A TIME TO QUESTION:
A STUDY OF THE INFORMATION NEEDS OF POSTMENOPAUSAL BREAST CANCER PATIENTS REGARDING ENDOCRINE THERAPY

by

Melissa Lynn TeBrake

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Abstract

When women are faced with the diagnosis and treatment options for their care, they have high a need for information that persists throughout the course of their illness. When information needs are met, women are able to make informed decisions regarding their care, have increased quality of life, and cope better with their illness. The objective of this study was to identify the information needs of postmenopausal women with early stage breast cancer making treatment decisions regarding endocrine therapy. An integrative review of research was conducted to collate and describe the information needs assessment methodologies used to identify information needs for women with breast cancer. Based on this review and our long-term goal of identifying a list of questions or information needs of women at this stage of their cancer treatment, we conducted a qualitative descriptive study to identify information needs and interviewed 17 postmenopausal women with early stage breast cancer and 4 healthcare providers. Women were asked to describe the questions they had or the information that they needed when endocrine therapy became part of their care. The healthcare providers described the information that they felt was important for women to know in regard to endocrine therapy. A list of 91 questions regarding endocrine therapy was identified; including information needs related to side effects, drug characteristics, financial cost, and survival/recurrence. Most women were not aware that they had a choice about the different types of endocrine treatment and often followed the physician’s recommendations. This study supports the assertion that postmenopausal women with breast cancer wish to be informed that they have a choice and desire information to make the best personal choice in collaboration with the physician. Healthcare professionals need to be aware of both the common and individual patients’ information needs and present options to assist women making the best decisions about their care.
Co-Authorship

This thesis presents the research of Melissa TeBrake in collaboration with her thesis supervisor Dr. Joan Tranmer and thesis committee: Dr. Deb Feldman-Stewart, Dr. Yolanda Madarnas, and Dr. Marianne Lamb.

**Manuscript 1:** *Information needs of early stage breast cancer patients: an integrative review of information needs assessment methodologies.* The original idea to explore the information needs of breast cancer patients while on treatment for breast cancer was M. TeBrake’s. Dr. Feldman-Stewart provided guidance in regard to the review methodology, based on her research expertise within this field. M. TeBrake carried out the literature search, article extraction, and synthesis of the studies included with the guidance of Drs. Tranmer and Feldman-Stewart. M. TeBrake composed the manuscript and interpreted the results with modifications by the thesis committee. All committee members edited and reviewed the manuscript.

**Manuscript 2:** *What information needs/questions do postmenopausal early stage breast cancer patients have regarding endocrine treatment?* M. TeBrake was responsible for the idea for this manuscript topic. Dr. Madarnas identified that little was known about the information needs of breast cancer patients on endocrine therapy. The committee provided feedback on the study design. Dr. Feldman-Stewart provided guidance with establishing the methodology, which was based on her previous work with prostate cancer patients. M. TeBrake conducted and transcribed the interviews. Dr. Lamb and Jeanette Suurdt, RN assisted with analysis of the interviews and synopsis of the findings. M. TeBrake completed the manuscript and the interpretation of the results with modifications by the thesis committee.
All other sections of this thesis, including Introduction, Literature Review, Discussion, and Appendices were written by M. TeBrake with editorial changes provided by the thesis committee.
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....and God, this is your handiwork!
Table of Contents

Abstract ............................................................................................................................................ ii
Co-Authorship ........................................................................................................................................ iii
Acknowledgements .......................................................................................................................... v
Table of Contents ............................................................................................................................ vi
Chapter 1 - Introduction ................................................................................................................... 1
  1.1 The issue ................................................................................................................................ 1
  1.2 Personal Experience ............................................................................................................... 2
  1.3 Purpose ................................................................................................................................... 2
  1.4 Thesis organization and outline ............................................................................................. 3
References ........................................................................................................................................ 4
Chapter 2 - Literature Review .......................................................................................................... 5
  2.1 Background ............................................................................................................................ 5
  2.1.1 Information needs ........................................................................................................... 6
  2.1.2 Clinical treatment with endocrine therapy ...................................................................... 7
  2.1.3 Healthcare decision-making: Integrating information with clinical treatment ............... 9
  2.1.4 Decisional conflict ........................................................................................................ 11
  2.1.5 Decision aids ................................................................................................................. 12
  2.1.6 Decision aid development ............................................................................................. 13
  2.1.7 Differentiation and consolidation theory ...................................................................... 14
  2.2 Purpose of Study .................................................................................................................. 15
References ...................................................................................................................................... 16
Chapter 3 - Information needs of early stage breast cancer patients: an integrative review of
information needs assessment methodologies ............................................................................... 23
  Abstract ...................................................................................................................................... 23
  3.1 Introduction .......................................................................................................................... 25
  3.2 Objectives ................................................................................................................................ 27
  3.3 Method ................................................................................................................................ 27
  3.3.1 Search Strategy ............................................................................................................. 28
  3.3.2 Procedure ...................................................................................................................... 29
  3.4 Summary of Studies ............................................................................................................. 30
  3.4.1 Quantitative assessment of information needs .............................................................. 30
  3.4.2 Qualitative assessment of information needs ............................................................... 32
3.4.3 Mixed methods assessment of information needs......................................................... 33
3.4.4 Common information needs.......................................................................................... 33
3.5 Synthesis, Critique, and Discussion of Methodologies................................................... 34
3.5.1 Patient perspective........................................................................................................ 36
3.5.2 Comprehensiveness of content.................................................................................... 36
3.5.3 Information accuracy.................................................................................................... 37
3.5.4 Use of Information........................................................................................................ 39
3.5.5 Limitations.................................................................................................................... 39
3.6 Conclusion........................................................................................................................... 40
References...................................................................................................................................... 51

Chapter 4 - What information needs/questions do postmenopausal early stage breast cancer
patients have regarding endocrine treatment?........................................................................ 57

Abstract...................................................................................................................................... 57
4.1 Introduction.......................................................................................................................... 59
4.2 Objectives .......................................................................................................................... 61
4.3 Methods ............................................................................................................................... 62
4.3.1 Study Design................................................................................................................. 62
4.3.2 Sample........................................................................................................................... 62
4.3.3 Recruitment................................................................................................................... 63
4.3.4 Data Collection ............................................................................................................ 64
4.3.5 Analysis of Data............................................................................................................ 65
4.4 Results.................................................................................................................................. 66
4.4.1 Demographics............................................................................................................... 66
4.4.2 Patients' information needs about endocrine therapy.................................................... 67
4.4.3 Side effects.................................................................................................................... 67
4.4.4 Drug background .......................................................................................................... 69
4.4.5 Potential benefits........................................................................................................... 71
4.4.6 Cost............................................................................................................................... 71
4.4.7 Family ........................................................................................................................... 72
4.4.8 Making the decision...................................................................................................... 72
4.5 Synthesis of content data: Identification of common questions.......................................... 78
4.6 Discussion............................................................................................................................ 78
4.6.1 Information needs ......................................................................................................... 79
4.6.2 Decisional process and choice ..................................................................................... 81
List of Tables

Table 1 - Quantitative information needs assessment methods of women with breast cancer ...... 41
Table 2 - Qualitative information needs assessment methods of women with breast cancer ........ 46
Table 3 - Mixed methods information needs assessment methods of women with breast cancer . 49
Table 4 - Questions Postmenopausal BCP Have Regarding Endocrine Therapy .................... 74
Chapter 1
Introduction

1.1 The issue

Breast cancer is a chronic disease that affects many women worldwide (Oxlad, Wade, Hallsworth, & Koczwara, 2008). The experience of cancer is different for each woman and will vary along the trajectory of illness - from diagnosis to treatment to survivorship. The impact of breast cancer can be substantial (Gray et al., 1998); the need for information is often great and questions occur frequently along the journey as women are often faced with a number of complex treatment decisions. Women often feel overwhelmed with the need for and the amount of information (Loiselle, Lambert, & Cooke, 2006). In this thesis, we are focusing on postmenopausal women who are provided the option for endocrine therapy. Often this decision is made after they have had their primary treatment and are moving into the follow-up and survivorship stage. During this stage, the focus is more on the clinical aspects of prevention and survival rather than on curative treatment and treatment decisions. In my clinical experience, often the importance of the endocrine treatment decision is overlooked and, therefore, the importance of this decision seems diminished.

Breast cancer patients are informed about different choices and options regarding their care, and encouraged to make informed choices. There is always a treatment choice, even if the choice is to take or not to take the treatment. Information is provided regardless of whether or not the patient wants to participate in decision-making. Information is typically perceived as important, even by those who want to play a passive role in treatment decision-making (Mills & Sullivan, 1999).

Given the current and ongoing advances in cancer care treatment, there will be changes to recommended treatments. However, if we ask women what questions they have about common treatment options, these questions are not likely to change overtime. Therefore, by identifying
questions that women have regarding endocrine therapy we are better positioned to provide relevant information to women to support informed decision-making by the patients at this time and in the future.

1.2 Personal Experience

The desire to study the information needs of breast cancer patients emerged from my nursing practice, where I work as a registered nurse at the Cancer Centre of Southeastern Ontario at Kingston General Hospital. In my role, I am involved in the care of women during diagnosis, chemotherapy administration, radiation, and follow-up care. I have cared for women who are struggling with decisions and unsure of what questions to ask. Patient education is one of my primary nursing responsibilities. In my experience, much of the patient teaching occurs at the initial consult visit and early on in the treatment phase as this is a time when many important decisions are occurring. My initial interest was in decision aids, which led to conversations with some key investigators and clinicians knowledgeable about decision-making and breast cancer at the Cancer Centre and Queen’s University. This conversation identified a need to explore the area of information needs for postmenopausal women who were making decisions about endocrine treatment. This specific treatment was chosen because the information needs of women who were considering surgery, chemotherapy, and radiation were well documented. Yet, there was a paucity of evidence in regard to information needs, and consequently decisional support, for postmenopausal women making treatment choices about endocrine therapy.

1.3 Purpose

The purpose of the research was to identify the questions or information needs that postmenopausal woman have about endocrine therapy for early-stage breast cancer. Identifying the questions would provide healthcare practitioners, including nurses and physicians, a better understanding of the information needs that breast cancer patients have regarding endocrine therapy. The specific objectives for this thesis project were to:
1.3.1 Review and synthesize the methodologies used in the research literature to assess and identify information needs of breast cancer patients.

1.3.2 Identify the information needs and questions that early stage postmenopausal breast cancer patients have regarding endocrine therapy, suggested by the literature.

1.3.3 Identify healthcare practitioners’ information priorities regarding treatment using endocrine therapy for postmenopausal women with early-stage breast cancer.

1.3.4 Establish a comprehensive list of questions that are important to postmenopausal breast cancer patients at the time they are encountering the decision regarding endocrine therapy.

1.4 Thesis organization and outline

This thesis is organized according to the Manuscript Form of Theses as specified by the School of Graduate Studies and Research at Queen’s University. Chapter 2 provides a review of the current scientific literature exploring information needs of breast cancer patients throughout their disease trajectory, with a focus on information needs relating to their treatment decisions.

Chapter 3 is the first manuscript entitled: Information needs of early stage breast cancer patients: an integrative review of information needs assessment methodologies, to be submitted to Journal of Advanced Nursing. Chapter 4 presents the second manuscript entitled: What information needs/questions do postmenopausal early stage breast cancer patients have regarding endocrine treatment?, which will be submitted to Psycho-Oncology. Chapter 5 provides a discussion, summary, and conclusions from the thesis work, outlining strengths, limitations, and implications for future policy and research.
References


Chapter 2

Literature Review

To provide context for this thesis, this literature review will review the current research evidence in regard to information needs and how they are defined and identified. The current clinical guidelines with regards to treatment of early stage breast cancer with endocrine therapy and some of the related challenges will be described. Next, we will review the current research evidence regarding healthcare decision-making, including decisional conflict and the use of decision aids, and discuss the complexities and factors that may influence decisions. This chapter will conclude with a description of a conceptual theory, the Differential Consolidation Theory, which was used as a guiding framework for the study. Finally, the overall problem statement for the thesis will be described.

2.1 Background

Breast cancer is the most common cancer among women (World Health Organization, 2006). The Canadian Cancer Society (2009) reports that the incidence for early-stage breast cancer is increasing, while the incidence for later stage breast cancer is decreasing, which is associated, in large part, to routine screening with mammograms and earlier detection. Women are living longer with breast cancer. Approximately, 8 out of 10 women diagnosed with early stage breast cancer survive beyond five years (Canadian Cancer Society, 2009). Survival can be attributed partly to the use of endocrine therapy for women who have hormonally sensitive tumours (Winer et al., 2005; Goss et al., 2005; Coombes et al., 2004; ATAC, 2002). Women have information needs that change throughout the continuum of illness and treatment and through the transition into survivorship.
2.1.1 Information needs

“Information need” is a broad term commonly used to define information that persons may need to enhance physical and psychological health (Gray et al., 1998). Information needs may include information about treatment, medication, procedures, supportive care, and psychological impact of disease. For this thesis project, information need is defined as information that patients desire at any point in their disease trajectory.

Various reviews have described the information needs of cancer patients (Rutten, Arora, Bakos, Aziz, & Rowland, 2005; Vivar & McQueen, 2005; Harris, 1998; Ankem, 2005). Not all patients have the same information needs. Studies that have looked at the information needs of women with breast cancer have found that often there is only moderate agreement of all women on the overall profile of information needs. Descriptive studies suggest, for example, that younger and more educated women may seek more information because they prefer more involvement in decision-making than older women (Wallberg et al., 2000); older women often feel comfortable with the information that is only essential (Thewes, Butow, Girgis, & Pendlebury, 2004); across the disease trajectory, information needs change with the apparent need for information highest at the time of diagnosis (Vogel, Bengel, & Helmes, 2008). Yet, descriptive evidence also suggests that providing information enhances: a) satisfaction with care (Davidson & Mills, 2005), b) understanding of current therapy and increased involvement in decision-making (Maly, Leake, & Silliman, 2004), and c) sense of control (Hack, Degner, & Dyck, 1994). Information seeking patients also report an increased ability to cope with stress during diagnosis, treatment, and after care (Harrison-Woermke & Graydon, 1993), reductions in anxiety and improved communication with family members (Arora, 2003), and better physical quality of life (Ransom, Jacobsen, Schmidt, & Andrykowski, 2005). Thus, it would seem that it is beneficial to provide women with the information that they want about their illness and treatment.
However, there are issues with information provision and information seeking, as well. Women with breast cancer often feel overwhelmed with all the information that is presented (McCaughan & Parahoo, 2000) and have difficulty getting the type and amount of information that they want (Rees & Bath, 2000). Often professionals lack time to discuss the questions that women might have. Frequently, there is a focus on the medical aspects of care leaving gaps in other areas of concern. For information to be relevant and useful it needs to address the questions that women have.

2.1.2 Clinical treatment with endocrine therapy

There are many different treatments for breast cancer. The focus of this thesis is on first-line endocrine therapy treatment, which includes selective estrogen receptor modulators (Tamoxifen) and aromatase inhibitors (Arimidex, Aromasin, and Femera). Treatment for breast cancer varies depending on characteristics of the disease and patient (National Cancer Institute, 2007). Treatment for early-stage breast cancer may involve surgery, radiation, chemotherapy, monoclonal antibody therapy, and/or endocrine therapy. Women who have lobular carcinoma in situ (LCIS) have the option of observation after diagnosis, endocrine therapy, or surgery. The recommendations for women diagnosed with stage I, II, IIIA, and, operable IIIC breast cancer may include surgery (breast conservation surgery or mastectomy), chemotherapy, radiation and/or endocrine therapy. The preceding recommendations are used in the adjuvant setting intending cure, not those with metastatic extensive disease. These adjuvant options are utilized to increase the overall survival of patients. Key factors considered by healthcare practitioners when recommending treatment options are age (pre vs. post menopausal), nodal status, hormone receptor status, and HER2/neu status. All stages of breast cancer may require complex treatment and management decisions by healthcare practitioners and, most importantly, by the patient.

Endocrine therapy is currently used to treat all stages of breast cancer (National Cancer Institute, 2007). Endocrine therapy can work in two different ways: preventing estrogen from
binding to its receptor (i.e. Tamoxifen), or blocking the production of estrogen by interfering with the enzyme aromatase (i.e. Aromatase Inhibitors [AI]). The goal of adjuvant endocrine therapy is to prevent recurrence and to improve the survival of patients with receptor-positive breast cancers. Adjuvant endocrine therapy has resulted in substantial improvements in disease-free and in overall survival for women with breast cancer (Winer et al., 2005). Recent clinical trials of AI’s versus Tamoxifen have shown AI’s to improve disease-free survival, but not overall survival when used initially or in conjunction with Tamoxifen (Eisen, Trudeau, Shelley, Messersmith, & Pritchard, 2008). Although, overall survival is not significantly improved with the use of AI’s, quality of life and patient preference should be considered when the use of endocrine therapy is an option for treatment.

Healthcare practitioners are challenged when providing postmenopausal women with information about endocrine therapy. There are four clinical options for the use of endocrine therapy in post-menopausal women with hormone receptor positive breast cancer (Winer et al., 2005). These are to initiate with an AI or Tamoxifen alone as up-front adjuvant therapy for 5 years, to switch to an AI after 2 to 3 years of adjuvant Tamoxifen, or to use extended adjuvant AI therapy after 5 years of Tamoxifen. Currently, clinical trials do not show any superiority of one strategy over another (Eisen et al., 2008). Also, women have the option to choose not to have any treatment at all, eliminating the potential to reduce the chance of recurrence and to increase survival from that achieved by the primary treatment alone.

The challenge for healthcare practitioners (HCP) when discussing treatment options with endocrine therapy is determining the best schedule of treatment for women. Anastrozole and Letrozole, both AI’s, have shown to be effective as initial treatment, and are preferred for postmenopausal women who have a contraindication to Tamoxifen (ATAC trialist Group, 2005). There is no conclusive research to indicate that AI’s should be used as initial treatment in postmenopausal women, unless Tamoxifen is contraindicated in the adjuvant setting (Winer et al.,
Studies have shown that switching women to an AI (Exemestane) after taking Tamoxifen for 2-3 years prevents more recurrences than continuing on Tamoxifen for the full five recommended years (Coombes et al., 2004). In a trial looking at the use of Anastrazole, it showed more adverse side effects when compared with Tamoxifen, yet the Tamoxifen side effects were more life threatening (Boccardo et al., 2005). The most reported side effects of AI’s include decrease in bone density, increased bone fracture risk, and increase in cardiovascular events (i.e. cardiac failure, myocardial infarction, or general cardiovascular disease) (Eisen et al., 2007). Tamoxifen’s most serious side effects include increase in blood clots, strokes, uterine cancer, and cataracts. Women also report common side effects of hot flashes, weight gain, vaginal dryness, joint pain, and leg cramps (National Cancer Institute, 2007). Individualized treatment decisions are recommended based on risk of relapse, other health concerns, treatment symptoms, and women’s preference (D’Hondt & Piccart, 2004).

2.1.3 Healthcare decision-making: Integrating information with clinical treatment

Making decisions about healthcare is complex, particularly for patients making decisions about their cancer care and treatment. The range of treatment options may bring both hope and anxiety. Within the oncology population, the complexity of decisions varies depending on a number of factors, such as decision-timing, nature of the choices, amount and quality of the information available, and diversity of the patients’ preferences (Blank, Graves, Sepucha, & Llewellyn-Thomas, 2006). The number of treatment choices that are presented to cancer patients varies from situations in which there is one clear, straight forward option to those with multiple choices and no clear single best option (Blank et al., 2006). At times, there is clear evidence to support treatment decisions, whereas at other times there are large gaps in clinical knowledge due to paucity of evidence. Most importantly, patients have different values and preferences with respect to desired health goals. Patients who have similar disease characteristics and same survival prospects may make different decisions based on their values for their health outcomes,
risk tolerance, and willingness to trade current for future health (Katz et al., 2005).

Although, there is limited literature about factors that may influence patient care decision-making of the use of endocrine therapy, we can build upon the research conducted about decision-making for other treatment options within the breast cancer population. When considering surgical treatment for breast cancer, fear of recurrence, survival, avoidance of further surgery, surgeon’s preference, and fear of dying can influence decision-making (Mastaglia & Kristjanson, 2001). Side effects, quality of life, time and schedule of treatments, and the influence of others may affect the decision about equivalent treatments using chemotherapy (Irwin, Arnold, Whelan, Reyno, & Cranton, 1999). Other key factors that have been associated with patients making decisions within the breast cancer population include: age (Crooks, 2001; Ganz, Greendale, Peterson, Kahn, & Bower, 2003; Romanek, McCaul, & Sandgren, 2005), socioeconomic status (Crooks, 2001), education (Graling & Grant, 1995), and geographic location of treatment centres (Halkett, Arbon, Scutter, & Borg, 2005). As well, physicians’ beliefs and practices, reluctance to participate in shared-decision-making, pessimism, and time may influence the process (Col, Duffy, & Landau, 2005). Therefore, we need to understand that healthcare decision-making is a complex, ongoing process that usually takes place between the patient and the healthcare provider, that is influenced by a number of personal, social and system factors (Halkett et al., 2005). Halkett and colleagues (2005) describe the factors that may influence decision-making of women with early stage breast cancer, which is additionally portrayed in a diagram (Appendix A).

The research and literature of effective healthcare decision-making processes has grown with an increasing emphasis on shared decision-making. Shared decision-making is defined as a decision-making process jointly shared by patients and their healthcare providers (Gravel, Legare, & Graham, 2006). The pure shared approach includes simultaneous interaction between the physician and the patient, 2-way information exchange, and a negotiated decision (Charles, Whelan, Gafni, Willan, & Farrell, 2003). The shared decision-making model is being utilized
increasingly over the more paternalistic medical model that dominated in the past (Charles, Gafni, & Whelan, 1999). The paternalistic model emphasized physician control with a one-way information exchange from physician to patient, although this may be a purposeful patient decision. The pure informed approach includes the physician sharing information with the patient, and the patient makes the decision on his or her own with no physician input (Charles et al., 2003).

The majority of breast cancer specialists report that they employ a shared decision-making process when interacting with patients about care decisions (Charles, Gafni, & Whelan, 2004). However, in a study to determine the information needs and decisional preferences of women with breast cancer, there was a substantial difference between the woman’s preferred and perceived levels of involvement with treatment decisions (Degner et al., 1997). Breast cancer patients indicated the need for more information about their cancer and more involvement in treatment decisions. Women wanted to be involved in a shared decision-making process, in which there was a more reciprocal relationship between the physician and patient (Hack, Degner, Watson, & Sinha, 2006). Shared decision-making allows the patient to consider their own values and preferences when making treatment decisions. The challenge for both providers and patients is the difficulty and complexity of sharing and processing information in the context of decisions about care.

2.1.4 Decisional conflict

Healthcare decision-making may be stressful. At the time of diagnosis, patients may experience decisional conflict (Halkett et al., 2005). Decisional conflict is described as “the state of uncertainty about the course of action to take” (O’Connor, 1995, p. 25). O’Connor (1995) identifies the components of decisional conflict: lack of information about alternatives and their consequences, unclear values, skill deficits in making decisions, emotional distress, and perceived pressure from important others. In a longitudinal study following women with breast cancer,
Hack et al (2006) reported that a significant number of women experienced decisional conflict when faced with treatment decisions, which often was associated with decisional regret. Thus, given the need to support effective shared health care decision-making and to minimize conflict, tools – such as health care decision aids – have emerged as a potentially helpful strategy.

### 2.1.5 Decision aids

As the number of treatment options has increased, there is an increasing need to help patients clarify values and preferences in order to make an optimal individualized decision. Decision aids have been useful in a number of oncology patient populations (O’Conner, et al., 2003). Decision aids are “designed to help people make specific and deliberate choices among different options by providing information on the options and outcomes relative to a person’s health” (Whelan & Loprinzi, 2005, p.1627). Decision aids are different from other health education material in that they explicitly describe treatment choices, provide quantitative estimate of risks and benefits, adjust information to individual patients, and provide a context in which patients can consider their own values when considering treatment options (O’Conner et al., 1999). Decision aids supplement, but do not replace, the traditional process of patient counseling by the physician and come in a variety of forms such as video, audio, poster, and interactive computer programs. The use of decision aids has decreased decisional conflict in women making decisions about breast cancer treatment (Whelan et al., 2004). A recent systematic review described the effect of decision aids on the choice for surgery for women with early stage breast cancer (Waljee, Rogers, & Alderman, 2007), concluding that decisions aids were important addition to the counseling that women already received. Women using decision aids had increased knowledge about treatment options, experienced less decisional conflict, and demonstrated increased satisfaction with the decision-making process.

When faced with treatment decisions, the majority of women with breast cancer want to be informed. Decision aids increase the chance that a woman will make an informed decision that is
consistent with her values and then acted upon (O’Conner, 1995). Decision aids are available for patients within the breast cancer population and have been used to assist patients making decisions about surgical treatment and adjuvant treatment. Currently, there are no documented decision aids that are available to patients for consideration of endocrine treatment options as continuation therapy or as initial therapy.

### 2.1.6 Decision aid development

The process of decision aid development is critical. A recent systematic review explored the information included in decision aids for adult patients, with the goal of determining if the information was complete, balanced and accurate (Feldman-Stewart et al., 2006). The review included a total of 98 decision aids, of which 68 were treatment decision aids. The review focused on the type of guidance used for the selection of information, the content of the decision aid, and accuracy of information. The reviewers concluded that the content within decision aids often does not reflect balance of the treatment options and may not include some information that would be important for informed decision-making to occur. The review also stated that only about half of the decision aids described the actual treatment procedures. Also, the creators of the decision aids relied predominantly on medical experts for guidance. The reviewers recommended that attention must be given to the accuracy of information and the completeness of the content in decision tools to avoid information and decision bias, to improve the patients’ understanding of health-care options and the quality of their decision. Because of these concerns, a quality criteria framework for the creation of patient decision aids has been created to guide development and measurement of the quality of decision aids (Elwyn et al., 2006). The criteria were considered in this research study (Appendix B).

Previous research about information needs has shown that there are key areas of information need including information about the diagnosis, treatment options, side effects of the treatment (Luker, Beaver, Leinster, Owens, Degner, & Sloan, 1995), chance of recurrence
(Graydon et al., 1997), and risk to family (Luker, Beaver, Leinster, & Owens, 1996). Women’s needs also change over time as they get further from diagnosis (Rees & Bath, 2000); as they move into recovery and follow-up, there is increased need for information about recurrence and survival (Vivar & McQueen, 2005). Most women are in the recovery phase when they are encountering information needs regarding endocrine treatment, which seems to be the optimal time for women to receive the information they need in order to ensure a sound decision.

2.1.7 Differentiation and consolidation theory

In order to begin to understand how information is important when making treatment decisions and the eventual development of tools such as decision aids, we need to understand the decision-making process. Svenson’s Differentiation and Consolidation (DiffCon) theory (1992) describes the process of decision-making that people typically follow when making a complex decision. The theory is based on the assumption that we make decisions in a manner that is intended to reduce the likelihood that we will experience cognitive dissonance at the time and regret later on; thus, the decision maker must feel that the selected option is clearly better than the other alternatives available when the choice is made. Arriving at a decision involves the process of differentiation, which is the means of establishing a difference between several choices. Eventually one alternative, the better one, is left. Process differentiation, which is most likely to be used when making treatment decisions, depends on the individual, the context, and the structure of the decision problem. One core concept of Svenson’s theory is that a decision is based on the integration of the patient’s values or information with the patient’s present decisions. After a decision is made, DiffCon theory describes that the person moves to a consolidation phase, in which the patient continues to compare the chosen option with other alternatives to confirm the decision. Consolidation allows the patient to deal with threats to the decision, such as regret or decision reversal. Therefore, by identifying the information needs that women have about endocrine therapy for breast cancer, we can assist them in the differentiation phase of
decision-making.

2.2 Purpose of Study

Understanding that women with breast cancer have information needs across the trajectory of their cancer and given the prior focus on providing information close to diagnosis and during treatment, there is a gap in our understanding of the information needs in women receiving endocrine therapy in the latter stages of their illness. The overall purpose of this study was to determine the information needs and questions that breast cancer patients have in regard to treatment decisions about endocrine therapy in the adjuvant setting.
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Abstract

Purpose. We undertook an integrative review of the literature to describe the information needs assessment methodologies used to identify the information needs of women with early stage breast cancer.

Method. A comprehensive search of MEDLINE, CINAHL, PsychINFO, EMBASE, and Evidence-based Medicine Reviews resulted in 25 primary research papers that identified information needs in patients with early stage breast cancer. The papers were examined to describe the different methodologies and to critique their methods based on the following criteria: perspectives used to guide methodology, comprehensiveness of content, and information accuracy.

Findings. Information needs were identified using qualitative, quantitative, and mixed methods methodologies; each offering a unique way to identify information needs that were reflective of study objectives. Approximately half of the studies consulted with patients in the development of an assessment tool or method, with the remaining studies relying solely on other sources such as health professionals and literature. The quantitative studies were able to categorize needs into common groupings, which allowed patients to rank their needs. The qualitative methods provided more detailed data on a more limited number of needs. Overall, the mixed-method approach allowed for comprehensive identification of information needs.

Conclusion. The studies that consulted patients provided different insights than those that only used professionals or literature. Therefore, it is important to consider patients’ perspectives and to ensure that the information for the patient is specific to the time in cancer disease trajectory.
and relevant clinical characteristics of the disease (i.e., treatment, symptoms). Each needs assessment methodology offers a unique and valued perspective if rigorous methods are applied. Needs assessment methodologies should be driven by the intended use of the information.

**Key Words:** integrative review, breast cancer, information needs, needs assessment, information seeking

**Summary Statement**

What is already known about this topic:

- Women with breast cancer have high information needs that occur across the disease trajectory; needs may differ depending on the stage of illness that they are in.
- One of the difficulties when determining the accuracy and comprehensiveness of identified information needs is the range of assessment and evaluation methodologies used.

What this paper adds:

- This review of the literature identifies that a wide range of information assessment methodologies are used to identify information needs of women with early stage breast cancer, with each offering unique perspectives.
- This review reinforces the importance of incorporating the patient perspective to guide the methodology, to ensure accurate and comprehensive content; and the need for rigorous application of quantitative, qualitative and mixed data collection and analytic methods.
3.1 Introduction

Breast cancer is the most common cancer among women worldwide (World Health Organization, 2009). In 2007, more than 1.3 million women worldwide were diagnosed with breast cancer, and the incidence of breast cancer is increasing, largely due to the increased use of screening and mammography (Canadian Cancer Society, 2009). The highest rates of breast cancer occur in Northern and Western Europe, Australia, and North America (American Cancer Society, 2009). As treatment effectiveness increases, women are living longer with a diagnosis of breast cancer, which may predispose women to physical, psychological, social, and financial stresses. When faced with these stressors, many women cope by seeking out information about their diagnosis, treatment options, and supportive care (Lauver, Connelly-Nelson, & Vang, 2007). Many women with breast cancer have high information needs (Bilodeau & Degner, 1996; Raupach & Hiller, 2002).

Information may assist women to gain control, and thereby reduce anxiety, improve adherence to treatment protocols, create realistic expectations, promote self-care and participation and, overall, generate feelings of safety and security (McCaughan & Parahoo, 2000). Similarly, women with breast cancer seek information to cope with their diagnosis, to increase their confidence, and to participate in the decision-making process (Rees & Bath, 2001; Harrison-Woermke & Graydon, 1993), to improve communication with family members (Arora, 2003), and to attain greater improvement in physical recovery and overall quality of life (Ransom, Jacobsen, Schmidt, & Andrykowski, 2005). Given the apparent benefits of providing information to women with breast cancer, it is important to ensure that the information women receive is accurate, timely, comprehensive, and appropriate to their information needs. Also, healthcare professionals have a professional and ethical responsibility to provide relevant and appropriate information, to support informed consent and an informed patient.
When women look for information on their own, they may encounter difficulties such as being overwhelmed by the vast amount of information, contradictory information, and criticism for wanting too much information. Women with breast cancer often feel that it is difficult to make sense of all the information (McCaughan & Parahoo, 2000) and have difficulty getting the type and amount of information that they want (Degner, Davison, Sloan, & Mueller, 1998). Women also report that poor communication of the healthcare practitioner is a barrier to comprehending treatment information (Cawley, Kostic, & Cappello, 1990). Often health professionals have limited time to discuss the questions that women might have; therefore, there may be a focus on the medical aspects of care leaving gaps in information about other aspects of care. Thus, the need to identify the information needs and questions that women have is critical in order to better support women as they engage in decision-making and coping with their breast cancer.

Several recent reviews have described the information needs of cancer patients (Finney Rutten, Arora, Bakos, Aziz, & Rowland, 2005; Vivar & McQueen, 2005; Ankem, 2005). Not all patients have the same information needs. Studies that have looked at the information needs of women with breast cancer have found that often there is only moderate agreement of all women on the overall profile of information needs (Degner et al., 1997). Younger and more educated women tend to seek more information because they prefer more involvement in decision-making than older women (Wallberg et al., 2000). Older women often feel comfortable with the information that is only essential and report that they often prefer not to receive information (Thewes, Butow, Girgis, & Pendlebury, 2004). Although, related to age, this may be related to other factors such as level of education. Over the disease trajectory, information needs also change. Women have the highest information needs at the time of diagnosis and seem to require less detailed information three to six months after diagnosis (Vogel, Bengel, & Helmes, 2008). Yet, it is not clear whether women require less information or different types of information, as they transition through the disease trajectory from diagnosis to survivorship.
One of the difficulties when trying to understand the literature on information needs is the range of methodologies used to accurately and comprehensively identify the needs. A number of reviews have synthesized information needs, but few have critiqued the methodologies used to identify the needs. Of the few critiques available, authors have commented on inconsistencies in scales of measurement, conceptualization of information needs variables, disconnect between measurement time and time elapsed since diagnosis (Ankem, 2005), and breadth and potential heterogeneity of the sample population (O'Leary, Estabrooks, Olson, & Cumming, 2007). Accurate and relevant identification of information needs requires an understanding of the methodologies used in the identification process. Therefore, this integrative review focused on the methodologies used to identify information needs in early stage breast cancer patients.

3.2 Objectives

The objectives of this review were to describe the methods used to identify information needs of women with breast cancer and to critique these methods according to the following criteria:

(1) Participants’ perspectives, the extent to which participants’ viewpoints were sought and incorporated

(2) Comprehensiveness, the level of detail in the content and scientific rigour of analysis

(3) Information accuracy, the extent to which the information is accurate for specific disease manifestation and time in disease trajectory.

3.3 Method

We conducted an integrative review and synthesized findings from studies designed to identify information needs of early stage breast cancer patients and focused on the rigour of the methodologies used to identify information needs. An integrative review was the most appropriate review strategy because it allowed for the inclusion of a diverse range of literature, including both quantitative and qualitative designed studies. We employed a review
methodology described by Whittemore & Knafl (2005), in which key articles were identified in the literature based on the defined sample. Data were evaluated and categorized based on the type of information needs assessment methodologies employed (i.e. qualitative, quantitative, or mixed methods). Next, the data were organized by the methodologies to enhance comparisons and to evaluate themes, patterns, and conclusions (Whittemore & Knafl, 2005).

3.3.1 Search Strategy

A comprehensive literature review was conducted using the following online databases: Cumulative Index to Nursing and Allied Health Literature (CINAHL), MEDLINE, PsychINFO, Exerpta Medica Database (EMBASE), and Evidence-based Medicine Reviews (Cochrane Database of Systematic Reviews, American College of Physicians Journal Club, Database of reviews of Effects, and Cochrane Central Register of Controlled Trials). Key words for searching the databases were breast cancer, breast neoplasm, informational needs, information needs, needs assessment, information seeking, patient participation, and patient education. The timeframe for the literature search was January 1990 to December 2008 in order to capture the latest clinical options for women with breast cancer. The review included experimental, observational, and qualitative studies to capture a broad spectrum of methodologies, yet was limited to primary research and articles published in English. Studies were included if information needs were one of the major outcomes of interest, including supportive, physical, psychological, psychosocial, practical, and educational needs, and the study population included breast cancer patients that were being treated with a curative intent. Using these criteria, a total of 83 articles were identified. Although titles and abstracts suggested that these articles were relevant to the review, only 38 met the criteria. Articles (n = 45) were excluded because the research included a broader population or metastatic patients (n = 14) or was not primary research (n = 8). Other articles focused on information sources and dissemination (n = 11), information-seeking behaviour (n = 5), and measuring satisfaction or knowledge related to information (n =
7), and therefore, they were excluded. Duplicates were accounted for and a total of 25 articles were retained in the analysis. When the articles were examined more closely, it was noted that some of the studies used the same information need assessment methodology; therefore, these articles were grouped together when they were analyzed.

3.3.2 Procedure

The primary author summarized each research article using the following criteria: purpose, population, sample size, methods, and outcomes. Then important aspects of each article’s methodology, such as development of the methods and quality of content were determined. Our evaluation methodologies were guided by a process used by Feldman-Stewart et al. (2006) in their review of information in decision aids. The following steps were followed:

1. We determined the details of the development of the method to identify information needs; specifically, who was consulted in the creation of the tool or method and the specific source of the items or questions on the survey or interview guide and the actual assessment methodology;
2. We established the level of detail used in the information measure; for example, if specific or categorical items were utilized and the number of items included;
3. We looked at how the information was collected (i.e., focus groups, questionnaires) and analyzed;
4. We examined the specific measures, and identified how the results were summarized;
5. We examined the study’s sample to determine the specificity of sample description including the time since diagnosis and number of participants;
6. We investigated whether there was a focus on a certain point in the disease trajectory when identifying the information needs;
7. We identified the research priorities of the study and the purpose of collecting the information; and
8. We compared the findings of the studies to determine if findings were similar across the various samples studies and times in the cancer continuum.

3.4 Summary of Studies

Information needs of breast cancer patients were assessed by quantitative survey (n=15); qualitatively (n=7); and mixed methods (n=3). Of the quantitative studies, 10 tools were identified including the: Informational Needs Questionnaire (Bilodeau & Degner, 1996), Self-Assessed Support Needs of Women with Breast Cancer Scale (SASNS) (Erci, 2007), Toronto Informational Needs Questionnaire – Breast Cancer (TINQ-BC) (Galloway et al., 1997), and other self-created tools and surveys. Seven articles retrieved were qualitative designs. Information need data in qualitative studies were collected using either semi-structured interviews in person or over the telephone (n=5), or focus groups (n=2). The remaining studies used a mixed-methods approach to create and validate the information needs assessment tool.

3.4.1 Quantitative assessment of information needs

Table 1 summarizes the extracted detail from the 15 studies reviewed. Six out of the 10 quantitative studies consulted patients to guide the development of the assessment tool/survey. Half of the quantitative studies consulted healthcare practitioners, which may have included people who were indirectly involved in patient care, when creating the tool or survey. The majority of these tools relied on external sources such as literature reviews, medical records, theory, and existing tools or methods that were adapted.

The sample size varied substantially in these studies (range: n=40 to n=1012). There was a large range in timing of the information needs assessment, with ranges from a few weeks to over five years from diagnosis at the time of the study. Over half of the quantitative studies identified the current needs of the patients, while the remaining studies identified needs retrospectively. The majority of the studies identified the stage of disease trajectory in which
they were interested. Nine of the studies were specifically targeting women who were in the treatment phase. One study targeted women at the diagnosis stage before treatment and four examined women in the follow-up stage of their illness. Four of the studies examined information needs across the disease trajectory, from diagnosis into survivorship.

The quantitative studies evaluated needs using Likert scales (n = 8); presence or absence of need (n = 1) or with Thurstone’s scaling technique (n = 6). With Thurstone scaling, participants are asked to choose higher priority needs from pairs of information categories. A total of nine categories were presented with each category being matched with every other category. The nine categories included patient’s need for information about: how advanced the disease was and how far it has spread; the likelihood of cure; how the treatment may affect the ability to carry on usual social activities; how family and close friends may be affected by the disease; caring for oneself at home; how the treatment may affect feelings about body or sexual attractiveness; different types of treatment and the advantages and disadvantages of each treatment; whether children or other family members are at risk of getting breast cancer; and unpleasant side effects of treatment. The final result produces a ratio for each category that is ranked on a scale; showing which category is preferred and by how much.

Our assessment of the quantitative surveys focused on the number and types of questions on the survey and the level of detail in items. The number of items on the measurement tools ranged from 13 to 148. Three of the 10 methods presented survey items categorically. For example, "side effects“ was utilized as an encompassing topic that could be associated with any side effects. The other surveys or questionnaires included closed ended questions that fit into a certain number of domains or categories. The most common information needs were related to supportive needs, follow-up care, treatment decision-making, psychosocial needs, practical needs, and education needs. Overall, the focus of the majority of the quantitative studies was to identify the prevalence of information needs to inform current clinical practice.
3.4.2 Qualitative assessment of information needs

Focus groups and individual interviews were used in the 7 studies retrieved for the review (Table 2). Two studies collected information needs through focus groups and the remaining 5 used individual interviews in person or over the telephone. We evaluated how the questions were defined and who was consulted in the creation of them. In the two studies that used focus groups, experts, which included the researchers, began the focus group with a small number of questions or prompts. Participants built on each other’s comments and questions. It was an iterative process. The remaining studies (n = 5) used individual semi-structured interviews. Health-care practitioners, principal investigators, literature, and theory guided the creation of interview questions and prompts. Two of the five studies that used individual interviews included all the questions that they asked participants.

The number of participants varied from six to just over 200 participants. The larger study utilized a large sample, which is unusual for a qualitative study, which often focuses on a smaller population to obtain more detail. All the samples were chosen with the specific purpose of the study in mind, which introduces bias, yet allows for the specific information to be gathered. The majority of the qualitative studies collected data until new themes or data no longer emerged. Two of the studies interviewed women at the time of treatment; the rest of the studies relied on retrospective recall. Overall, the participants included women who were at all stages of the disease trajectory, yet each sample was purposely chosen to address the specific goals of the study. Thewes and colleagues (2003) wanted to identify the fertility and menopausal information needs of younger breast cancer patients; therefore, the participant sample included women under the age of 45 who had breast cancer.

All of the studies stated that they used open-ended questions and reported using qualitative coding to establish themes from the data collection, which showed the rigour of the methods. Despite the qualitative inquiry design, four authors reported on frequency of needs, which is typically not recommended in qualitative studies. Overall, the information needs were
sought in the qualitative studies to aid in treatment decision-making and to contribute to the improvement of clinical practice, such as supporting women’s educational, psychosocial, and supportive needs.

3.4.3 Mixed methods assessment of information needs

Three of the reviewed articles (Table 3) used mixed methods to identify information needs in breast cancer patients. All of the studies used qualitative techniques to create a tool to identify information needs, which was followed by application and evaluation of the tool using quantitative methods. Breast cancer patients contributed to the development of the information needs assessment tool; two studies consulted healthcare practitioners and literature as well. After the actual tools or measures were created, they were then tested in an appropriate sample with the number of participants ranging from 221 – 489. The information needs surveys contained a range of 13 to 140 items. One questionnaire had 8 additional open-ended questions. All of the questionnaires used a 4 or 5 point Likert scale to measure responses, which were evaluated using either mean scale scores or frequencies. One of the studies used categorical items, which grouped similar items together under one group, rather than specific needs. Women who were at all stages in the disease trajectory were targeted in two of the studies, while one study focused on only the follow-up needs of breast cancer patients. Two of the studies assessed the current needs, and the remaining study asked women to think back to a specific time in their disease process. The overall goal of all the mixed methods studies was to create and test tools for use in care of patients with breast cancer.

3.4.4 Common information needs

Overall, consistent with the literature, many women have high information needs throughout their entire disease trajectory. During the initial diagnosis, women reported a high need for information related to: prognosis, diagnosis (disease characteristics), and treatment options. Similarly, during the treatment, women reported having similar needs: disease, treatment
and side effects, recurrence, and investigative tests. In addition to this, women had information needs about familial risk, sexuality, fertility, and general lifestyle and supportive care needs. During the follow-up phase, women required information about post-treatment care and rehabilitation opportunities, and as well as information about, likelihood of cure, recurrence of new cancers and on-going adjuvant treatment, and side effects.

Similar needs were identified in the qualitative and quantitative studies. The information needs identified in the quantitative studies were usually grouped into themes or categories (Vogel, Bengel, & Helmes, 2008; Luker et al., 1996). For example, Vogel and colleagues used the following categories: diagnosis, prognosis, treatment, medication & side effects, examination & medical tests, etc. The qualitative methods identified a broader range of concerns, in particular emotional or psychological concerns, such as, fear of recurrence and depression (Stephens et al., 2008); and sexuality and fertility related issues (Thewes Meisener et al., 2003). Although the quantitative and qualitative methods reported similar needs at the same points in care, the qualitative methods described the needs in a more detailed manner. For example, Gray and colleagues (1998) were able to identify more specific information needs related to recurrence, such as how to monitor their bodies, when to be concerned, and what they needed to do if they feared recurrence. Overall, the studies that were categorized as mixed methods identified the same needs as both the qualitative and quantitative studies (Lindrop & Cannon, 2001; Raupauch & Hiller, 2002; Gustafson et al., 1993).

3.5 Synthesis, Critique, and Discussion of Methodologies

This review has contributed to the body of research with regards to methods used to identify information needs in breast cancer patients. A range of information needs assessment methodologies were used; each offering a unique way for women to identify information needs and voice their questions and concerns. Quantitative inquiry provides a means to understand and describe needs on a broader population-based level, to understand issues such as prevalence of
needs, variability of need characteristics, and the relationship with other factors (i.e., age, education) on needs; qualitative inquiry provides a means to gather an in-depth understanding of the different types and nature of needs at an individual level. Both means of research inquiry are needed and complement each other; however, the methodology used must be driven by the identified research objective or questions and be rigorous in design, analysis and reporting.

Quantitative surveys and questionnaires have the potential to become standardized and validated tools that could be used by others in a variety of ways (i.e., standardized needs assessment) (Gopal et al., 2005; Galloway et al., 1997). Therefore, comprehensive quantitative assessment allows for accurate identification, ranking, and prioritizing of information needs which eventually could inform the development of information sharing tools, such as decision aids (Feldman-Stewart, 2004). Quantitative information needs assessment measures can be used in conjunction with other validated measures. Assessing information needs in addition to understanding the relationship between the amount of information and preference for information (Harrison et al, 1999) or participation in decision-making (Wallberg, et al., 2000).

Alternatively, qualitative methods allow women to give more details about their needs. This method has the potential to be more time-consuming due to the nature of an open-ended conversation, yet through this process participants have the ability to tell their story in a more interactive and intimate environment, which allows for elaboration of their needs, that could be physical, psychological, social and spiritual in nature (Thewes et al., 2003; Stephens et al., 2008). Methodological rigour in qualitative analysis ensures that findings are relevant to the research questions posed (Brown et al., 2000). Without this rigour, findings related to these studies need to be interpreted with caution.

The mixed methods design seems to bring the best of both methods together. Often the qualitative measures are used as a stepping-stone to explore the needs, which later are verified or validated within a quantitative study (Lindop & Cannon, 2001; Raupauch & Hiller, 2002; Gustafson et al., 1993). Because both methodologies are used, this process may be lengthier, but
is likely to lead to a more accurate, valid, and reliable assessment. Recently, in a review of the content of screening and treatment decision aids, the authors reported that the qualitative-quantitative approach to collecting information for the content of the decision aids is the most rigorous method (Feldman-Stewart et al., 2006). This methodology allows for studies to build on each other ensuring that the quantitative methods are fully informed and that the qualitative findings are utilized.

3.5.1 Patient perspective

This review highlighted the importance of information accuracy when assessing information needs. First, the source of information used in the development phase of the assessment methodology is critical. Obtaining the patient perspective during method development allows essential and relevant assessment content to be included and more thorough outcomes to be achieved (Brown et al., 2000; Bilodeau & Degner, 1996). In decision-making support research, it is highly recommended that the creation of tools such as decision aids consider and incorporate patient’s input as they are the targeted audience (Feldman-Stewart et al., 2006). In addition, other non-patient sources can be considered such as, theory, literature, healthcare professionals, medical charts, and experts in the field of interest, in order to augment the patient-derived needs. Use of these sources alone does not allow for incorporation of patients’ perspectives and may compromise the validity and accuracy of the tool.

3.5.2 Comprehensiveness of content

A comprehensive description of the content, such as the questionnaire items and the analytic methods used to categorize and evaluate the information collected, allows users to determine the prevalent and important needs. Although categorical items allow the general need to be identified, often categories fail to capture the complexity of the need and details may be missed. For example, Degner’s Information Needs Questionnaire includes 9 categories, including “information about unpleasant side effects of treatment”. This category is broad and patients may
have differing understandings about the meaning of unpleasant side effects (Degner & Bilodeau, 1996). Also, the use of categories does not allow for specific information needs to be expanded upon. Specificity of detail needs to be balanced within the broad range of potential information needs to ensure accuracy of content. Moreover, few, if any of the questionnaires were rigourously tested psychometrically. Most reported on internal consistency of scales (n = 12), but did not determine other psychometric properties such as construct validity, sensitivity and specificity of measure. Although, the purpose of the studies was to determine the prevalence of needs, it would seem that we need to expand upon this descriptive work to develop questionnaires or tools that are reliable measures of information needs. The qualitative studies captured detailed information; yet, an exhaustive list of needs may not be depicted depending on the sample population that has been chosen and probing questions that are asked. For example, Davis et al. (2003) conducted telephone interviews to assess rural women’s needs with regards to their breast cancer focusing on the rural experience; therefore, women may have had additional needs unrelated to their location. Due to the in-depth approach of qualitative research, the sample size is usually small, which may preclude the findings to be representative of a broader population. There is a potential for researcher bias, as the information is collected, therefore, it is imperative that documented qualitative analysis is carried out. Methodological and analytic rigor is key to accurate identification of needs.

### 3.5.3 Information accuracy

Finally, complexities may exist when considering the factors that may affect a person's information needs, especially regarding a treatment decision. First, there is variability between people about the information needs they have. For example, some women may place importance on the long-term survival and others may focus on quality of life as they make their treatment decisions (Degner et al., 1997). In another study, younger women are more likely to consider body image and perceived risk of recurrence as a factor in decision-making regarding surgical
treatment for breast cancer (Romanek, McCaul, & Sandgren, 2005). Second, the accuracy of the information needs assessment is influenced by specific details, like disease manifestation and time in disease trajectory. If defining information needs for women from all stages in the disease process (diagnosis to survivorship), than a broad range of needs will be identified from a large range of participants. Therefore, some of the needs identified by one subgroup are likely to be irrelevant to members of another subgroup, yet all information needs must be considered. For example, it is understandable that breast cancer patients are asking about treatments close to diagnosis, as they are making treatment decisions at this point in time (Stephens et al., 2008). Yet, information about treatment and diagnosis is a continuing information need for women after their initial treatment because they may be continuing on other adjuvant treatments or be dealing with lingering treatment effects (Cappiello, Cunningham, Knobf, & Erdos, 2007), indicating the importance of a comprehensive assessment of need throughout the disease trajectory. When considering accuracy of information, it is essential that patient sample is considered specifically with the project purpose in mind. For example, Thewes and colleagues (2003) were particularly interested in fertility and menopausal needs, therefore, younger pre-menopausal women were targeted for this particular study. Fertility needs are more likely to be a concern of younger women than of women who are post-menopausal. Yet, information related to menopause would be important for older women who may experience menopausal symptoms. The sample for the study was chosen to gain the most representative information in order to meet the objectives of the study; but in selecting this sample, they may have missed important information from older women.

Thirdly, another aspect to consider is that the need for information is a continuous process, as are the decisions that individuals make. If patients are given an information needs survey at the time of diagnosis, they may indicate that all information is extremely important to have, because they are at a time of high stress and may need to have as much information to cope with their anxieties (Harrison-Woermke & Graydon, 1993). Yet, patients at another point in
their disease experience may want less information and only want to know things that are essential. Women may recall different needs depending on the number of months they are from diagnosis (Rees & Bath, 2000). Asking patients to recall up to five years ago is difficult and can be biased. The results can potentially be affected by experience and memory may affect the recall of information given. Previous research indicates that, depending on the intensity of the experience one is wishing to explore, it is important to have an appropriate amount of distance from the event in order to be able to talk about it with ease (Morse & O’Brien, 1995). It is important to consider that information needs may continue even though there is not even a decision to be made at the time.

3.5.4 Use of Information

It seems fundamental, based on the information needs literature (Feldman-Stewart et al., 2000), to appropriately identify the need for and the anticipated use of the findings when you are choosing a method to identify information needs. Much of the data findings from the quantitative surveys were used for organizing needs, planning consult sessions, and teaching opportunities when interacting with patients. As well, the quantitative findings informed the creation of a tool or decision aid or in preparation for an education pamphlet. Qualitative studies were conducted to explore the information needs and to understand the phenomenon of needs. In most cases these studies were followed up with a quantitative study to create a tool or survey to determine information needs.

3.5.5 Limitations

One of the limitations of this review is that we did not critique the surveys or tools that were used. In some cases, the study itself included only partial descriptions of the methods used to assess information needs. Because we were primarily interested in breast cancer patients’ information needs, we limited the studies to those of the breast cancer population, which may have eliminated unique methods that have been conducted in other populations.
3.6 Conclusion

The results suggest that it is important to consider the following components of the methodology when identifying the information needs of breast cancer patients in order to have results that are reliable and valid and comprehensive: development of the methods, time in disease trajectory, targeted population, level of detail used in the method, and how the information is going to be used. Both qualitative and quantitative methodologies contribute to assessing the needs of breast cancer patients throughout the disease trajectory. Overall, we understand that women have information needs at all stages of their cancer disease, from diagnosis to follow-up. When trying to identify the needs of breast cancer patients, there does not appear to be one method that is the “best.” This is largely due to the broad spectrum of goals that were covered across the studies. Qualitative methods allow the researcher to explore information needs more intimately and on an individual level, which allows the experience of information needs to be explored. When trying to prioritize the needs of patients during teaching sessions or consults, quantitative needs assessment methods allows health practitioners to focus on the needs that are important to the patient at that specific time. When creating a tool or measure, using a mixed methods approach seems to be the most appropriate because you can build on the qualitative data that is collected and verify it using quantitative means. Most importantly, it is paramount that patients are included in determining their own needs.
Table 1

Quantitative information needs assessment methods of women with breast cancer

(n=15 studies; 10 tools/questionnaires)

Legend:

BCP – Breast cancer patient
S – Survey
Q – Qualitative (i.e. interview, focus group)

<table>
<thead>
<tr>
<th>Method (design)</th>
<th>Author (year)</th>
<th>Purpose (related to information needs)</th>
<th>Source(s) used to guide method development</th>
<th>Method details</th>
<th>Evaluation of method</th>
<th>Population</th>
<th>Key information needs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survey</td>
<td>Vogel et al. (2008)</td>
<td>To analyze BCP’s information needs and experiences with information received in the course of the first 6 months of treatment</td>
<td>Breast and melanoma patients; adapted from previously used tool</td>
<td>Survey; 8 categorical items; 5-point Likert Scale; frequency analysis</td>
<td>not noted</td>
<td>Women with a diagnosis of breast cancer within one week of beginning their initial treatment (Germany) n=135</td>
<td>diagnosis; treatment; prognosis; medication and side effects; examinations and medical tests</td>
</tr>
<tr>
<td></td>
<td>Cawley et al. (1990)</td>
<td>To assess whether the</td>
<td>Literature; Oncology)</td>
<td>Exploratory descriptive; Survey;</td>
<td>Self-evaluated by</td>
<td>Women with early stage</td>
<td>diagnosis; recurrence;</td>
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<tr>
<td>Title</td>
<td>To determine the information needs of BCP and her preferences for participation in decision-making</td>
<td>To determine the information needs of women choosing breast conservation therapy with radiation were being met</td>
<td>To identify and prioritize BCP's information needs</td>
<td>To establish the priority of information needs of women newly diagnosed with breast cancer</td>
<td>To determine the preferences for different types of treatment; pre-operative information; side effects; post-treatment care</td>
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<td>Patient (S); Literature; Theory</td>
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<td>Information Needs Scale</td>
<td>Survey; Information needs scale; 36 items in 9 categories; Thurstone scaling analysis</td>
<td>Open-ended and yes/no questions; Frequency/descriptive analysis</td>
<td>Survey; Information needs scale; 36 items in 9 categories; Thurstone scaling analysis</td>
<td>Survey; Information needs scale; 36 items in 9 categories; Thurstone scaling analysis</td>
<td>Survey; Information needs scale; 36 items in 9 categories; Thurstone scaling analysis</td>
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<td>Consistency</td>
<td>Consistency = 0.988 Agreement = 0.299</td>
<td></td>
<td>Consistency = 0.922 Agreement = 0.348 (moderately agree)</td>
<td>Consistency = 0.979 Agreement = 0.257</td>
<td>Consistency = 0.979</td>
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<tr>
<td>Women</td>
<td>Women with a diagnosis of breast cancer within the last 6 months treated with surgery (Sweden) n=201</td>
<td>women choosing breast conservation therapy with radiation were being met</td>
<td>Women recently diagnosed with breast cancer in the last 6 months treated with surgery (Canada) n=74</td>
<td>Women newly diagnosed with breast cancer (UK) n=150</td>
<td>Women newly diagnosed with breast cancer</td>
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<tr>
<td>UK</td>
<td>treatment; pre-operative information; side effects; post-treatment care</td>
<td>breast cancer who had breast-conserving surgery followed by radiation within the last 2 years (US) n=68</td>
<td>Women with breast cancer who had breast-conserving surgery followed by radiation within the last 2 years (US) n=68</td>
<td>Women with breast cancer who had breast-conserving surgery followed by radiation within the last 2 years (US) n=68</td>
<td>Women with breast cancer who had breast-conserving surgery followed by radiation within the last 2 years (US) n=68</td>
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<td>Country</td>
<td>US</td>
<td>Sweden</td>
<td>Canada</td>
<td>UK</td>
<td>Canada</td>
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<tr>
<td>Sample Size</td>
<td>n=68</td>
<td>n=201</td>
<td>n=74</td>
<td>n=150</td>
<td>n=74</td>
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Consistency = 0.922 Agreement = 0.348 (moderately agree)
<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Methods</th>
<th>Measures</th>
<th>Reliability</th>
<th>Disease Stages</th>
<th>Information Needs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degner et al. (1997)</td>
<td>Women with a diagnosis of breast cancer regardless of time from diagnosis (Manitoba, Canada) n=1012</td>
<td>Patients (S); Literature; Theory</td>
<td>Survey; Information needs scale; 36 items in 9 categories; Thurstone scaling analysis</td>
<td>Consistency = 0.95 Agreement = 0.206</td>
<td>Women newly diagnosed with breast cancer (3-4 months from diagnosis) receiving adjuvant treatment (Malaysia) n=100</td>
<td>likelihood of cure; stage of disease; treatment options</td>
</tr>
<tr>
<td>Gopal et al. (2005)</td>
<td>Women newly diagnosed with breast cancer (3-4 months from diagnosis) receiving adjuvant treatment (Malaysia) n=100</td>
<td>Patients (S); Literature; Theory</td>
<td>Survey; Information needs scale; 36 items in 9 categories; Thurstone scaling analysis</td>
<td>Agreement = 0.76</td>
<td>Women newly diagnosed with breast cancer (3-4 months from diagnosis) receiving adjuvant treatment (Malaysia) n=100</td>
<td>likelihood of cure; sexual attractiveness; stage of disease</td>
</tr>
<tr>
<td>Informational Needs Questionnaire – Breast Cancer (INQ-BC)</td>
<td>Women receiving radiation for breast cancer (Canada) n=40</td>
<td>Healthcare practitioners (Q); Literature</td>
<td>Informational Needs Questionnaire-Breast Cancer; 75 questions in 7 categories; 5 point Likert scale; means of importance</td>
<td>Inter-rater reliability – 0.91</td>
<td>Women receiving radiation for breast cancer (Canada) n=40</td>
<td>diagnosis; treatment; physical needs; investigative tests</td>
</tr>
<tr>
<td>Toronto Informational Needs Questionnaire – TINQ</td>
<td>Galloway et al. (1997)</td>
<td>To develop a questionnaire to measure the information needs of women during the first course of treatment for a recent diagnosis of breast cancer</td>
<td>Literature; Theory; Oncology nurses (Q, S)</td>
<td>51 questions in 5 domains; 5 point likert scale; percentage/means</td>
<td>Consistency = 0.96 (overall) = 0.81-0.93 (subscales) Evaluated by BCP, lay people, healthcare providers</td>
<td>Women with a recent diagnosis of breast cancer in the treatment phase receiving surgery, radiation, or chemotherapy (Canada) n=114</td>
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<td>Harrison et al. (1999)</td>
<td>To determine the amount and type of information BCP want during a course of radiation and the relationship between the amount and preference for information</td>
<td>Literature; Theory; Oncology nurses (Q, S)</td>
<td>51 questions in 5 domains (2 specifically related to radiation treatment); 5-point Likert scale; percentage/mean</td>
<td>Consistency = 0.97 (overall) = 0.75-0.97 (subscales)</td>
<td>Breast cancer patients that had breast conserving therapy beginning first course of radiation therapy (Canada) n=125</td>
<td>Breast cancer; treatment; investigative tests; chance of recurrence</td>
</tr>
<tr>
<td>Graydon, et al. (1997)</td>
<td>To determine the information needs of women during their early treatment for breast cancer</td>
<td>Literature; Theory; Oncology nurses (Q, S)</td>
<td>51 questions in 5 domains; 5 point likert scale; percentage/mean</td>
<td>Consistency = 0.94 (when tool was created)</td>
<td>Women with breast cancer being treated by surgery, chemotherapy, or radiation (Canada) n=70</td>
<td>Breast cancer; treatment; investigative tests; chance of recurrence</td>
</tr>
<tr>
<td>Menopause/ fertility Questionnaire</td>
<td>Thewes et al. (2005)</td>
<td>To assess fertility and menopause related information</td>
<td>Patient (S, Q); Menopause/fertility Questionnaire; 25 closed questions; survey; mean</td>
<td>not noted</td>
<td>Younger women with a diagnosis of early stage breast cancer</td>
<td>Fertility; contraception; menopause</td>
</tr>
<tr>
<td>Instrument</td>
<td>Authors/Year</td>
<td>Purpose</td>
<td>Methodology</td>
<td>Details</td>
<td>Country</td>
<td>Sample Size</td>
</tr>
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<tr>
<td>Self-assessed support needs of women with breast cancer scale (SASNS)</td>
<td>Erci (2007)</td>
<td>To adapt the self-assessed support needs of women with breast cancer scale</td>
<td>Patient (Q); Patient medical records</td>
<td>Self-Assessed Support Needs of women with breast cancer Scale; 54 questions in 7 categories; 5-point Likert scale; mean</td>
<td>(Australia) n=228</td>
<td></td>
</tr>
<tr>
<td>Breast Cancer Patients Needs Questionnaire (BR-CPNQ)</td>
<td>Girgis et al. (2000)</td>
<td>To assess the prevalence of unmet needs among women with BC and identify predictors for unmet needs</td>
<td>Adapted from existing Cancer Patients Needs Questionnaire</td>
<td>60 questions covering 5 domains including 8 specific questions relating to BCP; 5 point likert scale &amp; 19 questions relating to demographics and health history; frequency</td>
<td>Rural and urban women diagnosed with breast cancer within 3-6 years (Australia) n=229</td>
<td></td>
</tr>
</tbody>
</table>
Table 2

Qualitative information needs assessment methods of women with breast cancer

<table>
<thead>
<tr>
<th>Method (design)</th>
<th>Author</th>
<th>Purpose (related to information needs)</th>
<th>Source to guide development</th>
<th>Methods - Number of items; response format; analysis</th>
<th>Evaluation of method</th>
<th>Population</th>
<th>Key information needs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus Groups</td>
<td>Gray et al (1998)</td>
<td>To identify the information needs of preferences of well breast cancer survivors</td>
<td>Patients; Expert experience</td>
<td>Qualitative – focus groups; One opening question; coding</td>
<td>Not documented</td>
<td>Physically well long-term survivors of breast cancer (Ontario, Canada) n=70</td>
<td>follow-up protocols; signs of recurrence; treatment &amp; side effects; prevention; lifestyle</td>
</tr>
<tr>
<td></td>
<td>Thewes, Meisner et al (2003)</td>
<td>To identify the degree of satisfaction with and the type of information younger breast</td>
<td>Patients; Expert experience</td>
<td>Qualitative – focus groups; Open-ended conversation; coding (transcendental realism)</td>
<td>Not documented</td>
<td>Pre-menopausal women diagnosed with early stage breast cancer in last 5 years; having started or</td>
<td>prognosis; fertility related needs; menopause related needs; sexuality</td>
</tr>
<tr>
<td>Type of Interviews</td>
<td>Study</td>
<td>Methods</td>
<td>Sample Description</td>
<td>Findings</td>
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<tr>
<td>Individual interviews</td>
<td>Thewes, Butow et al (2004)</td>
<td>To gather qualitative data on the needs of breast cancer survivors and identify the needs of younger and older survivors</td>
<td>Healthcare Professionals; Literature; Expert experience</td>
<td>Qualitative – individual interviews; Semi-structured interviews; Triggering questions (not included); coding (Transcendental realism)</td>
<td>Interview guide evaluated by an expert panel (Radiation Oncologist, 2 psychologists involved in Cancer Care)</td>
<td>Women with early stage breast cancer 6-12 months post-completion of their treatment (Australia) n=24</td>
<td>fertility; menopause; recurrence; treatment &amp; symptoms</td>
</tr>
<tr>
<td>Davis et al (2003)</td>
<td>To assess the practical and psychosocial needs of rural women with early stage breast cancer and to recommend strategies to ensure equal availability and access to services</td>
<td>Healthcare Professionals; Expert experience</td>
<td>Qualitative - individual interview over the phone; Open ended questions &amp; structured questions (choice of 3 responses); frequency</td>
<td>Face validity – &quot;good&quot; Item reliability &gt; 0.6 Kappa on core items followed a pilot tested population</td>
<td>Rural women who had been diagnosed with early stage breast cancer within 6-12 months (Australia) n=204</td>
<td>finances; radiation treatment; breast reconstruction; support when away from home</td>
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</tr>
<tr>
<td>Semi-structured interviews</td>
<td>Cappiello et al (2007)</td>
<td>To describe the information and support needs of women with early stage breast cancer after treatment</td>
<td>Literature; theory; investigator experience</td>
<td>Qualitative descriptive – Semi-structured interviews; Opened &amp; closed ended questions (interview guide included);</td>
<td>Not documented</td>
<td>Women diagnosed with early-stage breast cancer within the last 5 years who had completed primary therapy (surgery, treatment side effects; emotional needs; lifestyle changes</td>
<td></td>
</tr>
<tr>
<td>Authors</td>
<td>Objective</td>
<td>Participants</td>
<td>Methodology</td>
<td>Additional Findings</td>
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<tr>
<td>Brown et al (2000)</td>
<td>To gain a better understanding of the experience of women who had surgery for non-invasive breast cancer</td>
<td>Patients</td>
<td>Qualitative – semi-structured interviews; Patient-guided open-ended questions; coding - Constructivist paradigm</td>
<td>chemotherapy, radiation (USA) n=20 Women who had undergone surgery for ductal breast cancer between 6 and 24 months (Australia) n=6 diagnosis; treatment; chance of recurrence; risk to family</td>
<td></td>
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</tr>
<tr>
<td>Stephens et al (2008)</td>
<td>To assess the early needs and concerns of newly diagnosed patients with breast cancer To identify the educational and emotional needs that women experience following diagnosis and surgery</td>
<td>Investigator experience</td>
<td>Qualitative – semi-structured telephone interviews; 3 open-ended questions; Descriptive exploratory; coding; percentages and frequency of answers</td>
<td>Not noted Newly diagnosed breast cancer patients (within 1 month) after their primary surgery (USA) n=199 fear of recurrence; treatment; prognosis; impact of diagnosis on life; depression</td>
<td></td>
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</tr>
</tbody>
</table>
Table 3

Mixed methods information needs assessment methods of women with breast cancer

(n=3)

Legend:
BCP – Breast cancer patient
S – Survey
Q – Qualitative (i.e. interview, focus group)

<table>
<thead>
<tr>
<th>Method (Report)</th>
<th>Author</th>
<th>Purpose (related to information needs)</th>
<th>Source (to guide development)</th>
<th>Methods</th>
<th>Evaluation of Method</th>
<th>Population</th>
<th>Key information needs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needs Assessment Survey</td>
<td>Gustafson et al. (1993)</td>
<td>To introduce the method of customer needs assessment and describe how it is used to assess the needs of breast cancer patients and their families</td>
<td>BCP’s, husbands and daughters of BCP, Nurse Practitioner, Cancer surgeon, researchers, theory</td>
<td>Qualitative – integrative group methodology; customer needs assessment theory; Quantitative – self-administered survey; 5-point Likert Scale; 13 categories; mean not reported</td>
<td>Qualitative: 2 women with breast cancer; 2 husbands of women with breast cancer; 2 daughters of women with breast cancer; 4 healthcare providers and researchers</td>
<td>Quantitative: Breast cancer patients from diagnosis to 9 months after diagnosis; n=221 (USA)</td>
<td>prognosis; treatment; recurrence; decision-making; rehabilitation; disease information</td>
</tr>
<tr>
<td>Survey</td>
<td>Lindrop &amp; Cannon (2001)</td>
<td>To identify self-assessed support needs of women with breast cancer at various points of illness To establish the range of needs women have To develop a standardized scale of needs for use by nurses to evaluate care</td>
<td>Interview with women and service providers; focus group with BCP; literature review; National (Australian) Cancer report</td>
<td>Qualitative – semi-structured interviews Quantitative – Survey; 54 items; 5 point likert scale; 6 categories; frequency</td>
<td>not reported</td>
<td>Qualitative: Women with a diagnosis of breast cancer throughout disease trajectory; n=12 Quantitative: Women with a diagnosis of breast cancer within past 5 years; n=489 (England)</td>
<td>diagnosis; treatment; general support; femininity &amp; body image; aftercare; general information; supporting family and friends</td>
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<td>Self-assessed support needs of women with breast cancer scale (SASNS)</td>
<td>Raupach &amp; Hiller (2002)</td>
<td>To describe issues about which women want information and whether women received that information To describe the sources used for information and support and satisfaction To describe changes in their factors with time since diagnosis</td>
<td>Patient (Q); Patient medical records</td>
<td>Qualitative – focus group Quantitative – survey; 140 closed items &amp; 8 open items; 4 point likert scale; mean</td>
<td>not reported</td>
<td>Qualitative: Women with breast cancer; n=not specified Quantitative: Women who had been diagnosed with breast cancer between 6 and 30 months ago; n=217 (Australia)</td>
<td>recognizing recurrence; chance of cure; risk to family; treatment (hormonal)</td>
</tr>
</tbody>
</table>
References


Chapter 4

What information needs/questions do postmenopausal early stage breast cancer patients have regarding endocrine treatment?

Abstract

Objective: Women with estrogen responsive breast cancer who have completed curative treatment are often presented with a number of options in regard to endocrine therapy as adjuvant treatment; options with little difference in overall survival. The overall purpose of this study was to determine the information needs or questions that early stage breast cancer patients may have in regard to treatment decisions about endocrine therapy and to synthesize this information into a comprehensive list of potential questions they may have.

Methods: A qualitative descriptive study was conducted. Seventeen post-menopausal women with early stage breast cancer were interviewed over the telephone. Recruitment stopped at that point as saturation was reached. Women described information needs with regard to decisions about their endocrine treatment. Four healthcare practitioners were interviewed in person and asked about breast cancer patients perceived information needs with regards to endocrine therapy. Interviews were transcribed and coded individually by two independent coders.

Results: A list of 91 questions emerged from the interviews. Women who were presented with options regarding endocrine therapy reported information needs related to side effects, drug characteristics, financial cost, and survival/recurrence. While each woman identified their unique questions, commonalities amongst questions emerged. Surprisingly, most women were not aware that they had a choice and often followed their physician’s recommendations.

Conclusions: Women should be informed of therapeutic choices and be offered relevant, timely and appropriate information that meets common needs, and be provided opportunities to address
individual questions or concerns. Healthcare professionals need to be aware of the common and
individual information needs, to best support and involve women in treatment and care decisions.

Key Words: breast cancer, endocrine therapy, information needs, treatment, decision-making, patient participation
4.1 Introduction

Breast cancer is the most common cancer among women worldwide (World Health Organization, 2009). The Canadian Cancer Society (2009) reports that the incidence for early stage breast cancer is increasing, while the incidence for later stage breast cancer is decreasing, associated with routine screening with mammograms. Women are living longer with breast cancer as a result of effective treatments, including endocrine therapy (Winer et al., 2005, Goss et al., 2005, Coombes et al., 2004, & ATAC, 2002).

Treatment for breast cancer varies depending on characteristics of the disease and patient (National Cancer Institute, 2007). Treatment recommendations for women with early stage breast cancer may involve surgery, radiation, chemotherapy, and/or endocrine therapy, which are used in the adjuvant setting intending cure. These options are utilized to increase the overall survival of patients. Key factors that are considered by healthcare practitioners when presenting treatment options are: age (pre vs. post menopausal), health-related co-morbidities, and tumor characteristics (BC Cancer Agency, 2010). Treatments for all stages of breast cancer require complex decisions by healthcare practitioners and, most importantly, by the patient.

Endocrine therapy is currently used to treat all stages of breast cancer in the curative and metastatic setting (National Cancer Institute, 2007). Endocrine therapy can work in two different ways: preventing estrogen from binding to its receptor (i.e., Tamoxifen), or blocking the production of estrogen by interfering with the enzyme aromatase (i.e., Aromatase Inhibitors [AI]). The goal of endocrine therapy is to prevent recurrence and to improve the survival of those patients with receptor-positive breast cancers. Adjuvant endocrine therapy has resulted in substantial improvements in disease-free and in overall survival for women with postmenopausal breast cancer (Winer et al., 2005). Tamoxifen still remains the gold standard for pre-menopausal and peri-menopausal breast cancer patients. Recent clinical trials of AI’s compared to Tamoxifen have shown AI’s to improve disease-free survival, but not overall survival when used
initially or in conjunction with Tamoxifen (Eisen et al., 2007). Thus, a number of clinical options are available for postmenopausal women being treated with endocrine therapy. Common options include: (1) an AI as initial adjuvant therapy for 5 years, (2) switch to an AI after 2 to 3 years of adjuvant Tamoxifen, or (3) use extended adjuvant AI therapy for 5 years after 5 years of Tamoxifen (Winer et al., 2005). Also, women have the option to take Tamoxifen alone for up to 5 years. Currently, clinical trials do not show any superiority of one of the previously mentioned strategies over another (Eisen et al., 2007). Another option is to omit all endocrine therapy altogether, although, studies show that women have a better overall survival, if they take some form of endocrine therapy (Lin & Winer, 2008). Given the number of treatment options, women and healthcare practitioners need to engage in complex discussions about treatment options. Currently there is not a clear understanding of the specific information needs of postmenopausal women engaging in these treatment discussions.

The process of identifying information needs or questions is critical, regardless of how this information will be used. A recent systematic review explored the information included in decision aids for adult patients, with the goal of determining if the information was complete, balanced, and accurate (Feldman-Stewart et al., 2006). The review included a total of 98 decision aids, of which 68 were treatment decision aids. The review focused on the type of guidance used for the selection of information, the content of the decision aid, and accuracy of information. The reviewers concluded that the content within decision aids often does not reflect balance of the treatment options and may not include some information that would be important for informed decision-making to occur. The review also stated that only about half of the decision aids described the actual treatment procedures. Also, the creators of the decision aids relied more on medical experts for content. The reviewers recommended that attention must be given to the accuracy of information and the completeness of the content in decision tools to avoid information and decision bias, to improve the patients’ understanding of health-care options and the quality of their decision.
Because of these concerns, a quality criteria framework for the creation of patient decision aids has been created to guide development and measurement of the quality of decision aids (Elwyn et al., 2006). These criteria were considered in the design of this research study in guiding the creation of questions for the interview and selecting the sample population.

4.2 Objectives

In a recent review of research methods used to identify information needs in breast cancer patients, the authors identified that a mixed methods approach was the preferred methodology to use when first identifying and assessing information needs (TeBrake, Feldman-Stewart, Madarnas, Lamb, & Tranmer, 2009, unpublished work). The first step in a mixed methods approach employs a detailed qualitative exploration of both patients' and providers' questions or information needs. Therefore, the overall purpose of this study was to determine the information needs or questions that early stage postmenopausal breast cancer patients may have in regard to treatment decisions about endocrine therapy. The objectives were:

1. To identify the questions that postmenopausal breast cancer patients’ have when considering the use of endocrine therapy as adjuvant therapy for breast cancer.

2. To identify the information priorities of healthcare practitioners when counseling postmenopausal breast cancer patients considering use of endocrine therapy as adjuvant treatment.

3. To synthesize a comprehensive list of information need priorities or questions about treatment decisions relative to endocrine therapy as adjuvant treatment for postmenopausal breast cancer.
4.3 Methods

4.3.1 Study Design

We employed a qualitative descriptive data collection strategy as it was the most appropriate methodology for a concise description of the phenomenon being studied (Sandalowski, 2000). This type of design is used to provide a comprehensive summary of an area of interest, using the language of the participants, and is often used by researchers who want direct answers to questions about specific phenomena. Qualitative content analysis allows the researcher to summarize the information contents of the data into themes or groups (Sandelowski, 2000). The content analysis is data-derived, meaning that themes are generated from the data themselves. Therefore, the analysis aimed to describe the questions that postmenopausal breast cancer patients had about treatment with endocrine therapy from the perspective of patients and healthcare providers. The questions and information needs were identified and common themes were identified.

4.3.2 Sample

Participants were postmenopausal women with early-stage breast cancer receptive to endocrine therapy and health care providers who primarily cared for women with breast cancer. All the patient participants had made a decision regarding endocrine therapy within the previous 6-21 months. As treatment decision-making was a key area of interest, we recruited women who had varying experiences in their treatment trajectory with regards to endocrine therapy. Endocrine therapy must have been offered to them as primary adjuvant treatment or offered to them following chemotherapy and/or radiation, which are possible treatments offered to women with early-stage postmenopausal breast cancer. Women were required to have telephone access, as interviews were conducted over the telephone. Women were excluded if they were part of a clinical trial that precluded them from making a decision about endocrine therapy, had recurrent disease, or metastatic disease. Patient recruitment and interviews continued concurrently until
saturation was reached, defined as no new themes in two successive interviews (Coyne & Cowly, 2006), which was affirmed by the research committee. Due to limited population of healthcare practitioners (HCPs), interviews were conducted with all eligible participants. Seventeen breast cancer patients and 4 healthcare practitioners were interviewed.

4.3.3 Recruitment

Ethics approval was obtained from the Research Ethics Board at Queen's University (Appendix C) and the Supportive Care Research Committee at Kingston General Hospital (Appendix D). Participants were recruited from breast cancer follow-up clinics at the Cancer Centre of Southeastern Ontario at Kingston General Hospital (CCSEO) in Kingston, Ontario between April and September 2008. Breast cancer patients were identified from the follow-up clinic patient roster by a medical oncologist or primary care nurse, and their names were forwarded to the researcher. Participants were given a letter at their follow-up appointment or mailed a letter describing the study’s objectives, which was signed by an oncologist from the cancer clinic. Women were called two weeks after the letter was given or mailed to them to ask if they had any other questions and if they were willing to participate in the study. Breast cancer patients were approached consecutively to participate in the study over a 6-month period. Interviews were transcribed and coded as they were conducted until saturation was met, and no new information resulted from the interviews. Thirty eligible breast cancer patients were approached to participate over a 6-month period. Twenty women received the letter of recruitment in a follow-up clinic and ten received it in the mail. Six patients (20%) could not be contacted for follow-up, 3 patients (10%) declined because they felt they did not want to contribute, 2 patients (7%) were too busy, and 2 patients (7%) were too sick to participate, resulting in a total patient sample of 17 women. Recruitment stopped at this point because no new information resulted from the last 2 patient interviews. All potential endocrine treatment
options were accounted for, except women who chose no treatment as they were not on treatment and would not normally be followed by a medical oncologist.

Healthcare practitioners (HCPs) who worked primarily with breast cancer patients at the CCSEO were approached to participate in the study. Three medical oncologists, 1 general practitioner in Oncology, 1 pharmacist, and 3 registered nurses were approached to participate. Two medical oncologists, whose primary treatment site was breast and 2 registered nurses, who primarily worked with breast cancer patients, agreed to participate.

4.3.4 Data Collection

Semi-structured telephone interviews were conducted in accordance with standard qualitative methodology by the primary researcher. Before the interviews were conducted in both groups, the interview guides were reviewed by the research committee, which included a medical oncologist, qualitative researcher, and a registered nurse. Verbal consent was obtained over the telephone. Participants were asked to think back to the time they were faced with the treatment decision regarding endocrine therapy. During the interview breast cancer patient participants were asked the following questions:

1. How long have you been on endocrine therapy?
2. Were you given a choice about treatment with endocrine therapy?
3. What were the things that you needed to know before you were able to make a decision about your treatment?
4. What questions did you have about your options?
5. What questions did you have about the specific treatment?
6. What factors were important in making your decision?

Women were also asked to imagine someone in their situation and suggest what information was important to know when making this treatment decision. All patient interviews were digitally recorded over the telephone.
HCP interviews were conducted in-person and digitally recorded. HCPs were asked to recall the information provided to patients who were being presented with the treatment decision regarding endocrine therapy. The following questions were also asked:

1. What typical information is provided to patients regarding endocrine therapy for breast cancer?
2. What questions do women have about their options?
3. What questions do women have about treatment with endocrine therapy?
4. What factors are important to consider when making a decision about endocrine therapy?

During the interviews, HCPs were given the opportunity to share any information that would be helpful for the research at hand.

The duration of patient and HCP interviews ranged between 5-40 minutes in length. Saturation, defined as collecting data until no new information was obtained (Coyne & Cowly, 2006), was met and recruitment was stopped after 30 patients had been approached and 17 patients had been interviewed. Due to limited population of HCPs, interviews were conducted with all eligible participants. Patient demographic data was collected partially in the interview and through review of the patient’s medical records.

4.3.5 Analysis of Data

The primary researcher (author, MT) transcribed all interviews verbatim. The transcripts were independently read and analyzed by the primary researcher and a second person, who was independent of the research committee. Individually, information needs and questions were identified and categorized into themes. After the individual coding was completed, they discussed their findings and discrepancies were resolved. Common codes and themes were determined and agreed upon. The primary researcher compiled a list of the information needs and created a corresponding question, which was confirmed by the second coder. A list of questions was created and duplicate questions were removed, and questions were organized into
determined themes. The final list of questions and categorization was reviewed by 2 authors (JT, DFS).

4.4 Results

4.4.1 Demographics

All women participants were diagnosed with postmenopausal early-stage breast cancer. Patients were treated at the Cancer Centre of Southeastern Ontario drawing from a large geographical area, which includes rural and small urban areas. The average age at the time of decision-making about endocrine therapy was 59 years, with a range of 53-86 years. All women except one were post-menopausal; one woman was peri-menopausal, but she was treated as if she was post-menopausal, and was provided the same options as the other women in the study. Ten women had received total or partial mastectomies and six women had lumpectomies as their surgical intervention. One woman had a lumpectomy followed by a mastectomy. Six women (35%) had both chemotherapy and radiation as adjuvant treatment. Five women (29%) only had radiation and 2 (12%) had chemotherapy alone. Four (24%) women did not require or choose to have chemotherapy or radiation before they started on endocrine therapy. The time frame between when the decision was made about treatment with endocrine therapy and the interview ranged from 6-20 months.

Nine of the women started on Tamoxifen and 8 women started on an AI at the time of decision-making. In the time between decision-making and the interview some women changed the type of drug that they were taking. Twelve (71%) remained on the same treatment since the decision-making time. Two women who had started with an AI changed to a different AI. One woman switched from Tamoxifen to an AI, while another woman switched from an AI to Tamoxifen. One woman who had started on an AI, switched to another AI, then changed to Tamoxifen, and then quit endocrine therapy altogether. All the women who reported that they
had changed or stopped treatment stated the reason was due to the side effects and the impact of the treatment on their quality of life.

Two medical oncologists participated in the study, one who had been treating women with breast cancer for over 30 years, and the other had been treating breast cancer patients for just over 10 years. Both oncologists primarily treated breast cancer patients. Two primary nurses that work specifically with breast cancer patients participated. One nurse had been working specifically with breast cancer patients for about 9 years and the other one 3 years. Each nurse had a wide experience of working with other cancer patients as well.

4.4.2 Patients' information needs about endocrine therapy

Even though most of the women were diagnosed at least 6 months previously and many had already had primary treatment, most reported that they had continuing information needs. Only one woman stated that she did not have any information needs regarding treatment. The most common cited information needs were side effects, drug characteristics, and questions about survival and recurrence; predominantly related to treatment-related information. A list of 91 questions resulted (see Table 4.1). Questions were organized into the following determined themes: general cancer background; my cancer background; drug background; making the decision; potential benefits; potential harms; other health concerns; family, cost; and other information.

4.4.3 Side effects

Not surprisingly, side effects or potential harms of the treatment were the most commonly reported information need that women had about endocrine treatment for their postmenopausal breast cancer. Women wanted to know what the specific symptoms were and how the side effects of each drug compared to each other. When they learned of the possible side effects, many women wanted to know whether they would be able to cope with the symptoms and if there were any treatments to deal with the side effects themselves. Many women wanted to
know when the side effects would appear, how long they would last, and how they would compare to the side effects of chemotherapy or radiation. A few women stated that the side effects were important to know, but they felt that the treatment was important enough that they would take it regardless of the symptoms that they felt. One woman reported that she was going to forgo the treatment because of the side effects that she experienced. One woman’s comment defines many of the women’s concerns,

   And I was worried about side effects. Like… well, first of all, it made you feel so terrible you couldn’t take it, and also I knew that there was sickness involved. Other than that? They told me in three weeks, if I could tolerate it or not and I seem to be okay.

Another woman shares,

   I was a little bit leery about it when they first put me on [endocrine therapy], you know reading up on the side effects. And it’s kind of scary when you think of what …what the side effects are.

Overall, most women wanted to know how the side effects were going to affect their quality of life.

   Similarly, HCPs stated that most women were interested in the side effect profile. Although they spent much of their counseling time discussing the nature of the side effects, HCPs felt that women were much less worried about the side effects of endocrine therapy compared to chemotherapy. One oncologist shared,

   Or at least what I believe I’ve observed is women who have already been through… have received their chemotherapy and their radiation, don’t seem to care that much or worry that much about the extent of side effects… So I tend not to get a lot of or quite as many questions from them.

Many women questioned how endocrine therapy would affect their current health issues, and in particular, if it would interfere with any medications they were taking. Some women made
choices based on their current health status and the potential issues that may arise from starting endocrine therapy. For instance, women who have arthritis may have increased bone pain, because AI’s can affect bone density. One woman stated,

*My concern is my age and my bone status and I’ve got arthritis very bad. And that is my big concern.*

This woman also indicated that her age was an important aspect to consider when she was choosing her treatment. Some women chose not to have treatment at all because they were elderly already and felt that they had lived a good life. Others felt that they wanted to be on treatment for as long as possible because they had so much to live for, such as grandchildren. Women considered factors such as quality of life and longevity when making decisions. HCPs noted that patients were aware of their own health issues and questioned how the endocrine therapy would affect them,

*So in my description of the side effects, women are often, keying into a particular element that either worries them, so they don’t want to get or that they already have and don’t want to aggravate, or that they want to avoid at all costs...*

**4.4.4 Drug background**

Women had many inquiries about the drug itself. It was important for some women to know how the different drugs worked in their body. Some women wanted to know how the drugs worked to stop the cancer from recurring even though the cancer was supposedly not there anymore after surgery, chemotherapy, and/or radiation. Some women were inquiring about the difference between hormone replacement therapy and endocrine therapy and the role of hormones in relation to their breast cancer. Also, women were concerned about how the inhibiting estrogen production would affect their bodies. How to take the medication and how strict one needed to be to a schedule was another area of importance. Many women preferred to hear about the research verifying the efficacy of the therapy, wanting to know about the research studies that proved increased survival. A few women in the study preferred not to know the details of the drugs at
all; fully trusting that their physician would give them that information that they needed, but they
did not require any more. One patient responded,

*Well, what it does for one thing. What am I taking [endocrine therapy] for? You’re sort of up in the air and you don’t know why. What’s it going to do for you?*

The theme of time occurred frequently; time related to the administration of the drugs and
the length of time that they would be on the medication. Some women chose one option because
they would be on the drug for a shorter period of time, and others chose an option that would
allow them to be on treatment for a longer period of time, which was seen as extra protection
from recurrence. Others wanted to know how they would be monitored if they took the
medications. They wanted to know the types of tests that would be done while they were on
treatment and how they would be followed.

Overall, HCPs that were interviewed identified similar information needs as the patients
identified themselves. Healthcare practitioners felt it was essential to discuss rationale for use of
endocrine therapy including risk reduction, efficacy, evidence, specific drug information, drug
mechanism, clinical options, side effect profile, benefit and risk, and administration. The
physicians noted two different times that a discussion about endocrine treatment could occur: 1)
at the initial consult time if chemotherapy was not part of the treatment plan, or 2) after the
chemotherapy was complete. Even though an endocrine therapy treatment discussion may not be
occurring at diagnosis, some women wanted to review the pathology of their breast cancer to
better understand how this new treatment worked. One physician described how questions about
disease are addressed,

*I often will draw a picture of a cancer cell and an estrogen receptor and estrogen molecules floating around in the blood. And I’ll sort of explain where each of [the endocrine therapy options] works.*
4.4.5 Potential benefits

Women wanted to understand the links between endocrine therapy and survival or chance of recurrence. Many of the women in the study spoke of needing the reassurance that the cancer was not coming back, and that taking endocrine therapy was one way they could better ensure this outcome. When women were taking endocrine therapy during the follow-up phase of their disease trajectory, many spoke of needing to hear continued reassurance from their physicians even after making decisions about their choice of therapy. Some women wanted to hear about specific percentages for chance of survival if and when they decided on specific treatment options. Here is what one woman said,

*I had to cover all my bases and this was just another step... Survival. Yes. I am a fighter and I want to do what it takes. And right now, if that’s all that’s available, then we have to do it.*

*There really isn’t a choice. To me....*

One woman described her choice not to continue on endocrine treatment and how it made her feel about the possibility of recurrence,

*Every once in awhile, I think about it. Oh, I’m not taking medication and my chance then for it to come back are greater. Could be greater...*

4.4.6 Cost

Under half of the women interviewed were over 65 years of age, and their medication costs were covered. The remaining women had to pay for their medication unless they had an existing private healthcare plan. One woman made her treatment choice based on the cost; choosing the less expensive one. One woman spoke about the importance of taking the treatment despite the cost,

*I may not be able to afford it. I am on a very limited budget. I have got exactly... after I pay all my bills and everything, I’ve got exactly $400 to live on a month. And the pills*
are $176 a month…. And that is a lot of money... So that’s a concern for people in my age bracket.

HCPs verified women’s questions about cost, but stated that they had to initiate the discussion about cost.

4.4.7 Family

“What is the best treatment for me?” was a common question asked by women in different ways. This was not surprising because each woman brings different perspectives to decision-making; therefore, it seemed important for women to address their individual needs. Some women wondered if they had a strong family history of breast cancer, was it more important for them to consider endocrine therapy. Others wondered if members in their family needed to be concerned. As one woman states,

And there’s no cancer in my family, so this is what, you know, really flabbergasts me. But I do have a daughter and granddaughter and they are taking precautions.

Some women wanted to know stories of how the drugs affected other women, and still others knew that they were different so they did not have to hear how other women coped.

4.4.8 Making the decision

A prominent theme that emerged was being offered a choice. Even though there were options that women had before them, many women did not realize that they were given or had a choice at all. Some women could remember the physician giving them options, but most felt they relied heavily on the recommendation of the physician and doing what the physician “felt was best” for her. One woman described how she felt that she really was not given a choice at all. When the doctor told her that she had to take it, even after suffering through intense side effects, she said he told her, “You have to take this.” Some women clearly felt that they had a choice, and spoke about being presented with options and taking time to talk to family and others who
had been through a similar decision. When being presented with the options, a few women spoke about already knowing what they were going to take based on literature that they had been given and read. Even though, women have a choice, their experiences were vastly different dependent on circumstances such as, how information was presented to them, their personal preferences, and their overall health. The complexity of the choice that confronted women was demonstrated in the following,

He knows more than me. And I know it is my responsibility to take my health into my hands, but at that point I just was so vulnerable.

They said that I didn’t have to go on it, but it was... I had my free choice to decide. The medical doctor that was assisting him gave me that insight, but she said I’d highly recommend it for you to go on it. So you really had a choice, but you didn’t have a choice, so to speak. But I felt that I had to do it. You know I had no choice.

Is there really a choice? I mean I can say, I am not taking it. Then where do we go? You know it has to be a benefit or they wouldn’t be telling you, you had to take it. I mean that’s the way I look at it....
He said, “You need to do this.”

Both physicians stated that they provide women with treatment options, but they admitted that they had a clear bias with regards to their recommendations involving endocrine therapy.

One physician stated,

So I usually give efficacy first; don’t know which of the strategies is best; some theory behind picking one; personal bias... and I do give that disclaimer... and then I make a bottom line recommendation... I’ll make a recommendation, but I give people an out or if they have strong feelings that any one of those strategies is preferable to them.

Physicians also alluded to the idea that treatment with endocrine therapy is often not seen as weighty as others,
Most will express a preference for one or the other... and many likely start with one and plan to switch to another down the road because it may break up the decision-making. It’s starting with one and planning to bring the other one in at some point. So it’s kind of opting for both, without the zero... without the narrowing it down to just one.

Patients and HCPs indicated that the choice about endocrine therapy could resurface again after initial treatment decisions, as patients may encounter side effects that may cause them to consider changing or stopping treatment.

Table 4

Questions Postmenopausal BCP Have Regarding Endocrine Therapy

| General Cancer Background | Is it good or bad that my breast cancer is hormone-receptor positive?  
What does a breast cancer cell look like? |
|---------------------------|--------------------------------------------------------------------------|
| My Cancer Background      | What is the extent of my breast cancer disease?                           
Does the extent or type of breast cancer I have influence the decisions for endocrine treatment?  
What does it mean that my tumor is "estrogen" or "progesterone" positive?  
What is the stage of my breast cancer?  
Why does my kind of breast cancer require endocrine therapy? |
| Drug Background           | What kind of medication is endocrine therapy?  
How does endocrine therapy work?  
What is the difference between hormone therapy and hormone replacement therapy? |
| Making the decision       | What is the doctor’s recommendation?  
Is it absolutely necessary that I take endocrine therapy?  
If I chose not to take endocrine therapy, what are my other treatment options?  
What do I make my decision based on?  
Does my health history effect my options? |
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>When do I have to make the decision?</td>
<td>Are options dependent on my risk of relapse?</td>
</tr>
<tr>
<td>Are options dependent on my risk of relapse?</td>
<td>What do most women in my situation do?</td>
</tr>
<tr>
<td>What do most women in my situation do?</td>
<td>Can I change my mind once I have made a choice?</td>
</tr>
<tr>
<td>Can I change my mind once I have made a choice?</td>
<td>If I decide to stop the treatment, will I still be able to be followed by an oncologist?</td>
</tr>
<tr>
<td>If I decide to stop the treatment, will I still be able to be followed by an oncologist?</td>
<td>Will my oncologist be angry if I stop treatment?</td>
</tr>
<tr>
<td>Potential Benefits</td>
<td>Does endocrine therapy protect me from a new breast cancer occurring?</td>
</tr>
<tr>
<td>Does the length of time I stay on endocrine therapy increase my survival?</td>
<td>What are the chances that the cancer will not return if I take endocrine therapy?</td>
</tr>
<tr>
<td>What are the chances that the cancer will not return if I take endocrine therapy?</td>
<td>How long will endocrine therapy increase my survival?</td>
</tr>
<tr>
<td>How long will endocrine therapy increase my survival?</td>
<td>If I am miserable on endocrine therapy, is it worth taking it?</td>
</tr>
<tr>
<td>If I am miserable on endocrine therapy, is it worth taking it?</td>
<td>If the cancer were to come back, where would it come back?</td>
</tr>
<tr>
<td>If the cancer were to come back, where would it come back?</td>
<td>Is it curative?</td>
</tr>
<tr>
<td>Is it curative?</td>
<td>Why do I have to take endocrine therapy if they &quot;got it all&quot;?</td>
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<tr>
<td>Why do I have to take endocrine therapy if they &quot;got it all&quot;?</td>
<td>If I had a double mastectomy, why do I need to take endocrine therapy?</td>
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<tr>
<td>If I had a double mastectomy, why do I need to take endocrine therapy?</td>
<td>I am not supposed to have hormones, so why am I taking hormone therapy</td>
</tr>
<tr>
<td>I am not supposed to have hormones, so why am I taking hormone therapy</td>
<td>Why should I take an aromatase inhibitor when I know that Tamoxifen has been around for long time?</td>
</tr>
<tr>
<td>Potential Harms</td>
<td>What are the main side effects of endocrine therapy?</td>
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<tr>
<td>What are the main side effects of endocrine therapy?</td>
<td>What are the severe side effects of endocrine therapy?</td>
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<td>What are the severe side effects of endocrine therapy?</td>
<td>What are the visible side effects of endocrine therapy?</td>
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<tr>
<td>What are the visible side effects of endocrine therapy?</td>
<td>When will I know if I will even get side effects?</td>
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<tr>
<td>When will I know if I will even get side effects?</td>
<td>When will I know if I will be able to tolerate the side effects?</td>
</tr>
<tr>
<td>When will I know if I will be able to tolerate the side effects?</td>
<td>Do I have to take medication to maintain my bone health while on endocrine therapy?</td>
</tr>
<tr>
<td>Do I have to take medication to maintain my bone health while on endocrine therapy?</td>
<td>Will endocrine therapy cause bone loss?</td>
</tr>
<tr>
<td>Will endocrine therapy cause bone loss?</td>
<td>Can endocrine therapy cause my bones to ache?</td>
</tr>
<tr>
<td>Can endocrine therapy cause my bones to ache?</td>
<td>Can endocrine therapy cause osteoarthritis?</td>
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<tr>
<td>Question</td>
<td>Answer</td>
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<tr>
<td>-------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
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<tr>
<td>How will they monitor my bone loss caused by the AI?</td>
<td>Do I have to take something to help with osteoporosis caused by Aromatase Inhibitors?</td>
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<tr>
<td>Will I get hot flashes?</td>
<td>If the hot flashes are not manageable, what can I do about them?</td>
</tr>
<tr>
<td>Will my hot flashes get worse over time?</td>
<td>Will the endocrine therapy affect my hair?</td>
</tr>
<tr>
<td>How severe will the hot flashes be?</td>
<td>Will I lose my hair?</td>
</tr>
<tr>
<td>When will the hot flashes occur? Day? Night?</td>
<td>Will my hair become thinner?</td>
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<tr>
<td>Does it affect my uterus?</td>
<td>Does endocrine therapy influence body weight?</td>
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<tr>
<td>Will I get vaginal burning?</td>
<td>Will the treatment change my body's appearance and body image?</td>
</tr>
<tr>
<td>How long does vaginal burning last if it occurs?</td>
<td>Will endocrine therapy make me anxious?</td>
</tr>
<tr>
<td>Does it cause vaginal dryness?</td>
<td>Is there a chance you can get ovarian or other cancers when you take endocrine therapy?</td>
</tr>
<tr>
<td>What can I do about vaginal dryness related to endocrine therapy?</td>
<td>Breast cancer can return in my bones. How can I tell the difference between the side effect of bone ache and the cancer coming back?</td>
</tr>
<tr>
<td>Will endocrine therapy make me nauseated?</td>
<td>Does endocrine therapy affect my sleep?</td>
</tr>
<tr>
<td>Will the endocrine therapy effect my hair?</td>
<td>Can the side effects of endocrine therapy be relieved?</td>
</tr>
<tr>
<td>Will I lose my hair?</td>
<td>Will endocrine therapy affect my ability to exercise?</td>
</tr>
<tr>
<td>Will my hair become thinner?</td>
<td>Will endocrine therapy cause muscle pains?</td>
</tr>
<tr>
<td>Does endocrine therapy influence body weight?</td>
<td>Will endocrine therapy cause me physical pain?</td>
</tr>
<tr>
<td>Will the treatment change my body's appearance and body image?</td>
<td>Can I do anything to prevent the side effects from occurring?</td>
</tr>
</tbody>
</table>
| How will the side effects compare to those from radiation and chemotherapy?  
| How will endocrine therapy affect my daily life? | Other health concerns |
| How will endocrine therapy affect the rest of my health?  
| How will endocrine therapy affect my arthritis?  
| How does my age affect the choice of drug?  
| How will endocrine therapy affect my diabetes?  
| How will endocrine therapy affect my asthma?  
| Will endocrine therapy interact with my asthma medication?  
| Will endocrine therapy affect my heart health issues?  
| Will the treatment interfere with the other medications that I am taking?  
| Will endocrine therapy affect my liver?  
| What can I do so that I can continue my regular exercise routine while on endocrine therapy? | Family |
| What precautions do my family members need to take to screen for cancer like mine?  
| If someone in my family had breast cancer, does that mean I am more at risk? | Cost |
| Can I financially afford endocrine therapy?  
| What financial help is available to help me cover the cost of the treatment if I am not over 65?  
| What financial help is available to help me cover the cost of the treatment?  
| What is the cost of the drugs?  
| Is there a difference in the cost of Tamoxifen versus Aromatase Inhibitors?  
| Do I have to pay for endocrine therapy out of my own pocket?  
| Does OHIP cover endocrine treatment? | Other Information |
| What if I have more questions about endocrine treatment?  
| Where can I go to get more information about endocrine therapy? |
4.5 Synthesis of content data: Identification of common questions

One of our objectives was to synthesize the qualitative content and to create a comprehensive list of questions that women might have about endocrine therapy; and to complement this with the providers’ perspective. Women reported information needs concerning side effects, diagnosis, and recurrence risk/survival. Additionally, women continued to be concerned about femininity and body image needs, which may be attributed to the fact that endocrine therapy inhibits hormone production. Although women still had questions about diagnosis, the questions themselves were related to understanding how endocrine therapy worked on their particular tumor and the role that estrogen played with regards to their body and the breast cancer itself. Women continued to report a need for information about how the treatment would affect their personal life and their family. In particular, women, especially those who had histories of breast cancer in their family, had questions about survival and recurrence and the possible precautions that their daughters or other female relatives needed to take.

4.6 Discussion

Findings from the qualitative descriptive study contribute to our understanding of the information needs that postmenopausal women have regarding endocrine therapy by (1) providing a comprehensive list of questions that they have during treatment decision-making; (2) providing insight to the decisional process; and (3) exploring their understanding of choice regarding endocrine therapy. The results of this study show that decision-making processes continue beyond the initial diagnosis and early treatment stage, and can continue as women continue into follow-up for their breast cancer, when the option to take endocrine therapy often presents itself. In addition, the findings suggest areas that healthcare professionals can focus on when counseling women facing a decision regarding endocrine therapy.
4.6.1 Information needs

Postmenopausal breast cancer patients making decisions about endocrine therapy expressed a wide range of information needs, particularly information about treatment side effects, specific drug information, and survival/recurrence. These needs were similar to those expressed by women making decisions about chemotherapy, radiation, and surgery (Stephens, Osowski, Fidale, & Spagnoli, 2008; Vogel, Bengel, & Helmes, 2008; Harrison, Galloway, Graydon, Palmer-Wickham, & Rich-van der Bij, 1999). In a recent review of information needs of cancer patients in general, the most frequently cited needs during diagnosis and initial treatment phase were related to information about their cancer and treatment related questions (Rutten, Arora, Bakos, Aziz, & Rowland, 2005). The current study also identified that the cited needs in the follow-up phase continued to be treatment related, specifically treatment side effects. Although, our study focused on information needs related to endocrine therapy, women reported additional needs in various areas such as emotional, practical, and psychological aspects of their life.

The majority of the breast cancer patients interviewed had questions about the potential side effects of endocrine therapy. This finding is not surprising because previous research indicates that the side effect profile is an important aspect of treatment that many women consider when making decisions (Beaver & Booth, 2007). Many of the women in the study had received surgery, radiation, and/or chemotherapy therefore they had previous experience with treatment and side effects, which may explain why they felt this information was essential. They may have experienced side effects with their previous treatment and would want to prepare themselves for the potential side effects. Therefore, HCPs should inform patients of potential side effects and explore questions and concerns that they may have.

Understandably, breast cancer patients requested information about the drug itself, such as how it works and how to administer it. Additionally, they wanted information about rates of recurrence and survival benefits of treatment. Often breast cancer patients who are starting on
endocrine therapy are entering into a follow-up phase, in which they have been through the intense curative treatment and are in the phase of treatment in which they are monitored by the physician at regular intervals for recurrence and treatment effects. Breast cancer patients have continuing information needs even though they may consider themselves a survivor of breast cancer (Gray, Fitch, Greenburg, Hampson, Doherty, & Labrecque, 1998).

There was little difference between what the patients and the HCPs deemed important information regarding endocrine therapy. Although both HCPs and patients felt that side effects were important to discuss, healthcare practitioners felt that women who had had previous treatment were less worried about the possible endocrine therapy side effects compared to the side effects of chemotherapy and radiation. This phenomenon may be that women feel like they have been through the most difficult part of their treatment and recovery. HCPs also discussed the need to inform their patients about the endocrine therapy strategies, yet many did not understand that they had a choice. When presenting endocrine treatment options to their patients, HCPs referenced scientific research and offered patients concrete percentages regarding survival even though patients may not have asked. The differences between the patients' and HCPs' perception of treatment choice may be related the fact that the patient is hearing all the information for the first time and they may be overwhelmed with the information and unsure of what to inquire about. Although some patients asked about cost, many were not aware that finances could be a factor until the medical oncologist introduced it as a possible issue. Physicians may fall into a routine of providing "usual" information about treatments and assume that all patients want to know similar things. Yet, individual patients may want to know details that are not routinely provided by the HCP, thus the need to explore in depth questions and concerns.

Most importantly, patients wanted detailed information. Not only did women want to know the side effects that they may encounter with endocrine therapy, they wanted to know how long they would have the side effects, how they could manage them, and when they would know
if side effects would be an issue. Breast cancer patients wanted to know more than just the name of the drug, they wanted to know when to take the medication, how it worked in their body, how hormones were involved, and how to take the medication. These insights into the details of the information needs and questions allow us to understand that women want to know more than the general information. They want to understand the impact on their individual functioning in daily life. There are a range of details that are apparent within each theme, as can be attested to by the large number of questions that were included within each theme. There are common needs, yet, there are individual needs depending on what the patient brings to the table.

4.6.2 Decisional process and choice

As we conducted the interviews, women often reported that they did not perceive that they actually had a choice when it came to endocrine therapy. Many women could not recall or stated that they did not have a decision to make. Although the HCPs that were interviewed clearly stated that they gave women a choice, they also stated that they also had their own bias and made the women aware of that. This may have influenced the women’s perception of choice. The process of healthcare decision-making and involving patients into the care process is complex.

The majority of breast cancer specialists report that their usual approach to treatment decision-making involves a shared decision-making process (Charles, Gafni, & Whelan, 2004). In a study to determine the information needs and decisional preferences of women with breast cancer, there was a substantial difference between the women’s preferred and perceived actual levels of involvement with treatment decisions (Degner et al., 1997). In this study, breast cancer patients indicated the desire for information about their cancer and involvement in treatment decisions. Women wanted to be involved in shared decision-making, in which there was a more reciprocal relationship between the physician and patient (Hack, Degner, Watson, & Sinha, 2006). Decision-making can be stressful, and therefore, women may not retain all the
information that they have been given. A study that examined contextual factors in shared decision-making suggested that most women trust their physicians in an uncertain situation, and therefore, will defer to their recommendation, and still see the decision as shared (Voldermaier, Caspari, Koehm, Kahlert, Ditsch, & Untch, 2009). Given the complexity of this decision and the treatment options available, and the nature of the clinician-patient interaction in busy clinic offices, tools that facilitate information sharing and decision-making could identify the choices and assist women and HCPs during this time.

4.6.3 Decisional importance

Some women who were aware of their options and choices appeared to think of the endocrine treatment decision as less crucial than other treatment decisions and their questions tended to more about breast cancer in general. Many women talked about their treatment decision-making with regards to chemotherapy and surgery when asked about specifically endocrine treatment. For the majority of the women, they had already made decisions regarding surgery, chemotherapy, radiation, and possibly breast reconstruction surgery as well. This treatment related decision was at the end of a long road of decision-making for some, and it seemed that this decision was less weighted than the others, perhaps, and naturally related to the impact of taking a pill once a day was not as invasive or intimidating as going through chemotherapy or surgery. Also, there was a perception that you could stop this treatment at anytime. There was a chance to go back and make a different decision, and this may have provided women with an extra sense of control and security. Women who have more control over their decisions report increased quality of life (Rees & Bath, 2001). There was not an urgency to make this decision, so women were perhaps more relaxed; often being allowed to take a prescription home with them and having the ability to fill it when and if they decided to take it. Given the flexibility of the decision, adherence may become an issue once they have made their decision (Miaskowski, Shockney, & Chlebowski, 2008).
Another reason why women may not have viewed this as a critical decision was that they may already feel cured. Breast cancer is often not perceived as a chronic condition (Oxlad, Wade, Hallsworth, & Koczwara, 2008). The importance of ongoing treatment or therapy to decrease the risk of breast cancer recurrence is key. But if a woman perceives that she is cured, further treatment may not be a priority for her.

The few women who made the decision about endocrine therapy at the time of consult were older than the other women who had previous primary treatment for their breast cancer as older women are often offered only endocrine therapy at consult. Older breast cancer patients may want less information and prefer a less collaborative doctor–patient relationship (Thewes, Butow, Girgis, & Pendlebury, 2004). They are more likely to comply with the physician’s recommendation. Even though a woman may chose a more passive role in decision-making, information is still seen as an important part of the consult (Gray et al., 1998). The pressure to make decisions quickly may leave women feeling they have no choice but to follow their physicians’ recommendation (Degner et al., 1997). Most women make their treatment decision about endocrine therapy when first raised within one clinic visit. Furthermore, the amount of information and support that women receive from healthcare professionals decreases as time from diagnosis increases (Raupach & Hiller, 2002). Endocrine treatment decision-making may occur later in the disease trajectory; therefore, the provision of information may be less.

Women making endocrine treatment decisions are consistently weighing the risks and benefits, and considering factors that are important to them; factors such as length of treatment to the size of the pill they will have to take. HCPs need to be aware of the information needs that these women have to give them access to the information needed to make their decision.

**4.6.4 Limitations**

The purpose of this study was to describe information needs for women making decisions about endocrine therapy. Women were asked to recall their experience. Thus there is a chance
that women could have forgotten key things that they may have been considering during the decision-making time. This study was conducted at one centre. Further study in other centres with other health care providers and patients would validate findings.

4.6.5 Implications

Postmenopausal breast cancer patients are making decisions about endocrine treatment, often later in their disease trajectory, and continue to have information needs. We have identified the needs and questions that are of concern for individual patients and may be of concern to a new patient in a similar situation. The next step in the process is to determine the prevalence of each identified concern in the population of patients. Given the potentially wide-ranging needs, the importance of ongoing treatment for these women and the many treatment options theoretically available, an endocrine treatment decision tool for postmenopausal women with early stage breast cancer is one way to address the needs of the individual in a systematic unbiased manner. The prevalence of each item in the list of questions produced in this study could be the basis upon which both a decision aid can be created and as a guide for health practitioners when counseling women regarding endocrine therapy.

4.7 Conclusion

In summary, the results of the present study verify that postmenopausal women have information needs when making decisions about endocrine therapy. Although, these needs are similar to the needs of women making different treatment decisions, they are unique because this decision usually occurs after the initial stress of diagnosis and possible other adjuvant treatment and are focused on specific aspects related to endocrine therapy. HCPs need to be aware of these needs, so that proper information provision can be given or reviewed. The results also suggest that often women are not aware that they have a choice at all when it comes to endocrine therapy. HCPs need to give clear indication that there is a choice regardless if the woman wants to make that decision alone or with assistance.
References


Chapter 5
Discussion

5.1 Summary of key finding

This thesis examined the information needs of postmenopausal breast cancer patients being treated with endocrine therapy with curative intent. In particular, this study was interested in what specific information these women needed in order to make a treatment decision. Treatment decision-making can be a particularly intense and stressful time and the complexity of decisions varies depending on a number of factors, such as decision-timing, nature of the choices, amount and quality of the information available, and diversity of the patients’ preferences (Blank, Graves, Sepucha, & Llewellyn-Thomas, 2006). The first manuscript was an integrative review of the information needs assessment methodologies. The second manuscript identified information needs of postmenopausal breast cancer patients who were on endocrine therapy within the Kingston region.

The results from the integrative review added to the literature by increasing our knowledge of the various methods available to measure information needs of breast cancer patients. Using the conclusions drawn from the integrative review, we designed a study to best assess the information needs of breast cancer patients being treated with endocrine therapy.

Findings indicate:

- The integrative review identified that a mixed method approach allowed for rich data to be obtained through qualitative means and then synthesized and tested using quantitative means. This was the ideal process to use when creating decisional tools. Overall, the information needs assessment methodologies captured similar results, although the qualitative techniques were able to provide detailed descriptions, and quantitative means were able to cover larger patient populations. Patient participation is key in the development of informational needs assessment methodology.
• Overall, and consistent with the literature, postmenopausal breast cancer patients indicated that they had information needs about diagnosis, treatment details, side effects, and survival/recurrence when presented with the options to be treated with endocrine therapy, although many of them are considered to be in the “follow-up” stages of their cancer experience.

• Many of the women in the study did not realize that they had a choice about endocrine treatment. This key finding indicates that we may need to develop strategies or tools to assist healthcare practitioners in presenting options to patients; and, as well, to provide opportunities for the patient to explore these options in an informed manner.

5.2 Revisiting the objectives

Objective 1: Review the methodologies used in the research literature to identify information needs of breast cancer patients. The first manuscript addressed the review of the information needs assessment methodologies. The review verifies that a mixed method approach is the recommended methodology to encompass the range of needs that women may have. When determining the methods, contributions from patients are encouraged to obtain a comprehensive review of the possible needs.

Objective 2: Identify the information needs and questions that early stage postmenopausal breast cancer patients have regarding endocrine therapy. The second manuscript reported the identified needs of postmenopausal women’s information needs regarding endocrine therapy. Breast cancer patients indicated that they had information needs about diagnosis, treatment details, side effects, and survival/recurrence, which were often after they had received primary treatment with surgery, chemotherapy, and/or radiation. Although information needs were recognized, women often did not realize that they had a choice regarding treatment with endocrine therapy for their breast cancer.
Objective 3: Identify healthcare practitioners' informational priorities regarding treatment using endocrine therapy for postmenopausal women with early stage breast cancer. The second manuscript addressed the informational priorities that health practitioners perceived as important for women, which included information regarding side effects, survival/recurrence, efficacy, characteristics of the medication, and clinical options. Healthcare practitioners indicated that they present women with the clinical options and will often provide their recommendation, of which the majority of women choose.

Objective 4: Establish a comprehensive list of questions that are important to postmenopausal breast cancer patients when encountering a decision regarding endocrine therapy. The second manuscript reported on the comprehensive list of questions that women might have regarding endocrine therapy. The list of questions indicated that it is crucial to inquire about any information needs that may arise in the follow-up setting.

5.3 Limitations

Past research has examined the informational needs of breast cancer patients. The concept “information need” is broad and has the potential to include a wide range of needs such as supportive needs, financial needs, and psychological needs, just to name a few. In the current review, we tried to focus on information regarding treatment decision, yet due to lack of definition in some studies, this definition was fluid. The conclusions generated from the integrative review are somewhat limited, as we did not obtain the actual tools or surveys that were used in the studies retrieved; therefore, we needed to rely on the author’s descriptions of the methods they used.

For the specific study sample, although saturation was met in the study, given the small sample size of the study, it may not be generalizable to all women with similar cancer. Therefore,
further study is needed to validate the importance of the information needs and questions within a larger population. Since this was a retrospective study, there is the chance that women could have forgotten key information needs they may have been considering during the decision-making time.

5.4 Strengths

To the best of our knowledge, this is the first reported study to explore the information needs of women regarding treatment with endocrine therapy for early stage breast cancer. There is lack of work focusing on this particular treatment, as much of the research has focused on initial treatments that commence closer to diagnosis. Presently, breast cancer is one of the leading cancers for women, and women are living longer with a diagnosis of breast cancer due to earlier detection, and therefore, survival, and the availability of treatment options. We need to understand their needs throughout their whole disease experience.

Within this study, qualitative research was carried out to collect the data, allowing our data to be rich and broad. Leading questions were used, and the participants were given the freedom to expand on their thoughts and answers, which provided personal experiences to be drawn upon.

5.5 Further research

This thesis research has explored the published research on how to identify the information needs of postmenopausal breast cancer patients, and a descriptive study about the information needs of breast cancer patients regarding endocrine therapy in one regional cancer centre. Although, often, breast cancer patients are making endocrine treatment decisions later in their disease trajectory, they continue to have information needs. Now that we have identified common needs that are important to make this specific treatment decision, further research could validate these identified needs in a larger population. We could then build on this to develop an endocrine treatment decision tool for postmenopausal women with early stage breast cancer.
References

Appendix A

Treatment decision-making complexities

Appendix B

International Patient Decision Aid Standards (IPDAS)

I. Content: Does the patient decision aid …

Provide information about options in sufficient detail for decision-making?

- Describe the health condition
- List the options
- List the option of doing nothing
- Describe the natural course without options
- Describe procedures
- Describe positive features (benefits)
- Describe negative features of options (harms/side effects/disadvantages)
- Include chances of positive/negative outcomes
- Additional items for test
  - Describe what test is designed to measure
  - Include chances of true positive, true negative, false positive, false negative test results
  - Describe possible next steps based on test results
  - Include chances the disease is found with/without screening
  - Describe detection/treatment that would never have caused problems if one was not screened

Present probabilities of outcomes in an unbiased and understanding way?

- Use event rates specifying the population and time period
- Compare outcome probabilities using the same denominator, time period, scale
- Describe uncertainty around probabilities
- Use visual diagrams
- Use multiple methods to view probabilities (words, numbers, diagrams)
- Allows the patient to select a way of viewing probabilities (words, numbers, diagrams)
- Allow patient to view probabilities based on their own situation (e.g. age)
- Place probabilities in context of other events
- Use both positive and negative frames (e.g. showing both survival and death rates)

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
- Ask patients to consider which positive and negative features matter most
- Suggest ways for patients to share what matters most with others

Include structured guidance in deliberation and communication?

- Provide steps to make a decision
- Suggest ways to talk about the decision with a health professional
- Include tools (worksheet, question list) to discuss options with others
II. Development Process: Does the patient decision aid …

Present information in a balanced manner?
- able to compare positive/negative features of options
- shows negative/positive features with equal detail (fonts, order, display of statistics)

Have a systematic development process?
- included developers’ credentials/qualifications
- finds out what users (patients, practitioners) need to discuss options
- has peer review by patient/professional experts not involved in development and field testing
- is field tested with user (patients facing the decision; practitioners presenting the options)

The field tests with users (patients, practitioners) show the patient decision aid is:
- acceptable
- balanced for undecided patients
- understood by those with limited reading skills

Use up to date scientific evidence that is cited in a reference section or technical document?
- Provides references to evidence used
- Report steps to find, appraise, summarize, evidence
- Report date of last report
- Report how often patient decision aid is updated
- Describe quality of scientific evidence (including lack of evidence)
- Uses evidence from studies of patients similar to those of target audience

Disclose conflicts of interest?
- Report source of funding to develop and distribute the patient decision aid
- Report whether authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aid

Use plain language?
- Is written at a level that can be understood by the majority of patients in the target group
- Is written at a grade 8 equivalent level or less according to readability score (SMOG or FRY)
- Provides ways to help patients understand information other than reading (audio, video, in-person discussion)

Meet additional criteria if the patient decision aid is Internet based?
- Provide a step-by-step way to move through the web pages
- Allow patients to search for key words
- Provide feedback on personal health information that is entered into the patient decision aid
- Provides security for personal health information entered into the decision aid
• Make it easy for patients to return to the decision aid after linking to other web pages
• Permit printing as a single document

Meet additional criteria if stories are used in the patient decision aid?
• Use stories that represent a range of positive and negative experiences
• Reports if there was a financial or other reason why patients decided to share their story
• State in an accessible document that the patient gave informed consent to use their stories

III. Effectiveness: Does the patient decision aid ensure decision making is informed and values based?

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

• Recognize a decision needs to be made
• Know options and their features
• Understand that values affect decision
• Be clear about option features that matter most
• Discuss values with their practitioner
• Become involved in referred ways

Decision quality. The patient decision aid…

• Improves the match between the chosen option and the features that matter most to the informed patient.

Appendix C
Ethics Approval
January 11, 2008

This Ethics Application was subject to:

☐ Full Board Review
Meeting Date:

☒ Expedited Review

Ms. Melissa TeBrake
School of Nursing
c/o Nursing Research Unit
Kingston General Hospital

Dear Ms. TeBrake,

Study Title: Helping women make treatment choices: Identifying the informational needs and questions that women with breast cancer have about endocrine therapy

Co-Investigators: Dr. Joan Tranmer

I am writing to acknowledge receipt of your recent ethics submission. We have examined the protocol, information notice and consent form for your project (as stated above) and consider it to be ethically acceptable. This approval is valid for one year from the date of the Chair’s signature below. This approval will be reported to the Research Ethics Board. Please attend carefully to the following list of ethics requirements you must fulfill over the course of your study:

➤ **Reporting of Amendments:** If there are any changes to your study (e.g., consent, protocol, study procedures, etc.), you must submit an amendment to the Research Ethics Board for approval. (see http://www.queensu.ca/vpr/reb.htm).

➤ **Reporting of Serious Adverse Events:** Any unexpected serious adverse event occurring locally must be reported within 2 working days or earlier if required by the study sponsor. All other serious adverse events must be reported within 15 days after becoming aware of the information.

➤ **Reporting of Complaints:** Any complaints made by participants or persons acting on behalf of participants must be reported to the Research Ethics Board within 7 days of becoming aware of the complaint. **Note:** All documents supplied to participants must have the contact information for the Research Ethics Board.

➤ **Annual Renewal:** Prior to the expiration of your approval (which is one year from the date of the Chair’s signature below), you will be reminded to submit your renewal form along with any new changes or amendments you wish to make to your study. If there have been no major changes to your protocol, your approval may be renewed for another year.

Yours sincerely,

[Signature]
Chair, Research Ethics Board

Date: Jan 14, 2008

Study Code: NURS-219-08

➤ Investigators please note that if your trial is registered by the sponsor, you must take responsibility to ensure that the registration information is accurate and complete
Appendix D
Supportive Care Research Committee Letter
February 1, 2008

Attention: Supportive Care Research Committee

Re: Proposed Research Project - Melissa TeBrake

Helping women make treatment choices: Identifying the informational needs and questions that women with breast cancer have about endocrine therapy.

To Committee Members,

Please find enclosed my graduate student research proposal for your review and approval.

I am a Masters Student at the School of Nursing at Queen’s University and a part time nurse at the Cancer Centre of Southeastern Ontario (CCSEO). My research thesis committee consists of Dr. J. Tranmer (co-supervisor), Dr. D. Feldman – Stewart (co supervisor), Dr. Y. Madarnas, and Dr. M. Lamb. I am interested in exploring aspects of the decision making process for oncology patients. The focus of my graduate research is on identifying the informational needs and questions that women with breast cancer have about endocrine therapy.

I have included a summary of my proposal with this letter. If there are any further questions or clarifications that need to me made, please feel free to contact me.

Thank you for taking the time to review my proposal. I look forward to conducting this graduate research in the Cancer Centre of Southeastern Ontario at Kingston General Hospital.

Regards

Melissa TeBrake, RN, BScN,
Queen’s University – School of Nursing
5mlt2@queensu.ca
613-531-9605
Attn: Supportive Care Research Committee

Helping women make treatment choices: Identifying the informational needs and questions that women with breast cancer have about endocrine therapy.

The goal of the study is to identify the questions that postmenopausal women with breast cancer at a Cancer Centre in Southeastern Ontario have regarding treatment with endocrine therapy.

The objectives are:
1. To identify breast cancer patients’ questions when considering the use of endocrine therapy as adjuvant treatment for breast cancer.
2. To identify the informational priorities of healthcare practitioners provide when consulting with breast cancer patients considering use of endocrine therapy as adjuvant treatment.
3. To synthesize a comprehensive list of questions that could impact the treatment decision of a breast cancer patient considering the use of endocrine therapy for their breast cancer.

To achieve the objectives of the study, in-depth semi-structured interviews will be conducted with post-menopausal breast cancer patients who have been given the option of treatment with endocrine therapy and healthcare practitioners that who work with this population. The interviews will be conducted over the phone or in-person depending on the preferences of the participant.

The participants will be recruited at the Cancer Centre of Southeastern Ontario at Kingston General Hospital. Recruitment will occur when the patient returns for a follow-up visit at the Cancer Centre, at which time they will be given a letter from their physician. Some patients maybe recruited for the study via a letter from their Medical Oncologist. After they have received the letter of information, they will be followed up with a telephone call from the researcher.

The target population is:
- Women who have recently (approximately one year) made a decision about treatment with endocrine therapy
- Women who have been diagnosed with a breast cancer that is responsive to endocrine therapy
- Postmenopausal
- Currently attending the Cancer Centre for follow-up
- No diagnosis of metastatic disease
- Not enrolled in a study that interferes with patients making a choice about treatment with endocrine therapy

We anticipate that we will have to conduct 8 interviews with healthcare practitioners and 30 interviews with breast cancer patients.
The proposed recruiting period will be February 2008-March 2008.

The contact with the patient will be dependent on the interview. It is anticipated that the interviews will take approximately 20 minutes to conduct.

From the interviews, a list of questions that may be important to postmenopausal breast cancer patients facing treatment decisions regarding endocrine treatment will be compiled. With the data that is collected, we hope that this could ultimately lead to the creation of a decision aid designed to assist women making treatment decisions regarding endocrine therapy.