

TREATMENT DECISION-MAKING NEEDS FOR LOCALLY RECURRENT  
PROSTATE CANCER

ASSESSING INFORMATION AND TREATMENT DECISION-MAKING NEEDS OF  
PATIENTS WITH LOCALLY RECURRENT PROSTATE CANCER

By

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## **Abstract**

**Introduction.** Treatment decisions for locally recurrent prostate cancer are difficult due to the number of available treatment options, varied evidence about their effectiveness and differences in side effects. It has been shown that decision aids improve information delivery and patient confidence in treatment decision-making.

**Purpose.** The purpose of this study was to identify and describe the decisional support needs of men with locally recurrent prostate cancer.

**Methods.** A two-phase descriptive needs assessment study employing both quantitative and qualitative methods was conducted to identify and describe the treatment decision-making needs of men with recurrent prostate cancer. Through a two-round Delphi process in Phase 1, physician consensus on treatment options for the decision aid was established. Phase 2 involved patient interviews to determine treatment decision-making needs.

**Results.** Oncologists and patients agreed that the treatment decision-making process took time, and may take several months. Some patients described feelings of regret and/or uncertainty about their treatment decision. Individualized patient needs for information and support were recognized. Key barriers to effective treatment decision-making included information overload and lack of access to unbiased information sources. Establishing a centralized information resource such as nurse-led information sessions was recommended by patients.

**Conclusions.** Treatment decision-making is time consuming for oncologists and patients. Despite these efforts, patients report unmet information needs and are not always

confident in their treatment decision. Time efficient and effective ways of improving patient confidence in treatment decision-making, as well as implications for nursing practice and future research are discussed.

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## **CHAPTER 1**

### **Introduction and Rationale**

Prostate cancer is the most common type of cancer diagnosed in men, with an estimated 24,600 new cases expected in Canada in 2010 (Canadian Cancer Society, 2010). Prostate cancer is also the third most common cause of male cancer-related deaths with an estimated 4,300 deaths in Canada in 2010. There have been numerous advances in the early detection and treatment of prostate cancer over the last two decades. The treatment options vary according to the stage of the disease, age, co-morbidity, the potential risks of treatment complications and impact on health related quality of life (HRQL) (Brink, Birney & McFarren, 2000; National Cancer Institute [NCI], 2010).

Prostate cancer is a chronic disease in which about 30% of those diagnosed with potentially curable, early stage disease will subsequently develop recurrent and more advanced disease (Landis, Murray, Bolden & Wingo, 1999; Levy, Gibbons, Collins, Perkins & Mao, 1993; Rukstalis, 2002). However, many patients with advancing stages of prostate cancer live for five, ten and up to 15 years (NCI, 2010). Several quantitative and qualitative research studies highlight treatment and disease-related information as an important but frequently unmet need for men with prostate cancer (Carter, Bryant-Lukosius, DiCenso, Blythe & Neville, 2011; Davison et al., 2002; Feldman-Stewart, Brundage, Van Manen & Svenson, 2004; McGuffin & Wright, 2004; Snow et al., 2007). Thus, strategies to improve information delivery and patients' confidence in treatment decision-making may lead to improvements in their overall psychosocial well-

being and quality of life over the long-term. An evidence-based information resource such as a decision aid may be one such strategy. Decision aids aim to prepare users for treatment decision-making by providing detailed and specific information on treatment options and outcomes (O'Connor et al., 2007). Users of decision aids may include practitioners, patients and other people involved in decision-making including family and friends (Jacobsen & O' Connor, 2006). Decision aids have been found to be effective for improving knowledge regarding treatment options, enhancing realistic expectations about benefits and harms of options, reducing decisional conflict and stimulating people to take an active role in decision-making (O'Connor et al.).

The optimum treatment for locally recurrent prostate cancer is often elusive as patients and practitioners are not always in agreement about treatment benefits and risks (Canadian Cancer Society, 2010; NCI, 2010). There are also varying levels of evidence to support the effectiveness and/or the risks associated with the short and long-term side effects of different treatment options. Treatment choices for recurrent disease are also dependent on the type of treatment patients received at initial diagnosis. Furthermore, patients may be emotionally and cognitively challenged and have difficulty processing information in situations requiring quick treatment decisions (Feldman-Stewart et al., 2004). Finally, there is a myriad of information available through the World Wide Web, books, journals, friends and family. The complexity of treatment choices faced by patients indicates a need for access to an information source that helps to explain their diagnosis of locally recurrent prostate cancer and helps them to understand and interpret how various treatment options apply to their health situation. Nurses in general, and

advanced practice nurses in particular, are knowledgeable partners in delivering high quality care to patients (Carper & Haas, 2006; Gosselin-Acomb, 2006) and can play a major role in supporting patients to meet their decisional needs. This can be done through patient education, which is recognized as an essential component of the professional nursing role and is an important primary intervention strategy (College of Nurses of Ontario, 2010; Templeton & Coates, 2003). A decision aid may also be a valuable tool for meeting the decisional needs of these patients; something that is currently lacking for this patient population (Ottawa Health Research Institute [OHRI], 2010). In addition, the involvement of users (patients and physicians) in the development of the aid may increase the likelihood of its acceptability and therefore its uptake for use in practice.

### **The Framework of Decision Support**

There are several frameworks that offer different approaches to guide decision aid development. For example, some frameworks emphasize mutual or shared decision-making between patients and healthcare providers (Charles, Gafni & Whelan, 1997; Mulley, 1995; Rothert & Talarczyk, 1987), evidence-informed choice (Entwistle, Sowden & Watt, 1998) and socio-political contexts and patient preferences (Llewellyn-Thomas, 1995). The Ottawa Decision Support Framework (ODSF) (See Appendix A) uses a decision-making behaviour framework that can be applied to a variety of methods such as clinical counseling, decision tools and coaching to improve decision quality (O'Connor & Jacobsen, 2003). The ODSF provided the conceptual foundation for this study. This framework was selected because it emphasizes the preparation of both the patient and practitioner to address determinants known to impact on optimal healthcare decision-



making (O'Connor & Jacobsen). According to the framework, the determinants of healthcare decisions are:

1. *Perceptions of the decision-maker* which may be related to knowledge and extent of uncertainty or decisional conflict.
2. *Perceptions of others* which may be related to “the variation in others’ opinions and practices” or perceived support for treatment decision-making (O'Connor & Jacobsen, p. 8).
3. *Personal and external resources* related to skills in shared decision-making

By addressing these determinants, decisions may be more informed and consistent with patients’ personal values and more likely to be implemented. A systematic review by O'Rourke (2001) of issues surrounding treatment decision-making reinforced the strategy of addressing these determinants of healthcare decisions. It recommended that a multidisciplinary approach be adopted in discussing treatment options and assisting patients in making balanced treatment decisions that incorporate their personal values and the best evidence about treatment risks and benefits.

### **Project Goals and Research Questions**

The ultimate goal of this thesis was to identify and describe the decisional support needs of men with locally recurrent prostate cancer. Study results will form the groundwork for the future development of an evidence-based treatment decision aid.

Patients with locally recurrent disease were selected as the focus of this study because of the wide range of treatment options available to them. The extensive number of available options contributes to a complex and challenging treatment decision-making

process. A review of the OHRI inventory of decision aids also revealed that no treatment decision aid has been developed specifically to meet the needs of this patient population (OHRI, 2010). The OHRI inventory is an up-to-date directory of available decision aids identified by the Cochrane Systematic Review Group that meet a minimal set of criteria.

Radiation oncologists were identified as important to include in this study as they are the primary healthcare providers involved in the treatment and follow-up care for this population. They are also responsible for providing initial information about treatment options.

The specific objective of this study was to identify and describe the decisional support needs of patients and opinions of physicians related to the treatment for locally recurrent prostate cancer, at two Ontario regional cancer centres by answering the following research questions:

1. To what extent is there consensus among radiation oncologists about the treatment options to be included in a decision aid?
2. What are patients' and radiation oncologists' perceptions of the most important treatment decisions for patients?
3. What are patients' and radiation oncologists' perceptions about the most difficult aspects of treatment decision-making for patients?
4. What are patients' and radiation oncologists' perceptions of the barriers and facilitators patients experience in making treatment decisions?
5. What types of information do patients and radiation oncologists perceive as most important to include in a treatment decision aid?

6. What are patients' recommendations about how information should be provided to assist them in making treatment decisions?

### **Format**

The remainder of this thesis consists of four chapters. Chapter 2 provides a review of the relevant literature beginning with an outline of the search strategy. The review covers literature on locally recurrent prostate cancer, treatment for locally recurrent prostate cancer, treatment decision-making and information needs in prostate cancer, decision aids, decision aids in prostate cancer and strategies for assessing treatment decision-making needs. This chapter also includes a review and comparison of the available decisions aids for prostate cancer. Chapter 3 focuses on the study methods, outlining the research design, recruitment methods, data collection and management and data analysis. A discussion about modifications to the initial data collection plan and methods is included. Chapter 4 summarizes the findings and describes the themes generated from the data analysis. Verbatim quotes are used to illustrate the findings and highlight the similarities and differences in physician and patient perceptions about treatment decision-making needs. Chapter 5 includes the discussion of the findings, study strengths and limitations, implications for nursing practice and directions for future research.

## **CHAPTER 2**

This chapter examines the literature on several topics relevant to decision-aid development for patients with locally recurrent prostate cancer. Topic areas addressed include: locally recurrent prostate cancer, treatment for locally recurrent prostate cancer, treatment decision-making and information needs in prostate cancer, decision aids, decision aids in prostate cancer and strategies for assessing treatment decision-making needs. Lastly, this chapter includes a review and comparison of the available decisions aids for prostate cancers.

### **Literature Search Strategy**

Literature cited in this review was identified through a search of Medline, Excerpta Medica Database (EMBASE), Cancerlit and Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases. Publications from 1996 to 2007 were included in the search strategy. Search terms included: decision-making, patient decision-making, clinical decision-making, patient participation, decision support techniques, decision boards, patient preference and information seeking behaviour. These search terms were then combined with the term prostate cancer resulting in a total of 170 citations. One hundred and fifty publications related to physician and patient decision-making about screening and treatment for advanced prostate cancer were excluded from the review. Twenty publications were retained for closer perusal and were included in the literature review. Literature related to treatment for locally prostate cancer was identified through a search of Evidenced Based Medicine (EBM) Reviews, Cochrane Database of Systematic Reviews and EMBASE. Publications from 1996 to 2007 were included in the

search strategy. Search terms included: prostate cancer, locally recurrent prostate cancer, hormonal therapy, radiotherapy, diagnostics and treatment of PSA progression after local primary therapy. A total of 36 citations were identified. Twenty four publications discussing treatment of advanced prostate cancer were excluded from the review. The 12 remaining publications were included in the literature review.

## **Literature Review**

### **Locally Recurrent Prostate Cancer (LRPC)**

The standard curative treatment options for LRPC include: radical prostatectomy and/or external beam radiation therapy (EBRT). Locally recurrent prostate cancer is defined as biochemical failure or relapse after treatment with curative intent (NCI, 2010). Biochemical failure is described as a rise in the level of prostate specific antigen (PSA) and may be a prognostic factor for clinical disease recurrence (NCI). The Radiation Therapy Oncology Group-American Society for Therapeutic Radiology and Oncology (RTOG-ASTRO) Phoenix Consensus group has set the standard definition for biochemical failure or PSA failure as a “rise by 2ng/ml or more above the nadir PSA ... after EBRT with or without HT [hormone therapy]” (National Comprehensive Cancer Network [NCCN], 2008, p. PROS-4). Prostate specific antigen is a more sensitive marker of disease recurrence than clinical measures such as physical exams or radiographic imaging. Furthermore, biochemical recurrence may precede clinical discovery of recurrent disease by three to five years (Grossfeld, Li, Lubeck & Carroll, 2002).

Despite improvements in the early detection and treatment of prostate cancer, a high incidence of under-staging at initial diagnosis contributes to the later development of

recurrent local disease or non-curable advanced disease in a substantial number of patients following initial treatment (NCI, 2010). For example, about 30% of patients diagnosed with early stage disease, who have not undergone a radical prostatectomy and the removal of the regional lymph nodes which is required for definitive pathological staging, will go on to develop locally recurrent or non-curable advanced disease following radical radiation therapy (Amling, 2006). The goal of curative therapy is prolonged disease-free survival, but with locally recurrent disease, treatment is rarely curative (NCI).

### **Treatment for LRPC**

The treatment options for biochemical failure post-radiation therapy are: watchful waiting, local therapy and hormone therapy (Anderson, Fourcade, Payne & Schulman, 2002). These treatments are also known as salvage therapies which is defined as treatment that is given after the cancer has not responded or has returned after other treatments (NCI, 2010). The local therapy treatment options for recurrent disease post-radiation therapy include, but are not limited to: surgery, re-irradiation, cryotherapy, high-intensity focused ultrasound (HIFU) and light-activated drug Tookad (Tookad) (Canadian Cancer Society, 2010; McGill University Health Centre [MUHC], 2007; NCI, 2010). Appendix B provides a summary of the benefits, limitations, eligibility criteria for and effectiveness of available treatment options for locally recurrent prostate cancer.

Standard salvage therapies for LRPC include watchful waiting and hormone therapy, also known as androgen deprivation therapy (ADT). The latter results in a median cancer-specific survival of 6 years (NCI, 2010). Ninety percent of patients

requiring salvage treatment after radiation therapy receive hormonal therapy (Canadian Cancer Society, 2010; Grossfeld et al., 2002): which delays metastatic disease but has no curative potential (Gelet et al., 2004). Local therapies include radical prostatectomy, cryotherapy and brachytherapy. In contrast to prostatectomy, brachytherapy and cryotherapy are experimental but have curative potential. Relatively new treatments that are still in clinical trials are HIFU and Tookad Laser. Radical prostatectomy following initial radical radiation therapy is a technically challenging but potentially curative therapy that is available to a few, very carefully selected patients (Gelet et al.). The NCCN (2008) recommends this for patients with positive biopsy results and no metastases. This therapy has a high morbidity rate in addition to the risks associated with any surgical procedure. However, the disease-free and disease specific survival rates after this procedure are comparable to other curative therapies.

Historically, cryotherapy following radical radiation therapy was associated with high morbidity rates, but the use of argon-based systems, 17-gauge CryoNeedles and other technical modifications has led to increased safety in tumor eradication and decreased morbidity (Lam & Belldegrun, 2004). The development of more sophisticated targeting techniques has also led to improvements in radiation therapy such as dose escalation and re-irradiation (Lam & Belldegrun). These targeted therapy techniques offer a minimally invasive option for suitable candidates.

Watchful waiting is considered to be a conservative treatment option and involves active disease monitoring without active treatment. The rationale for this option is that some patients have a higher probability of dying from other causes than from their

prostate cancer (Pirtskhalaishvili, Hrebinko & Nelson, 2001). Although this option was thought to be harmless, it can be accompanied by significant morbidity. Pirtskhalaishvili et al. found that 41% to 90% of patients require at least one transurethral resection during the course of watchful waiting. The NCCN (2008) also found that patients undergoing watchful waiting may experience increased anxiety and uncertainty about their long-term prognosis and disease progression.

After a period of watchful waiting, patients may become candidates for hormone therapy. The optimal timing for initiating early versus delayed hormone therapy is still controversial (Anderson et al., 2002; NCCN, 2008). Hormone therapy may also be administered continuously or intermittently, although the latter approach is gaining popularity due to its improved toxicity profile. Choices for hormonal therapy include traditional hormone monotherapy (LHRH agonists, orchiectomy), or combined androgen blockade (medical or surgical castration combined with an antiandrogen) and intermittent androgen blockade (NCCN). Hormone therapy can be given before, during or after radiation treatment and it has been found to prolong survival in selected patients (NCCN). Some side effects of ADT include loss of libido, impotence, hot flashes, gynecomastia and osteoporosis (NCI, 2010). New studies have also revealed the potential for cardiovascular side effects such as coronary artery disease, myocardial infarct and cardiovascular death (Keating, O'Malley, Freedland & Smith, 2010; Levine et al., 2010).

High-intensity focused ultrasound is a minimally invasive treatment that may provide patients with recurrent cancer a chance for long-term cure. A study by Gelet et al. (2004) found that morbidity related to HIFU was lower than that reported for other



salvage therapies and led to a favorable risk/benefit ratio. Tookad Laser is another minimally invasive therapy that is currently in phase II clinical trials. A phase I trial demonstrated complete eradication of prostate cancer after radiation treatment in 46% of patients who had recurrent disease (MUHC, 2007). The associated drug is eliminated from the body in about two hours, but damage to the tissue that is exposed to the laser is permanent.

The availability of such a wide range of treatment options can make treatment decision-making challenging, especially when these options are associated with varying degrees of long-term disease control and varied risks for short and long-term treatment side effects. The optimal timing and type of treatment for patients with recurrent prostate cancer is also controversial due to the lack of feasible and effective ways to accurately diagnose local versus distant disease recurrence (Grossfeld et al. 2002). Accurate staging is important because patients with local recurrence may still have the opportunity to achieve a cure or long-term disease control with further treatment. The inaccuracy in clinical staging techniques makes it important for other factors to be considered as a component of treatment decision-making, such as patient values and preferences related to the potential benefits and risks associated with different treatment options (O'Rourke, 2001).

### **Treatment Decision-Making and Information Needs in Prostate Cancer**

Several quantitative and qualitative research studies highlight treatment and disease-related information as an important but frequently unmet need for men with prostate cancer. The majority of these needs assessment studies have focused on men with

early stage prostate cancer at the time of initial diagnosis (Davison et al., 2002; Gray, Fitch, Phillips, Labrecque & Klotz, 1999) or treatment (Feldman-Stewart et al., 2004; McGuffin & Wright, 2004; Moore & Estey, 1999; Philips et al., 2000; Snow et al., 2007). In these studies patients ranked information needs related to recurrence, side effects, and treatment options as the most important, followed by needs related to care delivery and support (Boberg et al., 2003). Couples identified similar priority information needs related to prognosis, stage of disease, treatment options and side effects (Davison et al.). However, the importance of specific types of information may vary among patients and their families (Feldman-Stewart, Brundage & Mackillop, 2001). At the time of initial diagnosis, patients with early stage prostate cancer identified information about various treatment options as being important for helping them to make decisions about having a radical prostatectomy (Gray et al.). Following radical prostatectomy, patients required accurate information regarding surgical side effects, possible treatment complications and expectations during the recovery period (Moore & Estey; Philips et al.). Likewise, patients who were offered radiation therapy as a treatment option were found to actively seek information about traditional treatments, treatment side effects and their particular type of cancer (McGuffin & Wright).

Gaps in meeting information needs have also been identified in a recent local study of men with advanced prostate cancer in the Hamilton-Wentworth region (Carter, Bryant-Lukosius, DiCenso, Blythe & Neville, 2010). In this study, patients and family members identified unmet information needs related to their disease, treatment and self-care as priorities to address in order to improve care delivery. Patients also questioned the

completeness and accuracy of treatment decision-making information provided to them by healthcare professionals at various time points throughout their illness experience, particularly at the time of initial diagnosis and at disease recurrence. These gaps made patients question if the right treatment decisions had been made, and raised concerns about the negative impact of these treatment decisions on their current health. Thus, an important finding of this study was that for men with advanced prostate cancer, uncertainty about past treatment decisions was a major source of psychological distress (Carter et al.).

A feasibility study for the development of a Canadian National Outcomes Data Base found that patients with prostate cancer want information on the progression of their disease and prognosis and the risks and benefits associated with different treatment options (Damberg et al., 2003). In a quantitative study by Davison et al. (2002) nurses distributed computerized questionnaires to 80 participants with prostate cancer and their partners at the time of diagnosis to identify and compare their information and decision-making preferences. Results indicated that men preferred to play an active or a collaborative role in decision-making with their physician (92.5 %) and this was the same for their partners (100%). Couples identified the top four information needs as: prognosis, stage of disease, treatment options and side effects. A limitation of this study is that older patients who may not have felt comfortable with computer technology may have withdrawn from the study and therefore may be under-represented. In addition, the needs of individual patients differed. For example, there was substantial variability among older couples regarding the importance of information on sexuality (Davison et al.). However,

patient acceptance of the computerized program was found to be moderate and the program is currently used by nurses at the Prostate Resource Centre at Vancouver General Hospital. Development of the tool was based on Degner and Sloan's (1992) Control Preferences Scale (CPS), which is used to elicit patients' preferences for control over treatment decision-making.

### **What are Decision Aids?**

Decision aids are interventions used to prepare patients for decision-making regarding professional care options (O'Connor & Jacobsen, 2003). They are intended to supplement professional counseling provided by healthcare practitioners about these options. The Cochrane Collaboration defines decision aids for professional care options as “interventions designed to help people make specific and deliberative choices among options by providing information on the options and outcomes relevant to a person's health status” (O'Connor et al., 2007, p. 2).

The different media by which decision aids can be administered include, but are not limited to: decision boards, one-to-one interviews, scripted telephone counseling, interactive video discs, computers programs, audiotapes, audio-guided workbooks, pamphlets and group presentations (Myers & Kunkel, 2000; O'Connor & Jacobsen, 2003). There is wide variation in the use of these different types of decision aids. Factors that impact on the effective use of decision aids include: the breadth and depth of information, ease of access and active promotion of the decision-making tool on the part of the organization (Damberg et al., 2003).

### **Benefits and Limitations of Decision Aids**

In this section, the research evidence regarding the effectiveness of decision aids is reported, followed by more specific examination regarding the effectiveness of decision aids in prostate cancer. Limitations related to the evaluation and use of decision aids are also identified.

Decision aids may offer numerous benefits to patients but the extent of their effectiveness has not been fully established. A systematic review regarding the effectiveness of decision aids indicated that some studies reported no difference in patient satisfaction with decision-making, levels of anxiety and health outcomes when compared to standard care (O'Connor et al., 2007). Similarly, although a systematic review of randomized controlled trials (RCTs) of cancer related decision aids for screening, prevention, and treatment decision-making found there was an overall decrease in decisional conflict and no increased anxiety with decision aids, there was no perceptible difference in decisional conflict when screening (average effect size - 0.15; 95% CI, - 0.44 to 0.13;  $p = .28$ ) and prevention/treatment studies (average effect size - 0.15; 95% CI, - 0.31 to 0.01;  $p = .07$ ) were analyzed separately (O'Brien et al., 2009). It can be argued that not all patients may want to be involved in decision-making. Holmes-Rovner et al. (2007) found that 25% of patients with various clinical conditions did not want to participate in clinical decision-making. Further, patients had different levels of interest in decision-making participation and varying degrees of interest in utilization of decision aids. These findings raise questions about the extent to which patients may be unaffected,

or even harmed, by the use of decision aids. However no studies to date have reported any harmful effects.

One systematic review of 18 decision aid studies involving patients with different types of cancer and cardiac conditions revealed that knowledge scores for patients randomized to use of decision aids were 9 to 30 points higher (weighted mean difference = 19 points, 95% CI 13-24) compared to those receiving usual care (O'Connor et al., 2007). This study also found that patients who used a decision aid with detailed descriptions of outcomes and probabilities were significantly more likely to have realistic expectations of treatment risks and benefits than those who did not receive this information (pooled relative risk = 1.4, 95% CI 1.1 -1.9).

Several studies involving patients with prostate cancer have identified a number of benefits associated with the use of decision aids. One pre-test/post-test study examined the impact of a decision aid on a convenience sample of patients with newly diagnosed, early stage prostate cancer and their partners (Davison, Goldenberg, Gleave & Degner, 2003). The intervention involved the delivery of individualized or tailored information for each couple. At four months post-intervention, patients in the intervention group reported more active involvement and their partners reported less active involvement in treatment decision-making than they had expected. Patients and their partners also experienced lower levels of psychological distress. These results suggest that decision aids may facilitate treatment decision-making and improve mental health and well-being. Important limitations of this study are the lack of a comparison group and the use of a convenience

sample. The study recommended that randomized clinical trials be conducted to evaluate the effectiveness of informational support.

In another pre-test/post-test study, a decision aid was used to examine patients with early-stage prostate cancer and the cognitive processes they used to select treatment preferences (Feldman-Stewart et al., 2004). The decision aid involved one-to-one interviews that provided a structured presentation of information, an attribute identification exercise and trade-off exercises to help weigh important attributes with other factors. At baseline, participants identified attributes related to bladder function, chances of the PSA rising, type of treatment procedure and sexual function as the most important factors for their decision-making. At a follow-up interview three months later, 78% of patients had changed their views about which attributes were most important and 72% had changed their ratings of treatment preferences (Feldman-Stewart et al.). Patients' ability to differentiate among treatment options was also found to be positively associated with stability of treatment choice, which means they did not actively change their mind overtime with choice of treatment, and lack of regret regarding their treatment decisions. The decision aid was found to be effective in facilitating the treatment choice of patients who were previously undecided; and for those who had already made a decision, the aid was found to clarify patients' values, consolidate their choices and reduce decisional regret.

A repeatability study to verify these results was conducted three months later with ten patients who were interviewed in the original study (Feldman-Stewart et al., 2004). The study found 85.6% (mean percent) of the original interview attributes were the same

(Feldman-Stewart et al.). This indicated long-term stability of participants' treatment choices. A limitation of this study was that patients had at least two consultations with specialists before making their decisions, which may have influenced their decision-making. In addition, the repeatability study did not provide information on how patients actually weighed each attribute and arrived at their preferred option.

A major criticism of decision aids is that few of them have been evaluated. O'Connor et al. (2007) found that of the 200 decision aids they reviewed, only 30 of them had been evaluated in randomized controlled trials. Other methods used to evaluate decision aids include before/after testing, testing for validity and reliability, and one acceptability study. The lack of standardized criteria to evaluate the content and quality of decision aids stimulated the development of International Patient Decision Aid Standards (IPDAS), which are presented in detail in Appendix C (Holmes-Rovner et al., 2007). The IPDAS were developed using a systematic process supported by the collaboration of over 100 participants from 14 countries around the world. The aim was to develop a set of best practice guidelines for decision aid development. These criteria are supported by theoretical and empirical research addressing 12 broad quality criteria. A two-round Delphi process was used to refine the criteria (IPDAS, 2006). Some of the IPDAS measures have been used to assess effectiveness of decision aids in a systematic review of 55 randomized trials (Holmes-Rovner et al.). However, further research is required to fully evaluate the effectiveness and appropriate use of decision aids.

Some physicians utilize treatment decision aids and have found them to be a structured and helpful approach to reviewing options and outcomes with patients



(Holmes-Rovner et al., 2007). However, greater decision aid use and commitment from more physicians is required. Changes in organizational policies and practices may also be required to support the utilization and effective implementation of decision aids (Holmes-Rovner et al.).

In summary, studies have identified a number of benefits associated with the use of decision aids including: reduced patient uncertainty; increased patient knowledge about diagnoses, treatment options and outcomes; more realistic patient expectations of treatment outcomes; improved agreement between treatment choices and patient values; reduced decisional conflict; increased patient participation in treatment decision-making and disease management; and improved HRQL. The studies also found that partners experienced lower levels of psychological distress and some reported less active involvement in treatment decision-making than they had expected. This thesis aimed to address identified gaps in the literature regarding the availability and appropriate development of decision aids for patients diagnosed with locally recurrent prostate cancer.

### **Decision Aid Design and Development**

O'Connor and Jacobsen (2003) recommend a seven step process for the development and evaluation of decision aids that has informed the development of this study. These steps are to: 1) assess the need, 2) assess feasibility, 3) define the objectives of the aid, 4) identify the framework for decision support, 5) determine the methods of decision support to be used in the decision aid, 6) select the designs and measures to evaluate the decision aid, and 7) plan the dissemination of the decision aid. This thesis

study focused on the first step of the process and assessed patient treatment decision-making needs. Witkin and Altschuld (1995) describe a needs assessment as a set of procedures undertaken to set priorities and make decisions about program development or improvements. Jacobsen and O'Connor (2006) emphasize that, in the context of decision-making, one focus of the needs assessment is to identify “what a patient population needs to make better decisions” (p.3). For this study, Jacobsen and O'Connor’s Population Needs Assessment Guide was used to develop an assessment of patients’ and practitioners’ (i.e. radiation oncologists) perceptions of patient decision-making needs regarding treatment for locally recurrent prostate cancer. The ODSF, which outlines decisional needs, was used to determine the type of information to be collected from study participants.

It is vital for physicians to be included in the development of treatment decision aids as they are instrumental in the patient treatment decision-making process. More importantly, needs should be defined from the perspective of potential decision aid users. O'Connor and Jacobson (2003) identify three sources of treatment choices to be considered when developing a decision aid; standards of care, guidelines and options. Each of these treatment choices is associated with varying levels of evidence to support their effective use. For example, treatment choices related to the *standard of care* (i.e., *standard therapy*) are those with strong evidence of effectiveness and strong agreement among patients about their value. There is more uncertainty for patients and practitioners when discussing *guidelines* (i.e., *investigative therapy*), as there is less agreement among patients regarding the value of these even though their outcomes are known. Treatment

choices are classified as *options (i.e. clinical trials)* when evidence about outcomes and agreement on values is variable or unknown. Appendix D provides a summary of these categories of treatment choices available for locally recurrent prostate cancer. Watchful waiting and ADT are in the category standard of care, while investigative therapies include salvage prostatectomy, cryotherapy and re-irradiation. High-intensity focused ultrasound and Tookad Laser are the current choices in the clinical trials category. The treatment choices in each category fluctuate to reflect updates in evidence-based research.

### **Assessing Treatment Decision-Making Needs**

Patient decisional needs are related to the perception of the decision to be made, the perception of others' opinions, and personal and external resources available to help make the decision (Jacobsen & O'Connor, 2006). Each of these needs are defined in Appendix A. According to Jacobsen and O'Connor when the determinants that affect treatment choices are not addressed, there is an impact on decisional needs and consequently patients' decision-making ability can be diminished.

It has been previously established that for patients with locally recurrent prostate cancer, numerous factors or determinants affect treatment choices and impact upon decisional needs. These factors can be divided into two broad categories: disease-related and patient-specific factors. Disease-related factors include: type of prior therapy, PSA kinetics, duration of prior remission, prostate cancer histology and extent of primary disease (Aranha & Vaishampayan, 2004; Canadian Cancer Society, 2010). Patient-specific factors include: age, co-morbid conditions, life expectancy, personal preference, life experiences, cancer experiences and the physician-patient relationship (Aranha &

Vaishampayan; NCI, 2010; O'Rourke, 2001). According to O'Connor and Jacobsen's (2003) framework, poor decision-making may occur when these determinants are not adequately addressed. For example, a patient's decision may be based on inadequate knowledge about treatment options, unrealistic expectations about outcomes, unclear personal values, inadequate support, or the inability to play the role that he or she prefers in the decision-making. Patients may also have inadequate access to resources such as information or advice. To help understand and assess the decisional needs of patients and practitioners, it is important to determine what difficulties they have with decision-making.

As discussed earlier in this chapter, patients with locally recurrent prostate cancer may be eligible for a wide range of treatment options with varied benefits and risks to their physical, psychosocial and functional well-being. There is also variability in the current level of evidence about the benefits and risks of different treatment options. The number of available treatment options puts this population of patients at risk for cognitive overload and inability to discriminate differences in treatment options. At the time early stage prostate cancer is diagnosed, the ability to discriminate differences in treatment options is associated with lack of stability and regret about treatment choices (Feldman-Stewart et al., 2004). In patients with early stage prostate cancer decision aids have been found to facilitate patient ability to discriminate among treatment options over time, promote active involvement in treatment decision-making and lead to improved psychosocial well-being (O'Connor et al., 2007). Decision support interventions, as outlined in the ODSF, have the potential to address suboptimal and potentially modifiable

determinants of treatment decision-making by providing information, realigning expectations, clarifying values and providing guidance and coaching for patients with locally recurrent prostate cancer. As a consequence, the quality of decision-making and decision outcomes may be improved.

### **Available Decision Aids in Prostate Cancer**

It is necessary to determine whether there are existing programs to meet the decision support needs for patients with locally recurrent prostate cancer (Jacobsen & O'Connor, 2006). Several decision aids have been developed for patients living with prostate cancer. Currently, available decision aids are geared towards prostate cancer screening and treatment for early stage disease but not locally recurrent prostate cancer (OHRI, 2010). Appendix E provides a summary of existing decision aids that is categorized by patient target group, treatment options, methods of information delivery and evaluation data. Decision aids included in this summary are those that meet the minimum criteria as outlined by the Cochrane Systematic Review Group (OHRI). These decision aids have also been assessed using the International Patient Decision Aid Standards (IPDAS). The IPDAS is a systematic evaluation tool, developed by a collaboration of researchers, practitioners and stakeholders from around the world, to determine the quality of patient decision aids (Elwyn et al., 2006). International Patient Decision Aid Standards criteria are divided into three major categories: content criteria, development process criteria and effectiveness criteria. Appendix C provides the full version of the IPDAS.

Based on the IPDAS ( Elwyn et al., 2006), most of the decision aids in Appendix E meet at least 60% of the content criteria and 50% of the development criteria. Three out of six do not adhere to any of the effectiveness criteria while the other three only meet 50% of these criteria. As such, these decision aids may provide reliable health information based on content criteria, but may not be effective for ensuring that treatment decision-making is informed and value-based. To date, full understanding of the benefits and limitations of decision aids has yet to be achieved , and there are inconsistent outcomes, with some studies reporting no difference and others reporting improvement in selected outcomes. Increased understanding of factors that influence the effective use of decision aids would also help to improve their development and delivery. For patients with locally recurrent prostate cancer, an effective treatment decision aid would not only offer information about disease and treatment options, but would also provide patients with the necessary tools to assist in understanding, interpreting and applying the information to their personal situations.

## CHAPTER 3

### Methodology

#### Introduction

This chapter focuses on the study methods. A brief definition of a needs assessment is provided, followed by an outline of the study and setting. The methods for Phase 1 and Phase 2 are then presented in sequential fashion. A discussion about modifications to the initial data collection plan and methods precedes the Phase 2 discussion. For each phase, study methods related to the sample, recruitment, data collection, data analysis, rigour and ethical issues are described.

**Needs assessment.** One of the development criteria outlined by the IPDAS is to determine what information users (patient and practitioners) need to discuss treatment options (Elwyn et al., 2006). This criterion is consistent with Step 1 of the O'Connor and Jacobsen (2003) framework and is the focus of this study. Step 1 involves conducting a needs assessment to determine the decisional needs of patients and physicians related to the treatment for locally recurrent prostate cancer. In this study our attention is centered on assessing patient decisional needs only.

A need is defined as a gap between the current and desired state of affairs (Witkin & Altschuld, 1995). In the ODSF, decisional needs are associated with the type, timing and stage of decision-making and one's inclination to choose one option over the other. Other factors such as pre-existing decisional conflict, baseline knowledge and expectations, personal values and the importance individual patients place on the

outcomes of each option, can impact on the decisional need (O'Connor & Jacobson, 2003). Demographic characteristics and clinical functioning may also affect one's capacity for decision-making but these aspects may not be amenable to change. Decision support interventions have the potential to influence decision quality by providing information, realigning expectations and values and providing guidance and coaching in decision-making. The ODSF and role of decision support interventions for meeting patient decisional needs and optimizing the quality of their treatment decisions is illustrated in Appendix A.

A needs assessment is defined as a research activity designed to determine a patient population's or community's health service needs and utilization patterns, in order to identify gaps in service provision, establish priorities for the creation or modification of health services or programs, and plan service delivery (Myers, 1988). In the context of decision-making, Jacobsen and O'Connor (2006) emphasize that a needs assessment is a systematic process for discovering more about what a patient population needs in order to make better decisions about their health care.

### **Study Design**

The specific objective of the needs assessment in this thesis was to identify and describe the decisional support needs of patients and the opinions of physicians related to the treatment for locally recurrent prostate cancer at two Ontario regional cancer centres by answering the following research questions:

1. To what extent is there consensus among radiation oncologists about the treatment options to be included in a decision aid?



2. What are patients' and radiation oncologists' perceptions of the most important treatment decisions for patients?
3. What are patients' and radiation oncologists' perceptions about the most difficult aspects of treatment decision-making for patients?
4. What are patient and radiation oncologist perceptions about the barriers and facilitators patients experience in making treatment decisions?
5. What types of information do patients and radiation oncologists perceive as most important to include in a treatment decision aid?
6. What are patients' recommendations about how information should be provided to assist them in making treatment decisions?

This needs assessment involved a two-phase descriptive study employing both quantitative and qualitative methods. A qualitative descriptive approach described by Sandelowski (2000) was used to guide the collection and analysis of qualitative data in both phases of the study. Qualitative descriptive studies are less interpretative than other types of qualitative studies and aim to present the facts about a specific situation in everyday language. This approach was consistent with the focus of this needs assessment study to identify concrete and practical information about treatment decision-making for locally recurrent prostate cancer.

In Phase 1, a Delphi process was conducted to establish physician consensus on the specific types of available treatment options they offer to patients with locally recurrent prostate cancer. The Delphi process also identified physician perceptions of the most difficult and important patient decisions relevant to these treatments and the

potential barriers and facilitators patients encounter when making treatment decisions (O'Connor & Jacobsen, 2003). Physician recommendations for strategies to overcome challenges and barriers were also identified.

The Delphi process technique was identified as the best method of data collection for Phase 1 as it is a systematic approach designed to obtain consensus on the opinions of 'experts' through a series of questionnaires using a group facilitation technique (Hasson, Keeney & McKenna, 2000). It is a multistage iterative process that seeks to combine individual perspectives into group consensus on a given subject. The Delphi process typically involves two or three successive rounds of questioning in attempting to ensure stability of results and achieve consensus. Round 1 typically involves individual exploration of the complex subject or issue using a questionnaire. The researcher then summarizes the results and develops a new questionnaire for Round 2 based upon the summary from Round 1. These results are again summarized and the researcher attempts to gain an understanding of the group's views of the issue. If there is significant disagreement, a third round of questioning is conducted to give participants an opportunity to re-rank their answers based on the group responses (Jones & Hunter, 1995). The Delphi process is time saving as it usually eliminates the need for face-to-face meetings. Further, involvement in the Delphi process can be anonymous, which allows participants to contribute their own opinions without undue influence from interaction with peers.

In Phase 2, face-to-face interviews were conducted with patients to determine their decisional needs. Similar to the questions posed to physicians, the interviews

examined patients' perceptions of the most important and difficult decisions, barriers and facilitators to making decisions about treatment options and strategies to overcome challenges. Patient preferences about methods or formats for delivery of a decision aid were also examined (O'Connor & Jacobson, 2003).

Phase 1 and Phase 2 were complimentary and not discrete stages of data collection. Patient interviews occurred concurrently with the Round 1 of the Delphi process survey so that patient data could be used to inform questionnaire development for the next Delphi process round. The combined data from Phases 1 and 2 were used to summarize concepts that describe the decisional support needs of the patients and to make recommendations about the format and content to be included in a treatment decision-aid for patients with locally recurrent prostate cancer.

### **Setting**

Participants were recruited from the Genitourinary Disease Site Teams (GU-DST) at Grand River Regional Cancer Centre (GRRCC) and the Juravinski Cancer Centre (JCC). The GRRCC is located in the Waterloo-Wellington Local Health Integration Network (LHIN) in the Grand River Region of Ontario. It serves Waterloo Region, Wellington County, the City of Guelph and a small part of Grey County; a region with approximately 700,000 residents (GRRCC, 2007). Therapies offered at the center include systemic treatment, cancer surgery and radiation treatment. The GRRCC also offers supportive care services for patients and families including: pain and symptom management, social work, nutritional counseling, spiritual care, physiotherapy and occupational therapy.

The JCC is located in Hamilton, in the Central West Region of Ontario, and is responsible for the delivery of cancer services for over 1.7 million of residents in the Hamilton Niagara Haldimand Brant LHIN, including Burlington and the majority of Norfolk County (JCC, 2004). In addition to therapies similar to those provided at the GRRCC, the JCC also provides an extensive supportive and palliative care program, an ambulatory drug infusion program and an extensive research program that investigates the cause, prevention and effective management of cancer from the perspective of laboratory studies, clinical trial, supportive care and health services research (JCC).

Compared to the GRRCC, the JCC runs a larger and more established cancer program that is also part of an academic teaching hospital linked to McMaster University. The JCC is a tertiary care facility that serves a larger population base and receives referrals from a much wider geographic area than the GRRCC. Both of the LHIN regions associated with the JCC and GRRCC include rural communities and large urban centres (Hamilton Niagara Haldimand Brant, 2008; Waterloo Wellington Local Health Integration Network, 2008). However, the JCC serves a more culturally and linguistically diverse population (Hamilton Niagara Haldimand Brant).

### **Phase I Methods: Delphi Process-Survey**

#### **Sample, Sample Size and Sampling Strategy**

The goal of sampling in a Delphi process is to bring together a group of experts whose knowledge and experience can be applied to address a certain issue (Akins, Tolson & Cole, 2005). Therefore, Delphi process survey participants are purposefully selected for their expertise. In this study we invited all radiation oncologists responsible for the

care of patients with newly diagnosed locally recurrent prostate cancer at the GRRCC and JCC to participate in this study, rather than drawing a sample of them. We wanted to include the entire population of radiation oncologists due to their small numbers and the importance of their involvement in treatment decision-making.

### **Practitioner Recruitment**

From April 2009 to August 2010, a number of strategies were used to recruit radiation oncologists for Round 1 of the Delphi process survey. The student researcher provided information sessions at GRRCC and JCC to inform radiation oncologists of the study's goals and objectives prior to recruitment. Radiation oncologists were then identified and contacted by the head of the GU-DST in their respective settings to obtain their permission to be contacted by the student researcher. Once the radiation oncologists agreed to be contacted, they received a personalized electronic information letter outlining the purpose of study (see Appendix F). To increase recruitment, hard copies of individualized information letters, the consent form and the questionnaire were mailed to potential participants. Personalized questionnaires and letters have been found to increase response rates (odds ratio 1.16, 95% CI 1.06 - 1.28) in a systematic review of 292 randomized controlled trials (Edwards et al., 2002). The personalized letter was followed by electronic mail or a telephone call to outline expectations of the physician's participation and to schedule a face-to-face interview for Round 1 of the Delphi process. A confirmation letter detailing the date, time and location of the interview along with the interview guide was then mailed to participants (see Appendix G for confirmation letter and Appendix H for interview guide).

Radiation oncologists who participated in the study also received a small token of appreciation in the form of a twenty dollar bookstore gift certificate. The systematic review by Edwards et al. (2002) found that use of similar modest incentives more than doubled the odds of survey participation (odds ratio 2.02, 95% CI 1.79 – 2.27).

In October 2010 recruitment was done for Round 2 of the Delphi process. All radiation oncologists initially invited to participate in the Round 1 were given an opportunity to participate in Round 2 of the Delphi process. The participants were given two weeks to respond. Following the initial response, reminders were sent by electronic mail along with the questionnaire. Edwards et al. (2002) found that follow up contact (odds ratio 1.44, 95% CI 1.22 - 1.70) and providing non-respondents with a second copy of the questionnaire (odds ratio 1.41, 95% CI 1.02 -1.94) were effective strategies for increasing response to surveys.

### **Data Collection**

The Delphi process consisted of two rounds of data collection. Consistent with qualitative descriptive methods (Sandelowski, 2000), Round 1 of the Delphi process involved face-to-face interviews to identify information or facts about patient treatment decision-making needs for locally recurrent prostate cancer, from the perspective of radiation oncologists. Round 2 involved a survey of radiation oncologists using an electronic questionnaire. The data from Round 1 were used to generate the structured questionnaire for Round 2 Delphi process. It was necessary to develop a quantitative questionnaire for Round 2 as it allowed participants to rank their agreement with each statement or item in a numerically meaningful way (Jones & Hunter, 1995). These

rankings could then be statistically summarized and used to assess the level of consensus in Delphi process.

In Round 1, face-to face interviews were conducted with the radiation oncologists at both cancer centres. Usually the Delphi process survey approach allows the researcher to overcome the challenge of arranging a face-to-face meeting with participants. However, the small number of radiation oncologists required for participation in this study made it feasible to conduct interviews. Other Delphi process studies have successfully employed semi-structured interviews to allow an in depth exploration of the subject (Hasson et al., 2000). Interviews are an effective way of collecting in-depth qualitative data that can be used to inform the development of a quantitative questionnaire such as the survey needed for Round 2 Delphi process (Hasson et al., 2000). Interviews also provide an opportunity to build rapport between participants and the interviewer and to enlist participants' cooperation in subsequent phases of data collection (Fowler, 1993a; Fowler, 1993b; Witkin & Altschuld, 1995).

Interviews were scheduled at a mutually convenient time and were conducted by the student researcher. The interviews took 30 to 40 minutes to complete and occurred in a private meeting room at the respective cancer centres. At the beginning of each interview, the radiation oncologists were asked to complete a demographic questionnaire so that study participants could be accurately described (see Appendix I). All interviews were audio-taped to enable the interviewer to focus on listening to the participant rather than on note-taking.

The ODSF includes a standardized template for a semi-structured interview guide designed to elicit information (facts) about treatment decision-making needs (Jacobsen & O'Connor, 2006). The interview guide includes some closed-ended but mostly open-ended questions with prompts to examine common issues in treatment decision-making. The interview guide was modified to generate information specific to treatment decision-making in locally recurrent prostate cancer. For example, based on a review of the literature, the interview guide elicited information about all evidence-based treatment options available for patients with locally recurrent prostate cancer (Appendix D).

In order to avoid biasing responses and setting artificial limits on participants, the use of closed-ended questions in the Round 1 is usually not recommended. In this study, it was important to ensure that radiation oncologists were aware of and could comment on patient decisional needs related to all available treatment options even though some treatments might not have been readily accessible at a particular practitioner's institution. For this reason, the interview guide included a list of all known treatments for locally recurrent prostate cancer including standard therapies, experimental/investigational therapies and clinical trials. To minimize the potential for bias, radiation oncologists had an opportunity to identify additional treatment options they felt were relevant to this patient population.

The quantitative questionnaire for the Delphi process in Round 2 was developed based on the summary data from Round 1 and the patient interviews. It included five questions which aimed to gain consensus on the content and priority of information to be included in a treatment decision-making aid for this patient population (Appendix J). It



was not necessary to conduct a third round as there was agreement on the main issues identified. A flow sheet of the procedures followed during the data collection is in Appendix K.

### **Data Analysis: Delphi process Survey**

In keeping with qualitative descriptive methods described by Sandelowski (2000), content analysis was used to examine the qualitative data derived from open-ended interview questions in Round 1 of the Delphi process. More specifically, Burnard's (1991) thematic content analysis technique was used to systematically and objectively identify, label and record emerging themes and concepts. The themes and concepts were compared to identify similarities and differences, and similar concepts were grouped into categories to create a final coding scheme. The computer software program, N-Vivo, was used to organize and manage the qualitative data. Data generated from the Round 2 of the Delphi process were analyzed to determine the strength of the support for and importance of the selected options. This included the extent of agreement regarding treatment options to include in a treatment decision aid and perceptions of challenging and important decisional needs for patients.

Quantitative data from structured interview questions in Round 1 and from the questionnaire in Round 2 were analyzed using SPSS 17.0 statistical software. Descriptive statistics (frequencies and percentages) were utilized to produce statistical summaries for demographic data, interview and questionnaire items, and to assess consensus.

### **Measures to Ensure Rigour: Delphi process Survey**

*Achieving credibility, auditability and confirmability for qualitative data.* The credibility of qualitative data refers to the internal validity of the research (Polit & Beck, 2004). Internal validity refers to the soundness of research or the ability of the study to measure what is intended (Grimes & Schulz, 2002). Credibility of the qualitative data was ensured by member checking or returning to participants to seek verification of the findings (Polit & Beck). Member checking was used to ensure that the student researcher correctly interpreted the information provided by radiation oncologists during the interview. A summarized copy of the preliminary analysis from Round 1 was mailed to each radiation oncologist and an opportunity to clarify the student researcher's interpretation was provided. There was no feedback provided by the radiation oncologists hence implying their agreement with the preliminary analysis. The radiation oncologists who participated in Round 2 of the Delphi process survey also had an opportunity to re-rank their answers.

Triangulation is another strategy that was used to ensure credibility of study findings. Triangulation is “a process of using multiple perceptions to clarify the meaning” or to interpret phenomenon as described by study participants by recognizing the diverse ways the phenomenon is viewed (Denzin & Lincoln, 2003, p.148; Sandelowski, 1995). Triangulation strategies used in this study included reviewer or investigator triangulation, the comparison of results with those of the previous studies conducted on this patient population and comparison of physician and patient interview data. Polit and Beck (2004) define investigator triangulation as the use of two or more researchers to make data

collection, coding and analytic decisions. In this study, two additional reviewers (both professors at McMaster University with combined research experience in prostate cancer of over 20 years) assisted with analytic decisions to ensure credibility of findings.

Theoretical triangulation refers to the use of multiple theoretical perspectives to draw inferences from data or the use of multiple professional perspectives to interpret a single use of data (Watson, McKenna, Cowman & Keady, 2008). In this study, the theoretical and clinical relevance of findings were assessed by comparing study results to existing literature.

Auditability and confirmability of the data were enhanced by the use of a decision trail (Polit & Beck, 2004). Auditability or dependability refers to the consistency and stability of data while confirmability refers to objectivity or neutrality of the data in that it is free of research bias. The student researcher maintained a journal to enhance the explicitness and congruence of the data analysis and interpretation process. Auditability and confirmability were also ensured by peer review of the research process at regularly scheduled meetings throughout the study with the student's supervisor and thesis committee (Creswell, 1998).

***Reliability and validity of quantitative data.*** Round 2 of the Delphi process included collection of descriptive quantitative data using close-ended questions to assess physician consensus on the content and priority information to be included in a treatment decision aid for this patient population. Reliability refers to the extent to which the findings of quantitative studies are reproducible under constant conditions on all occasions (Polit & Beck, 2004). Hasson et al. (2000) found that a limitation of surveys

used in a Delphi process is the inability to demonstrate reliability of the results. Conversely, Jones and Hunter (1995) found that the criticisms by Hasson et al. were aimed at poor study quality rather than the actual methodology. In the current study, methods to enhance reliability included application of the ODSF and adaptation of its needs assessment interview guide and strategies to ensure a maximum response rate. The challenging of participant assumptions that occurs in the iterative process in each consecutive Delphi process round helps to enhance internal validity because multiple people are less likely to arrive at a poor decision than a single individual (Hasson et al., 2000). In addition, knowledgeable participants and the use of consecutive rounds of questionnaires enhance the content and concurrent validity of the Delphi process. The radiation oncologists had an opportunity to re-rank their agreement with each statement in the Round 2 questionnaire. Results were compared to existing literature to further enhance content validity.

***Ethical issues.***

*Process for obtaining consent.* Consent to the conduct the study was obtained from both the Hamilton Health Sciences/McMaster Faculty of Health Sciences Research Ethics Board (REB) and the GRRCC Tri-Hospital Research Ethics Board (THREB). Written consent to participate in the study was obtained from each radiation oncologist prior to the initial one-on-one interview (see Appendix L for information sheet/consent form). The consent form included a telephone number to call if the participant decided to discontinue participation and did not want further contact. To ensure ongoing informed consent, at each data collection point participants were reminded of the voluntary nature

of their participation. In Round 2, an electronic copy of the information sheet/consent form was attached to the questionnaire.

*Maintaining confidentiality for study participants.* Participants were asked to complete a brief demographic questionnaire before commencement of the interview. They were informed that the interviews would be audio-taped and transcribed by an experienced transcriptionist who signed a confidentiality agreement. In addition, an identity code would be assigned to all transcripts and any identifying information provided during the interview would be removed from the transcripts. They were also informed that the study data would be accessible only to the researcher and research team and it would be kept in a locked filing cabinet in the thesis supervisor's office. Finally, participants were told that the audio-tapes would be destroyed after a ten year period in accordance with Hamilton Health Sciences/McMaster Faculty of Health Sciences REB guidelines.

In Round 2, to ensure a greater than 70% response rate for the questionnaire, non-respondents were followed up with reminders and thus it became necessary for the student researcher to know the identity of participants. Therefore the participants' judgments and opinions remained confidential but not anonymous (McKenna, 1994 as cited in Hasson et al.). Due to the small sample size, only aggregate data rather than practice setting-specific information was reported so that individual physicians could not be identified.

### **Phase 2 Methods: Patient Interviews**

Focus groups and/or interviews using minimally to moderately structured open-ended questions are the most common methods for collecting data in qualitative descriptive studies (Sandelowski, 2000). The initial plan was to conduct focus groups because the dynamic and interactive exchange among participants has the potential for synergy that can produce multiple stories from diverse experiences (Brown, 1999). This creates an atmosphere in which more ideas and data can be generated than will be obtained by individual interviews. It also allows the collection of in-depth data through active listening of the moderator, as participants share and compare experiences, feelings and opinions (Morgan & Krueger, 1998). As with all research methodologies, focus groups have some limitations. The logistics of planning focus groups is resource intensive and participants may be uncomfortable sharing personal information with a group of stranger (Morgan & Krueger). Due to the small number of patients receiving treatment and the length of time between appointments, it was not possible to recruit sufficient numbers of patients for a full focus group for this study. Thus it was necessary to modify the methods for data collection. Patients who were originally invited to participate in a focus group completed a joint interview with one other patient or a one-on-one interview. The joint interviews were advantageous because they provided an opportunity for patients to interact by sharing opinions and comparing experiences hence generated more data compared to the individual interviews. All subsequent patients were invited to participate in a one-on-one interview only.

Interviews were an appropriate method of data collection for this needs assessment because they elicit in-depth information from participants regarding their perceptions, feelings and thoughts about a phenomenon (Holloway & Wheeler, 2002). Interviews have the potential of giving patients an opportunity to reflect on their experience and their response to it. This methodology has been previously used to study patient-focused decision-making in early-stage prostate cancer involving a cognitive based decision aid (Feldman-Stewart et al., 2004) and information-seeking behavior among individuals with cancer (Lambert, Loiselle & Macdonald, 2009). The methods section below focuses on the methods related to interviews only and not focus groups

### **Sample and Sampling Strategy**

Sampling in qualitative descriptive studies and for interviews is usually purposive with a goal of selecting individuals who can provide rich in-depth information about the topic of interest; thus representativeness is not assured (Holloway & Wheeler, 2002; Patton, 1990). Two sub-groups of purposive sampling were used; criterion and maximum variation sampling. Polit and Beck (2004) describe criterion sampling as studying cases that meet a predetermined criterion of importance and this was demonstrated by including patients who were receiving or who had completed treatment for locally recurrent prostate cancer at the GRRCC or JCC. Maximum variation sampling involves ensuring that people with diverse backgrounds are represented in the sample so as to capture different perspectives on the issue. This was demonstrated by aiming to recruit patients with diverse demographic characteristics related to age, gender, education, marital status, ethnicity, occupation, locale and health status. Patton asserts that no guidelines exist for

sample size in qualitative research as this depends on the research question and achieving data saturation. Data saturation occurs when themes and categories become redundant or when no new information is generated from data collection (Polit & Beck). However, Holloway and Wheeler suggest that six to eight participants are adequate for a homogenous sample, such as patients who have received treatment for locally recurrent prostate cancer.

### **Patient Recruitment**

From May 1, 2009 to August 31, 2010, men receiving treatment for locally recurrent prostate cancer at the GRCC and JCC were approached by the nurse or radiation oncologist to participate in the study during their regularly scheduled clinic appointments. A brief screening tool was provided to the primary nurse and radiation oncologist teams to assist them in identifying eligible patients (see Appendix M). The radiation oncologists obtained patients' permission to be contacted by the student researcher. The student researcher contacted interested patients by telephone to explain the study purpose, potential risks and the nature of participant involvement (see Appendix N). Patients who agreed to participate were asked to provide their preferences for the timing and location of their interview. They also received a mailed confirmation letter detailing the date, time and location of the interview (see Appendix O). To minimize attrition, patients received a reminder telephone call before the scheduled interview to confirm their attendance. At the conclusion of the interview, participants were provided with a small token of appreciation in the form of a twenty dollar bookstore gift certificate. Participants were also reimbursed for parking and did not incur any other costs.



### **Sample Size**

It was anticipated that a minimum of six to eight participants would be required to capture the full range of patient issues. To achieve data saturation, we were prepared, if necessary, to increase the sample size.

**Inclusion criteria.** Eligible patients were those who had received salvage treatment for locally recurrent prostate cancer in the last two years, following initial curative treatment with radical radiation therapy. Specifically, this included patients who had pathologically confirmed low or intermediate risk prostate cancer at time of diagnosis (patients with initial PSA < 20, Gleason score  $\leq$  8 and no T3 tumor) and no clinical or biopsy evidence of distant metastases at the time of recurrence (NCCN, 2008). Gleason scores range from 2 to 10 and they indicate how likely it is that a tumor will spread. The lower the Gleason score the more similar the cancer tissue is to normal prostate tissue and the tumor is less likely to spread and vice versa (NCI, 2010). Recurrent disease is defined as biochemical failure or relapse after treatment that was given with curative intent (NCI). Other eligibility criteria included a PSA level of 10 or less within the previous six months. Eligible patients were also able to speak, read, and understand English and had the physical and cognitive abilities to participate in a 60 minute interview.

**Exclusion criteria.** Men who were ineligible for this study were defined as those who had developed recurrent disease following initial treatment of radical prostatectomy. The standard treatment for recurrence post-prostatectomy is radiation therapy which is still curative. This group has a better prognosis than those with recurrent disease

following radiation therapy alone, and has different treatment options and issues to consider in the decision-making process compared to the patients included in this study.

### **Data Collection**

In this study, patients participated in an individual interview or an interview with one other patient. At the beginning of all interviews, patients completed a brief demographic questionnaire (see Appendix P). During the interviews, patients were asked to describe their past and present experiences with treatment decision-making related to locally recurrent prostate cancer, the challenges they experienced during the decision-making process and the resources they used for support. Recommendations for improving supports provided to patients during the treatment decision-process were also explored (see Appendix Q).

The interviews took 30 to 60 minutes to complete. The length of interview time varied according to different patient experiences. Interviews involving two participants were also longer than those with one participant. Holloway and Wheeler (2002) suggest that interviews should be approximately 60 minutes long to allow in depth exploration of the topic. The interviews were taped using two digital audio recorders, one as primary recording device and the other as backup. Afterwards, the recordings were transcribed verbatim by a professional transcriptionist. The student researcher also reviewed and edited the transcripts to ensure accurate grammar, punctuation and spelling and the completeness of transcript data while listening to the digital recordings.

The student researcher, who is an experienced practitioner in neuro-surgical nursing (but not in prostate cancer), completed all of the patient interviews. As a seasoned

nurse with 5 years of experience, the student researcher has conducted many patient interviews but not for the purpose of research. Strategies employed during the interviews included: asking questions in simple and clear language, being sensitive and open-minded, steering the dialogue to stay focused on treatment decision-making needs, being critical in order to challenge participants responses if necessary, interpreting and clarifying participants' statements without imposing meaning on them and being balanced in the dialogue so that participants are not overwhelmed (Kvale & Brinkmann, 2009).

The semi-structured guide used to facilitate the interviews was adapted from the standard template from the ODSF for eliciting needs (see Appendix Q) (Jacobsen & O'Connor, 2006). The semi-structured interview guide enabled similar types of data to be collected from all participants (Holloway & Wheeler, 2002) and was used to keep the participants focused on the study objectives without stopping the natural flow of ideas. The semi-structured interview guide had built-in prompts to facilitate the conversation and encourage participants to explore topics in greater depth. Important social skills used by the interviewer to collect high quality data included active listening and non-verbal prompts such as maintaining eye contact and the use of silence (Kvale & Brinkmann, 2009).

### **Data Analysis: Patient Interviews**

The computer software program, NVivo 8 was used to organize, manage and code the transcribed interview data in an efficient manner. Consistent with methods for qualitative descriptive studies (Sandelowski, 2000), Burnard's (1991) thematic content analysis method was used to analyze the transcribed data. Concepts from all the

interviews were compared to identify similarities and differences, and similar concepts were grouped into themes or categories to create a coding scheme.

Investigator triangulation was utilized to assess the consistency of identified themes and to obtain reviewer consensus on the final coding scheme and themes. Three reviewers, including the student researcher, thesis supervisor and a committee member, independently analyzed the data to identify categories and themes related to specific decisional needs for each identified treatment option, patient perceptions about the most important and difficult decisions, barriers and facilitators to making decisions about treatment options, strategies to address any challenges, and patient preferences about methods or formats for how a decision aid should be delivered. In cases of reviewer disagreement the entire thesis committee was consulted. Concurrent data collection and analysis enabled verification and clarification of redundant and emerging themes or questions and to determine when data saturation was reached.

### **Measures to Ensure Rigour: Patient Interviews**

**Achieving credibility.** The criteria for ensuring rigour of qualitative research are defined in the description of Phase 1 methods Delphi process survey section. Similar to the interviews with radiation oncologists, the student researcher demonstrated bracketing by identifying and describing any personal biases at onset and during the study that might influence the collection, analysis and interpretation of the data. For example, the student researcher believes that it is important for patients to actively participate in treatment decision-making. The student researcher also engaged in ongoing bracketing through use of a journal throughout the study. In addition, member checking with patient participants

was done by summarizing the interview data at the end of the interview and giving participants a chance to clarify the student researcher's interpretation. Member checking was also done by presenting study results to a prostate cancer community patient support group.

**Achieving fittingness or transferability.** Similar to the Delphi process, detailed demographic information about the study participants was collected and reported, to allow readers to determine whether study findings are transferable to their settings. In addition, a detailed description of the context in which care was given has been provided.

**Achieving auditability and confirmability.** The use of a decision trail in the form of a journal maintained by the researcher enhanced explicitness and congruence of the data analysis and interpretation (Polit & Beck, 2004). The steps and rationale for decisions made during the research process were recorded in a journal along with details about literature searches, data collection, data coding and analysis.

**Ethical issues.**

***Process for obtaining consent.*** Informed written consent by patient participants was obtained by the student researcher on the day of the interviews (see Appendix R). Prior to the interview, the information sheet/consent form outlining the purpose and voluntary nature of the study was reviewed with potential participants. Strategies to ensure confidentiality were also reviewed. In addition, data management plans and the use of a digital audio recorder to record the interview were discussed before commencement of each session to ensure that all participants were aware of this process.

The participants were also reminded that the student researcher was not employed by or associated with either practice setting.

The participants were reminded that they could withdraw at any time during the interview and that all data collected up until their withdrawal would be included in the data analysis. In addition, participants were reassured that their participation or withdrawal from the study, would in no way influence their healthcare.

When the data collection method changed from focus groups to interviews, an amendment of the proposal and a revised information sheet/consent form were submitted and approved by REB (see Appendix S).

*Maintaining confidentiality for study participants.* Participants were asked to complete a brief demographic questionnaire before commencement of the interview. No information was collected that could identify the participants. Participants were given a numbered identity code and only these codes were transcribed to further ensure confidentiality. When two patients participated in an interview, both were identified separately in the transcripts and in the analysis using a number code (i.e. patient 1, patient 2). The transcriptionist also signed a confidentiality agreement. Only the student researcher, thesis committee members and the transcriptionist had access to the audio digital data and interview transcripts. The CDs containing audio digital data and transcripts were stored by the thesis supervisor in a locked filing cabinet in a secured office.

Participants were also informed that the interview audio digital data would be destroyed after the ten year minimum recommended by REB. The participants were

reassured during the interview that their responses would not be communicated to their healthcare team. The student researcher and thesis committee members were not involved in the care of this patient population.

Possible benefits patients may have experienced through their study participation included the satisfaction of knowing they have contributed new knowledge about the needs of men with locally recurrent prostate cancer and ways to improve their treatment decision-making: this was conveyed to the participants during the consenting process. In similar studies, participants have often reported therapeutic benefits such as increased personal insight and/or improved understanding of an issue following their involvement in focus group discussions or in-depth interviews (Morgan & Krueger, 1998). Patients were also informed of the potential to experience emotional upset when describing their concerns and they were made aware that if this occurred we could 1) take a break or discontinue interview, and 2) assist them to contact family physician or cancer care team for further support if required.

In summary, this chapter has described the study methods for Phase 1 and Phase 2 in detail including rationale for modification to the initial data collection plan for Phase 2. In Phase 1, a two round Delphi process was conducted to establish physician consensus on the specific types of available treatment options they offer to patients with locally recurrent prostate cancer. In Phase 2, interviews were conducted with patients to determine their decisional needs. Burnard's (1991) thematic content analysis was used to analyze the qualitative data and quantitative data were analyzed using SPSS statistical software. Various measures were taken to ensure a rigorous and ethical study

environment. The next chapter will present the study findings from Phase 1 and Phase 2 of data collection.



## CHAPTER 4

### Results

This chapter describes the results of all data collected during Phase 1 and Phase 2 of this study. First, Phase 1 results are presented including a description of physician participants and the three main content themes identified from Round 1 of the Delphi process. A summary of the participants' characteristics and the results of Round 2 of the Delphi process then follows. This chapter concludes with Phase 2 results. The characteristics of patient participants are described and the five main themes generated from the content analysis of the interviews are reported.

#### **Phase 1 – Delphi Process Survey Round 1**

**Physician participants.** Of the ten radiation oncologists eligible for the study, three consented to participate and were interviewed for Round 1 of the Delphi process. Two of the radiation oncologists worked at the JCC and one worked at GRCC. Individually, they had 7 to 16 years of experience in providing treatment for men with prostate cancer. All three oncologists described their role as providing patients with information, emotional support and consultation about various treatment choices (Table1). There was less consistency in radiation oncologists' reported roles related to coordination of care and referral for psychological counseling and support.

Table 1

*Characteristics of Radiation Oncologist Roles*

<b>Role activities</b>	<b>Participants n = 3</b>
Radiation therapy	3
Consultation about various treatment choices	3
Coordination of care	1
Consultation with health care team	3
Emotional support	3
Psychological counseling and support	1
Information	3
Family support	2

**Delphi process survey results – Round 1.** The following section describes the results from physician interviews in Round 1 of the Delphi process. Three main themes were identified and used to develop the questionnaire for Round 2 of the Delphi process. The main themes include: the decision to be made, the perceived role of others in treatment decision-making and resources for treatment decision-making.

*Perception of the decision to be made.*

*Treatment options.* Radiation oncologists recognized that patients had a number of treatment options available to them, and thus, there was a treatment decision to be made. Radiation oncologists perceived that they provided information about a range of treatment options relevant to the patient's specific situation. The patient's prior treatment for prostate cancer influenced the treatment options that were presented. As one radiation oncologist explained:

If they were treated primarily with radiation, the real option comes down to

observation versus hormone therapy. There are theoretical options such as salvage prostatectomy, brachytherapy implant, surgery, HIFU and other things. It primarily comes down to keeping an eye on the PSA and/or starting hormone therapy.

*Time.* Radiation oncologists reported that clinic days were very busy but felt they had enough time to provide patients with adequate information about treatment choices. Patients were provided with treatment information and if a patient needed more time to think about the treatment options, another appointment was made to clarify outstanding concerns. Radiation oncologists also noted that for many patients there was no rush to make a treatment decision and described the treatment decision-making as a process similar to that of a *slow conversation* that took place over several visits.

*Factors that influence treatment decision-making.* In addition to prior treatment, radiation oncologists identified other factors that influenced treatment decision-making related to patient characteristics (i.e., age) and disease. Disease-related factors included co-morbid conditions and the rate at which the PSA was rising.

The lack of sufficient evidence-based data about the effectiveness or superiority of different treatment options was also identified as a challenge in providing treatment information. Radiation oncologists reported that there were few randomized control trials on the effectiveness of secondary treatments for recurrence compared to those on initial primary therapies for prostate cancer.

Radiation oncologists revealed that they provided information to patients on the pros and cons of various treatments, relevance of the PSA and options to participate in

clinical trials. In the following example a radiation oncologist describes how patient preferences and availability of clinical trials can influence what information is shared with patients:

If the PSA is going up fast or if they aren't keen on participating in anything [treatment], then participation in the E-Lat study of early vs. late hormone therapy [is an option]. And I sort of explain this as well the other theoretical options. For the most part [theoretical options] only apply to men with low-risk disease because if radiation failed to eradicate the disease then almost all the other treatments would fail as well. And [theoretical options] have a really high rate of incontinence. So if they want more information [about these options] I'll tell them for the most part, or refer them on to someone else. But for the most part they are happy to keep going into E-Lat study.

Radiation oncologists referred patients for alternative treatment options on a case by case basis. As one radiation oncologist said, "I've sent people to Toronto, to Dr. X for cryosurgery because they have a study going on there... And no one's [been randomized to] it yet."

When radiation oncologists encountered patients who were having difficulty with the decision or needed more information, they would occasionally refer them to a specific informational website such as the Cancer Care Ontario or British Columbia Cancer Agency websites. However, they rarely reported referring patients for additional counseling, even though they were aware that supportive care services such as this were available.

Radiation oncologists also acknowledged that uncertainty about achieving a specific outcome or the risks of experiencing certain toxicities and side effects, made treatment decision-making challenging for them and their patients. Radiation oncologists relied heavily on retrospective treatment data. They were often faced with patients who had several treatment options but no data to identify the superior or optimum treatment. The need for randomized control trials to provide more accurate data about the best treatment options for their patients was identified. As these two radiation oncologists explained:

Oncologist 1: I think the best way would be if we had randomized data to show what the optimum treatment is. That would be huge!

Oncologist 2: I think in terms of lack of information, I think that's also the lack of information for physicians as well. I'm not aware of any randomized trials that tell us which of those options [is best or] if there are any superior options or not.

***Perceived role of self and others in treatment decision-making.*** Radiation oncologists identified themselves as the primary source of treatment information for their patients. One radiation oncologist said, “it’s really just the conversation that we have, it would be the vast majority of information that [patients] are given.” Radiation oncologists felt that an important aspect of their role was to help patients understand why they were not candidates for certain treatments even after the treatment decision had been made. One radiation oncologist commented:

I find in the review clinic that I’m often spending time sort of deconstructing their learning and trying to tell them, “Look what you got was appropriate for you,

what somebody else is getting is appropriate for them.” But prostate cancer is a disease with an enormously large continuum of aggressiveness and the appropriate treatment is very variable between patients. [I am] not saying we don’t have guidelines, but those guidelines are very patient-population specific.

Radiation oncologists noted that spouses often accompanied men to their appointments but children only did so occasionally. Spouses acted as a source of emotional support and sometimes participated in treatment decision-making. One radiation oncologist described a spouse providing emotional support to an overwhelmed husband by saying, “Calm down and we are just going to come back in six months and let them know that’s what [treatment] we’re doing.” In this situation the spouse helped to calm her husband and remind him that there was no urgency in making the treatment decision.

***Resources for treatment decision-making.*** Radiation oncologists agreed that there was a need for increased support during treatment decision-making. In keeping with patient-centred care and the drive from consumers for more information, some radiation oncologists felt an information source that was kept current through research updates would be useful. They also suggested what to include in the resource, namely: information on treatment options; benefits and effectiveness; and the likelihood, severity and impact of treatment side effects on quality of life and function. One radiation oncologist spoke about the possible benefits of take-home information for patients to review, “I think having potentially more information for them to take home ... to give to their wives more often than not, and to make sure everyone is happy, would be

reasonable.” Other participants concurred and added that the information provided should be open-ended and not leading or directing the patient towards a specific treatment option.

When discussing the possibility of a centralized information source for patients radiation oncologists identified the main treatment options as watchful waiting and hormone therapy. Other treatment options included *theoretical options*, such as HIFU and cryotherapy. They also agreed that information about treatment toxicity was important to include in patient education materials. As this radiation oncologist explained:

Toxicities are important. So even for hormone therapy we go through the whole toxicities. You know the efficacy would be important because you know, some men obviously and their wives are concerned when the PSA is going up. ... So I explain, you know, the blood tests will go down, the cancer will stay away longer but whether you live longer or live better is a completely other matter.

Information about the time and follow up involvement required for certain treatments was also identified as an important factor to consider. Such information was seen as important to help patients make treatment decisions that best fit their lifestyle.

This radiation oncologist explained:

[Patients need] a description of the logistics... Because if they are still working, especially if you own your own business, you just don't have the time to take off to get a prostatectomy. And so for those guys they might just be interested in either just watching or you know, maybe getting a little bit of hormone treatment, every six months.

In summary, radiation oncologists in the Round 1 of the Delphi process perceived that there are several treatment options available for patients with locally recurrent disease; thus, there is a treatment decision to be made. The radiation oncologists identified themselves as the primary source of treatment information and they felt that they allowed enough time during clinic to provide treatment related information to patients. They also spoke about several prior treatment, patient and disease-related factors that influenced treatment decision-making. Radiation oncologists identified lack of sufficient evidence about superiority of different treatment options as the primary challenge to providing treatment information to patients. They also recognized the need for increased support during treatment decision-making through resources such as take-home information or a centralized information resource. In the next section the results of the Round 2 of the Delphi process are reported.

### **Phase 1 – Delphi Process Survey Round 2**

**Physician participants.** Eight of the ten radiation oncologists eligible to participate in the study were contacted by electronic mail for Round 2 of the Delphi process, of which four completed the electronic questionnaire. Two radiation oncologists were not approached because they declined study participation in Round 1. All three radiation oncologists from Round 1 participated in Round 2. No additional demographic data were collected in Round 2.

**Delphi process survey results – Round 2.** The questionnaire for Round 2 of the Delphi process was developed from key findings identified in Round 1 of the Delphi process and from patient interviews. The first question aimed to seek consensus on



treatment options to be included in a treatment decision aid for patients with locally recurrent prostate cancer. There was agreement among radiation oncologists that watchful waiting and clinical trials should be included in a treatment decision aid. The majority of the radiation oncologists also supported the inclusion of prostatectomy and HIFU, but were divided about the inclusion of re-irradiation and ADT. Fewer radiation oncologists felt that cryotherapy should be included as a treatment option. All radiation oncologists agreed that Tookad should not be included in a treatment decision aid at the present. The above results are summarized in Table 2.

Table 2

*Radiation Oncologist Consensus on Treatment Options to Include in a Decision Aid for Patients with Locally Recurrent Prostate Cancer*

<b>Treatment option</b>	<b>Yes n = 4</b>	<b>No</b>
Watch and wait	4	0
Prostatectomy	3	1
Re-irradiation (brachytherapy)	2	2
Cryotherapy	1	3
High-intensity Focused Ultrasound (HIFU)	3	1
Light activated Tookad	0	4
Clinical trial	4	0
Androgen deprivation therapy	2	2

The second question asked participants to rate how frequently patients in their practice experienced specific challenges or difficulties during treatment decision-making (Table 3). Lack of good research-based information about the effectiveness of treatment options and the likelihood of treatment side effects were identified by most participants as frequent challenges experienced by patients. Psychological distress (emotional liability) and lack of problem-solving skills or cognitive ability to make this type of decision were

also thought to occur somewhat frequently. Confusion due to information overload, and to a lesser extent, patient understanding about their treatment goals and readiness to make a decision, were reported as frequent challenges experienced by patients. Treatment decisions were often seen to be complicated by consideration of family needs and preferences or pressures from others to make certain treatment decisions. Treatment decision-making challenges resulting from psychological distress and mental health disorders were identified as a less common and rarely occurring issue.

Table 3

*Radiation Oncologist Perceptions of the Frequency of Patient Challenges During Treatment Decision-Making in Round 2 of the Delphi process*

Patient challenges	Rating by radiation oncologist (n = 4)				
	1	2	3	4	5
Lack of good research-based information about the effectiveness of treatment options	0	0	1	2	1
Lack of good research-based information about the likelihood of treatment side effects	0	1	1	1	1
Confusion due to information overload	1	0	2	1	0
Unsure about their treatment goals and what is most important to them	0	3	1	0	0
Feel pressure from others to make certain choices (e.g. family, friends, health care providers)	1	2	1	0	0
Don't feel ready to make a decision	0	2	1	1	0
Lack the problem solving skills or cognitive ability to make this type of decision	0	4	0	0	0

Wanting to choose on the basis of family needs/preferences	0	2	2	0	0
Other responsibilities	0	4	0	0	0
Psychological distress (emotional labile)	1	2	0	1	0
Mental Health Disorders (anxiety, depression)	2	2	0	0	0

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*Note.* 1 = Never, 2= Somewhat Frequently, 3= Frequently, 4= Very Frequently and 5 = Always

The third question asked participants to indicate the level of importance they would give to specific patient characteristics and resources that facilitate patient treatment decision-making (Table 4). External and other resources related to the patient's social network were rated as important in treatment decision-making. There was some variability in the perceived importance of personal resources related to previous experience, self-confidence and emotional health. In contrast, there was more agreement among participants that physical, social and cognitive health were important aspects for enabling patient treatment decision-making.

Table 4

*Radiation Oncologist Perceived Importance of Patient Characteristics and Resources for Facilitating Patient Treatment Decision-Making*

Patient characteristics and resources	Rating (n = 4)				
	1	2	3	4	5
<b>Personal resources:</b>					
Previous experience with the situation	2	0	1	0	1
Self-confidence	2	1	0	0	1
Skill in decision making	0	4	0	0	0
Physical health	0	1	0	1	2
General emotional health	0	3	1	0	0
Good analytic skills (cognitive health)	0	0	3	1	0
Good social connections (social health)	0	0	4	0	0
<b>External resources:</b>					
Availability and access to information	2	0	2	0	0
Advice from formal health care system	0	0	3	1	0
Advice from social network (e.g. family, friends)	0	1	3	0	0
Emotional support	0	0	3	1	0
Help with practical things (e.g. transportation to appointments)	0	0	2	2	0
Financial assistance	0	1	1	2	0
<b>Other resources:</b>					
Social network (e.g. family, friends)	0	0	3	1	0
Support groups	0	1	1	0	2
Voluntary agencies (e.g. motorcycle ride for dad)	2	1	1	0	0
Formal health care system	0	0	2	2	0
Formal and informal education sessions	0	0	3	1	0

*Note.* 1 = Not important, 2= Somewhat Important, 3= Important, 4= Very Important and 5 = Extremely Important

The fourth question asked the participants to identify their agreement on the individuals who should participate in the treatment decision-making process (Table 5).

The radiation oncologists agreed that the patient, spouse and health care provider (treating physician) should be involved in the treatment decision-making process. The majority of

radiation oncologists agreed that children and the family physician or primary care provider should also be involved while only half thought that friends should participate in this process.

Table 5

*Radiation Oncologist Perceptions of Who Should Participate in the Treatment Decision-Making Process*

Individuals	Yes n= 4	No
Patient	4	0
Spouse	4	0
Family (children)	3	1
Friend	2	2
Health care provider (treating physician)	4	0
Family physician or primary care provider	3	1

The fifth question asked the participants to identify their agreement on the types of information to include in a treatment decision aid (Table 6). There was 100% agreement to include information about treatment benefits and effectiveness; the likelihood, severity and impact of treatment side effects on quality of life and function; and the personal relevance of each treatment option for individual patients. The majority of radiation oncologists agreed on the inclusion of information about prognosis or life expectancy and a description of the treatment protocols, process and logistics (i.e. preparation required, costs, and number of treatments). All participants agreed that information about enrolling in clinical trials should not be included in a treatment decision aid.

Table 6

*Types of Information that should be Included in a Treatment Decision Aid*

<b>Types of information to be included</b>	<b>Yes n= 4</b>	<b>No</b>
The benefits of each treatment option	4	0
The effectiveness of each treatment option (response rate)	4	0
Possible side effects of each treatment option	4	0
Likelihood of side effect occurrence for each treatment option	4	0
Likelihood of side effect severity for each treatment option	4	0
Eligibility or relevance of all available treatment options for each patient's personal situation	4	0
Prognosis or life expectancy	3	1
A description of the treatment protocol, process and logistics (preparation for, costs, and number of treatments)	3	1
Potential impact on quality of life (minimal treatment side effects)	4	0
Potential impact of treatment option on physical function	4	0
Information on participating in a clinical trial (drug study)	0	4

In summary, the radiation oncologists agreed that watchful waiting and clinical trials should be included in a treatment decision aid for patients with locally recurrent prostate cancer and that Tookad should not. They all agreed that information on enrolling in clinical trials should not be included in a treatment decision aid. Although radiation oncologists recognized that patients experience several challenges during treatment

decision-making, the lack of good research-based information about the effectiveness of treatment options and the likelihood of treatment side effects were reported to frequently occur. This challenge impacts on the quality of information that radiation oncologists can give to their patients and subsequently impacts the quality of decisions patients make. There was agreement among the radiation oncologists that physical, social and cognitive health were important aspects for enabling treatment decision-making, which in turn impacts on optimal health and well-being of patients. Finally, there was agreement among radiation oncologists on the type of information to include in a treatment decision aid. This included information about treatment benefits and effectiveness; the likelihood, severity and impact of treatment side effects on quality of life and function; and the personal relevance of each treatment option for individual patients. In the next section, the results of Phase 2 are reported.

## **Phase 2 – Patient Interviews**

**Patient participants.** A total of eight men who met the eligibility criteria were approached and five consented to participate in the study. Emotional distress was given as the reason for non-participation. Our initial intent was to conduct focus groups; four men participated in interviews with one other patient. One man participated in an individual interview after method of data collection changed. After 15 months of recruitment, the study was closed due to slow enrolment. The interviews took 30 to 60 minutes to complete and were held at the patients' respective cancer centres. Two men were interviewed at GRRCC and three at the JCC.

Patient participants were Caucasian men aged 71 to 84 years of age who had completed high school and/or university education (Table 7). The majority of these men were married, lived with a spouse or family member and were retired. All participants had at least one co-morbid condition such as high blood pressure, diabetes, and/or circulatory problems. Two men had more than one co-morbid condition (Table 8).

Table 7

*Patient Demographics Characteristics (N=5)*

<b>Characteristics</b>	<b>Range or Frequency (n)</b>
Age range (years)	71-84
Education	
Grade School	1
High School	2
University	2
Race	
Caucasian	5
Marital Status	
Married	4
Widower	1
Number of children (Mode)	2
Living arrangements	
With spouse	4
With family	1
Employment Status	
Retired	4
Working full-time	1



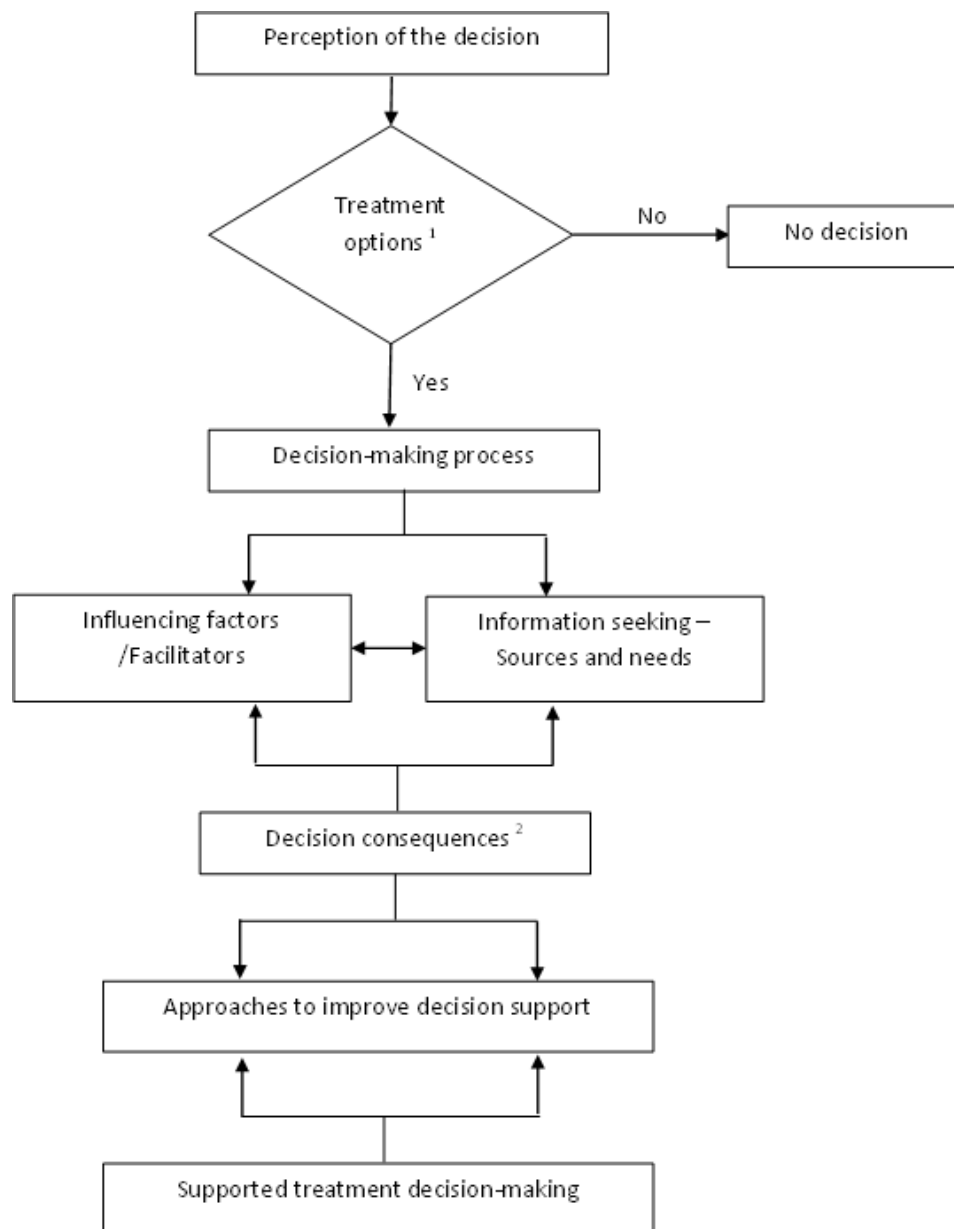
All five patients had received external beam radiation at the time of initial diagnosis of prostate cancer and three patients had received a second course of radiation. Most participants were currently engaged in watchful waiting and one patient was receiving radiation therapy for the second time (Table 8).

Table 8

*Health and Prostate Cancer Treatment History of Patient Participants*

<b>Characteristics</b>	<b>Participants (N = 5)</b>
<b>Co-morbid health conditions</b>	
Diabetes	2
Breathing	1
Circulation	1
Heart	1
High Blood Pressure	2
Arthritis	1
Vision	1
<b>Number of co-morbid conditions</b>	
None	1
One	2
Two	1
Five	1
<b>Treatment received in the past</b>	
External Beam Radiation Therapy	5
Re-irradiation	3
Watch and Wait	2
<b>Present treatment</b>	
Re-irradiation	1
Watch and Wait	4

**Patient interview results.** The following section describes the themes identified from patient interviews. Five overarching themes were identified: perception of the decision to be made, decision-making process, decision-outcomes, approaches to decision support and recommendations/strategies for supporting patients during treatment decision-making. These themes reflect a logical sequence of events in the decision-making process as displayed below (Figure 1).



*Note.* 1 = Watchful Waiting, Androgen Deprivation Therapy (ADT), Salvage Prostatectomy, Cryotherapy, Re-irradiation, High Intensity Focused Ultrasound (HIFU) and Tookad Laser

2 = Decisional conflict (uncertainty) and decision regret

Figure 1: Summary of Themes from Patient Data

***Perception of the decision to be made.***

*No options.* Three of the five participants did not perceive that they had a treatment decision to make because their physicians had not presented them with different treatment options and some participants deferred to the physician to make the treatment decision. The lack of information patients perceived about treatment options and the influence physicians had over treatment decisions are illustrated by these two patients:

(Patient 1) If (the physician) say I have to have it, I took it.

(Patient 2) I was never asked, not by Dr. X, not by any physician, what I wanted, they told me what they would do.

Like the following patient, others also expressed the need for more information about treatment options at the time of disease recurrence:

No, I didn't have choices. Yeah, you know I would rather have had it explained to me by the physician about why he wouldn't do this or wouldn't do that or could have done this. You know, but he didn't. ... No, he felt it wasn't necessary.

I don't know; [its] too late now.

Several participants noted that they followed their physician's treatment recommendation. While for some this was perceived as not having options, for others such as the following participant, the decision was to accept the physician's recommendation and not to pursue other treatment opinions:

Dr. X said my best recommendation is to make an appointment for radiation therapy. He said this is the best one (treatment option) for you at this point in time and I just accepted that.

*Treatment options.* Two of the five patient participants perceived that their physician had discussed available treatment options with them. One participant commented that his physician had explained various treatment options as *thoroughly as he could*. Treatment options that were discussed with patients included watchful waiting, ADT, salvage prostatectomy, re-irradiation, HIFU and clinical trials.

***Decision-making process.***

Men with locally recurrent prostate cancer described several factors relevant to the selection of a specific treatment option. The influencing factors enable, complicate or delay treatment decision-making. They appear to be disease/treatment related factors and personal or patient related factors (Table 9).

Table 9

*Summary of Factors that Influence Patients’ Treatment Decision-Making*

<b>Positive factors ( enable decision-making)</b>	<b>Negative factors (delay/complicate decision-making)</b>
Prior health care knowledge and/or experiences	Lack of knowledge
	Complexity of information and difficulty translating information into meaningful pieces of data
Family involvement	Inability of family to be involved
	Anxiety about side effects they may not experience
Personal meaning and importance of side effects (i.e. want to avoid certain more undesirable side effects); helps to eliminate some treatment options and select others	

Patient understanding of their goals related to prognosis and survivorship helped to identify/eliminate/choose treatment options

*Fatalistic view*

*Treatment effectiveness*

*Active vs. passive treatment*

Disease and treatment related factors  
Age, rate of disease progression and prior therapy make one ineligible for some treatments which limits treatment options/decisions

Disease and treatment related factors can make one eligible for more treatment options which increases the number of treatment options to consider

Need for referral for assessment of treatment options results in delays

Shock of recurrence

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*Influencing factors.* Prior healthcare knowledge or experience facilitated patient understanding of treatment information provided by the radiation oncologists. For example, one participant was quite knowledgeable and understood the information because of his occupation. He explained:

So some people are very fearful of the radiation. And I call it something else. Call it radiation if you like; I call it electron surgery. The company I worked for built these radiation machines actually, in California.

Conversely, another patient commented on how a lack of knowledge and the timing of when treatment information is provided may have affected his treatment decision:

Maybe I didn't know enough... maybe if (the physician) would have (provided treatment options) later on. Yes, I probably would have picked something else.

The extent of family and spouse involvement and influence in treatment decision-making varied among participants. Some participants welcomed family involvement in the treatment decision-making process and others did not. One participant described his daughter as being matter of fact and encouraging him to make a decision by saying, “Oh yeah get over it. Get on with it you know.”

In contrast, another participant described how he could not discuss his cancer or treatment with his son because the son was too upset:

He cannot look at tomorrow without me and he is just devastated. I don't talk about cancer in front of him or anything else. He can't handle it and he is very concerned about me. I'm not the least bit concerned because I just simply don't care.

The personal meaning or importance of some treatment side effects varied among participants. The extent to which treatment options were perceived to offer a reprieve from certain side effects influenced decision-making. For example, one participant was concerned about long-term side effects and in particular loss of bladder control. He was eager to participate in a clinical trial after consulting with a different physician because he felt the clinical trial would offer him state of the art treatment with a lower risk of side effects:

[The clinical trial] used these markers, gold seed markers in the prostate to target the radiation. It used tattoos to target the radiation [and] CT scans. Everything I read about [suggested it] is just the most advanced and up-to-date state of the art treatment for prostate cancer. And the really good part was [it's] unlikely to have

any long-term side effects. So I switched, I changed my mind I said, okay I'm going to try this clinical trial and I signed up for it.

The importance patients placed on long-term survival also influenced the treatment decision-making process. Some patients had a fatalistic view and had less anxiety or concerns about treatment effectiveness. This concept of fatalism is demonstrated in the following comments by two patients:

I'm not afraid of dying but I'm not looking forward to it either. What will be, will be. When you are in mid-80's lots of people have gone before.... And the cancer ... it doesn't bother me. When they told me I had cancer I thought, oh, so big deal. I don't care and I really didn't care whether I got the treatment. And if somebody said, you are going to die tomorrow, I don't care. I have had a good life.

For other patients, comparing the effectiveness and likelihood of cure offered by different treatments was important. As one patient said:

The efficacy ...of surgery or radiation for the first 10 years is about the same. In other words, the results, the likelihood of good results for the cancer, curing cancer, is about the same for radiation and surgery according to clinical experience for the first 10 years... They just don't know whether having the prostate actually removed, whether most people are going to have a better result long-term, than people who have had radiation. But like ... I've read stories about people who have gone the opposite route, they went and had the surgery first, then



they had a recurrence after surgery and then they went and had radiation and when that didn't work they went to [the next treatment]. So it could go either way.

Prognosis also influenced the choice between what was perceived to be passive or active treatment. Patients described watchful waiting as a passive treatment, “where all you do is go for check up”. Other treatments, such as radiation therapy, were thought to be more active or “doing something” and lead to a better prognosis. The following two patients describe how prognosis influenced their decision to have active treatment:

Patient 1: Dr. A said if I didn't have the radiation or do something, I probably would not last a year or two. And then he said....if I do have it [I]... should live to be 95.

Patient 2: I had asked about 'Watch and Wait' and [the physician] enquired about my family history and found that there was longevity in my family history. I have a relative who is 102. I don't understand how long I will [live]; you never know.... Anyway, he said that was not an option, the 'Watch and Wait,' because he said you never can tell; [prostate cancer] could suddenly bloom on you and you might be in serious trouble. So that's why I took the route that I did and it's okay.

Treatment and disease related factors affected the treatment options patients were eligible to receive, and sometimes complicated or simplified the decision-making process. These included prior treatments, Gleason score and PSA velocity, which is the measurement of how fast PSA levels in the blood increase over time (NCI, 2010). One participant spoke about getting a referral for salvage prostatectomy after radical radiation but the urologist told him, “That's not an option.... I wouldn't recommend it and [I don']

think anybody else would do it.” This patient returned to his radiation oncologist to review other options. Another participant talked about being on watchful waiting after his initial treatment which included regular testing to monitor his PSA:

Well velocity, they talk about velocity of the PSA, not just how fast it is going up.

The reason they became concerned for me was because it made a jump from about 3.5 to 5.5 over a year. ... [The PSA] started to creep up and I was referred for a biopsy.

Patients frequently identified that personal characteristics such as their age impacted on the treatment options available to them. The following two patients described how they did not qualify for certain treatments because of their age:

Patient 1: The (radical prostatectomy) was not an option because I think I was 81 or 82 at the time.

Patient 2: I asked about surgery and he said no. I was 74 at the time and he said no.

The shock of recurrence also impacted on treatment decision-making. Participants described their initial shock in learning that the cancer had returned as immobilizing and that it delayed the treatment decision-making process. This patient stated:

After it came back, really I didn't make any decisions. I was a little shocked of course, I thought radiation would clear it all up and be done with it. ... I didn't believe it.

The ability to translate treatment related information into meaningful treatment choices was another factor that affected the decision-making process. For example,

complex disease related information such as PSA velocity was relevant to some patients and their personal treatment choice while other patients indicated they did not pay too much attention to PSA results. One patient explained:

People shouldn't necessarily pay attention to numbers until there is a change. And that's what you have to look for is a change in the PSA. The fact that you have a 2 or a 3 or a 5 or a 6 is irrelevant, it's over time and it's going up, that's the issue here I am talking about they have to pay attention to that. So I agree with you, they should routinely give blood tests but they don't have to worry about those numbers.

*Facilitators.* Participants often identified a person that enabled them to choose one treatment option over another as a key facilitator. For example, participants reported that confidence in their physician helped them to follow treatment recommendations. One participant explained:

I was rather quite confident in Dr. X ... He gave me his quick reasons for surgery and radiation. He said radiation is your "... better bet ..." That's when I decided; he recommended the radiation and so I said that's it, let's just do that.

Seeking second-opinions from other physicians or friends was another facilitator influencing treatment choice. The following patient described his experience:

I am under the watch and wait at the moment. Yeah, I have had Dr. A as well, who suggested, what do you call, it, the prostatectomy. So he sent me back to Dr. B, the urologist and I just spoke to him and he said "That's not an option." He

said, “I wouldn’t recommend it” and said he doesn’t think anybody else would do it.

Stories from other patients also helped participants make decisions, particularly when the outcome of the story was not positive. One patient described how *horror stories about surgery* led to his decision to dismiss this as a treatment option. Another patient, who opted to receive radiation therapy, shared the story of a friend who opted for hormone therapy and how this influenced his decision-making:

(He had) the hormone therapy and ... he was a little bit older than I. I’m 75 and he was 83 when he died...He said no radiation...It’s your option, as Dr. X says you don’t have to have anything if you don’t want to. It may go on for quite some time and be fine; you might die of a heart attack first.

Given the many factors patients weigh in making their decision related to treatment, the following patient’s statement captures the reflective back and forth process involved in treatment decision-making:

My physician said I could see Dr. A the urologist. When I went to see him I got the big finger and then he took the biopsy. And then he called me back sometime after that and he said it was malignant. So from there on we just said, well what do we do about it? I basically went along with what he said, but I said I would get a second opinion. I talked to my friend out in Winnipeg, I think three times, because he kept calling me. I don’t know. I still wasn’t convinced that I was going to have the radiation and then I thought well, I took (the friend’s) word for it and I went through it.

*Information seeking.* Patients reported the use of various information sources involving different levels of engagement. For example, some patients described less active or passive information-seeking activities such as reading information brochures provided by the cancer clinic or discussions with family. Others described more deliberate and active involvement through searches of electronic media such as the Internet, seeking input from friends in the health care field, or getting a second opinion from other healthcare professionals. The types of information patients wanted varied from general information about treatments to more specific data on treatment side effects and comparison of the effectiveness of different treatment options.

*Sources of information.* Patients identified friends and peers as a good source of information. One said:

I had friend out in Winnipeg who is a urologist...I talked to him two or three times on the phone by the hour. ... In the end he said that ... if he was in my body [radiation was]what he would do. So I probably had a whole lot more information than most people get.

While electronic media was frequently identified by patients as an easily accessible information source, the Internet in particular was sometimes fraught with challenges, including uncertainty about information quality, information overload and the risk of obtaining misleading information. These participants explained:

Patient 1: I do use the Internet, except there is one problem with it; you get far too much information and you can get misleading information.

Patient 2: Like there is a lot of information on the Internet but the quality isn't always the same. There's no guarantee what you're going to get.

Another patient described how the level of detail and presentation of Internet information was sometimes *scary* and led him to *want to learn more* but also made him feel sicker than he really was.

Patient information such as pamphlets and brochures were also identified as another important source of information. This type of information was given to patients at their clinic appointment. Information from the internet and from clinic appointments was also shared with family members. One man said, "My wife and I will sit and discuss things; she has been a nurse for a long time."

Patients' radiation oncologists were another source of information. One study participant recalled the visit to the physician when he was diagnosed with a recurrence:

When he called me back in and said that I had a malignant tumour, I said "So?"

And so he sat there and talked to me for about half an hour all about pros and cons and this and that. I said well I would get back to him.

Other participants felt that treatment information should not be given at the same time they were being told about the cancer recurrence and feeling emotionally overwhelmed. They felt that treatment information could be provided at a later date by their family physician, rather than the oncologist.

*Information needs.* In addition to information about treatment options, patients also received information about treatment side effects. They described the need for physicians to better explain the variation and probability of side effects for different

treatment options. They felt this information would allow patients to make a more informed treatment choice based on their current life style needs. One participant said:

I think I would have preferred (a different treatment); (like) when they put those little radioactive pellets into the prostate. I think I would have preferred that because I got some good (information) from ...that TV show on CBC. But I was never asked.

Another participant who received more information about treatment side effects remembered his physician saying:

Sure there are risks that you may become incontinent. [Incontinence is] one of the concerns but he didn't think that was likely. There's problems with erectile dysfunction; not being able to get an erection. So those were the nasty side effects and you might even lose your bowel function but that effect is very rare. ...

[Prostatectomy's] a more invasive procedure so there's a higher risk of dying although I think that's extremely rare.

On the other hand, all participants described the need for information relevant to their personal circumstances that is delivered in a way to help them interpret the meaning of the information for their health. Some patients struggled with a need for information about possible treatment side effects, while at the same time not wanting to become overwhelmed by the fear of side effects they may ultimately not experience. As this patient said:

I think [impact on quality of life's] an individual thing ... I think it would be a good idea if [the physician] said look, a side effect could be this way... don't

worry about it because it may not happen but it's a possibility. I don't know if it's worth scaring somebody like that anyway.

Comparing and contrasting treatment choices allowed patients to participate in treatment decision-making and make informed choices based on the most current information. One man reported listening to an information program on television that explained the side effects of each treatment well. He said:

Yes, they described it... [the physician] described the options that you had and he described the kinds of side effects that could occur...He discussed it very thoroughly from the point of view the pros and the cons. He didn't over-emphasize the cons and he didn't over-emphasize the pros; the good parts. I thought he explained it very well.

Participants identified the need for detailed information about the timing, duration and probability of experiencing specific treatment side effects. One participant said:

There was one other thing that I was going to mention, and that is I had bleeding in the bowel a year after the radiation treatments. Immediately after [treatment] there was nothing... but a year later there it was. On and off, on and off, not regularly but on and off there was blood in the bowel.

Another participant described his experience of treatment side effects as opposite to what he expected. He said:

So anyway, I got the radiation and I'm all through with the radiation and I'm waiting for the diarrhea to show up and it never did. It was exactly the opposite.



Now I'm going to tell you and you're going to say, "Oh I don't think so"... [but it was] five weeks to the day that I never pooped.

The need to better understand the type of care and investigations required during and after treatment was identified by participants. Some participants mentioned that they did not understand why they received one test versus another.

***Decision consequences.***

*Decision regret.* Some participants expressed regret about the treatment choices they made because of the long-term side effects they were experiencing and the subsequent negative impact on day-to-day life. This patient commented:

[The treatment] affected my walking a lot and my balance to quite a degree. And I still work, like I have a business. I sand floors, refinish old hardwood floors and that.

*Uncertainty.* Uncertainty about whether they made the right treatment decision was another negative consequence expressed by some participants. One patient said, "I often wonder if I did the right thing, but I'm still here." Yet another said, "I had thought I might not have done the best thing you know but then I had no choice."

Lack of information and lack of support to help interpret information gathered from non-physician sources contributed to patient feelings of uncertainty. This patient explained:

One of the things I noticed was.... I didn't think I was getting enough guidance. Like each [physician]...the surgeon would sort of focus on surgery and the radiation specialist would focus on radiation, but I wasn't really getting to [what

was best in my particular case]. Like I had to make the decision and with me the final result was I got a little bit of input from the Internet. But it was a guess as to which way do you go? You just hope you make the right decision.

*Reliability/predictability of data regarding treatment effectiveness, treatment side effects and survival.* The unpredictability of survival was another issue participants grappled with. These men were near the end of their lives and some wanted to know how many more years of life this treatment was going to give them. One man said:

I don't think you can predict, I don't think you can tell by the [treatment], how long [to live] you have... I looked at my age and I looked at Dr. X and said, how can you guarantee me anymore? I might die walking out the door, not of cancer but of something else.

*Approaches to improve decision support.* Participants recommended an education group or seminar as one strategy that would allow them access to quality information regarding their treatment options. One participant said:

If you had somebody like a trained oncology nurse who was, you know, had taken the education and was trained to provide that kind of seminar and [could] explain options and answer questions, or at least tell people where they could get answers [it would be helpful].

Further, participants wanted current information regarding treatment effectiveness and side effects. When discussing the benefits of HIFU one participant said:

[Treatment effectiveness is] the kind of information that could be provided in a seminar and it could be updated every year too, so that you know, the person who

is giving it would get the updated material. So the presentation would be a little different like each year.

Participants also talked about having a computer-generated (Power Point) presentation which could be accessed from the Internet or a Digital Versatile Disc (DVD) as a decision support aid. One participant said:

I was on Chat 23 Cogeco on the local station and periodically they had health issues on there. And [his physician] was on it, giving lectures on prostate cancer, you know, a computer-generated presentation and it was excellent. I followed up on him any time I knew he was on [television]. I wanted to find out [if] he is telling anybody [something] different than what he told me. He was very thorough. What I am really trying to say is, if you can get someone to do that kind of thing. Like he [provides information] in layman's terms, there's no fancy language. It's thoroughly understandable. If you can, get somebody to do that and then get people to use this as a resource.

Participants also recommended that information be presented to patients by an independent source, separate from the treating physician. They wanted unbiased data that was not influenced by the physicians' area of specialty. One participant said:

So, I think an education seminar with one or two sessions where um, the differences and reasons for using a prostatectomy or a laparoscopic prostate [are described]. In other words, you are getting it from a more independent source [that is] exclusively relating information as opposed to somebody who is involved in providing the treatment.

Participants also wanted guidance on how to look for additional information such as websites with quality information. One participant described:

It would be helpful to know what sites are good sites to visit [and that] you can trust them because it's validated research...having someone you know kind of counsel you about good places on the Internet to get the information. That would be helpful.

Participants went on to discuss the need for selected vignettes from previous patients who had already received treatment, to illustrate the treatment experience. One participant said:

You get far too many sad stories you know. There's another word for sad, there's scary, and what you need are some good ones. I don't mean Pollyanna or preaching. There has to be some good [stories] in there you know like, "Don't worry too much."

For some patients, there was no treatment decision to be made while others described a back and forth process as they gathered information from various sources and weighed the importance and/or potential impact of different factors on their health. Some factors enabled or complicated treatment decision-making, and at times individual people or facilitators helped to tip the balance toward a specific treatment option. Patients also expressed uncertainty and decision regret as adverse consequences of their decisions. Various strategies to improve decision support were discussed including: an education group or seminar, a computer generated presentation and guidance on how to find additional high quality information from reliable sources.

In summary, this chapter described the themes from 1) the two-round Delphi process involving radiation oncologists, and 2) in-depth interviews with patients. The process of treatment decision-making was described and treatment decision-making needs were identified. In general, it was found that radiation oncologists recognized the challenges patients experienced during treatment decision-making and that there was a need for increased support for patients by the healthcare team during this process. Patients identified a number of information needs related to treatment options, effectiveness and side effects, as being important for decision-making. Patients and radiation oncologists reported that the lack of good research-based information about the effectiveness of treatment options and the likelihood of different treatment side effects, negatively impacted the quality of information provided to patients, and subsequently, the quality of the decisions patients made. Physicians and patients alike felt that an information source that was kept current through research updates would be a useful resource for improving decision support. Physicians generally agreed on the treatment options they think should be included in an information aid for patients, and made suggestions on what elements it could include such as information on treatment options, benefits and effectiveness, and the likelihood, severity and impact of treatment side effects on quality of life and function. Patients made similar suggestions regarding the type of information to be included in an information resource. The next chapter will discuss the implications of study results for the development of a treatment decision aid, nursing practice and future research.

## **CHAPTER 5**

### **Discussion**

#### **Introduction**

This chapter discusses and summarizes the results of this study which examined treatment decision-making needs and processes related to locally recurrent prostate cancer. Findings were identified through a two round Delphi process with radiation oncologists and in-depth interviews with patients. First, key study findings are examined by comparing and contrasting the views and experiences of radiation oncologists and patients about the decision to be made and the decision-making process related to influencing factors, facilitators, sources of information and information needs. These findings are also discussed in relation to existing research literature. Second, the consequences of treatment decisions are further examined. This is followed by recommendations for improving decision support. The impact of study findings on patient treatment decision-making needs and for development of a treatment decision aid are explored followed by discussion about strengths and limitations of the study. The implications for nursing practice and future research are also considered. Finally, a brief conclusion is presented.

#### **Key Findings**

##### **Comparison of Radiation Oncologists' and Patients' Perceptions of the Decision to be Made**

There was not a consistent level of agreement or consensus among radiation oncologists about what treatment options to include in a treatment decision aid. It is possible that the small number of radiation oncologists who participated in this study

contributed to this observed lack of consensus. However, even when radiation oncologists were in agreement about which treatment options to include, these views differed with those of patients. For example, most of the radiation oncologists agreed that a treatment decision aid should include information on watchful waiting, prostatectomy, HIFU and clinical trials and that information on cryotherapy and light activated tookad should not be included. There was less agreement among radiation oncologists about the inclusion of brachytherapy and androgen deprivation therapy, the latter of which is surprising as it is the most common treatment for recurrent prostate cancer (Canadian Cancer Society, 2010; Grossfeld et al., 2002). In contrast, patients wanted to hear about all treatment options and why they were or were not eligible for some of these options

Radiation oncologists also perceived that they spent quite a lot of time with patients and provided them with detailed information to enable treatment decision-making. However, some patients reported that they had insufficient information to make a treatment decision and they spent a considerable amount of time looking for information from other sources. On the other hand, some patients followed their physicians' recommendation and felt they had no decision to make. It could be argued that they made their decision simply by accepting the physician's recommendation and not pursuing other opinions. The observation that some participants perceived they had no treatment options presented to them is consistent with the study by Carter et al. (2011) reporting that patients and family members identified unmet information needs related to their disease and treatment. There may be at least three explanations for our findings. First, some men may not have considered 'doing nothing' as a treatment option. Although

“watchful waiting” involves active surveillance and monitoring it does not involve active medical treatment, so some men may not have considered this to be a treatment option.

Second, some patients may not have perceived they had options due to poor recall of their conversation with the radiation oncologist. For example, if they learned about the recurrence during the same appointment in which options were discussed, their recall may have been affected due to stress. Patients in the study reported being shocked about the news of recurrence; they did not expect their cancer to recur. The shock of the news may have affected their memory and decreased their recall of events. Other studies have also reported that the ability to actively listen and make a treatment decision is affected by an emotional state in which some patients describe the news of recurrence as immobilizing (Feldman-Stewart et al., 2004).

A third explanation is that radiation oncologists may not have described or provided information about all options, but only those most relevant to the patient or treatments provided at their cancer centre. Some radiation oncologists talked about “theoretical” options such as HIFU or cryosurgery with patients but did not go into an in-depth discussion about them. Thus, it is unclear whether there is consistency in the information radiation oncologists provide about treatment options.

### **Decision-Making Process**

This section describes the decision-making process as perceived by radiation oncologists and patients. The factors and facilitators that influence treatment decision-making are described. This is followed by an account of the information seeking activities including the sources of information used and the identified information needs.



The treatment decision-making process is complex and was described by radiation oncologists and patients as a period filled with information seeking activities, punctuated with periods of reflection on various factors and culminating in facilitators that enabled selection of a treatment. The treatment decision-making process in this study was described by some patients as being circular in nature. It involved receiving news of recurrence, being given some information on treatment options versus “no choice”, weighing the benefits and risks of treatment options, seeking more information, and eventually making a return visit to the radiation oncologist for clarification and treatment. These findings are consistent with the O’Connor and Jacobsen (2003) framework that guided this study. In the ODSF, decisional needs are associated with the type, timing and stage of decision-making and inclination to choose one option over the other. Other factors such as pre-existing decisional conflict, baseline knowledge and expectations, personal values and importance of the outcomes of each option for the individual can impact on the decisional need (O’Connor & Jacobsen, 2003).

Radiation oncologists also described treatment decision-making as being circular in nature with information deliberately being provided to patients over time. However, radiation oncologists found that some patients felt that there was a rush to make the treatment decision. This potentially impacted on the patient’s ability to deliberate about the information they had received and denied them the opportunity to seek more information before making a treatment decision.

**Influencing factors on the decision-making process.** When patients were asked about the factors that influenced treatment decision-making, they talked about the

information they received from their radiation oncologists, consultations with other specialists, family and friends and other sources such as the internet. They also discussed the meaning of a cancer diagnosis, treatment related factors and personal factors that influenced their decision. The treatment decision-making process was further complicated by patients' personal values and the weight they placed on specific treatment outcomes. This is similar to findings in the needs assessment study by Feldman-Stewart, Brundage and Mackillop (2001) which revealed that the importance of different types of information varied among patients and families. On the other hand, radiation oncologists listed disease related factors such as previous treatments received, PSA kinetics, side effects and patient factors such as age, life expectancy and co-morbidity as being important for treatment decision-making. Similar factors were also described by Aranha and Vaishampayan (2004), the Canadian Cancer Society (2010) and the NCI (2010) as being relevant for treatment decision-making.

The radiation oncologists identified that they played an important role in explaining treatment options and ensuring that patients understood why they were not candidates for certain treatments. On the other hand, patients described their struggle with translating treatment related information into meaningful messages that could inform treatment choice. They sought to understand the meaning of the medical terminology and the various medical reports describing disease progression such as PSA levels and Gleason scores. Lack of patient understanding about many aspects of their prostate cancer and treatment may have had an impact on treatment decision making. A treatment decision aid is a tool that can be used to explain to patients not only treatment options and

their outcomes but also the meaning of medical terminology like the Gleason score (O'Connor et al., 2007).

Disease related factors such as previous treatment received, PSA velocity and Gleason score affect eligibility for different treatment options (Aranha & Vaishampayan, 2004; Canadian Cancer Society, 2010). Patient specific factors such as age, life expectancy and previous health condition were other factors considered by radiation oncologists when discussing treatment options. Aranha and Vaishampayan (2004), NCI (2010) and O'Rourke (2001) described the importance of these factors for physicians when assisting patients in treatment decision-making. Patients discussed being informed of the relevance of age in treatment choice. In addition, those who understood the meaning of the medical terminology, such as PSA level or Gleason score, said that increasing scores and evidence of disease progression marked the time when they chose to go from passive (conservative) treatment such as watchful waiting to active treatment.

The extent of family and spousal involvement positively influenced treatment decision-making. The presence of a support person at an appointment can act as a buffer when news of recurrence is given (Rodin et al., 2008). The support person can provide emotional support and instrumental support by taking notes during appointments, expressing the patient's interest and/or asking questions on his behalf. Some participants relied on family involvement and took their spouses to the clinic appointments with them while others did not want to burden their families. These results are similar to findings in other studies in which different levels of spousal/partner support have been reported (Davison et al., 2002; Feldman-Stewart et al., 2001). Radiation oncologists perceived that

spouses were present primarily to provide emotional support and less often to participate in treatment decision-making. This is consistent with Davison et al. (2003) who found that some participants relied on their partners for cognitive and emotional support. Patients sometimes included their children and friends in the treatment decision-making, and most radiation oncologists agreed that family members should be included in the process. There was less agreement among radiation oncologists about allowing patients' friends to participate in treatment decision-making.

In addition, the concept of a fatalistic approach was discussed. While some participants were anxious about selecting the appropriate treatment option, others were less concerned. Some of the latter group could be described as accepting that death is part of the cycle of life and the inevitable end of a life well lived. Other men also recognized that they were at a stage in life where they could die of other causes and not just prostate cancer.

**Facilitators of the decision-making process.** Treatment equivalence, amongst other factors, can make it difficult for a patient to select one treatment over another. A facilitator is someone who or something that enables a patient to choose one treatment option over another, and is critical in the decision making process. In the ODSF a facilitator is related to the inclination to choose one treatment option over another (O'Connor & Jacobsen, 2003). Patients identified radiation oncologists and other patients' stories as facilitators.

Confidence in the reputation or authority of the radiation oncologist allowed two study participants to follow physician recommendations without seeking alternatives. The

patients in this study were aged 71 to 84 years of age. It could be argued that there may be an age based effect in which older men believe in the authority of the physicians' clinical knowledge. In their study, on variability in patient preferences for participation in medical decision-making, Robinson and Thomson (2001) found that the desire for a more paternalistic approach to decision making may be stronger in older and less well educated patients. Although participants in this study were older, they were fairly well educated, having completed a high school and/or undergraduate university education.

The experiences of other patients diagnosed with prostate cancer steered some patients in the study to select one treatment over another. For example, they spoke of the effect of shared "horror stories" as a deterrent from seeking a surgical option. The story of a friend who opted for hormone therapy and then died shortly thereafter, steered another participant to opt for radiation therapy. Past experience is particularly relevant when creating a treatment decision aid as patients expressed wanting to hear patient stories and outcomes in vignettes. They also spoke about the need for balanced information that was neither "scary" nor "Pollyanna."

***Sources of information for treatment decision-making.*** Radiation oncologists were discussed as the initial and most trusted source of information when patients returned to clarify information. Patients also discussed wanting information regarding screening and treatment to be available at the family physicians' offices instead of the specialists' offices where they were already emotionally overwhelmed. Some of the patients attributed the need for screening information to their family physicians' failure to

provide this information and/or perform the routine physical examination for screening and early detection.

When necessary, radiation oncologists referred patients to other specialists for a second opinion and review of other available treatment options such as HIFU or cryotherapy. Occasionally when patients had difficulty with decision-making, radiation oncologists referred them to a specific website for more information. Although sometimes fraught with ‘scary’, ‘misleading’ and ‘overwhelming’ details, electronic media were also identified by patients as a frequently used source of information. Information pamphlets/brochures from the cancer clinic were also identified as useful by patients and could be shared at home with family members.

Radiation oncologists rarely referred patients to supportive care even though they were aware that this service was available. This could be because these physicians did not perceive the patients to be distraught. Nevertheless, the importance of supportive care services was demonstrated by patient descriptions of being shocked at news of recurrence and the need for external resources for emotional support, advice from the formal healthcare system and their social network to facilitate treatment decision-making. Similarly the study by Carter et al. (2011) on supportive care needs of men with advanced prostate cancer found that patients were unaware of what supportive care services were available to them.

Friends and peers were discussed as another important source of information. Some men had friends who were physicians and some had family members in the healthcare field with whom they discussed treatment options. As evident in several needs

assessment studies of men with early stage prostate cancer at initial time of diagnosis or treatment, men often include spouses during their treatment decision-making (Davison et al., 2002; Davison et al., 2003; Feldman-Stewart et al., 2001).

***Information needs for treatment decision-making.*** Radiation oncologists' views about information needs differed from those of patients and they perceived that they provided patients with sufficient information regarding the treatment options.

Patients on the other hand reported that they required more information or clarification specifically about treatment options and treatment side effects. This is similar to the findings of Carter et al. (2011) in a study on supportive care needs for men with advanced prostate cancer. Some radiation oncologists reported discussing the main treatment options such as watchful waiting and hormone therapy in detail and briefly mentioning the other options. Structuring information delivery in this format may deny patients an opportunity to fully participate in informed treatment decision-making as they have only received partial information. Some radiation oncologists were more inclusive in their approaches and referred patients to various specialists if they were eligible for other treatment choices. For example, some radiation oncologists referred patients to other centres that provide treatments not offered at their facility such as HIFU and cryosurgery. This type of referral was done when patients requested it or if the radiation oncologist felt it was needed. Patients also reported seeking second-opinions from other physicians or friends on their own.

Patients reported that they struggled with the meaning of test results such as the PSA score and other medical terminology used during the treatment discussion. Some

patients discussed spending time to look up information and they displayed a good understanding of medical terminology during the interviews. Other patients demonstrated a lack of knowledge about basic aspects of their prostate cancer treatment during the interviews. Patients felt that information about the meaning of test results and other medical terminology would have allowed them to be more aware of their position in the illness to wellness continuum.

Patients also reported seeking information on treatment effectiveness, as they perceived this would allow them to be confident in their choice. Information on prognosis is another factor that was discussed as being important during treatment decision-making. This was because patients had to weigh the risks and benefits of treatment and survival against facing their mortality.

The need to understand specifics of treatment and follow-up, such as the duration and number of radiation treatments required, was highlighted by patients as having the potential to reduce anxiety during the treatment phase. Some patients mentioned that they did not understand why they received one test versus another. Patients felt that information on treatment specifics would have allowed them to make more informed treatment choices based on their personal life style and the impact on their quality of life. Further, they felt that comparing and contrasting treatment choices and outcomes would allow more of an opportunity to participate in treatment decision-making and help them to make choices based on the most current information. A decision aid would be one such source of information that would be useful in allowing patients to make comparisons among treatment options during treatment decision-making. Radiation oncologists agreed



with patients about the inclusion of specific treatment information such as number of radiation treatments required and details of follow-up in a treatment decision aid. In a recent feasibility report on developing a national outcomes database to assist patients with making treatment decisions, patient advocates and healthcare providers also supported this idea of including information about treatment logistics in a centralized information source (Damberg et al., 2003).

### **Decision Consequences**

The following section discusses the impact on the patient of the treatment decision and consequent treatment. The concept of decision regret as a result of decisional conflict is discussed followed by the concept of uncertainty. This is followed by a discussion of the impact of reliability/predictability of research data regarding treatment effectiveness, treatment side effects and survival on treatment decision-making.

### **Decision Regret**

Some participants expressed regret with the treatment choice they made because they experienced decisional conflict as a consequence of feeling uninformed about all of the relevant options available. This may be due to the inconsistency in how and what information radiation oncologists provided to patients when making treatment decisions. Other men questioned their treatment choices because of the impact of side effects on their quality of life. Our study results and those of others illustrate that treatment decision-making can be a complex and challenging process for many patients. Several studies report that decisional conflict was experienced by 43% to 63% of individuals who were making treatment related decisions related to cancer or terminal illness (Fiset et al.,

2000; Stacey et al., 2003; Steginga, Occhipinti, Gardiner, Yaxley & Heathcote, 2004).

The high number of patients reporting decisional conflict indicates the need for an intervention to provide consistent information to facilitate treatment decision-making and perhaps avoid future misgivings or regrets about their decision. A systematic review by O'Connor et al. (2009) found that decision aids lowered decisional conflict related to feeling uninformed (mean difference -8.3; 95% CI -11.9 to -4.8) and lowered decisional conflict related to feeling unclear about personal values (mean difference -6.4; 95% CI -10.0 to -2.7). Thus, decision aids may be an important intervention to help decrease the level of decisional conflict and subsequent decision regret in patients with locally recurrent prostate cancer.

### **Uncertainty**

Uncertainty was another decision consequence expressed by participants. Some patients expressed doubt about the effectiveness of treatment options they selected; whereas, others felt they lacked guidance during the decision-making process and thus were not confident they had made the right choice. Uncertainty about treatment decisions may be partially attributed to patients' questioning of the accuracy or the completeness of information they received from their healthcare providers. This is similar to findings by Carter et al. (2010) where patients with advanced prostate cancer also questioned the completeness and accuracy of treatment decision-making information provided to them by healthcare professionals particularly at the time of initial diagnosis and at disease recurrence. Uncertainty about treatment decisions may also be due to lack of good research data about the predictability of treatment outcomes as described by radiation

oncologists in Round 1 of the Delphi process. This finding about the need for good research evidence for treatment decision-making, is consistent with the report by Damberg et al. (2003) that supports the development of a National Outcomes Database to allow physicians and patients to track current patients' treatment outcomes and enable an added layer of confidence in treatment choice.

### **Reliability/Predictability of Data Regarding Treatment Effectiveness, Treatment Side Effects and Survival**

Radiation oncologists and patients described struggling with the unpredictability of treatment side effects. One participant reported being unprepared to manage the difficulty of increasingly severe constipation instead of the expected diarrhoea. Patient advocates in the report by Damberg et al. (2003) also acknowledged challenges in making treatment decisions when side effects were unpredictable.

The unpredictability of treatment benefits, particularly related to survival rates, was another issue that physician participants in our study confronted. Radiation oncologists described the lack of research data available to accurately predict the number of additional years of life each treatment might provide. On the other hand, long term survival was not that important to some patients because they recognized that they were at the end of their lives and there was a potential that they could die from other causes. In addition, radiation oncologists found the lack of high quality research evidence from randomized control trials was a barrier to making recommendations to patients about which treatment would offer the “superior” or “optimum ” outcome.

### **Recommendations for Improving Decision Support**

Patients made several suggestions about ways they could be better supported during treatment decision-making. Patients questioned physician objectivity in providing treatment information and commented on how physicians were more likely to recommend or emphasize the particular treatment they provide. Patients also discussed the need to have unbiased information presented to them by an independent person or source not involved in their medical care. The example of this was a trained oncology nurse. Findings from other studies indicate that the preferred or most accessed source of information was a healthcare professional, such as the radiation oncologist or trained oncology nurse, followed by print materials (Rutten, Arora, Bakos, Aziz & Rowland, 2005; Smith et al., 2004; Wong et al., 2002). A trained oncology nurse, particularly one who is an advanced practice nurse, would be a knowledgeable professional who could play a major role in supporting patients to meet their decisional support needs (Carper & Haas, 2006; Gosselin-Acomb, 2006). A trained oncology nurse can also facilitate the use of a treatment decision aid as a support for decision-making. A treatment decision aid is one example of a single point of unbiased data that can be used to provide information on options and outcomes relevant to a person's health status (O'Connor et al. 2007). Nevertheless, the onus lies with the practitioner to provide patients with balanced information about the advantages and disadvantages of all relevant treatment options.

There is a need for better research evidence about the effectiveness of treatment in recurrent prostate cancer. Patients expressed a desire for current information regarding treatments, effectiveness and the side effects. Likewise radiation oncologists wanted to

see more randomized control trials comparing treatment options so as to determine the superiority of treatments. The feasibility study for a national outcomes database by Damberg et al. (2003) also found that patients and healthcare providers wanted timely information on outcomes of various treatment choices instead of having to rely on follow-up studies from patients treated ten or more years ago.

An educational group or seminar was identified as one strategy that would allow patients to access high quality information regarding their treatment options. Patients also identified the need for portable information or a decision support aid that they could review on their own or with their family before making a treatment decision. Radiation oncologists concurred and suggested that a take home information guide would be useful. The example patients gave was a computer-generated PowerPoint presentation which could be accessed from the internet or on a DVD. Decision aids have been developed in many different formats, and thus, can be a flexible resource to improve treatment decision-making (Myers & Kunkel, 2000; O'Connor & Jacobsen, 2003).

Patients also wanted guidance on how to look for additional information beyond what the healthcare team provided. Some patients felt the need to validate and clarify the information they had received and this included seeking good quality information from various sources such as the internet. On the other hand, some radiation oncologists described spending a lot of time re-educating patients regarding misinformation after treatment. A treatment decision aid is a potential source of valid information that may reduce the risk of patients receiving poor information or misinterpreting information they receive from varied sources. Patients discussed the need for access to selected vignettes

from other patients who had received various treatments to illustrate different treatment experiences and outcomes. This recommendation is similar to the suggestion by Damberg et al. (2003) for a national outcomes database that could be accessed by patients and healthcare providers for current information on treatment outcomes.

### **Treatment Decision-Making Needs and the Development of a Treatment Decision Aid**

The need for a treatment decision aid was demonstrated in two ways by the study results: 1) identification of information and treatment decision-making needs that could be addressed through a decision aid, and 2) specific patient and radiation oncologist recommendations for improving treatment decision-making.

One of the information challenges faced by patients was the ability to recall the initial conversation with the radiation oncologist. Some patients did not recall being provided with treatment options by the radiation oncologist while some did not remember the specifics about treatment logistics, such as number of radiation treatments required. Patients also reported a lack of recall about treatment outcomes. Treatment decision aids are an example of an information source that has been demonstrated to improve recall of options for patients facing challenging decisions (Davison et al., 2003; O'Brien et al., 2009; O'Connor et al., 2007). Poor recall may account for the lack of knowledge and understanding about the disease and treatment as exemplified by patients in this study. A systematic review of nine decision aids by O'Connor et al. (2007) demonstrated that knowledge scores improved for patients who used decision aids. This is a potential strategy to improve recall in men with prostate cancer during treatment decision-making.

Patients' prior healthcare experience influenced their ability to understand information provided by the radiation oncologists. This is consistent with the ODSF model which indicates that baseline knowledge and expectations have an impact on decisional needs (O'Connor & Jacobsen, 2003). Some participants were quite knowledgeable and understood the information more readily because of their field of work, while others were unaware. The latter patients may have been more easily overwhelmed by new information (Feldman-Stewart et al., 2004). A treatment decision aid with portable medium, such as a take-home DVD, has the potential to offer information without overwhelming patients as they can review it at their own pace.

Patients in the study reported learning about their recurrence and its treatment from the radiation oncologists at the cancer centre. In addition, most patients reported looking elsewhere for supplementary information, and engaged in various levels of information seeking, ranging from casual conversations with family and friends to active searches of the internet and consultations with other specialists. Information they accessed varied from general treatment information to more specific information on treatment side effects or self-care. These information seeking activities are similar to those identified by Carter et al. (2011) in a study describing the unmet information needs of men with advanced prostate cancer. Patients in both studies described spending considerable time and energy seeking additional information, often from internet based sources that may not have provided reliable high quality data relevant to their particular health situation. Also, variability in the quality of information from other sources affected patient confidence in using the data to make decisions. Therefore patients may potentially

base their treatment decision on incorrect or incomplete information, which has the potential for adverse consequences such as decision uncertainty and regret. Patients' time and effort would have been better utilized reviewing an evidence based information source such as a treatment decision aid for their specific condition, and preparing relevant questions to review with their physician to assist them in making an informed choice. Further, decision aids have been found to enhance realistic expectations about benefits and harms of options, and thus would be valuable for the patient population in the current study (O'Connor et al., 2007).

Another important factor was the need for the most advanced, up-to-date information regarding treatment options. Patients not only wanted the best treatment, they also needed some reassurance that there would be few or no long term side effects. Similarly Damberg et al. (2003) found that patient advocates wanted a centralized data base to provide up-to-date information that would help patients make an informed treatment decision. Occasionally this desire led some patients to select riskier clinical trials over standard treatment. In our study some patients viewed clinical trials as offering state of the art treatments because they were new or innovative, and did not understand the lack of evidence about the effectiveness of investigational treatments and the need for further study. Nevertheless, for some participants clinical trials may be the only treatment option available. In keeping with their goal to find better ways to treat cancer and improve the overall standard of cancer care, the NCCN (2008) also advocates for the use of clinical trials as the best management for any cancer patients who fit the eligibility criteria. Radiation oncologists likewise expressed the need for better randomized control



trials to identify the superior treatment options for their patients. A treatment decision aid can easily be updated as new research evidence becomes available.

The meaning of a cancer diagnosis and its impact was discussed in various ways by patients. They struggled between wanting more information about treatment side effects and the fear of anticipating harms that might not happen. Treatment decision aids have the potential to provide information on treatment side effects in a balanced way and have been demonstrated not to increase levels of anxiety (O'Connor et al., 2007). Further, decision aids have been found to enhance realistic expectations about treatment side effects (O'Connor et al.).

The development of a treatment decision aid for patients with locally recurrent prostate cancer should address the needs and recommendations identified by radiation oncologists and patients. Content should include information to meet the patients' knowledge needs about the relevance of various treatment options for their situation and specific information about each treatment option including the benefits and effectiveness; and the likelihood, severity and impact of treatment side effects on quality of life and function. Other criteria for a treatment decision aid include: 1) easy to understand information to explain complicated medical terminology, 2) mechanisms to assess the currency of information such as documented data updates, 3) portable or widely accessible information that can be reviewed in various locations such as the clinic and at home, 4) freedom from undue influence or emphasis on any one treatment option, and 5) inclusion of patient stories or vignettes that provide balanced illustration of treatment advantages and disadvantages.

Further, in this study, radiation oncologists specifically identified the content to include in a centralized information source, such as a treatment decision aid, that would support patient treatment decision-making. In their view, the content of the decision aid should include the main treatment options such as watchful waiting and hormone therapy and less common “theoretical options” such as HIFU and cryotherapy. Although all radiation oncologists agreed that clinical trials should be included as a treatment choice in a treatment decision aid, they did not think that detailed information should be provided. Not all radiation oncologists agreed that the information on all options should be shared, but patients actively sought out this information and experienced decisional uncertainty about their treatment choices because they were unsure if they received the necessary information to make the right choice. Therefore information should be provided about why some available options are not appropriate for the patient.

Specific treatment features to include in a treatment decision aid, as suggested by patients and radiation oncologists, were information on: toxicities, treatment efficacy, who may benefit most from the treatment, benefits and risks, actual percentages of the range of side-effects and duration of benefit, disease survival rate and alterations to quality of life. A section describing terminology and treatment specific logistics such as specific details about the time and process involved in receiving each treatment would also be essential to aid in understanding the information. Other studies have also documented the importance of including the above treatment features in a decision aid for patients (Davison et al., 2002; McGuffin & Wright, 2004).

### **Study Strengths and Limitations**

The variability in practice settings, between GRRCC and JCC, was helpful in identifying a wide range of patient needs to be addressed in developing a decision aid. However, it is possible that not all patient needs related to treatment decision-making for locally recurrent prostate cancer have been identified in this study for several reasons. First, patients in this study were all Caucasian and over 70 years of age. Younger men and those with other ethnic backgrounds may have different treatment decision-making needs (Davison et al., 2002; Levinson, Kao, Kuby & Thisted, 2005). In addition, the men who declined to participate in the study because of emotional distress may have different needs.

Second, there were challenges in recruiting patients for the study due to the long time periods (i.e. three to six months) between follow-up appointments for patients on watchful waiting. This made it very difficult to organize sufficient numbers of patients for a focus group at any one time, and necessitated a change in data collection methods to one-on-one interviews. Five patients were interviewed for this study and on the fifth interview no new themes or issues were generated. Thus, it is likely that data saturation was achieved. However, one or two additional interviews would have been beneficial to confirm that data saturation had occurred.

A strength of this study is that the findings were presented to a community patient support group attended by 25 participants with different stages of prostate cancer. Support group participants confirmed many of the treatment decision-making challenges described by study patients. In particular, support group members described as

challenging the shock of recurrence and lack of understanding of medical terminology about their illness. Support group members also identified several information and treatment decision-making needs including the need for more information regarding the different treatment choices and their side effects and potential impact on quality of life. Similar to our study participants, support group members also noted the need for an objective individual, such as trained oncology nurse, to provide unbiased treatment information. The experiences of the support group members validated study findings and acted as an opportunity for member checking. This validation potentially ameliorates some of the study limitations such as low recruitment and confirmation of data saturation. The fact that support group participants with varied stages of prostate cancer had similar experiences to patients in our study, also raises the concern that gaps in meeting patient information and treatment decision-making needs is a common and wide spread occurrence not limited to locally recurrent disease.

As was the case in this study, other studies have reported difficulties recruiting physicians as study participants (Bower et al., 2009). Various strategies were utilized in this study to maximize radiation oncologist recruitment including information sessions, telephone calls, electronic mail, repeat information sessions and personalized questionnaires. In a systematic review of 292 randomized controlled trials, personalized questionnaires and the use of incentives were found to increase response rates for study participants in general (Edwards et al., 2002); both of these strategies were employed in this study. In Round 2 of the Delphi process, recruitment was done using electronic mail and the questionnaire was embedded in the body of the message. This was an effective

recruitment strategy as radiation oncologists responded quickly to complete the questionnaire and one more radiation oncologist participated. This more positive response in Round 2 may be because radiation oncologists saw the preliminary results from Round 1 of the Delphi and thus had greater insight about the relevance of the study to their practice.

Some reasons radiation oncologists gave for non-participation were that they did not treat patients with locally recurrent prostate cancer frequently, and thus, did not feel qualified to contribute to the study; and that the treatment choices for patients with locally recurrent prostate cancer were perceived to be limited; thus, there was no need for a treatment decision aid. The latter reason contradicts the rationale for the study and research evidence about the various treatment options available for locally recurrent prostate cancer. Radiation oncologist views about the relevancy of treatment options may partially explain study results suggesting a lack of consistency in the information radiation oncologists provide to patients and the tendency of some to emphasize one treatment over others.

Third, the regional focus of this study may also limit the transferability of results only to patients and radiation oncologists at the JCC and GRRCC. This is because centres that offer a broader (or narrower) range of treatment options may be more or less receptive to or have different resources and strategies to support treatment decision-making.

Due to time constraints and the nature of the study, the expert panel in the Delphi survey was homogenous, consisting only of radiation oncologists and no other members

of the interdisciplinary healthcare teams involved in prostate cancer care at the JCC and GRRCC. Jacobsen and O'Connor (2006) suggest that, depending on the available resources, participant selection should be prioritized in order of importance in meeting the study objectives. Radiation oncologists are the primary practitioners involved in treatment decision-making for patients with locally recurrent prostate cancer; hence, the decision to focus data collection efforts on this group of providers.

However, the contributions of other health care team members and support partners such as spouse or children must be recognized as they play various supportive and influential roles in patient decision-making. Family members would provide a perspective on how men make decisions, their own roles in supporting decision-making and their personal needs related to the support they provide. Other members of the interdisciplinary team would provide a better understanding of the different types of information and decision support required along the illness trajectory for this patient population. The perspective of nurses and allied health team members would give insight into their role in providing information needed to make treatment decisions, as well as their role as patient advocates.

The interview guides used in Round 1 of the Delphi process and the patient interviews were adapted from the standard template of the ODSF for eliciting needs. In addition, a review of the literature was done to adapt the interview guides to the current decision-making context and to ensure comprehensiveness. The study could have been further strengthened by formal assessment of the content validity of the interview guides. However, it is unlikely that this limitation had an impact on study results as there was no

difficulty reported from participants in completing or answering the interview questions. In hindsight, given the small number of radiation oncologists, the first interview could have served as a pilot and the data still included for analysis.

To minimize or prevent personal assumptions from influencing data collection and analysis in the study, I bracketed my belief that all patients should actively participate in treatment decision-making. Before the commencement of each interview, I reviewed the research questions as outlined in the guide and during the interviews I made a conscious effort to allow the true perspectives of the research participants to be expressed. During data analysis and interpretation, I kept a journal in which I could document the process and keep this assumption at the forefront so that it did not influence the results. Use of reviewer triangulation to assess the consistency of identified themes and to obtain consensus on the final coding scheme and themes also ensured that my personal bias did not unduly influence the interpretation of study data.

### **Implications for Nursing Practice**

As leaders and change agents, advanced practice nurses can advocate with administrators and policy makers for the role of nurses in providing decision support for patients with locally recurrent prostate cancer. This role would include coordinating the development of a systematic way to deliver information to patients and support their treatment decision-making needs. The findings from this study suggest that an intervention based on the ODSF in which there is a multidisciplinary (family physicians, urologists, medical oncologists, nursing, allied health team) approach to decision support, is an appropriate next step to address the treatment decision-making needs of men with

locally recurrent prostate cancer. This intervention could be in the form of treatment decision aid and/or nurse led information sessions.

Patients identified nurses with oncology training as potential facilitators to deliver unbiased information. Nurses can capitalize on pre-existing therapeutic nurse-client relationships and ensure that patients have access to the resources they need to support them during treatment decision-making. Although nurses cannot recommend specific treatment, they can empower patients by giving them instrumental support such as: 1) assisting them to develop skills in decision-making, 2) defining unclear terminology and assessing patient interpretation and understanding of information, 3) providing information and resources such as brochures to reinforce learning, 4) facilitating the process of receiving medical care by explaining and preparing patients for what to expect during the treatment process, and 5) ensuring they have access to emotional support.

In addition, nurses play an important role in assisting patients to navigate the healthcare system. This should include strategies to ensure that patients have access to available services to support them in treatment decision-making. While several patients in our study reported aggressive efforts to seek additional information, no patients described accessing high quality information resources that are readily available. It is possible that patients in our study would have benefitted from accessing resources such as psycho-oncology services at specific hospital sites, community support groups, and various credible websites such as Cancer Care Ontario and the Canadian Cancer Society's Cancer Information Services (CIS). The CIS aims to provide patients with confidential information that is tailored to their needs (Canadian Cancer Society, 2010). The CIS



obtains information from the International Cancer Information Services Group which is a worldwide network of more than 50 organisations that shares information and expertise about cancer and support services for patients, family, the general public and healthcare professionals. To improve treatment decision-making, nurses and other healthcare providers looking after patients with prostate cancer need to make patients aware of existing support and information services as part of standard practice, as they have the potential to be invaluable to patients during such a challenging time.

### **Implications for Future Research**

To further enhance our understanding of treatment decision-making and information needs related to locally recurrent prostate cancer, recruitment strategies in future studies should include younger patients and those with more diverse ethnic backgrounds in order to learn about viewpoints. Bower et al. (2009) suggests that one major way to improve research recruitment for both clinicians and patients is to promote the positive contribution they can make to enhancing the quality of care and the wider development of health services. Other specific strategies to increase physician recruitment include focusing on those with a special interest in the subject of study, and targeting physicians who show readiness to change and/or those who are uncertain about the benefits of some treatments (Bower et al.). Strategies to increase patient recruitment include use of lay advocates or lay recruitment described as use of social marketing research to engage the population and promote primary care research as routine (Bower et al.).

Further research should also confirm data saturation regarding patient perceptions of their treatment decision-making needs and obtain broader input from a more representative expert panel from the interdisciplinary team involved in patient care. These team members include family physicians, urologists, medical oncologists, nursing, allied health providers and family members. Expert panel involvement of all those with vested interests would foster commitment to acting on and using study results to improve care practices and services to better support patients in making treatment decisions. Given the small sample of radiation oncologists who participated in this study, further research to determine their level of agreement or consensus on treatment options is warranted along with an examination of factors that influence physician perceptions of which treatment option to include in a treatment decision-aid.

### **Conclusion**

In general, radiation oncologists recognized the challenges patients experienced during treatment decision-making and that there was a need for increased support during this process. Patients identified a number of information needs related to treatment as being important for decision-making, including options, effectiveness and side effects. Both patients and radiation oncologists reported that: 1) there is a lack of good research-based information about the effectiveness of treatment options; and 2) uncertainty about the likelihood that different treatment side effects would occur negatively impacted the quality of information provided to patients, and subsequently, the quality of decisions patients made. This highlights the need for more randomized controlled trials on treatments for locally recurrent prostate cancer. Radiation oncologists and patients alike

felt that an information source that was kept current through research updates would be a useful resource for improving decision support, and a treatment decision aid is a good example of such a source. Another important finding relates to the lack of radiation oncologist agreement about inclusion of all treatment options in a treatment decision aid and patients' desire to hear about all treatment options. Most radiation oncologists agreed on the inclusion of watchful waiting, clinical trials, prostatectomy and HIFU in and a treatment decision aid. There was lack of agreement about the inclusion of brachytherapy, hormone therapy and cryotherapy. Despite the limitations of this study, the results provide a preliminary view of men's treatment decision-making needs related to locally recurrent prostate cancer. The findings provide the basis for developing an unbiased decision-making intervention to address the treatment decision-making needs of men with locally recurrent prostate cancer.

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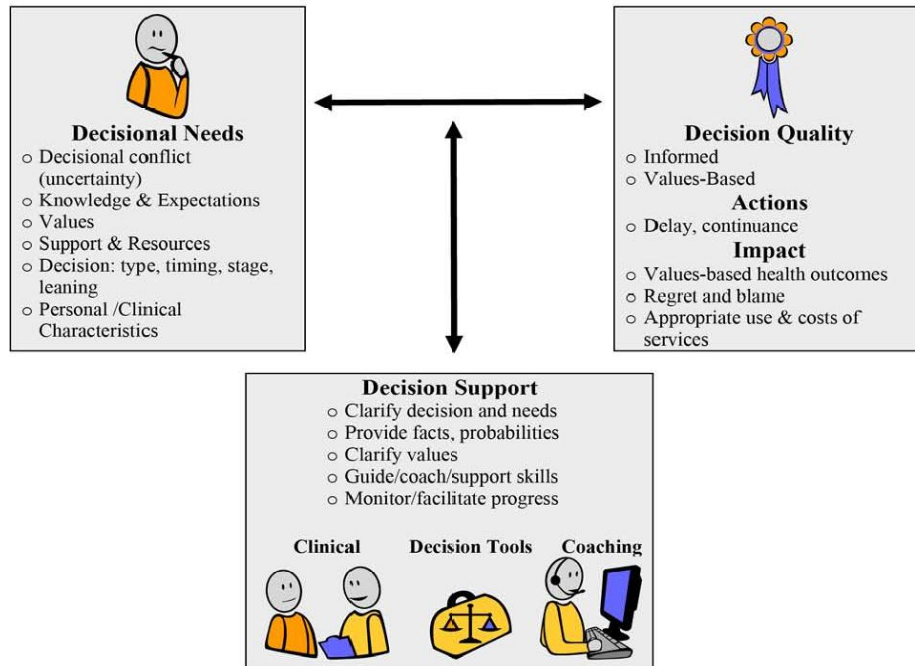
## Appendix A

### The Ottawa Decision Support Framework to Address Decisional Conflict

#### Ottawa Decision Support Framework to Address Decisional Conflict

The Ottawa Decision Support Framework (Fig 1) uses concepts and theories from general psychology (Tversky & Kahneman, 1981), social psychology (Ajzen & Fishbein, 1980), decision analysis (Keeney, 1982), decisional conflict (Janis & Mann, 1977), values (Fischhoff, Slovic & Lichtenstein), social support (Norbeck, 1988; Orem, 1995), and self efficacy (Bandura, 1982).

Figure 1. Ottawa Decision Support Framework



The framework applies to all participants involved in decision making, including the individual, couple, or family, and their health practitioner. The framework asserts that participants' decisional needs will affect decision quality (informed, values-based choices), which in turn affects actions or behaviour (e.g. delay), health outcomes, emotions (regret, blame), and appropriate use of health services. (See **Glossary of Terms for Ottawa Decision Support Framework**)

Decision support in the form of clinical counselling, decision aids and coaching can improve decision quality, by addressing unresolved decisional needs.

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**Glossary of Terms for the Ottawa Decision Support Framework**

<p><b>DECISIONAL NEEDS</b></p> <p><b>DECISION</b>  <b>Type:</b> class or characteristic of the choice that needs to be made [e.g. developmental transition or clinical options (screen, test, treat, palliate); number of options, degree of risk/uncertainty, seriousness of outcomes, whether it is irrevocable  <b>Timing:</b> time frame or urgency with which a decision needs to be made  <b>Stage:</b> phase of decision making: not thinking about options; considering options; close to selecting an option; taking steps towards implementing option; have already carried out choice. Categories are similar to Prochaska's Stages of Change (1), with one important difference. Deciding <u>not</u> to change is a viable option because often there is no recommended course of action, e.g. amniocentesis.  <b>Leaning:</b> inclination to choose one option over the other</p>
<p><b>DECISIONAL CONFLICT</b>                  uncertainty about course of action to take when choice among options involves risk, loss, regret, challenge to personal life values</p>
<p><b>KNOWLEDGE &amp; EXPECTATIONS</b>  <b>Knowledge:</b> cognizance of the health problem or situation, options, and outcomes  <b>Expectation:</b> perceived likelihood or probability of outcomes of each option</p>
<p><b>VALUES</b>                  desirability or personal importance of outcomes of options</p>
<p><b>SUPPORT &amp; RESOURCES</b>  <b>Others' opinions/ practices:</b> perceptions of what others decide or what others think is the appropriate choice. This may include a person's spouse, family, peers, and practitioner(s). For practitioners: the patient, professional peers, and personal network  <b>Pressure:</b> perception of persuasion, influence, coercion from important others to select one option  <b>Role in decision making:</b> the way a participant is or wants to be involved in decision making; do they prefer to: make the choice themselves after considering opinions; share decision making with another; have others decide after considering their opinion  <b>Experience:</b> past exposure to the situation, options, outcomes, decision making process  <b>Self-efficacy:</b> confidence or belief in one's abilities in decision making, including shared decision making  <b>Motivation:</b> readiness and interest in decision making, including shared decision making  <b>Skill:</b> abilities in making and implementing a decision  <b>External support:</b> Available, accessible assets from others that are required to make and implement the decision. Types include: information, advice, emotional support, instrumental help, financial assistance, health &amp; social services. Sources include: social networks, professional networks, support groups, voluntary agencies, and the formal health care, education, and social sectors</p>
<p><b>PERSONAL &amp; CLINICAL CHARACTERISTICS</b>  <b>Patient:</b> Age, gender, education, marital status, ethnicity, occupation, locale, diagnosis &amp; duration of condition, health status (physical, emotional, cognitive, social)  <b>Practitioner:</b> age, gender, ethnicity, clinical education, specialty, practice locale, experience, counselling style</p>
<p><b>DECISION SUPPORT</b></p>
<p><b>PATIENT DECISION AIDS</b>                  Evidence-based tools to prepare people to participate in making specific and deliberated choices among healthcare options in ways they prefer. They supplement (not replace) clinician's counseling and aid decision making by: a) providing evidence-based information about a health condition, the options, associated benefits, harms, probabilities, and scientific uncertainties; b) helping people to recognize the values-sensitive nature of the decision and to clarify the value they place on the benefits, harms, and scientific uncertainties. Strategies include: describing the options in enough detail that clients can imagine what it is like to experience the physical, emotional, and social effects; and guiding clients to consider which benefits and harms are most important to them; and c) providing structured guidance in the steps of decision making and communication of their informed values with others involved in the decision (e.g. clinician, family, friends).</p>
<p><b>DECISION COACHING</b>                  Support provided to people facing a decision by a trained facilitator who is supportive but neutral in the decision. Coaching can be provided face to face (individual, group) or using communication technologies (telephone, Internet). Decision coaching is used alone or in combination with patient decision aids. The strategies may include: a) clarifying decision and monitoring needs; b) facilitating access to evidence-based information, verifying understanding, clarifying values, building skills in deliberation, communication, and accessing support; and c) monitoring and facilitating progress in decision making and decision quality.</p>
<p><b>DECISION QUALITY</b></p>
<p><b>QUALITY OF THE DECISION</b>                  The extent to which the chosen option best matches informed clients' values for benefits, harms, and scientific uncertainties</p>
<p><b>QUALITY OF THE PROSESS OF DECISION MAKING</b>                  The extent to which a person is helped to: a) recognize that a decision needs to be made; b) know about the available options and associated procedures, benefits, harms, probabilities, and scientific uncertainties; c) understand that values affect the decision; d) be clear about which features of the options matter most to them (e.g. benefits, harms, and scientific uncertainties); e) discuss values with their clinician(s); and f) become involved in decision making in ways they prefer.</p>

Taken from: Ontario Health Research Institute (2008). Patient decision aids, Ottawa Decision Support Framework. Retrieved June 13, 2008 from <http://decisionaid.ohri.ca/odsf.html>

**Appendix B**

**Evidence about the Effectiveness and Side Effects of Different Treatments for Locally Recurrent Prostate Cancer**

Type of Treatment	Limitations/Benefits of Treatment	Patients Eligible for the treatment	Effectiveness of treatment
<p>Watchful waiting or expectant management:</p> <p>Active disease monitoring with digital rectal exam (DRE) and PSA every 6 months for life expectancy <math>\geq 10</math> years and every 6 to 12 months for a life expectancy <math>\leq 10</math> years (NCCN, 2008; NCI, 2010)</p>	<p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>• uncertainty about the long-term history of disease</li> <li>• increased anxiety</li> <li>• risk of progression</li> <li>• subsequent need for more intensive treatment</li> <li>• it requires regular PSA testing — PSA isn't an infallible test, and some cancers spread before PSA rises</li> </ul> <p><b>Benefits :</b></p> <ul style="list-style-type: none"> <li>• avoidance of possible treatment side effects and therefore ability to maintain current levels of HRQL and activities of daily living (NCCN, 2008)</li> </ul>	<ul style="list-style-type: none"> <li>• Asymptomatic patients</li> </ul>	
<p>Salvage Surgery</p>	<p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>• carries all the risks of any major surgery, including heart attack, pulmonary embolism, bleeding, infection, reactions to anesthesia or medications</li> <li>• high morbidity rates for severe incontinence (23% to 64%), rectal injury (15%), bladder neck contractures and urethral strictures (7% to 28%) (Lam &amp; Belldegrun, 2004)</li> </ul>	<ul style="list-style-type: none"> <li>• Surgery is an option for patients in good health with no major comorbid conditions</li> <li>• Original clinical stage of disease classified as T1-T2, NX or NO, life expectancy <math>&gt;10</math> y, Gleason <math>&lt; 7</math> and PSA now <math>&lt;10</math>ng/ml (Anderson, Fourcade, Payne &amp; Schulman, 2002; NCCN, 2008)</li> </ul>	<ul style="list-style-type: none"> <li>• A 10-year disease-free survival of 43% ( Amling et al. as cited by Gelet et al., 2004)</li> <li>• In several clinical series the 5-year cancer-specific survival rate was found to be 64% to 88% with a PSA progression-free survival rate of 83% (Lam &amp; Belldegrun, 2004)</li> </ul>

Type of Treatment	Limitations/Benefits of Treatment	Patients Eligible for the treatment	Effectiveness of treatment
Re-irradiation or salvage brachytherapy	<p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>• rectal ulcers or bleeding requiring colostomy (6%)</li> <li>• significant dysuria (6%)</li> <li>• the need for transurethral resection of the prostate (14%) (Lam &amp; Belldegrun, 2004)</li> </ul>	<ul style="list-style-type: none"> <li>• This is an option for patients with PSA value &lt;10ng/m, histological confirmed local recurrence, no distant metastases and normal urodynamic function (Aranha &amp; Vaishampayan, 2004; Gelet, Chapelon and Poissonnier et al. 2004)</li> </ul>	<ul style="list-style-type: none"> <li>• 5-year relapse free survival is 50% and this can be as high as 80% for patients with low Gleason scores (Aranha &amp; Vaishampayan, 2004)</li> <li>• 34% actuarial rate of biochemical disease-free survival at 5 years (Lam and Belldegrun, 2004)</li> </ul>
Hormone therapy or ADT {This includes traditional hormone monotherapy (LHRH agonists, orchiectomy), combined androgen blockade, or nontraditional oral therapies. }	<p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>• erectile dysfunction</li> <li>• diabetes and cardiovascular disease</li> <li>• hot flashes and breast enlargement</li> <li>• loss of bone mass, possible bone fractures loss of muscle mass</li> <li>• loss of sex drive</li> <li>• the cancer may eventually become resistant to hormonal drug therapy</li> </ul> <p><b>Benefits:</b></p> <ul style="list-style-type: none"> <li>• it can temporarily slow the growth of prostate cancer and shrink existing tumors, therefore reducing symptoms and prolonging life.</li> <li>• therapy can be stopped, allowing the return of normal hormone production (if treatment is intermittent)(NCCN, 2008)</li> </ul>	<ul style="list-style-type: none"> <li>• Candidates for this therapy are those with local recurrence</li> <li>• NCCN (2008) recommends that candidates who meet the criteria for local therapy but have positive studies for metastases should have hormone therapy</li> </ul>	<ul style="list-style-type: none"> <li>• Early hormone therapy has shown a significant improvement in survival in patients with Gleason &gt; 7 or PSA doubling time of 12 months or less and PSA ≤5 ng/mL(NCI, 2010)</li> <li>• It offers prolonged disease control with a median cancer-specific survival of 6 years (NCI, 2010)</li> </ul>
Salvage cryotherapy	<p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>• fistula (3%), incontinence (6.7%), sloughing (5%), retention/lower urinary tract infections (8.5%) and incidence of impotence (34 to 100%) (Lam and Belldegrun, 2004)</li> </ul>	<ul style="list-style-type: none"> <li>• The best candidates are those with initial clinical stage T1-T2N0M0 disease and PSA ≤ 10ng/ml (Izawa, Perrotte, Greene et al., 2001)</li> <li>• PSA &gt; 5ng/ml, histological</li> </ul>	<ul style="list-style-type: none"> <li>• Candidates who meet the eligibility criteria have a higher rate of negative biopsies after salvage cryotherapy</li> <li>• PSA level before cryotherapy of &lt; 10 ng/mL and an undetectable</li> </ul>

Type of Treatment	Limitations/Benefits of Treatment	Patients Eligible for the treatment	Effectiveness of treatment
	<ul style="list-style-type: none"> <li>incontinence rates of about 42% and incidence of long term incontinence of approximately 28% (Aranha and Vaishampayan, 2004)</li> <li>incontinence rates 69% to 73%, 67% for obstructive symptom and 8.7% for fistula occurrence Gelet et al., 2004)</li> </ul> <p><b>Benefits:</b></p> <ul style="list-style-type: none"> <li>the hospital stay is a day or less</li> <li>there is little blood loss. It has a short recovery time of one to two weeks</li> </ul>	confirmation of local recurrence and no distant metastases (Lam and Belldegrin, 2004)	<p>PSA nadir in 50% to 60% of patients after cryotherapy were associated with the highest Biochemical Recurrence-Free Survival (De la Taille, Hayek and Benson et al. 2000)</p> <ul style="list-style-type: none"> <li>Follow-up studies are required to determine the biochemical relapse free survival of this therapy. Some studies have found it to have a low 5-year disease-free survival rate of 31% (Gelet et al., 2004)</li> </ul>
High-intensity focused ultrasound (HIFU)	<p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>rectourethral fistula in 6%, grade 3 incontinence in 7%, bladder neck stenosis in 17% (Gelet et al., 2004)</li> </ul> <p><b>Benefits:</b></p> <ul style="list-style-type: none"> <li>This is a minimally invasive treatment alternative</li> <li>Morbidity is lower than the morbidity reported after other types of salvage therapy, leading to a favorable risk/benefit ratio (Gelet et al., 2004; Huang, et al., 2007)</li> </ul>	<ul style="list-style-type: none"> <li>Pre-HIFU Gleason scores ranged from 2 to 6 in 24 patients, 7 in 13 patients and 8 to 10 in 34 patients in the study by Gelet et al. (2004)</li> </ul>	<ul style="list-style-type: none"> <li>Follow-up studies are required to determine the biochemical relapse free survival of this therapy</li> <li>Post-HIFU 80% of the patients had negative biopsies and 61% had a nadir PSA level of less than 0.5 ng/mL within 3 months (Gelet et al., 2004)</li> </ul>
Light-activated drug Tookad	<p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>The damage caused to tissue exposed to light is permanent (MUHC, 2007)</li> </ul> <p><b>Benefits:</b></p> <ul style="list-style-type: none"> <li>It is eliminated from the body in about two hours (MUHC, 2007)</li> </ul>		<ul style="list-style-type: none"> <li>Treatment during a phase I trial yielded a complete removal of prostate cancer in 46 percent of patients (MUHC, 2007)</li> </ul>

## Appendix C

### International Patient Decision Aid Standards (IPDAS) Criteria for Evaluation

#### IPDAS Criteria

#### **I. Content: Does the patient decision aid ...**

##### **Provide information about options in sufficient detail for decision making?**

describe the health condition 2.1

...

list the options 2.2

list the option of doing nothing 2.3

describe the natural course without options 2.4

describe procedures 2.5

describe positive features [benefits] 2.6

describe negative features of options [harms / side effects / disadvantages] 2.7

include chances of positive / negative outcomes 2.8

##### **Additional items for tests**

describe what test is designed to measure 2.9

include chances of true positive, true negative, false positive, false negative test results 2.10

describe possible next steps based on test result 2.11

include chances the disease is found with / without screening 2.12

describe detection / treatment that would never have caused problems if one was not screened 2.13

##### **Present probabilities of outcomes in an unbiased and understandable way?**

use event rates specifying the population and time period 3.1

compare outcome probabilities using the same denominator, time period, scale 3.2, 3.3, 3.6

describe uncertainty around probabilities 3.4

use visual diagrams 3.5

use multiple methods to view probabilities [words, numbers, diagrams] 3.7

allows the patient to select a way of viewing probabilities [words, numbers, diagrams] 3.8

Allow patient to view probabilities based on their own situation 3.9

Place probabilities in context of other events 3.10

use both positive and negative frames 3.13

##### **Include methods for clarifying and expressing patients' values?**

describe the procedures and outcomes to help patients imagine what it is like to experience their physical, emotional, social effects 4.1

ask patients to consider which positive and negative features matter most 4.2

suggest ways for patients to share what matters most with others 4.3

#### **Include structured guidance in deliberation and communication?**

provide steps to make a decision 6.1

suggest ways to talk about the decision with a health professional 6.2

include tools [worksheet, question list] to discuss options with others 6.3

## **II. Development Process: Does the patient decision aid ...**

#### **Present information in a balanced manner?**

Able to compare positive / negative features of options 9.1

shows negative / positive features with equal detail [fonts, order, display of statistics] 9.2

#### **Have a systematic development process?**

includes developers' credentials / qualifications 1.1

Finds out what users [patients, practitioners] need to discuss options 1.2, 1.3

has peer review by patient / professional experts not involved in development and field testing 1.8b

is field tested with users [patients facing the decision; practitioners presenting options] 1.4, 1.5

#### **The field tests with users [patients, practitioners] show the patient decision aid is:**

acceptable 1.6, 1.7

balanced for undecided patients 9.3

understood by those with limited reading skills 10.6

#### **Use up to date scientific evidence that is cited in a reference section or technical document?**

provides references to evidence used 11.1

report steps to find, appraise, summarise evidence 11.2

report date of last update 11.3

report how often patient decision aid is updated 11.4

describe quality of scientific evidence [including lack of evidence] 11.5b

uses evidence from studies of patients similar to those of target audience 11.6

#### **Disclose conflicts of interest?**

report source of funding to develop and distribute the patient decision aid 7.1, 7.2

report whether authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aid 7.3, 7.4

#### **Use plain language?**

is written at a level that can be understood by the majority of patients in the target group 10.3



is written at a grade 8 equivalent level or less according to readability score [SMOG or FRY] 10.4

provides ways to help patients understand information other than reading [audio, video, in-person discussion] 10.5

#### Meet additional criteria if the patient decision aid is Internet based

provide a step-by-step way to move through the web pages 8.1

Allow patients to search for key words 8.2

provide feedback on personal health information that is entered into the patient decision aid 8.3

provides security for personal health information entered into the decision aid 8.4

Make it easy for patients to return to the decision aid after linking to other web pages 8.5

permit printing as a single document 8.6

#### Meet additional criteria if stories are used in the patient decision aid

use stories that represent a range of positive and negative experiences 5.2

State in an accessible document that the patient gave informed consent to use their stories 5.5

reports if there was a financial or other reason why patients decided to share their story 7.5

### **III. Effectiveness: Does the patient decision aid ensure decision making is informed and values base**

#### **Decision processes leading to decision quality. The patient decision aid helps patients to ...**

recognise a decision needs to be made 12.1

know options and their features 12.2. 12.3

understand that values affect decision 12.4

be clear about option features that matter most 12.5

discuss values with their practitioner 12.6

become involved in preferred ways 12.7

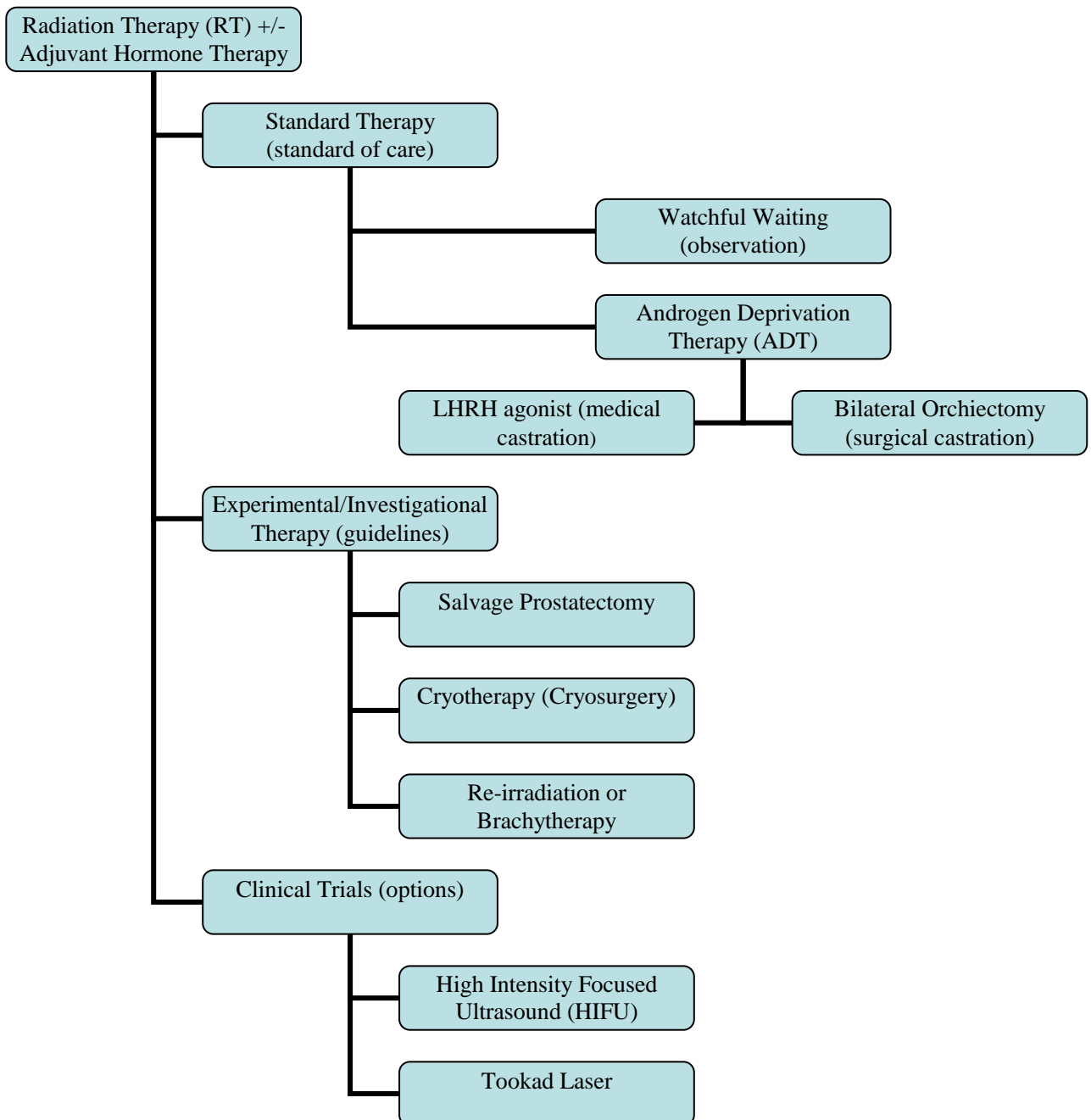
#### **Decision quality. The patient decision aid ...**

improves the match between the chosen option and the features that matter most to the informed patient 12.8

Taken from: International Patient Decision Aids Standards (IPDAS) (2006). IPDAS checklist for judging the quality of patient decision aids, retrieved July 12, 2008 from [http://ipdas.ohri.ca/IPDAS\\_checklist.pdf](http://ipdas.ohri.ca/IPDAS_checklist.pdf)

## Appendix D

### Treatment Sources for Patients who Experience Recurrence Post Radiation Treatment (RT)



**Appendix E**

**Summary of Decision Aids Available in Prostate Cancer**

<b>Name of decision aid</b>	<b>Patient Target Group</b>	<b>Treatment Options</b>	<b>Methods of Information delivery</b>	<b>Evaluation Data</b>
<p>“Hormone therapy: When PSA rises after prostate cancer treatment” (OHRI, 2010)</p>	<p>Targets men with rise in PSA post curative therapy with surgery or radiation who have no spread beyond the prostate.</p>	<p>Two options:</p> <ul style="list-style-type: none"> <li>• Hormone therapy</li> <li>• Watchful waiting</li> </ul>	<p>DVD Paper Video</p>	<p>It meets:</p> <ul style="list-style-type: none"> <li>• 8 out of 14 of the content criteria</li> <li>• 8 out of 9 of the development process criteria</li> <li>• 1 out of 2 of the effectiveness criteria</li> </ul>

Name of decision aid	Patient Target Group	Treatment Options	Methods of Information delivery	Evaluation Data
<p>“Prostate cancer guide” (OHRI, 2010)</p>	<p>Targets men diagnosed with early-stage prostate cancer who are considering their treatment options.</p>	<p>Six options:</p> <ul style="list-style-type: none"> <li>• Radiation therapy: <i>external beam radiation and radioactive seed implants</i></li> <li>• Surgery</li> <li>• Watchful waiting</li> <li>• Combination therapy</li> <li>• Hormone therapies</li> <li>• Emerging therapies: <i>cryotherapy and laparoscopic surgery</i></li> </ul>	<p>World Wide Web Paper</p>	<p>It meets:</p> <ul style="list-style-type: none"> <li>• 10 out of 15 of the content criteria</li> <li>• 3 out of 9 of the development process criteria</li> <li>• 0 out of 2 of the effectiveness criteria</li> </ul>
<p>“Should I have radiation therapy or a prostatectomy for locally prostate cancer?” (OHRI, 2010)</p>	<p>Targets men diagnosed with locally prostate cancer</p>	<p>Three options:</p> <ul style="list-style-type: none"> <li>• Watchful waiting</li> <li>• Radical prostatectomy</li> <li>• Radiation therapy</li> </ul>	<p>World Wide Web Paper</p>	<p>It meets:</p> <ul style="list-style-type: none"> <li>• 11 out of 14 of the content criteria</li> <li>• 4 out of 9 of the development process criteria</li> <li>• 0 out of 2 of the effectiveness criteria</li> </ul>

Name of decision aid	Patient Target Group	Treatment Options	Methods of Information delivery	Evaluation Data
“Treatment choices for Prostate Cancer” (OHRI, 2010)	Targets men diagnosed with early stage prostate cancer	Three options: <ul style="list-style-type: none"> <li>• Radical prostatectomy</li> <li>• Radiation therapy: <i>external beam and brachytherapy</i></li> <li>• Watchful waiting</li> </ul>	Video Paper DVD	It meets: <ul style="list-style-type: none"> <li>• 14 out of 15 of the content criteria</li> <li>• 8 out of 9 of the development process criteria</li> <li>• 1 out of 2 of the effectiveness criteria</li> </ul>
“Is a Prostate –Specific Antigen (PSA) test right for you?” (OHRI, 2010)	A screening decision aid. Targets men who are considering having a PSA test but have no prostate cancer diagnosis.	Two options: <ul style="list-style-type: none"> <li>• To have a PSA test</li> <li>• Not to have a PSA test</li> </ul>	DVD Paper Video	It meets: <ul style="list-style-type: none"> <li>• 17 out of 19 of the content criteria</li> <li>• 8 out of 9 of the development process criteria</li> <li>• 1 out of 2 of the effectiveness criteria</li> </ul>
“Should I have a prostate-specific antigen (PSA) test to screen for prostate cancer?” (OHRI, 2010)	A screening decision aid. Targets men who are considering PSA testing but have no prostate cancer diagnosis.	Two options: <ul style="list-style-type: none"> <li>• To have a PSA test</li> <li>• Not to have a PSA test</li> </ul>	World Wide Wed Paper	It meets: <ul style="list-style-type: none"> <li>• 11 out of 18 of the content criteria</li> <li>• 4 out of 9 of the development process criteria</li> <li>• 0 out of 2 of the effectiveness criteria.</li> </ul>

## **Appendix F**

### **Information Letter for Radiation Oncologists who Work with Men with Locally Recurrent Prostate Cancer**

My name is Gladys Mokaya. I am a Registered Nurse and Master's student in the School of Nursing at McMaster University. I am working with health care providers from the Grand River Regional Cancer Centre and Juravinski Cancer Centre to conduct a study about locally recurrent prostate cancer.

I would like to invite you to participate in this research study that has been funded by the Grand River Hospital through donations from a prostate cancer fundraising event called the Motorcycle Ride for Dad. One purpose of the study is to learn more about the treatment decision-making needs of men with locally recurrent prostate cancer. We also want to learn more from patients and radiation oncologists about the type of information that should be included in educational materials to assist men affected by locally recurrent prostate cancer to meet their decisional needs.

The results of this study may be used by health care providers to help them plan for and provide information and treatment decision-making resources that are important for patients and families who are affected by locally recurrent prostate cancer.

If you agree to be part of this study, you will participate in a 3 round Delphi process survey, with the Round 1 being a 30 minute structured interview with the student researcher. You will also be asked to complete a very brief survey about your practice prior to the structured interview. Completion of the survey will take about 5 minutes. In round two and three of the Delphi process survey you will be asked to complete an electronic questionnaire that will take about 15 minutes to complete. The questionnaire will ask about your perceptions of the most difficult and important decisions relevant to patient treatment decision-making. You will also be asked about potential barriers and facilitators that affect patient treatment decision-making. Finally, you will be asked to identify the types of treatment and information that should be included in patient education materials.

Eight radiation oncologists will be requested to participate in this study. Approximately 6 to 8 men with locally recurrent prostate cancer will be asked to participate in interviews as a part of this study.

For more details about the study please review the attached information sheet/consent form. If I have not received a response from you within two weeks, I will send another email followed by a telephone call to find out if you wish to participate.

If you have any questions or concerns, you can call me at (905) 525-9140 ext. 22806 or you could also speak to the Local Principal Investigator of this study, Dr. Denise Bryant-Lukosius at (905) 525-9140 ext. 22408.

If you have any questions regarding your rights as a research participant, you may contact the Office of the Chair of the Hamilton Health Sciences/Faculty of Health Sciences Research Ethics Board at 905-521-2100 ext. 42013.

If you do not wish to participate in this study, please leave a message at 905-525-9140 ext 22806, and you will not be contacted.

## Appendix G

### Confirmation Letter for Radiation Oncologists

Dear \_\_\_\_\_

Thank you for agreeing to participate in this research study looking at the treatment decision-making needs of men with locally recurrent prostate cancer. We want to learn more from patients and radiation oncologists about the type of information that they would want to be included in education materials to assist men affected by locally recurrent prostate cancer to meet their decisional needs.

You will participate in a 3 round Delphi process survey, with the Round 1 being a 30 minute structured interview with the student researcher. The interview will be recorded using an audiotape recorder and then transcribed. You will also be asked to complete a very brief survey about your practice prior to the structured interview. Completion of the survey will take about 5 minutes. In round two and three of the Delphi process survey you will be asked to complete an electronic questionnaire that will take about 15 minutes to complete. The questionnaire will ask about your perceptions of the most difficult and important decisions relevant to patient treatment decision-making. You will also be asked about potential barriers and facilitators that affect patient treatment decision-making. Finally, you will be asked to identify the types of treatment and information that should be included in patient education materials.

Participation in the study is completely voluntary. Your employment will not be affected in any way if you choose not to participate. You may also choose to withdraw at any time during your participation in the study. It is also important to know that your participation in the study is confidential and that any information you provide will not be shared with your employer. You will not be identified in the reporting of the study results. Study results shared in presentations or in publications will only be provided in aggregate form so that no identifying information such as age, place of work or work experience could identify individual participants.

The study is being done at the Grand River Regional Cancer Centre and the Juravinski Cancer Centre. The project is funded by the Grand River Hospital through donations from a prostate cancer fundraising event called the Motorcycle Ride for Dad. It has been approved by the research ethics board at McMaster University and the Tri-Hospital Research Ethics Board Grand River Regional Cancer.

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**Your Face-to-Face Interview will be held on \_\_\_\_\_ at \_\_\_\_\_**



**Location:** \_\_\_\_\_

Please contact me if you need to reschedule. You will be given a \$20 bookstore gift certificate as a token of appreciation.

Sincerely,

Gladys Mokaya, Principal Investigator, Master's Student, Faculty of Health Sciences (Nursing), McMaster University, Tel: (905) 525-9140 ext. 22806, e-mail: [mokayagk@mcmaster.ca](mailto:mokayagk@mcmaster.ca)

**Appendix H**

**Interview Guide for Radiation Oncologists Delphi process Round 1**

**PERCEPTION OF THE DECISION**

**1. What decisions do patients with locally recurrent prostate cancer have to make in your practice?**

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**2. Focusing on treatment decisions, what do you see as the main treatment choices that your patients have?**

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Watch and wait (expectant management)  Prostatectomy (surgery)  Re-irradiation or (brachytherapy)  hormonal therapy(ADT)  Cryotherapy  High-intensity focused ultrasound (HIFU)  Light-activated drug Tookad (Tookad Laser)  Clinical trial/drug study

other \_\_\_\_\_

**Approximately how much time did you spend explaining the different treatment choices?**

10 to 15 minutes  15 to 30 minutes  30 to 45 minutes

Did you think that was sufficient time?

Yes  No

**3. What do you see as the main benefits and risks of the treatment choices?**

Choice	Benefit	Risk
Watch & Wait		

<b>Prostatectomy</b>		
<b>Re-irradiation (brachytherapy)</b>		
<b>Hormonal therapy(ADT)</b>		
<b>Cryotherapy</b>		
<b>High-intensity Focused Ultrasound (HIFU)</b>		
<b>Light-activated drug Tookad</b>		
<b>Clinical trial/drug study</b>		
<b>Other:</b>		
<b>Other:</b>		

**4. People may experience difficulty making this type of decision, how do patients in your practice feel when making their treatment decision?**

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**5. What factors do you think make it difficult for a patient to make a treatment decision?**

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Probe:  lack of information about options, benefits, risks  lack of information on the probability of occurrence of the benefits and harms  confusion from information overload  unclear about what is important to them  feeling unsupported in decision making.  lacking information on what others decide  feeling pressure from others  lacking motivation or not feeling ready to make a decision  lacking the skill or ability to make this type of decision  too anxious  wanting to

choose on the basis of family needs/preferences  conflicting needs (ill husband/children)  other responsibilities   
emotional stability  lack of confidence  depression  anxiety  confusion/conflicting feelings  other's needs

## PERCEPTION OF OTHERS

### 6. What is your usual role in making this decision?

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Do you usually:  make the decision for the patient  share the decision with the patients'  provide support or advice for patients to make the decision on their own

### 7. What factors make it difficult for you to support your patients' treatment decision making?

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lack of time  lack of support staff  other

### 8. Who else beside yourself and the patient is usually involved in treatment decision making?

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Spouse  family  friend  health care provider  other

### 9. What is their usual role in treatment decision making?

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make the decision for the patients  share the decision with the patients  Provide support or advice for patients to make the decision on their own  don't know  Other

## RESOURCES

### 10. How do patients in your practice usually go about making their treatment decision?

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Do they:  get information on choices  get information on the chances of benefits and risks  consider the personal importance of the benefits and risks  get information on how other patients go about deciding or what they would recommend  find ways to handle the pressure while making the decision  get support from others (or advice from loved ones)  follow your advise

**11. What do think are some of the resources that would help patients make this decision and/or overcome some of the barriers to treatment decision-making?**

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**Personal resources:**  previous experience with the situation  self-confidence  Motivation  Skill in decision making  physical health  general emotional health  good analytic skills (cognitive health)  good social connections (social health )

**External resources:**  availability and access to information  advice  emotional support  help with practical things  financial assistance

**Other sources:**  social network  professional network (specify: \_\_\_\_\_)  support groups  voluntary agencies  formal health care system  education  social sector (Friends)  employer

**12. What are some ways to improve the support for the men faced with this challenging treatment decision?**

**Counseling from health practitioner**, IF YES, what type of practitioner

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**Discussion groups of people facing the same decisions.** IF YES, what type of organization or group \_\_\_\_\_

**Information materials** IF YES, specify format  booklets, pamphlets

Internet  videos or DVDs or CDs

other, specify \_\_\_\_\_

**Information materials** IF YES, specify content  Health condition description

Treatment options

Benefits and risks of treatment

The probabilities of the benefits and risks occurring

Help considering the personal importance of benefits versus risks

Guidance in the steps of deliberation and communication

Other, specify \_\_\_\_\_

**13. Now thinking about future decisions, when preparing the information materials should all treatment choices be presented OR should only a few choices be provided?**

**14. How should the choices be narrowed down?**

**15. In order to narrow down the choices, it helps to know what matters most to you as the health care provider. Can you tell me which features of treatment matter most or should be included in information materials?**

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Probe:  how effective the treatment is (response rate)  Quality of life (minimal treatment side effects)  ability of the treatment to control the symptoms of the disease  disease-free survival or survival rate)  information on participating in a clinical trial (drug study)  morbidity rates of the treatment

other \_\_\_\_\_

## Appendix I

### Radiation Oncologists Demographic Questionnaire –

#### Locally Recurrent Prostate Cancer Treatment Decision Aid Study

1. What is your current role regarding the treatment of men with locally recurrent prostate cancer?

\_\_\_\_\_

2. In total, how many years have you worked as a radiation oncologist?

\_\_\_\_\_ Years

3. In total, how many years have you treated men with locally recurrent prostate cancer?

\_\_\_\_\_ Years

4. In a typical week, estimate the number of hours you spend focused on the care of men with locally recurrent prostate cancer and their families

\_\_\_\_\_ Hours per week

5. Please describe the service(s) you provide for men with locally recurrent prostate cancer (Check ALL that apply)

- Pain & symptom management
- Radiation therapy
- Consultation about various treatment choices
- Coordination of care
- Consultation with health care team
- Emotional support (e.g. coping with cancer)



- Psychological counselling & support (e.g. for mental health problems such as anxiety or depression)
- Information
- Family support
- Other (please specify) \_\_\_\_\_

## Appendix J

### Questionnaire for Radiation Oncologists Delphi process Round 2

Dear xxx,

A few months ago, you were asked to participate in the **Round 1 of data collection for a Delphi process study examining radiation oncologist perceptions about the treatment decision-making needs of patients with locally recurrent prostate cancer**, following initial curative treatment with radiation therapy. During this same period, we collected similar data from patients with prostate cancer.

I am inviting you to comment on the importance of key findings from the physician and patient data collected to date, by participating in this **Round 2 of the Delphi process survey**.

**Your participation is very important** because information from this survey will be used to determine the content and priority information to be included in a treatment decision-making aid for this patient population at the Juravinski Cancer Centre/Grand River Regional Cancer Centre.

The survey is very brief and will only take 5 to 10 minutes to complete.

Please find attached a detailed information letter about the Study and a consent form. Please attach an electronically signed copy of the consent form with your response. To complete the survey, click reply and fill the questionnaire in the body of the email. The deadline to complete the survey is October 15th, 2010. A reminder email will be sent 7 days prior to the deadline. Your quick response will be highly appreciated.

### Questionnaire

- Which of the following treatment options should be included for discussion in a treatment decision aid for patients who require treatment for localized recurrent prostate cancer?

(Indicate whether you **Agree (Yes)** or **Disagree (No)** )

Treatment option	Yes (Y)	No (N)
Watch and Wait		
Androgen Deprivation Therapy (ADT)		
Prostatectomy		
Re-irradiation (brachytherapy)		
Cryotherapy		

High-intensity Focused Ultrasound (HIFU)		
Light activated tookad		
Clinical trial/drug trial		

2. Using a scale of 1 to 5, please rate how frequently patients experience the following challenges or difficulties during treatment decision-making in your practice?

**Where 1 = Never, 2= Somewhat Frequently, 3= Frequently, 4= Very Frequently and 5 = Always**

Patient Challenges	Rating				
	1	2	3	4	5
Lack of good research-based information about the effectiveness of treatment options					
Lack of good research-based information about the likelihood of treatment side effects					
Confusion due to information overload					
Unsure about their treatment goals and what is most important to them					
Feel pressure from others to make certain choices (e.g. family, friends, health care providers)					
Don't feel ready to make a decision					
Lack the problem solving skills or cognitive ability to make this type of decision					
Wanting to choose on the basis of family needs/preferences					
Other responsibilities					
Psychological distress (emotional labile)					
Mental Health Disorders (anxiety, depression)					
Poor quality information e.g. from some internet sites					
Personal characteristics e.g. age, comorbidities, rate/rise of PSA					

3. Using a scale of 1 to 5, indicate the level of importance you give to the following patient characteristics and resources for facilitating patient treatment decision-making?

**Where 1 = Not important, 2= Somewhat Important, 3= Important, 4= Very Important and 5 = Extremely Important**

Patient Characteristics and Resources	Rating				
	1	2	3	4	5
<b>Personal resources:</b>					
Previous experience with the situation					
Self-confidence					
Skill in decision making					
Physical health					
General emotional health					
Good analytic skills (cognitive health)					
Good social connections (social health)					
<b>External resources:</b>					
Availability and access to information					
Advice from formal health care system					
Advice from social network (e.g. family, friends)					
Emotional support					
Help with practical things (e.g. transportation to appointments)					
Financial assistance					
<b>Other Resources:</b>					
Social network (e.g. family, friends)					
Support groups					
Voluntary agencies (e.g. motorcycle ride for dad)					
Formal health care system					
Formal and informal education sessions					

4. Identify your agreement on the individuals who should participate in the treatment decision-making process?

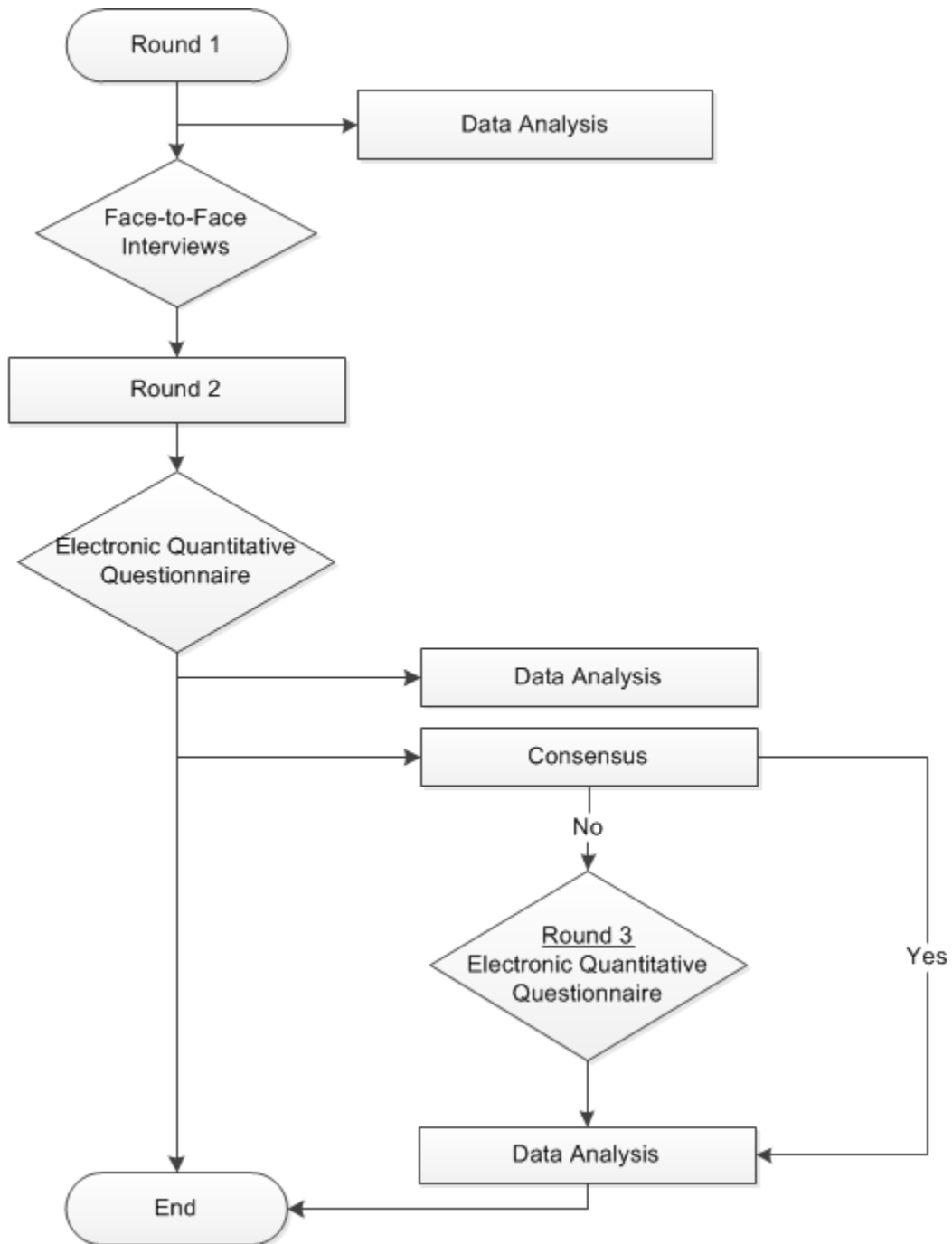
<b>Individuals</b>	<b>Yes (Y)</b>	<b>No (N)</b>
Patient		
Spouse		
Family (children)		
Friend		
Health care provider (treating physician)		
Family physician or primary care provider		
Other (specify)		

5. Identify your agreement on the types of information that should be included in a treatment decision aid:

<b>Types of Information to be Included</b>	<b>Yes (Y)</b>	<b>No (N)</b>
The benefits of each treatment option		
The effectiveness of each treatment option (response rate)		
Possible side effects of each treatment option		
Likelihood of side effect occurrence for each treatment option		
Likelihood of side effect severity for each treatment option		
Eligibility or relevance of all available treatment options for each patient's personal situation		
Prognosis or life expectancy		
A description of the treatment protocol, process and logistics (preparation for, costs, and number of treatments)		
Potential impact on quality of life (minimal treatment side effects)		
Potential impact of treatment option on physical function		
Information on participating in a clinical trial (drug study)		
Other:		

### Appendix K

#### Flow Sheet for the Delphi process Survey



## Appendix L

### Information Sheet/Consent Form for Radiation Oncologists



### **PARTICIPANT INFORMATION SHEET (Radiation Oncologists)**

**Title of Study:** Development of a Treatment Decision Aid: Assessing Information and Treatment Decision-Making Needs for Patients with Locally Recurrent Prostate Cancer

**Local Principal Investigator, Department/Institution:**

Denise Bryant-Lukosius, RN, PhD, Assistant Professor, Faculty of Health Sciences (Nursing), McMaster University

**Principal Investigator and Department/Institution:**

Gladys Mokaya, Master's Student, Faculty of Health Sciences (Nursing), McMaster University

**Co-Investigator(s)**

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Carolyn Ingram, RN, DNSc, CON(C)

Margaret Black, RN, PhD

Ian Dayes, MD, MSc, FRCP(C)

Dilip D. Panjwani, MD, MRCPI, FRCP(C)

**Sponsor:** Motorcycle Ride for Dad/Grand River Hospital

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You are being invited to participate in this research study because you are a Radiation Oncologist and you have experience treating men with locally recurrent prostate cancer. This is a student research project conducted under the supervision of **Denise Bryant-Lukosius, RN, PhD**. The study will help the

student learn more about treatment decision-making and to develop skills in research design, collection and analysis of data, and writing a research paper.

In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate.

This study is being funded by the Grand River Hospital through donations received from the Motorcycle Ride for Dad, which is a fundraising event for prostate cancer.

### **WHY IS THIS RESEARCH BEING DONE?**

Locally recurrent prostate cancer is cancer that has returned after initial treatment with radiation therapy but is confined to the prostate gland. Men with locally recurrent prostate cancer have many treatment choices available to them. Previous research has found that men with locally recurrent prostate cancer want more information to assist them in making treatment decisions. Treatment choices are influenced by many factors such as past treatment, personal characteristics such as physical health and age, as well the patient's own preferences. This can make treatment decision-making difficult. There is no central place where patients can get information and support to help make treatment decisions.

### **WHAT IS THE PURPOSE OF THIS STUDY?**

The study is being done to find out more about the treatment decision-making needs of men with locally recurrent prostate cancer. We will also want to learn from men and radiation oncologists about the types of information that should be included in resources to help patients make treatment decisions for locally recurrent prostate cancer.

### **WHAT WILL MY RESPONSIBILITIES BE IF I TAKE PART IN THE STUDY?**

If you agree to participate in this study, we will ask you to do the following things:

You will be invited to participate in a 3 round Delphi survey. A Delphi survey involves a series of confidential questionnaires that seek to obtain agreement on a topic among key experts. The first round of the Delphi survey will involve a 30 minute structured interview with the student researcher. You will be contacted by telephone to set up a convenient time, date and location for the interview. The



interview will be recorded using an audiotape recorder and then transcribed. You will be asked to complete a very brief survey about your practice prior to the interview. Completion of the survey will take about 5 minutes.

In round two and three of the Delphi survey you will be asked to complete an electronic questionnaire that will take about 15 minutes to complete. The questionnaire will ask about your perceptions of the most difficult and important decisions relevant to patient treatment decision-making. You will also be asked about potential barriers and facilitators that affect patient treatment decision-making. Finally, you will be asked to identify the types of treatment and information that should be included in patient education materials.

### **WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

It is possible that you may experience some discomfort when describing the treatment decision-making needs of your patients.

### **HOW MANY PEOPLE WILL BE IN THIS STUDY?**

Eight radiation oncologists will be requested to participate in this study. Each radiation oncologist will participate in an individual interview and then all 8 will participate in the 2 consecutive rounds of the electronic Delphi survey. Approximately 6 to 8 men with locally recurrent prostate cancer will participate in one-on-one interviews as a part of this study.

### **WHAT ARE THE POSSIBLE BENEFITS FOR ME AND/OR FOR SOCIETY?**

We cannot promise any personal benefits to you from your participation in this study. However, possible benefits include the satisfaction of knowing that you have contributed to the research that increases what we know about the information and treatment decision needs of men with locally recurrent prostate cancer. Your participation may help other people with locally recurrent prostate cancer in the future.

### **IF I DO NOT WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?**

It is important for you to know that you can choose not to take part in the study. Choosing not to participate in this study will in no way affect your employment.

### **WHAT INFORMATION WILL BE KEPT PRIVATE?**

Your participation in this study will be confidential and only known to the student researcher and her supervisor. No information you that you provide in the Delphi survey will be shared with your immediate supervisors. All personal information such as your name, address and phone number will be removed from the data and replaced with a number. A list linking the number with your name will be kept in a secure place, separate from your file. The data, with identifying information removed will be securely stored in a locked office on a secure server. Only the transcriptionist, the student researcher and her supervisor will be allowed to listen to the audiotapes. The data for this research study will be retained for ten years. The transcribed notes will be analyzed by the student researcher and the thesis committee. If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent to the disclosure. Study results shared in presentations or in publications will only be provided in aggregate form so that no identifying information such as age, place of work or work experience could identify individual participants.

#### **CAN PARTICIPATION IN THE STUDY END EARLY?**

If you agree to be in this study, you may withdraw or decide to stop participating at any time. This will in no way affect your employment. Any information collected from you, up until the time you withdraw from the study, will be included in the final study results.

#### **WILL I BE PAID TO PARTICIPATE IN THIS STUDY?**

If you agree to take part, you will receive a \$20 bookstore gift certificate as a token of appreciation.

#### **WILL THERE BE ANY COSTS?**

Your participation in this research project will not involve any cost to you.

#### **IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CALL?**

If you have any questions about the research now or later, please contact:

Gladys Mokaya at (905) 525-9140 ext. 22806 or the Local Principal Investigator for this study, Denise Bryant-Lukosius, RN, PhD at (905) 525-9140 ext. 22408.

If you have any questions regarding your rights as a research participant, you may contact the Office of the Chair of the Hamilton Health Sciences/Faculty of Health Sciences Research Ethics Board at 905-521-2100 ext. 42013.

**CONSENT STATEMENT**

**SIGNATURE OF RESEARCH PARTICIPANT**

I have read the preceding information thoroughly. I have had the opportunity to ask questions, and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that I will receive a signed copy of this form.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Signature of Participant

Date

\_\_\_\_\_

Consent form administered and explained in person by:

\_\_\_\_\_  
Name and title

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

## Appendix M

### Treatment Decision-Making Study: Locally Recurrent Prostate Cancer

#### Patient Screening Tool for Primary Nurses/Radiation Oncologists

Recurrent disease is defined as a rise in Prostate Specific Antigen (PSA) by 2ng/ml or more above the nadir after initial treatment for localized (T1 or T2) prostate cancer

#### Eligible patients are those who meet all the criteria below:

- Have locally recurrent prostate cancer following initial curative treatment with external beam radiation therapy with or without hormone therapy
- Had pathologically confirmed low or intermediate risk prostate cancer at time of diagnosis (PSA < 20, Stage T1 or T2 tumor, Gleason Score ≤ 8)
- Have received treatment for locally recurrent prostate cancer within the last two years
- The PSA level is less than 10 ng/ml within the last 6 months
- There is no clinical evidence of distant metastases
- Are able to speak and understand English
- Have the physical and cognitive ability to participate in a 90 minute meeting outside the home

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**Patient meets all the above criteria**

#### Patient agrees to be contacted by the student researcher regarding the study:

Yes     If yes, provide the following information

Patient Name \_\_\_\_\_ Phone Number \_\_\_\_\_

No

What is the reason for not participating?

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**Source of patient referral for study:**  Nurse       Radiation Oncologist

Other

## **Appendix N**

### **Information Letter/Telephone Script for Contacting Patients with Locally Recurrent Prostate Cancer**

My name is Gladys Mokaya. I am a Registered Nurse and a Master's student in the School of Nursing at McMaster University. I am working with health care providers from the Grand River Regional Cancer Centre and Juravinski Cancer Centre to conduct a study about locally recurrent prostate cancer.

I would like to invite you to participate in this research study that has been funded by the Grand River Hospital through donations from a prostate cancer fundraising event called the Motorcycle Ride for Dad. One purpose of the study is to learn more about the treatment decision-making needs of men with locally recurrent prostate cancer. We also want to learn more from patients and radiation oncologists about the types of information that should be included in educational materials to assist men affected by locally recurrent prostate cancer in making treatment decisions.

The results of this study may be used by health care providers to help them plan for and provide information and treatment decision-making resources that are important for patients and families who are affected by locally recurrent prostate cancer.

If you agree to be a part of this study, you will participate in a one-on-one interview. The one-on-one interview will take place at a time that is convenient for you and in a private meeting room in your community. You will also be asked to complete a very brief survey about you and your prostate cancer treatment just prior to the focus group discussion. Completion of the survey will take about 5 minutes. During this one-on-one interview discussion, I will ask you to talk about your treatment decision-making needs, the concerns you experienced in making a treatment decision and the types of resources you used to help make a treatment decision. I will also ask you for suggestions and ideas on how we can better meet your information needs and the types of information that should be included in education materials designed to help with treatment decision-making. The one-on-one interview discussion will last for about 60 minutes. The one-on-one interview discussion will be recorded using an audiotape recorder and later typed out in a written report.

About 6 to 8 men with locally recurrent prostate cancer will participate in this study.

Participation in the study is completely voluntary and your cancer care will not be affected in any way should you choose not to participate. You may also choose to withdraw at any time during your participation in the study. It is also important to know that your participation in the study is confidential and that any information you provide

will not be shared with your health care providers. You will not be identified in the reporting of the study results.

Thank you for your consideration of our request. Do you have any questions at this time?

If you have any further questions or concerns or change your mind about participating in this study at a later time, you can call me at (905) 525-9140 ext. 22806 or you could also speak to the Local Principal Investigator of this study, Dr. Denise Bryant-Lukosius at (905) 525-9140 ext. 22408.

If you have any questions regarding your rights as a research participant, you may contact the Office of the Chair of the Hamilton Health Sciences/Faculty of Health Sciences Research Ethics Board at 905-521-2100 ext. 42013.

If patient accepts invitation to participate:

Thank you for accepting to participate. Would you prefer an interview in the morning or afternoon? I will call you back with a specific date, time and location. I will also mail you a confirmation letter and directions to the location if you wish. May I have your address please?

## Appendix O

### Confirmation Letter for Patients

Dear \_\_\_\_\_,

Thank you for agreeing to participate in this research study looking at the treatment decision-making needs of men with locally recurrent prostate cancer. We want to learn more from patients and radiation oncologists about the type of information that they would want to be included in education materials to assist men affected by locally recurrent prostate cancer to meet their decisional needs.

You will participate in a one-on-one interview and you will also be asked to complete a very brief survey about you and your prostate cancer treatment just prior to the interview. Completion of the survey will take about 5 minutes. During this one-on-one interview discussion, I will ask you to talk about your treatment decision-making needs, the concerns you experienced in making a treatment decision and the types of resources you used to help make a treatment decision. I will also ask for suggestions and ideas on how we can better meet your information needs and the types of information that should be included in education materials designed to help with treatment decision-making. The one-on-one interview will last for about 60 minutes. This interview will be recorded using an audiotape recorder and later typed out in a written report.

Participation in the study is completely voluntary. Your care will not be affected in any way if you choose not to participate. You may also choose to withdraw at any time during your participation in the study. It is also important to know that your participation in the study is confidential and that any information you provide will not be shared with your health care provider. You will not be identified in the reporting of the study results.

The study is being done at the Grand River Regional Cancer Centre and the Juravinski Cancer Centre. The project is funded by the Grand River Hospital through donations from a prostate cancer fundraising event called the Motorcycle Ride for Dad. It has been approved by the research ethics board at McMaster University and the Tri-Hospital Research Ethics Board at Grand River Regional Cancer.

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**Your one-on-one interview will be held on \_\_\_\_\_ at \_\_\_\_\_**

**Location: \_\_\_\_\_**



Please contact me if you are unable to attend this one-on-one interview. The costs of your parking will be paid and you will be given a \$20 bookstore gift certificate as a token of appreciation.

Sincerely,

Gladys Mokaya, Principal Investigator, Master's Student, Faculty of Health Sciences (Nursing), McMaster University, Tel: (905) 525-9140 ext. 22806, e-mail: [mokayagk@mcmaster.ca](mailto:mokayagk@mcmaster.ca)

## Appendix P

### Patient Demographic Questionnaire –

#### Locally Recurrent Prostate Cancer Treatment Decision Aid Study

1. What year were you born? \_\_\_\_\_
  
2. What is your present marital status:

<input type="checkbox"/> Married	<input type="checkbox"/> Living together/common-law
<input type="checkbox"/> Separated	<input type="checkbox"/> Divorced
<input type="checkbox"/> Widowed	<input type="checkbox"/> Never Married
  
3. How many children do you have? \_\_\_\_\_
  
4. What are your current living arrangements?

<input type="checkbox"/> Alone	<input type="checkbox"/> With a spouse
<input type="checkbox"/> With family	<input type="checkbox"/> With friends
<input type="checkbox"/> Other (specify) _____	
  
5. Please circle the highest level of education you have **COMPLETED**  
Grade School: Grade 1 2 3 4 5 6 7 8  
High School: Grade 9 10 11 12 13  
Post Secondary School:

<input type="checkbox"/> College Diploma
<input type="checkbox"/> University degree
  
6. What is your current employment status?

<input type="checkbox"/> Full time work for pay	<input type="checkbox"/> Part time work for pay
<input type="checkbox"/> Volunteer	<input type="checkbox"/> Student
<input type="checkbox"/> Retired from work	<input type="checkbox"/> Disabled/Unable to work
<input type="checkbox"/> Unemployed	<input type="checkbox"/> Other (specify) _____

7. What year were you diagnosed with prostate cancer?

---

8. What treatment are you receiving **NOW** for locally recurrent prostate cancer:  
(Check ALL that apply)

- Watch and wait (no treatment initially but monitor PSA levels and then treat when PSA rises)
- Prostatectomy (surgery)
- Hormone therapy such as Lupron, Viadur, Eligard, Trelstar Depot, Casodex, or Flutamide
- Cryotherapy
- High-intensity focused ultrasound (HIFU)
- Light-activated drug Tookad (Tookad Laser)
- Re-irradiation (brachytherapy or external beam radiation therapy)
- Clinical trial/drug study
- Other:

---

(describe)

9. What treatment have you received in the **PAST** for locally recurrent prostate cancer: (Check ALL that apply)

- Watch and wait (no treatment initially but monitor PSA levels and then treat when PSA rises)
- Prostatectomy (surgery)
- Hormone therapy such as Lupron, Viadur, Eligard, Trelstar Depot, Casodex or Flutamide
- Cryotherapy
- High-intensity focused ultrasound (HIFU)
- Light-activated drug Tookad (Tookad Laser)
- Re-irradiation (brachytherapy or external beam radiation therapy)
- Clinical trial/drug study
- Other:

---

(describe)

10. In addition to prostate cancer, do you have any other health problems that require medical follow up and or/treatment? (Check ALL the problems that apply to you)

- Heart or Cardiac (heart attack, congestive heart failure, angina or chest pain)
- Circulation (peripheral vascular disease, stroke or blood clot)
- High blood pressure
- Breathing or Respiratory (asthma, bronchitis or emphysema)
- Diabetes
- Arthritis
- Another Cancer (specify)

- 
- Hearing
  - Vision
  - Mental illness (depression or anxiety)
  - Other (please specify)
-

## Appendix Q

### Interview Guide for One-on-One Interviews

#### PERCEPTION OF THE DECISION

1. **How did you find out your cancer had returned (recurred/progressed)?**
2. **What were the most important decisions that you faced at the time your prostate cancer returned?**
3. **Thinking about the time when you were told your cancer had come back, what treatment choices were you provided to you?**
4. **What other treatment options are you aware of?**

Watch and wait (expectant management)  Prostatectomy (surgery)  Re-irradiation or (brachytherapy)  hormonal therapy(ADT)  Cryotherapy  High-intensity focused ultrasound (HIFU)  Light-activated drug Tookad (Tookad Laser)  Clinical trial/drug study  other \_\_\_\_\_

5. **How did you become aware of the other options?**
6. **At the time you were considering the treatment choices, what was your understanding of the main advantages and disadvantages of those choices?**
7. **How did you feel when making this treatment decision?**
8. **What were some of the factors that made the treatment decision difficult for you?**

#### PERCEPTION OF OTHERS

9. **When you were making the treatment decision, who else was involved in making this decision and what was their involvement?**

the physician (radiation oncologist or other person) made the decision for you  the physician (radiation oncologist or other person) shared the decision-making with you  the physician (radiation oncologist or other person) provided support or advice for you to make the decision on your own

## RESOURCES

### 10. Thinking back to when you were first told the cancer had returned, how did you go about making the decision about the best treatment choice for you?

Did you:  get information on choices  get information on the chances of benefits and risks  consider the personal importance of the choices  get information on how other patients go about deciding or what they would recommend  find ways to handle the pressure while making the decision  get support from others (or advice from loved ones)  follow MD's advise

### 11. What really helped you make the treatment decision?

**Personal resources:**  previous experience with the situation  Trusting yourself (self-confidence)

Motivation  Skill in decision making  physical health  general emotional health  good analytic skills (cognitive health)  good social connections (social health )

**External resources:**  availability and access to information e.g. from the health care team  advice  emotional support  help with practical things  financial assistance

**Other sources:**  social network  professional network (specify: \_\_\_\_\_)  support groups  voluntary agencies  formal health care system  education  social sector (Friends)  employer

### 12. Is there something that could have helped you to overcome some of the things that got in the way (hindered) of making the treatment decision?

### 13. What are some of the ways you think we can provide support?

**Counseling from health practitioner**, IF YES, what type of practitioner

**Discussion groups of people facing the same decisions**, IF YES, what type of organization or group

**Information materials** IF YES, specify format  booklets, pamphlets

Internet  videos or DVDs or CDs

other, specify \_\_\_\_\_

### 14. What type of information do you think would be important to include in patient resources?

Content on  Health condition description

Treatment options

Benefits and risks of treatment (advantages and disadvantages)

- The probabilities (trade off) of the benefits and risks occurring
- Help considering the personal importance of benefits versus risks
- Guidance in the steps of deliberation and communication
- Other, specify \_\_\_\_\_

**15. Now thinking about future decisions, when preparing the information materials should all treatment choices be presented OR should only a few choices be provided?**

**16. How should the choices be narrowed down?**

**17. Can you tell me which features of treatment matter most?**

Probe:  how effective the treatment is (response rate)  Quality of life (minimal treatment side effects)  ability of the treatment to control the symptoms of the disease  living longer (or disease-free survival or survival rate)  frequency of visits (Specify)  participating in a clinical trial (drug study)  oral treatment that I can take at home  avoiding certain side effects of treatment (specify: hair loss, incontinence, loss of libido, other \_\_\_\_\_)

## Appendix R

### Information Sheet/Consent Form for Patients



### PARTICIPANT INFORMATION SHEET (Patients)

**Title of Study:** Development of a Treatment Decision Aid: Assessing Information and Treatment Decision-Making Needs for Patients with Locally Recurrent Prostate Cancer

**Local Principal Investigator, Department/Institution:**

Denise Bryant-Lukosius, RN, PhD, Assistant Professor, Faculty of Health Sciences (Nursing), McMaster University

**Principal Investigator, Department/Institution:**

Gladys Mokaya, Master's Student, Faculty of Health Sciences (Nursing), McMaster University

**Co-Investigator(s)**

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Carolyn Ingram, RN, DNSc, CON(C)

Margaret Black, RN, PhD

Ian Dayes, MD, MSc, FRCP(C)

Dilip D. Panjwani, MD, MRCPI, FRCP(C)

**Sponsor:** Motorcycle Ride for Dad/Grand River Hospital

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You are being invited to participate in this research study because you have locally recurrent prostate cancer. This is a student research project conducted under the supervision of **Denise Bryant-Lukosius, RN, PhD**. The study will help the student learn more about treatment decision-making and to develop skills in research design, collection and analysis of data, and writing a research paper.



In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family.

This study is being funded by the Grand River Hospital through donations received from the Motorcycle Ride for Dad, which is a fundraising event for prostate cancer.

### **WHY IS THIS RESEARCH BEING DONE?**

Locally recurrent prostate cancer is cancer that has returned after initial treatment with radiation therapy but remains confined to the prostate gland. Men with locally recurrent prostate cancer have many treatment choices available to them. Previous research has found that men with locally recurrent prostate cancer want more information to assist them in making treatment decisions. Treatment choices are influenced by many factors such as past treatments, personal characteristics such as physical health and age, as well the patient's own preferences. These factors can make treatment decision-making difficult. There is no central place where patients can get information and support to help make treatment decisions.

### **WHAT IS THE PURPOSE OF THIS STUDY?**

The study is being done to find out more about the treatment decision-making needs of men with locally recurrent prostate cancer. We will also want to learn from men and radiation oncologists about the types of information that should be included in resources to help patients make treatment decisions.

### **WHAT WILL MY RESPONSIBILITIES BE, IF I TAKE PART IN THE STUDY?**

If you agree to participate in this study, we will ask you to do the following things:

You will be asked to come to a 60 minute one-on-one interview. The one-on-one interview will take place at a time that is convenient for you and in a private meeting room in your community. You will be asked to complete a very brief survey about you and your prostate cancer treatment just prior to the one-on-one interview discussion. Completing the survey will take about 5 minutes. During the one-on-one interview, you will be asked by the student researcher about your treatment decision-making needs, the concerns you experienced in making a treatment decision and the types of resources you used to help make a treatment

decision. You will also be asked for suggestions and ideas about how we can better meet patient information needs and the types of information that should be included in education materials designed to help with treatment decision-making. The one-on-one interview discussion will be recorded using an audiotape recorder and then typed out in a written report.

### **WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

It is possible that you may experience some emotional upset when describing the concerns you have experienced as a result of having locally recurrent prostate cancer. If this happens you may take a break from the discussion and return if wish to do so. You may also contact your family doctor or cancer care team for further assistance.

### **HOW MANY PEOPLE WILL BE IN THIS STUDY?**

About 6 to 8 men with locally recurrent prostate cancer will participate in this study. We are also asking radiation oncologists to participate in a separate survey.

### **WHAT ARE THE POSSIBLE BENEFITS FOR ME AND/OR FOR SOCIETY?**

We cannot promise any personal benefits to you from your participation in this study. However, possible benefits include the satisfaction of knowing that you have contributed to the research that increases what we know about the information and treatment decision needs of men with locally recurrent prostate cancer. Your participation may help other people with prostate cancer in the future.

### **IF I DO NOT WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?**

It is important for you to know that you can choose not to take part in the study. Choosing not to participate in this study will in no way affect your cancer care or treatment.

### **WHAT INFORMATION WILL BE KEPT PRIVATE?**

The information you provide in the one-on-one interview **will not** be shared with health care providers involved in your care without your permission. The taped information from the interview discussion will be typed without any information that can personally identify you. Only the typist, the student researcher and her supervisor will be allowed to listen to the audiotapes. The information on the audiotapes will be deleted once it has been verified for accuracy. The typed notes

will only be read by the student researcher and her research committee. The data for this research study will be retained for ten years. If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent to the disclosure. Audiotapes will be kept in a locked cabinet and all electronic data related to the study will be kept on password protected computers. You may view the data we have collected from you at any time.

### **CAN PARTICIPATION IN THE STUDY END EARLY?**

If you agree to be in this study, you may withdraw or decide to stop participating at any time. This will in no way affect the quality of care you receive. Any information collected from you, up until the time you withdraw from the study, will be included in the final study results.

### **WILL I BE PAID TO PARTICIPATE IN THIS STUDY?**

If you agree to take part, we will reimburse you for any parking costs to attend the one-on-one interview. You will receive a \$20 bookstore gift certificate as a token of appreciation.

### **WILL THERE BE ANY COSTS?**

Your participation in this research project will not involve any cost to you.

### **IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CALL?**

If you have any questions about the research now or later, please contact:

Gladys Mokaya at (905) 525-9140 ext. 22806 or the Local Principal Investigator for this study, Denise Bryant-Lukosius, RN, PhD at (905) 525-9140 ext. 22408.

If you have any questions regarding your rights as a research participant, you may contact the Office of the Chair of the Hamilton Health Sciences/Faculty of Health Sciences Research Ethics Board at 905-521-2100 ext. 42013.

**CONSENT STATEMENT**

**SIGNATURE OF RESEARCH PARTICIPANT**

I have read the preceding information thoroughly. I have had the opportunity to ask questions, and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that I will receive a signed copy of this form.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

Consent form administered and explained in person by:

\_\_\_\_\_  
Name and title

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

## Appendix S

### Ethics Board Approval of Amendment to Study

Wed, 25 Nov 2009 10:19:15 -0500

Dear Gladys,

The amendment for Student REB Project 09-003-S, “Development of a Treatment Decision Aid: Assessing Information and Treatment Decision-Making Needs for Patients with Locally Recurrent Prostate Cancer”, has been approved.

The consent forms have been stamped with the REB approval stamp and are ready for pickup in Health Research Services.

Thank you,

Melina

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Melina (Carmela) Mirabella

Health Research Services

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