients out of 100, likely to experience the outcome/side effect. Here is an **example** to help you visualize this concept:



The image on the right shows that **4 out of 10** people are shaded and **6 out of 10** people are not shaded

This means that **40%** or **4 out of 10** people, will likely experience the presented outcome or side effect, and **60%** or **6 out of 10** people will likely not experience the outcome or side effect

We also present probability information using **Number Needed to Treat (NNT)** and **Number Needed to Harm (NNH)** – these are ways of summarizing the effect of a treatment choice (direct to surgery with/without PRT) on patient outcomes or side effects.

The probabilities we present are based on results from recent research studies* which provide averages for a group of people who are diagnosed with the same disease as you *and* have received surgery alone or with PRT – there is always uncertainty with the probability of an outcome for an individual patient

As you are guided through the ODARC please remember that both choices involve certain risks and benefits - **there is no right or wrong choice**. Your doctors are able to speak with you about any questions or issues that arise as you review this decision aid

Appendix Aii: Treatment Options Section

TREATMENT OPTIONS

**DIRECT TO
SURGERY
WITHOUT
PREOPERATIVE
RADIATION (PRT)**

**DIRECT TO
SURGERY WITH
PREOPERATIVE
RADIATION (PRT)**

Appendix Aiii: Main Clinical Outcomes – Local Recurrence

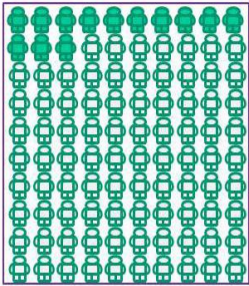
TREATMENT OPTIONS

DIRECT TO SURGERY WITHOUT PREOPERATIVE RADIATION (PRT)

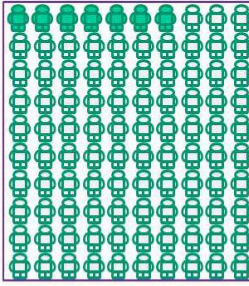
DIRECT TO SURGERY WITH PREOPERATIVE RADIATION (PRT)

MAIN CLINICAL OUTCOMES

LOCAL RECURRENCE
STATE OF TUMOUR RETURNING IN THE PELVIC AREA



PERCENTAGE RANGE FOR LOCAL RECURRENCE IS
11% to 15%



PERCENTAGE RANGE FOR LOCAL RECURRENCE IS
5% to 8%

NUMBER NEEDED TO TREAT (NNT)
FOR EVERY **17** PATIENTS TREATED WITH PREOPERATIVE RT, **1** PATIENT WILL AVOID A LOCAL RECURRENCE

SURGERY WITH PREOPERATIVE RT SIGNIFICANTLY DECREASES THE RISK OF A LOCAL RECURRENCE

Appendix Aiv: Main Clinical Outcomes – Overall 5-year Survival

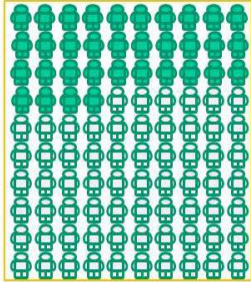
TREATMENT OPTIONS

DIRECT TO SURGERY WITHOUT PREOPERATIVE RADIATION (PRT)

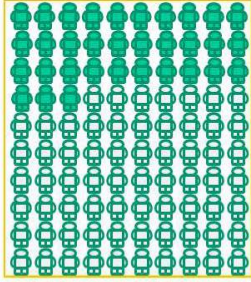
DIRECT TO SURGERY WITH PREOPERATIVE RADIATION (PRT)

MAIN CLINICAL OUTCOMES

OVERALL 5-YEAR SURVIVAL
STATE OF BEING ALIVE



PERCENTAGE RANGE FOR BEING ALIVE AT 5 YEARS IS
63% to 68%



PERCENTAGE RANGE FOR BEING ALIVE AT 5 YEARS IS
64% to 70%

NO NNT STATEMENT SINCE TREATMENT WITH PRT DOES NOT IMPROVE CHANCES OF OVERALL SURVIVAL AT 5 YEARS

SURGERY WITH PREOPERATIVE RT DOES NOT IMPROVE CHANCES OF BEING ALIVE AT 5 YEARS

Appendix Av: Treatment Side Effects – Bowel Dysfunction

TREATMENT OPTIONS

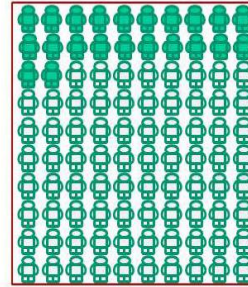
DIRECT TO SURGERY WITHOUT PREOPERATIVE RADIATION (PRT)

DIRECT TO SURGERY WITH PREOPERATIVE RADIATION (PRT)

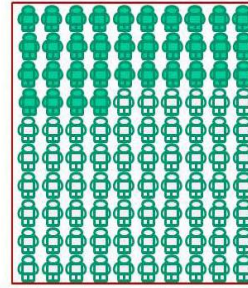
TREATMENT SIDE EFFECTS

BOWEL DYSFUNCTION

STATE OF HAVING INCONTINENCE LEADING TO SEVERE DAILY SOCIAL RESTRICTIONS (WORK & HOUSEHOLD ACTIVITIES)



PERCENTAGE FOR BOWEL DYSFUNCTION IS 22%



PERCENTAGE FOR BOWEL DYSFUNCTION IS 34%

NUMBER NEEDED TO HARM (NNH)

FOR EVERY 8 PATIENTS TREATED WITH PREOPERATIVE RT, 1 PATIENT WILL EXPERIENCE BOWEL DYSFUNCTION THAT LEADS TO DAILY RESTRICTIONS IN HOUSEHOLD AND WORK ACTIVITIES

SURGERY WITH PREOPERATIVE RT SIGNIFICANTLY INCREASES THE RISK OF BOWEL DYSFUNCTION

Appendix Avi: Treatment Side Effects – Female Sexual Dysfunction

TREATMENT OPTIONS

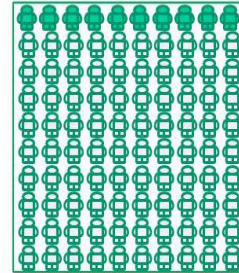
**DIRECT TO
SURGERY
WITHOUT
PREOPERATIVE
RADIATION (PRT)**

**DIRECT TO
SURGERY WITH
PREOPERATIVE
RADIATION (PRT)**

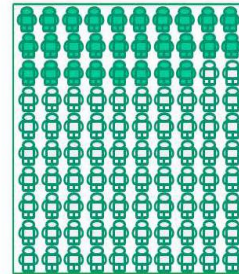
TREATMENT SIDE EFFECTS

FEMALE SEXUAL DYSFUNCTION

STATE OF HAVING NO SEXUAL ACTIVITY AT 2 YEARS AFTER TREATMENT



PERCENTAGE FOR SEXUAL DYSFUNCTION IS **10%**



PERCENTAGE FOR SEXUAL DYSFUNCTION IS **28%**

NUMBER NEEDED TO HARM (NNH)

FOR EVERY **6** PATIENTS TREATED WITH PREOPERATIVE RT, **1** PATIENT WILL EXPERIENCE SEXUAL DYSFUNCTION THAT LEADS TO NO SEXUAL ACTIVITY AT 2 YEARS

SURGERY WITH PREOPERATIVE RT SIGNIFICANTLY INCREASES THE RISK OF FEMALE SEXUAL DYSFUNCTION

Appendix Avii: Treatment Side Effects – Male Sexual Dysfunction

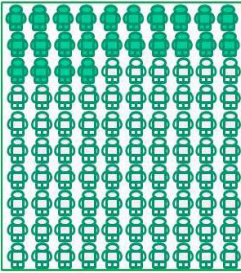
TREATMENT OPTIONS

DIRECT TO SURGERY WITHOUT PREOPERATIVE RADIATION (PRT)

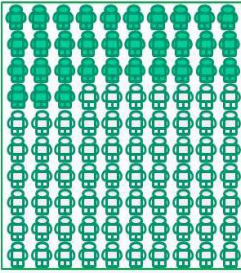
DIRECT TO SURGERY WITH PREOPERATIVE RADIATION (PRT)

TREATMENT SIDE EFFECTS

MALE SEXUAL DYSFUNCTION
STATE OF HAVING NO SEXUAL ACTIVITY AT 2 YEARS AFTER TREATMENT



PERCENTAGE FOR SEXUAL DYSFUNCTION IS 24%



PERCENTAGE FOR SEXUAL DYSFUNCTION IS 33%

NUMBER NEEDED TO HARM (NNH)
FOR EVERY 11 PATIENTS TREATED WITH PREOPERATIVE RT, 1 PATIENT WILL EXPERIENCE SEXUAL DYSFUNCTION THAT LEADS TO NO SEXUAL ACTIVITY AT 2 YEARS

SURGERY WITH PREOPERATIVE RT SIGNIFICANTLY INCREASES THE RISK OF MALE SEXUAL DYSFUNCTION