THE DECISION MAKING PROCESS IN WOMEN DIAGNOSED WITH ESTROGEN RECEPTOR-POSITIVE BREAST CANCER EXPERIENCING SIDE EFFECTS RELATED TO ORAL ENDOCRINE THERAPY

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Dedication

I am lucky enough to have received the supportive gift of amazing people in my life, without all of whom, this work would not have been completed.

Therefore, it is without hesitation I dedicate this dissertation to my family.

Thank you to….

Joe, Amelia, Ben, and Evelyn for your love and belief in me that one day I would finish. Without your encouragement, this would have been a lonely place.

Dad who instilled the importance of education which led to a love of learning – I wish you were here to see this!

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Oral endocrine therapy (OET) is standard therapy for millions of estrogen receptor-positive breast cancer survivors (ER+BCS). OET reduces recurrence, mortality, and metastasis. ER+BCS often do not take their OET as recommended due to adverse side effects. The purpose of this dissertation was to develop an explanatory framework of decision making by women with ER+ breast cancer who report experiencing side effects from OET. This project was comprised of two components.

The first component was a systematic review with three main findings: (1) side effects negatively impact OET non-adherence, (2) there is an absence of decisional supports provided to or available for ER+BCS who are experiencing OET side effects,, and (3) ER+BCS likely have unmet decisional needs related to OET.

The second component was a grounded theory study that included 31 ER+BCS reporting OET side effects. During a single semi-structured interview, participants described the experience of OET over time. This study produced two qualitatively derived projects.

First, a theoretical framework was developed that depicted four stages through which the experience of OET decision making unfolded. The stages were (1) being told what I need to do to live, (2) doing what I need to do to live, (3) enduring what I need to do to live, and (4) deciding how I want to live.

Second, a typology was developed that depicted six sources of external decisional supports (healthcare providers, husbands, other breast cancer survivors, friends and family, the internet and other media sources, and God) that met four types of

decisional needs (information about OET and its side effects, in-depth discussions about side effects, help in managing side effects, and emotional support).

Findings can be used to develop interventions, such as decision aids, to promote quality decision making in women experiencing OET side effects.

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List of Abbreviations

Abbreviations	Terms
AI	Aromatase inhibitors
BC	Breast cancer
BCS	Breast cancer survivor
ER+	Estrogen receptor positive
ER+BC	Estrogen receptor positive breast cancer
ER+BCS	Estrogen receptor positive breast cancer survivor
OET	Oral endocrine therapy

Chapter 1

1.1 Introduction

This chapter provides an overview of the dissertation topic on oral endocrine therapy (OET) decision making by women with estrogen receptor positive (ER+) breast cancer who report experiencing side effects. The chapter includes a discussion on the significance of the topic, the study purpose and specific aims, and the study approach. The results of this dissertation are disseminated in three papers, which are presented in chapters 2, 3, and 4, respectively.

1.2 Significance

The importance of OET

Breast cancer is the most common cancer among women in the United States.[1] About 232,670 new cases of breast cancer were diagnosed in the United States in 2014.[1] Currently, there are more than 2.8 million breast cancer survivors (BCS) living in the United States. About 75% of all breast cancer diagnoses are ER+,[1] and these women receive a recommendation for OET,[1] which is prescribed to prevent reoccurrence by blocking certain hormones that fuel cancer growth. Examples of OET are selective estrogen receptor modulators (e.g., Tamoxifen) given to pre-menopausal women, and aromatase inhibitors (e.g., letrozole) given to post-menopausal women. These medications block estrogen from binding at receptor sites or stop the peripheral conversion of androgens to estrogen. Tamoxifen has been shown to decrease recurrence by 41% and mortality by 34%, whereas aromatase inhibitors have been shown to reduce recurrence by 30-41%, metastasis by 16-18%,[2,3] and mortality at rates similar to tamoxifen.[17,23]

Adherence to OET

Adherence is defined as the extent to which a person's health behaviors correspond with agreed-upon recommendations from a healthcare provider.[24] Many women with breast cancer do not take their OET as recommended. Using the PubMed search engine, a systematic review was conducted to determine rates of adherence to OET in breast cancer survivors.[25] The review included 19 relevant articles and data from 26,631 women. The findings revealed that 64-88% of women decided to initiate OET and among these 30-50% of women were non-adherent to daily or twice daily pill ingestion, and 70% were non-adherent by discontinuing OET prior to the recommended 5 year period.[7,10,26-42] These rates include women who have tried one or more OETs.

OET adherence as a decision making process unfolding over time

OET adherence is not a single event decision, but rather is a psychosocial process unfolding over time. Health related decision making in women is a psychosocial process, and throughout the duration of the recommended 5 year period the decision to initiate, adhere, or prematurely stop OET occurs within a social context. Using the framework of Walker and Avant,[43] a concept analysis was conducted to understand health-related decision making in women. Following a careful review of 19 relevant articles, attributes defining health-related decision making were determined. These indicated that (1) decision making occurs between two people or groups of people, (2) women must be aware that a decision needs to be made, (3) women must be able to clearly understand the health information being presented to them, (4) unrestricted communication of risks and benefits must occur, and (5) a woman's preferences must be taken into consideration.[44-61] The identified attributes demonstrate the psychosocial process of health related decision making in women. In addition, social interactions with

providers, family, friends, and mainstream media have been shown to specifically influence OET decision making in women who have experienced OET side effects.[15,16,18,20,21,62] Therefore, decision making regarding OET is best considered a psychosocial process where the social interaction between a women and her environment influences the psychological process of deciding.

Side effects and OET decision making

Although our understanding of OET decision making is limited non-adherence is a common response to OET side effects.[5-8,10,11,20,27,63-69] Side effects caused by Tamoxifen include hot flushes, sleep problems, weight gain and loss of libido, and less commonly thromboembolic disease or endometrial pathologies.[20] Aromatase inhibitors also cause hot flushes and have been associated with arthralgia, sleep problems, increased fractures, rash, and gastrointestinal upset.[20] A systematic review aimed at reporting the current state of the science of OET adherence and side effects was conducted. Using the PubMed search engine, 24 relevant articles representing 11,044 women showed that women who report OET side effects are 2 to 4 times more likely to discontinue therapy earlier than 5 years,[5,6,8,9,14] and women who report severe side effects are 5 times more likely to discontinue therapy earlier than 5 years.[9] Qualitative research also reports women purposely interrupting OET to temporarily avoid side effects. This is evident from narrations such as “I never saw the doctor I just took it upon myself to stop the medication and I thought I’m going to start them again, so I started them again and although I felt little bits of nausea it wasn’t nearly as bad… so I’ve just kept on taking them since”.[19] Some women attempt to eliminate side effects through switching their OET.[11,20,69] Unfortunately, although side effects cause women to switch OETs, switching did not prevent further side effects or decisions to interrupt or stop OET.[11] In one study of 503 women,[83] (17%) decided to switch to a different aromatase

inhibitor due to side effects and among those, only 32 (38.6%) continued the therapy for a median of 13.7 months.[11]

The Ottawa Decision Support Framework (ODSF)

Knowing how women make decisions about OET, particularly when experiencing side effects, is foundational to quality OET decision making. Quality decisions are defined as decisions that are informed and based on an individual's values.[12] The ODSF suggests that quality decisions are based on a patient's understanding of decisional needs and availability of decisional supports.[12] Decisional needs are defined as a person's need that results in a difficulty to make a decision.[12] Decisional needs are based on the knowledge, degree of certainty, expectations, and values one may have regarding the decision to be made.[12,13] Decisional support is defined as any support that is given to meet an identified decisional need.[12] The goal of decisional support is to address modifiable determinants of decision making that are suboptimal. These determinants can include inadequate knowledge, unrealistic expectations, unclear values, unclear norms, unwanted pressure, inadequate support, and inadequate personal and external resources to make the decision.[12,13,62] Optimal decision making involves low levels of decisional conflict (uncertainty about course of action to take when choice involves risk, or challenge to personal life values) and decisional regret (disappointment with decision) and results in high levels of decisional satisfaction (high quality decision where chosen option matches patient preference).[12]

Missing decisional support

When the decision making process is well-understood, decisional support often comes in the form of a decision aid. A decision aid is an intervention that helps patients make specific and deliberative choices among the available options. Decision aids often

provide information on treatment options and outcomes relevant to a person's health status, and include methods to clarify values.[47] The Patient Decision Aids Research Group affiliated with the Ottawa Hospital Research Institute is an international research team that designs and tests decision aids and decisional support training programs for patients and health practitioners. The group manages a database of decision aids that can be uploaded and shared if they adhere to established guidelines that include the following: (1) meets the definition of a decision aid, (2) is not more than 5 years old, (3) provides references to scientific evidence, and (4) is publicly available.[12] There is only one relevant decisional support tool that exists in this database. It is a decision aid for OET that focuses only on post-menopausal women making the initial decision to initiate therapy and does not take into consideration OET side effects or decision making as a process unfolding over time.[22]

Unmet decisional needs

Women are inadequately informed about OET side effects and are therefore likely to have unmet decisional needs. Information has been consistently shown to influence behavior in women, both generally,[21] and in those with a diagnosis of breast cancer.[70,71] Several studies have indicated that women receive insufficient information regarding OET and OET side effects.[11,14-18] A systematic review was conducted with an aim to understand how information on OET side effects influenced OET adherence. Eleven relevant articles were identified in the PubMed database.[8,9,14-16,18-21,62,72,73] Findings showed that women seek additional information related to their OET side effects because the information they had been provided was not sufficient.[8,14-16,19-21] Sources of information provided to the women were from provider,[8,14-16,19,21] peer,[15] and media (internet, television, and books).[8,15,19,20] The review demonstrated that women receive insufficient information regarding OET and OET side effects, and that women

report being in distress because information from providers lacks specificity about the cause of OET side effects.[15]

In another qualitative study, women reported seeking additional information from media sources (internet, television, and books), because the side effect information they had received from their physicians was inadequate.[19] However, research has shown that the accuracy of available information can vary depending on its source.[74-76] Women who report experiencing OET side effects and have inadequate decisional support may be seeking information from inaccurate sources in order to meet their decisional needs.

Summary

Information is needed about how women who receive OET make decisions about their therapy, especially when they report experiencing side effects. By obtaining first-person narratives of women who have been prescribed OET, the goals of the dissertation were to develop an explanatory framework that describes their OET experience as it unfolds over time and their salient decisional needs and decisional supports. A grounded theory approach was used to allow the basic psychosocial process of decision making to emerge naturally.

1.3 Study Purpose and Specific Aims

The purpose of this study was to develop an explanatory framework of decision making by women with ER+ breast cancer who reported experiencing side effects. This study had four specific aims:

Aim 1: Describe responses to OET side effects among women with ER+ breast cancer.

Aim 2: Identify common decisional needs of women with ER+ breast cancer who report experiencing OET side effects.

Aim 3: Identify common decisional supports sought by and provided to women with ER+ breast cancer who report experiencing OET side effects.

Aim 4: Describe how women with ER+ breast cancer who report experiencing OET side effects experience OET over time.

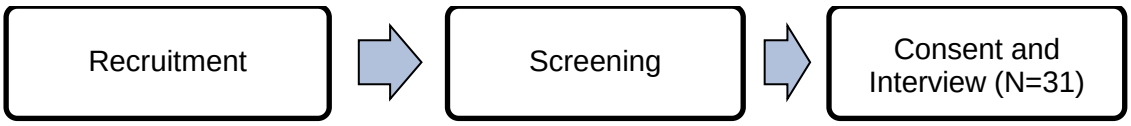
The framework developed from this study will provide foundational information for understanding women's experience with OET as it unfolds over time. This information will ultimately be useful for developing decisional support materials aimed at meeting decisional needs and improving OET decisional quality. As a result of this program of research, there may be better congruence between a woman's decisional needs and the decisional support she receives.

1.4 Approach

Design

A grounded theory approach was used to develop the explanatory framework.[77,78] Grounded theory describes the responses of people sharing a common challenge. This methodology focuses on the complexities of people undergoing change, the influence of social interactions and social context on the phenomenon of interest, and critical junctures in psychosocial processes.[79] For this study, grounded theory was the most appropriate method due to the following reasons: (1) women with ER+ breast cancer share the common challenge of OET and its side effects; (2) decision making related to OET is best understood as a complex process that changes over time and is driven by women's decisional needs; and (3) the process is influenced by sociocultural context, including decisional supports. Women who reported experiencing OET side effects participated in a single face-to-face interview (see Figure 1.1).

Figure 1.1: Study Design



Sample

Inclusion criteria and their rationale were the following: (1) women (breast cancer rarely occurs in men); (2) aged between 40 and 75 (breast cancer rarely occurs in children, and age limit will control for the developmental stage of childbearing and for possible cognitive changes that occurs with aging; (3) first-time diagnosis of ER+ non-metastatic breast cancer (to ensure no previous recommendation for OET); (4) completed primary therapy (finished with chemotherapy, radiation, and surgery – may be taking Herceptin); (5) received a prescription for OET and initiated therapy 6-24 months ago (literature shows that this timeframe allows for the experience of side effects and a response to the side effects. E.g., switching or discontinuation of OET)[11]; (6) reported having had side effects from OET (target population); and (7) fluent in English (a translator is outside the scope of this study). Exclusion criteria were: (1) had a health proxy or guardian making decisions on their behalf; (2) self-reported current or previous diagnosis of serious mental disorder (e.g., schizophrenia, psychosis, or dementia); or (3) self-reported inability to recall OET decision making over time (to assure robust recall of the phenomenon).

Additional rationale: In grounded theory, participants are initially selected because they have knowledge of the phenomenon being studied (in this study it was OET). Because the narratives of women who decide to discontinue OET are needed to fully understand the decision making process over time, women were included regardless of whether they were taking OET at the time of the study interview. In

addition, the timing for inclusion allowed for a narrative description of the OET experience as it unfolded over time.

Sample size

A purposive sample (n=31) was recruited. An exact determination of sample size could not be established a priori and was dictated by the emerging explanatory framework. Grounded theory methodologists recommend a sample size with 20 to 50 participants, but the final number is related to the heterogeneity of the sample and the complexity of the research questions.[80,81] Because the participants shared the same challenge (the experience of OET and its side effects) and the theoretical framework focused on the primary phenomena of decision making, it was anticipated that approximately 30 women would be adequate to achieve the study purpose and the specific aims. The final sample included 31 participants. Based on prior adherence studies,[2-4] it was estimated that approximately 19 to 26 participants (63 to 87%) would be taking OET at the time of the interview, and 4 to 11 (13 to 37%) would have discontinued OET. At the time of the interview, 12 participants (38.7%) were on their original tamoxifen, 1 participant (3.2%) was on tamoxifen after switching from AI, 8 participants (25.0%) were on their original Aromatase inhibitors (AI) prescription, 2 participants (6.5%) were on AI after switching from Tamoxifen, 3 participants (9.6%) were on a different AI after switching from their original AI, 4 participants (12.9%) stopped after original OET and did not switch to another, and 1 participant (3.2%) stopped after switching OET.

Study procedures

Institutional review and approval: The study protocol was approved by the IUSCC Scientific Review Committee and the Indiana University Institutional Review Board. A

waiver of written informed consent and written authorization was requested and approved by Institutional Review Board.

Recruitment

Several recruitment strategies were used. First, the primary researcher placed study fliers announcing the study in local hospitals and clinic locations where women diagnosed with breast cancer were likely to frequent, such as clinic waiting rooms and hospital parking garages. Second, the primary researcher created a Facebook study page. Facebook page sharing with breast cancer groups and Facebook paid advertising were used to notify potentially eligible women of the study. Third, local agencies that supported minority breast cancer survivors emailed study notifications to local women. Fourth, with the assistance of local physician collaborators, study invitations were directly mailed to the homes of potentially eligible women identified through clinic- and registry-based databases. Women interested in learning more about the study were invited to telephone or email the study team.

Eligibility screening and scheduling the study visit

Women were contacted and screened for eligibility over the phone. The study was explained using a study information sheet. If eligible, name and contact information were retained and the study visit was scheduled. The majority of women were interviewed over the phone.

Data collection and measures

During the interview appointment, prior to the start of any data collection, a study information sheet was reviewed with the women. It included language about authorization to use protected health information. Data collection included:

- A demographic and treatment information form (see appendix). Self-reported treatment information was provided by the participant. All data on this form were used to describe the sample.

- A minimally structured interview (60 min) with open-ended questions about the participant's OET decision making process was conducted using the interview guide (see appendix). Although the interview guide set the parameters of the interview, the questions were open-ended and administered with flexibility in order to provide an opportunity for participants to describe salient experiences from their own perspectives. The sample interview questions were designed to elicit information about women's responses to side effects, their decisional needs, the decisional support sought by and provided to them, and the series of decisions they have made regarding their OET. Field notes were recorded during and after the interview focusing on the tenor of the discussion and relevant non-verbal cues. All interviews were audio-recorded.

Compensation

All participants received a $35 gift card in recognition of their time and effort.

1.5 Analysis

Data management

Each participant was assigned a unique study identification number to help maintain confidentiality. Contact information (participant names, addresses, phone numbers, and emails) was collected via voicemail or email and stored in separate electronic files. Demographic and treatment information form data was entered into a secure, limited access, password protected database. Data entry was verified at least 7 days after initial data collection. A professional transcriptionist employed as an approved

vendor for the university transcribed each recorded interview verbatim. Accuracy of each transcript was verified by reading each transcript while listening to the recorded interview. Corrections were made as necessary and transcripts were de-identified by removing any identifying names. Transcripts, surveys, field notes, and memos were stored in a locked file cabinet in a locked private office (paper copies) and on a limited access folder on a limited access and password-protected university server (electronic copies).

Quantitative analysis

All demographic and treatment data were examined for out-of-range values. Questionable or outlying values were verified with original documents. Sample characteristics were described using descriptive statistics appropriate for the level of measurement (e.g., means, standard deviations, frequencies, and percentages) using SPSS™ version 21 (IBM, Armonk, NY).

Qualitative analysis

When conducting the analyses, decisions were made to combine the analysis of Aim 1 with Aim 4 and Aim 2 with Aim 3. Details of the qualitative analysis methods are presented in Chapter 2 (for Aims 1 and 4) and in Chapter 3 (for Aims 2 and 3). The final products of the analysis therefore included types of responses to side effects, common decisional needs, and common decisional supports as well as a framework of the experience of OET over time in women who experienced side effects.

Conclusions

The framework developed from this study will provide foundational information for understanding the experiences of ER+BCS (estrogen receptor positive breast cancer

survivors) with OET as it unfolds over time. This information will ultimately be useful for developing decisional support materials aimed at meeting decisional needs and improving decisional quality. Decisional support materials may include health messages about the importance of continued OET, or include a decisional support tool that addresses the problem (side effects from OET), alternatives, benefits, and risks related to deciding whether to take or not to take prescribed therapies. As a result of continued work in this area, there may be better congruence between a woman's decisional needs and the decisional support she receives.

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Chapter 2

This chapter presents the results of a systematic review that examined literature pertaining to OET non-adherence and side effects using the Ottawa Decision Support Framework (ODSF) categories of decisional supports and decisional needs as requisites for quality decision making.

2.1 Introduction

Oral endocrine therapy (OET) is standard therapy for estrogen receptor-positive (ER+) breast cancer.[2.1] An estimated 75% of women with breast cancer receive a recommendation for life-saving OET such as tamoxifen or aromatase inhibitors.[2.11] OET is prescribed for ER+ breast cancer to prevent recurrence by blocking certain hormones that fuel cancer growth.

The approach to OET in breast cancer survivors (BCS) with ER+ breast cancer depends on whether or not a woman is in menopause. Tamoxifen is prescribed to pre-, peri-, or post-menopausal women and has been shown to decrease breast cancer recurrence by 41% and mortality by 34%.[2.2,2.3] Aromatase inhibitors (AIs), prescribed only for postmenopausal women, have been shown to reduce recurrence by 30-41% and metastasis by 16-18%, with mortality rate reductions similar to tamoxifen.[2.2,2.3,2.4]As a class, the AIs have consistently been shown to improve outcomes for postmenopausal women with hormone receptor-positive breast cancer compared with tamoxifen.[2.44] Each AI agent is taken on a daily basis for the duration of a minimum of 5 years, and sometimes longer.

Despite the benefits of OET for BCS diagnosed with ER+ breast cancer, many BCS decide not to take their OET as recommended.[2.7-2.9,2.13,1.17,2.30]The decision to take OET is not a single event decision, but a complex process that occurs over time as a

series of one time daily decisions or twice daily decisions. Studies show that 30-50% of BCS who initiate therapy are not adherent to daily or twice-daily pill ingestion, and alarmingly 70% prematurely stop the therapy before the end of the once recommended 5-year period.[2.2,2.3]More recently, trials have suggested that 10 years of tamoxifen treatment is better than 5 years and that a program of extended adjuvant therapy of tamoxifen for 5 years followed by AI for 5 more years is effective for suitable candidates.[2.4] This new recommendation causes more concern regarding the 70% early termination rates seen with a 5 year course of therapy.

Understanding BCS's decisional supports (e.g. any support given to meet an identified decisional need) and decisional needs (e.g. any need a person may have that makes it difficult to make a quality decision) is important to help facilitate adherence to OET, particularly when side effects are experienced.[2.15] Tamoxifen side effects include hot flashes, weight gain, and loss of libido, and less commonly thromboembolic disease or endometrial pathologies.[2.4-2.] Side effects of AI include hot flashes, arthralgia, increased fractures, rash, and gastrointestinal upset.[2.5,2.5,2.10-2.14] Understanding the decisional needs and support is a first step in creating a patient centered intervention to increase the percentage of BCS that correctly use this potentially life-saving treatment.

2.2 Purpose and Aims

The purpose of this review was to examine literature pertaining to OET non-adherence and side effects using the Ottawa Decision Support Framework (ODSF) categories of decisional supports and decisional needs as requisites for quality decision making. Study aims were to use the available literature to summarize the following: (1) general nature of the studies, (2) link between incidence of non-adherence and side effects, (3) details of BCS's decisional supports, and (4) thematic categories of BCS's unmet decisional needs.

2.3 Conceptual Framework

The ODSF was the conceptual framework for this study. The framework suggests that quality decisions result when decisional needs (e.g. knowledge, expectations, values) are understood and appropriate decisional supports (e.g. coaching, counseling, providing facts and probabilities) are provided.[2.15] Decisional support is defined as any support that is given to meet an identified decisional need. [2.15] The goal of decisional support is to address modifiable determinants of decision making that are suboptimal. These determinants can include inadequate knowledge, unrealistic expectations, unclear values, unclear norms, unwanted pressure, inadequate support, and inadequate personal and external resources to make the decision.[2.4,2.15,2.16] Decisional needs are defined as any need a person may have that makes it difficult to make a decision.[2.15] Decisional needs are based on the knowledge, degree of certainty, expectations, and values one may have regarding the decision to be made.[2.15,2.16]

2.4 Methods and Search Strategy

A systematic literature search was performed in PubMed and CINAHL. The PubMed database was selected because biomedical topics and the sciences are the primary foci of articles contained in this database, and the content areas directly relate to the topic for this review. In addition, PubMed includes all articles indexed in MEDLINE.[2.37] CINAHL was selected instead of OVID for its coverage of full-text nursing medical journals published by many different publishers. OVID searches are limited to articles published only by OVID and its publishing partners.[2.38] Only peer reviewed articles were included in the review so PROQUEST or other dissertation search engines were not included. The search strategy for PubMED and CINAHL databases combined the search terms “aromatase inhibitors and adherence” and “tamoxifen and adherence.” In order to maximize inclusion, study type and publication date were not limited in the search strategy and articles including all factors associated with OET non-adherence

(not just side effects as a single factor) were included. In addition, reference lists of identified review articles were manually searched to identify potentially relevant additional articles. First, titles and abstracts were screened. Second, the full texts of all potentially relevant articles were obtained and read to determine suitability for inclusion. Articles were identified for inclusion by the primary author (PhD candidate) according to predetermined criteria and then verified by a second reviewer.

Inclusion and exclusion criteria

To be eligible for this review, manuscripts had to meet the following inclusion criteria: (1) study population of adult females with a diagnosis of breast cancer, (2) intake of tamoxifen or AIs, (3) quantitative or qualitative analyses between medication and adherence (e.g. reported side effects attributed to non-adherence), and (4) full-length, original research. All types and stages of breast cancer were included. Articles that were excluded were: (1) in non-English language, (2) focused solely on reporting adherence rates and not including factors contributing to non-adherence, (3) reviews, or (4) editorials, opinion papers, or abstracts.

Data extraction

Data were extracted and organized into 4 separate tables, which are described below. All extracted data were verified by a second reviewer. Table 2.1 shows a general overview of the study characteristics including author, publication year, country where the study was conducted, study design, length of study, cancer stage of participants, sample size, and the class of medication (tamoxifen or AI). Table 2.2 focuses on the rates of non-adherence to the OET assessed in each study, the prevalence of side effects reported, and whether or not side effects were reported as a reason for non-adherence. Data extracted into Table 2.3 focused on decisional support participants reportedly received when receiving the OET prescription or at follow-up visits during the recommended treatment. Using categories from the ODSF, the table delineates the type,

source, timing, and content of provided support. Table 2.4 focuses on decisional needs. Identified needs are grouped according to four thematic categories that emerged from the available data within the articles: (1) regimen (not understanding timing, dose, or duration of OET), (2) beliefs about benefits and risks (OET being unhelpful, not necessary, or other negative or neutral beliefs about OET), (3) inadequate information (insufficient or confusing information, inadequate knowledge of side effects, or inadequate knowledge of tumor hormone status), and (4) having no one to ask questions to (inadequate support to gather information). For studies that contained no detailed information, decisional needs were marked as “not reported.”

2.5 Results

The search in the PubMed electronic database yielded 222 articles. After title and abstract screening, 99 articles were identified as potentially relevant. After removing 18 duplicates, 81 full-text versions were screened in detail. Finally, 24 studies were included based on the inclusion and exclusion criteria. The search in the CINAHL electronic database yielded 98 articles. After title and abstract screening, 24 articles that were duplicated in the PubMed were excluded and 6 articles were screened in detail. Finally, one additional article from the CINAHL search was included in the review. The manual search and reference check revealed no further relevant publications. The flowchart in Figure 2.1 illustrates the selection process.

Characteristics of studies

The characteristics of identified studies are summarized in Table 2.1. Most articles were published after 2012 (n=13, 54.0%), [2.5,2.6,2.10-2.14,2.17-2.22,2.36]with publication dates ranging from 2001-2014. Many studies were conducted in the United States (n=12, 48.0%),[2.5-2.7,2.9,2.12-2.14,2.21,2.23-2.25] used quantitative methods, and reported on data collected using standardized self-report measures. Duration of study time points varied from a single one-time mailing to 12 years, but not all studies reported this information.

Stage of breast cancer ranged from 0-IV with not all studies reporting this information. Sample sizes ranged from 30 BCS to 1,531 online posts by BCS. Participant ages ranged from 18 to >85. Class of OET studied was fairly well distributed across the relevant literature with 9 studies (36.0%) including both types of OET, 9 studies (37.5%) reporting on tamoxifen, and 7 studies (29.1%) reporting on AIs.

Prevalence of non-adherence and side effects

As shown in Table 2.2, non-adherence rates to tamoxifen ranged from 7.3% to 54.0% and to AI it ranged from 5.8% to 61.0%. Studies also reported 3.0-58.0% non-adherence rates to overall therapy and not individually by drug adherence rates.

As shown in Table 2.2, Tamoxifen side effect prevalence ranged from 8.0-66.7% and AI side effect prevalence ranged from 18.2-66.7%. In studies that reported prevalence to overall therapy and not individually by drug, side effect prevalence rates ranged from 3.0-69.8%. Four studies did not provide side effect prevalence rates but did include narrative description of the impact of experiencing side effects on adherence to OET.

Side effects were a reason for non-adherence in 23 out of 25 (92.0%) identified studies. Studies that focused on both tamoxifen and AIs often did not report side effects by drug. Four studies (16.0%) did not include information on specific side effects experienced. In addition, 1 study (4.2%) measured only severity and not the type of side effects, 2 studies (8.3%) were specific to a single side effect, and 1 study (4.2%) reported the general experience of side effects. Hot flashes were described in 13 studies (54.2%), joint pains in 8 studies (33.3%), fatigue/loss of energy in 7 studies (29.2%), mood problems in 6 studies (25.0%), sexual dysfunction in 5 studies (20.8%), night sweats in 4 studies (16.7%), and sleep problems in 2 studies (8.3%).

Decisional supports

Details on decisional support were absent in 13 (52.0%) of the identified studies, either because decisional support was not assessed or was not reported as part of the results. As shown in Table 2.3, types and sources of decisional support included verbal information from providers as well as print or media (internet, magazines, television, books). The time when decisional support was provided or sought by BCS was commonly reported as following initial prescription, but some articles also alluded to support being provided prior to initial prescription and also at follow-up visits. Message content was not always described within the articles. In 4 other studies (16.7%), information was limited to side effects only. In addition, in 4 studies (16.7%), participants specifically described the information they received as being insufficient. Only 1 study (4.2%) included information that BCS were informed of the importance of taking OET at almost every visit and had the opportunity to discuss side effects with their provider.

Decisional needs

Decisional needs are summarized in Table 2.4. Decisional needs were not consistently assessed or reported, with 10 studies (40.0%) not reporting any information on decisional needs of BCS experiencing side effects from OET. In the remaining 15 studies (62.5%), the most common categories of decisional needs were inadequate information (n=7 studies). One study described anxiety and uncertainty in BCS regarding their symptom experience, especially when physicians could not explain the exact etiology of their symptoms.[2.26] Another study included data about BCS not having anyone to ask questions to and not understanding the duration, timing, or dose of their medication or having anyone available to answer questions.[2.18]

2.6 Discussion

In addition to providing a summary of the general nature of the studies that have been conducted on OET non-adherence in BCS who are experiencing side effects, there

are 3 main findings resulting from this review. First, the review summarizes evidence of the relationship between the experience of having side effects and OET non-adherence. Second, this review demonstrates the absence of decisional supports provided or available to BCS who are experiencing OET side effects. Third, this review demonstrates BCS have unmet decisional needs in their OET side effect-related decision-making processes. Each of these findings is discussed in detail below.

Relationship between non-adherence and side effects

The relationship between OET non-adherence and side effects underscores the importance of this clinical problem and provides evidence supporting the widespread notion that OET side effects are a major reason for non-adherence. Reported non-adherence rates are thought to be dependent on a range of parameters, including whether the patients are participating in a clinical trial, the period since initiating treatment, and methods used to assess adherence and medication use.[2.27] It is likely that rates of non-adherence varied within these studies for similar reasons. Regardless of rates, non-adherence was primarily attributed to the experience of side effects. Within this literature, women who reported experiencing OET side effects were two to four times more likely to discontinue OET earlier than five years,[2.5-2.9] and women who reported severe side effects were five times more likely to discontinue therapy earlier than five years.[2.10] Although side effects caused women to switch to a different OET, switching did not prevent further side effects and many women subsequently discontinued even the second OET.[2.11]

Methods used to assess side effects of OET varied. Side effects were not assessed using comprehensive self-report measures, which interfere with understanding the true experience of the effect of these drugs. In addition, side effects were reported from overall OET, limiting our full understanding of side effects experienced by the drug.

Regardless, our review findings suggest that future research should be focused on improved understanding and elimination of non-adherence caused by side effects.

Absence of decisional supports

A second major finding of this review was the absence and inadequacy of available decisional supports for this population. The most frequently endorsed source of informational support was verbal direction from the provider occurring at the time of OET prescription. Details about existing support were limited, but when support was available, it was aimed mostly at the potential experience of side effects. Current support seemed to be lacking the side effect management strategies or stressing the importance of remaining on a regimen even when experiencing side effects.

Even when BCS reported receiving support, they reported that it was inadequate. BCS reported that they were not given understandable OET-related information. The information they did receive was not sufficient, and they did not have the opportunity to ask questions. Limiting support only to information and not considering additional determinants of decision making such as unrealistic expectations, unclear values, unclear norms, or inadequate personal and external resources increases the potential for poor quality decisions.[2.16]

The absence of decisional support may be partially due to the lack of decisional support tools for this population. Decisional support tools often come in the form of a decision aid, which is an intervention that helps patients make specific and deliberate choices among options. Decision aids often provide information on treatment options and outcomes relevant to a person's health status, and they include methods to clarify patients' values.[2.28] The Patient Decision Aids Research Group, affiliated with the Ottawa Hospital Research Institute, is an international research team that designs and tests decision aids and decisional support training programs for patients and health practitioners. The group manages a database of decision aids that can be uploaded and

shared if they adhere to established guidelines, provided that they (1) meet the definition of a decision aid, (2) are not more than 5 years old, (3) provide references to scientific evidence, and (4) are publicly available.[2.15] When the authors searched this database for decision aids that would support the OET decision-making process, only one tool was found. This decisional support tool is a decision aid for OET that focuses only on post-menopausal BCS making the initial decision to initiate therapy and does not take into consideration OET side effects or decision making as a process unfolding over time, which can last 5-10 years.[2.29] This further shows that there are inadequate resources for patients and providers to address the side effects and resulting impact on adherence to OET.

Unmet decisional needs

More importantly, this review showed that decisional needs are not systematically assessed in research or clinical practice. Assessment of decisional needs is important in decision making because it can identify what is important for the decision making, as well as what could be done better in the form of effective decisional support.[2.15]

A revealing finding from this review was the influence of beliefs about OET on adherence. BCS held complex beliefs about their OET, and for a number of BCS the decision to discontinue OET seemed to be the result of rational but misguided beliefs about their experience of side effects.[2.30] Attempting to address their unmet decisional needs through seeking inaccurate information likely contributed to the formation of inaccurate beliefs about OET. This finding is important for adherence because it has been shown that BCS with negative or neutral beliefs about the value of OET were more likely to discontinue it.[2.7] BCS report having unmet needs regarding information they receive, and they report seeking additional information from sources other than their provider. Although BCS turn to alternative sources for OET-related information, these

sources may not provide adequate benefit due to the uneven quality, conflicting claims, redundancy, and difficulties associated with assessing information accuracy and applicability.[2.31]

2.7 Limitations

Review findings should be interpreted in light of some limitations. First, information on needs and support had to be extracted from methods and results sections. Thus, our findings may actually under-represent BCS's supports and needs, suggesting that a more detailed and purposeful study of supports and needs is warranted. A logical next step for research would be to conduct a detailed, basic, descriptive study of BCS's decision-making processes and the unfolding of their decisional needs and supports over time. Second, the literature search was limited to English language articles. Search limitations could have limited the search results and potentially omitted additional findings published in other languages or identified in less popular journals not indexed within PubMed or CINAHL.

2.8 Conclusions

Overall, the prevalence of side effects was quite high and was cited as the major reason for discontinuing OET. Our study confirms that non-adherence to OET due to the experience of side effects remains an importance issue, primarily because BCS experiencing OET side effects have unmet decisional needs and lack adequate decisional supports.

This review indicates that more decisional support for BCS experiencing side effects related to OET may be needed. Although we know that side effects contribute to BCS's decisions to stop OET, we do not understand the details of the process or how that process may contribute to decision making. In addition, although we know that BCS state that they receive insufficient information about side effects from providers and seek out additional information, we do not fully understand that process or how it may relate to

decision making. Future research is needed to further define the concepts of decisional needs and decisional supports for BCS experiencing side effects from OET in order to develop patient-centered materials to improve outcomes of OET therapy. Narrative accounts by BCS who are experiencing OET side effects will provide foundational descriptive information needed to generate interventions to improve quality decision making, such as a decision aid. In order to address the gap in currently available decision aids, next steps should include qualitative descriptive research to generate a full understanding of the decision-making process in BCS who experience OET side effects.

2.9 Implications for practice

This review generates some insights for providers who treat BCS with OETs, particularly when they are assessing OET adherence and side effects. The decision to take OET is not a single event decision, but a complex social process that occurs over time as a series of one time daily decisions or twice daily decisions over the course of up to 10 years. This decision making is further complicated for BCS who experience side effects. Categories of side effects, adherence, decisional support, and decisional needs are all associated with OET decision making, and each of these categories is associated with specific clinical implications as discussed below.

At some point during OET treatment, a large proportion of BCS are likely to experience some type of side effect.[2.5-2.7,2.10-2.12,2.17-2.20,2.23-2.26,2.30,2.32-2.35] Inadequately managed side effects potentially increase non-adherence, leading to an increased risk of breast cancer recurrence.[2.2,2.3] Current methods to assess side effects are inconsistent and unstandardized across the research literature.[2.36] Existing literature suggests that providers are failing to document the assessment of side effects. Furthermore, this review indicates that little is known about how information regarding side effects is communicated. Clinician recorded side effects tend to emphasize serious, life-

threatening adverse events rather than patient-reported issues affecting quality of life. Information communicated to women by providers may not fully encompass the true side effect burden that may result from OET. Poor or inadequate communication fuels lack of understanding, which can further negatively impact clinicians' abilities to support BCS in the management of their side effects and poor quality decisions made by BCS regarding their OET. We recommend that provider assessments include patient report of the experience of side effects from OET at every clinical visit as well as an assessment of adherence.

Decisional support for BCS can be provided in several different ways. Decisional support from providers may include health messages about the importance of continued OET or include a decisional support tool that addresses the problem (side effects from OET), alternatives, benefits, and risks related to whether or not to take prescribed therapies. By providing decisional support to BCS using these methods, unmet decisional needs may be minimized, leading to a quality decision. Results of this review suggest that the lack of decisional support for BCS may lead to unmet decisional needs and provide a basis to guide health provider encounters with BCS taking OET.

According to the ODSF, the primary driver of individuals able to make quality decisions is based on whether their decisional needs are understood and supported.[2.15] BCS who are inadequately informed about OET side effects or the importance of adherence are likely to have unmet decisional needs. By identifying unmet decisional needs, health providers can then be guided towards the types of patient centered OET health information BCS need in order to have adequate support. Providers can determine unmet decisional needs and tailor decisional support provided to BCS during patient encounters resulting in quality decisions that lead to side effect management ultimately resulting in improved adherence to OET.

Figure 2.1: Information Sources

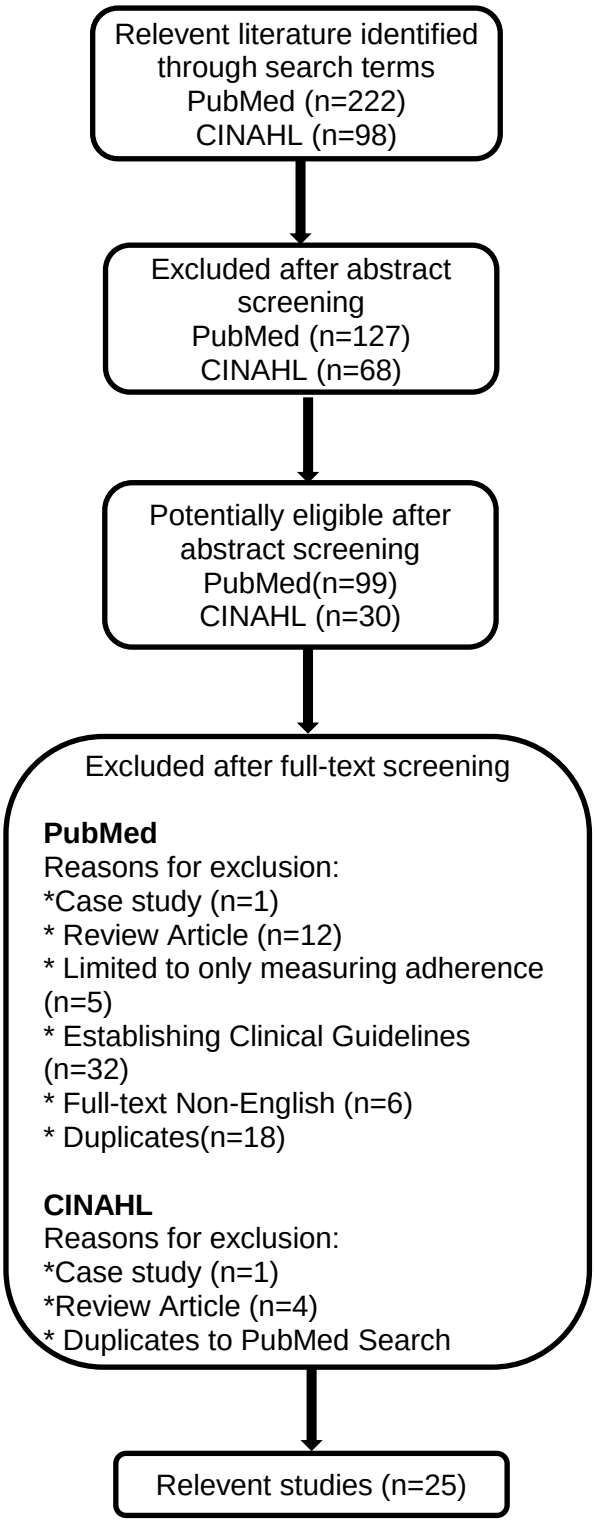

Table 2.1: Study Characteristics

Author, year, country	Study Design and Length		Sample		Medication	
			Stage	N	TAM	AI
Aiello Bowles et al., 2012, USA	Cross-sectional survey	3 mos.	1,2	538	X	X
Atkins & Fallowfield, 2006, UK	Cross-sectional survey	NR		131	X	X
Bell et al., 2013, Australia	Prospective longitudinal survey	4 yrs.	1,>1	1193	X	X
Boonstra et al., 2013, Netherlands	Cross-sectional observational study	3 mos.	1,2,3	57		X
Bramwell et al., 2009, Canada	Randomized , placebo-controlled trial	12 yrs.	1,2,3	672	X	
Chim et al., 2013, USA	Cross-sectional survey	18 mos.	1,2,3	437		X
Cluz et al., 2012, France	Prospective longitudinal survey	3.5 yrs.	1,2,3	196	x	
Demissie et al., 2001, USA	Prospective longitudinal survey	3 yrs.	1,2	292	X	
Fink et al., 2004, USA	Prospective longitudinal survey	3 yrs.	1,2,3a	597	X	
Grunfield, 2005, UK	Cross-sectional survey	NR	NR	110	X	
Harrow, A. et al., 2014, UK	Qualitative semi-structured interviews	6 mos.	NR	30	X	X
Henry et al., 2012, USA	Randomized clinical trial	4 yrs.	0,1,2,3	503		X
Kahn et al., 2007, USA	Prospective Cohort Study	4 yrs.	1,2,3	881	X	
Kemp, 2014, Australia	Observational	5 yrs.	All	1531	X	X
Kirk & Hudis, 2008, USA	Online survey	6 yrs.	All	328	X	X
Kyvernitakis et al., 2014, Germany	Randomized clinical trial	2 yrs.	1,2,3	180		X

Lash et al., 2006, USA	Prospective longitudinal survey	3 yrs.	I,2,3a	462	X	
Mao et al., 2013, USA	Content analysis	NR	All	25256 posts		X
Oberguggenberger et al., 2011, Austria	Cross-sectional survey	5 yrs.	1,2,3	280		X
Owusu et al., 2011, USA	Prospective cohort study	5 yrs.	1-2b	961	X	
Pellegrini et al., 2010, France	Qualitative Grounded theory study	NR	NR	34	X	
Schover et al., 2014, USA	Cross-sectional survey	single mailed survey	1-2a	129		X
Simon et al., 2014, Canada	Cross-sectional survey	6 mos.	0-4	161	X	X
Stanton, Petrie & Partridge, 2014, USA	Cross-sectional survey	2 weeks	0-4	1465	X	X
Wouters et al., 2013, Netherlands	Qualitative Focus Groups and individual interviews	<1 year post-OET completion	NR	37	X	X

Abbreviations: NR, not reported; yrs., years; mos., months; OET, oral endocrine therapy; X, medication included in study TAM, Tamoxifan; AI, Aromatase Inhibitor.

Stage is cancer stage.

Table 2.2: Side Effects

Authors	**Prevalence of Non Adherence (stopping OET prior to 5 years)**			**Prevalence of Side Effects**		**Side Effect Noted as Reason for Non-adherence**
	TAM	*AI*	*Both*	*TAM*	*AI*	
Aiello Bowles et al.	43.9% (n=43)	22.4% (n=22)	33.7% (n=33)	66.70% (n=32)	59.10% (n=39)	X
Atkins & Fallowfield	54% (n=39)	61% (n=22)		NR	NR	X
Bell et al.	7.30% n=88	5.80% n=69	NR	[a]	[a]	X
Boonstra et al.		31%			74%	NR
Bramwell et al	26% (n=173)			8% (n=29)		X
Chim et al.		11% (n=47)			82% (n=358)	X
Cluze et al.	40% (n=27)	42% (n=5)[aa]		47% (n=92)	[aa]	X
Demissie et al.	15% (n=26)			63% (n=104)		X
Fink et al.	17% (n=88)			45% (n=271)		NR
Grunfield	13% (n=13)			46% (n=6)		X
Henry et al.	43% (n=216)				33% (n=163)	X
Kahn et al.	21% (n=185)			21% (n=185)		X
Kemp			58% (n=888)	NR		X
Kirk & Hudis	NR	NR	17% (n=53)	69.80% (n=37)		X
Kyvernitakis et al.		22% (n=40)			100% (n=159)	X
Lash et al.	31% (n=143)			49% (n=227)		X
Mao et al.		13% (n=110)		18.2% (n=4,596 posts)		X
Owusu et al.	46% (n=442)			NR		X
Oberguggenberger et al.		NR			59.6% (n=167)	X
Schover et al.		15.5% (n=20)			79% (n=53)	X
Stanton, Petrie, & Partridge			3% (n=44)	48% (n=326)		X

Harrow, A. et al.			10% (n=3)	NR	NR	X
Mao et al.		13% (n=110)			18.2% (n=4,596 posts)	X
Pellegrini et al.	18% (n=6)			NR		X
Simon et al.	NR	NR	6% (n=7)	6% (n=7)	X	
Wouters et al.			19% (n=7)	NR	NR	X

Abbreviations: NR, not reported; TAM, tamoxifen; AI, aromatase inhibitor; X, side effect noted as reason
for non-adherence, empty boxes indicate information not available.
[a]some BCS reported more than one side effect, some reported none. All answers were included; prevalence could not be determined.
[aa]Rates of interruption of AI reported on larger cohort sample not included in analyses.

Table 2.3: Decisional Support

Details Contained in Articles on the Type, Source, Timing, and Content of Messages Given for Decisional Support				
Author(s)	Type	Source	Timing	Message Content
Aiello Bowles et al.	*	*	*	*
Atkins & Fallowfield	*	*	*	*
Bell et al.	Verbal	Provider	Following RX	*
Boonstra et al.	Verbal	Provider	Prior to RX and at follow-up	Side effects information
Bramwell et al	*	*	*	*
Chim et al.	*	*	*	*
Cluz et al.	Verbal	Provider	Following RX	BCS reported they were not given understandable OET-related information BCS reported they did not consider their information sufficient BCS reported they did not have the opportunity to ask questions at diagnosis
Demissie et al.	Print, media, verbal	Books Magazines Television Provider	Following RX	*
Fink et al.	*	*	*	*
Grunfield	*	*	*	*
Harrow, A. et al.	Print, media, verbal	Internet Provider	Following RX	Even though given side effects information, BCS reported not being asked whether or not they were still taking the medication at follow-up visits
Henry et al.	*	*	*	*
Kahn et al.	Verbal	Provider	Following RX	BCS reported not receiving information about side effects in advance from their provider BCS reported not receiving adequate information from their provider
Kemp	*	*	*	*
Kirk & Hudis,	Verbal	Provider	Following RX and at follow-up visits	BCS told importance of taking OETs at almost every visit BCS discussed side effects with provider
Kyvernitakis et al.	*	*	*	*

Lash et al.	*	*	*	*
Mao et al.	Media	Internet message boards	Not specified	Side effects information
Oberguggenberger et al.	*	*	*	*
Owusu et al.	*	*	*	*
Pellegrini et al.	Print, media, verbal	Peers, Provider Internet	Following RX	Side effects information described OET as hormone or anti-hormone
Schover et al.	Verbal	Provider	Following RX	Side effects information
Simon et al.	*	*	*	*
Stanton, Petrie, & Partridge	*	*	*	*
Wouters et al.	Verbal	Provider	Following RX	Side effects information provided BCS reported they were not given information that taking OET at the same time every day was important BCS reported that the duration of therapy was unclear

Abbreviations: RX, Prescription; *, no relevant information available in article.

Table 2.4: Decisional Needs

Author	Regimen (timing, dose, duration)	Beliefs of Benefits & Risks	Inadequate Information	No One to Ask Questions	No Information Reported
Aiello Bowles et al.		X			
Atkins & Fallowfield					X
Bell et al.			X		
Boonstra et al.			X		
Bramwell et al					X
Chim et al.					X
Cluz et al.					
Demissie et al.		X			
Fink et al.		X			
Grunfield		X			
Harrow, A. et al.				X	
Henry et al.					X
Kahn et al.			X		
Kemp					X
Kirk & Hudis,		X			
Kyvernitakis et al.					X
Lash et al.					X
Mao et al.					X
Oberguggenberger et al.					X
Owusu et al.			X		
Pellegrini et al.			X		
Schover et al.			X		
Simon et al.					X
Stanton, Petrie, & Partridge		X			
Wouters et al.	X		X		

Abbreviations: X = article described unmet decisional needs within this category.

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Chapter 3

This chapter presents an exploratory framework depicting the process through which women's experiences unfold over time.

3.1 Introduction

About 75% of all breast cancer diagnoses are estrogen receptor positive (ER+BC).[3.1] Women diagnosed with ER+BC receive a prescription for oral endocrine therapy (OET), which prevents breast cancer recurrence by blocking certain hormones that fuel cancer growth. Examples of OET are tamoxifen and a class of medications called aromatase inhibitors (AIs, e.g., anastrazole, Letrozole, or exemestane). Tamoxifen decreases breast cancer recurrence by 41% and mortality by 34%, whereas AIs reduce recurrence by 30-41% and metastasis by 16-18%.[3.8]

Despite the benefits of OET, many women diagnosed with ER+BC do not take it as recommended, often due to its adverse side effects.[3.3] Common side effects, which include hot flashes, sleep disturbances, muscle aches and pains, and difficulty concentrating, are difficult for women to endure, especially because OET is currently recommended for five or more years.[7]

The OET experience is a complex process that evolves over time and frequently involves dealing with troubling side effects. Understanding women's experience of OET can provide a foundation for developing strategies to support women taking OET. However, studies on women's experience with OET are limited. The purpose of this study, therefore, was to develop a theoretical framework that depicts the process through which women's experiences with OET unfold over time.

3.2 Methods

Design

Grounded theory, a method of qualitative inquiry used to construct theory through rigorous analysis of data, was used in this study.[3.4] Grounded theory focuses on the complexities of people undergoing change, the influence of social interactions and social context on the phenomenon of interest, critical junctures in psychosocial processes, and the description of responses of people sharing a common challenge.[3.4] We chose grounded theory for this study because women with ER+BC who are prescribed OET and experience side effects share a common challenge and respond to this challenge through a complex process that changes over time and occurs in the sociocultural context of breast cancer treatment practices.

Sample

Women who were diagnosed with ER+BC, prescribed OET, and had experienced side effects from the OET comprised the sample. Additional inclusion criteria were (1) age 40 to 75 years, (2) first time diagnosis of ER+BC, (3) completion of primary therapy, (4) receipt of OET prescription 6-24 months prior to interview, and (5) the ability to read, speak, and understand English. The age limit controlled for childbearing and possible age-induced cognitive changes, first time diagnosis avoided patients with previous OET recommendations, and the 6-24 months timeframe allowed patients to experience side effects and respond to them by switching or discontinuing OET. Exclusion criteria included having (1) a health proxy or guardian that made decisions on the patients' behalf, (2) a current or previous diagnosis of a serious mental disorder such as psychosis or dementia, or (3) a poor recall of OET experience.

Recruitment

The study was approved by the appropriate Institutional Review Board and Scientific Review Committees. Potential participants were recruited with several strategies. First, study fliers were placed where women diagnosed with breast cancer were likely to frequent, such as clinic waiting rooms. Second, a Facebook study page was shared with breast cancer groups and Facebook paid advertising notified potentially eligible women for the study. Third, local agencies that supported minority BCS emailed study notifications to local women. Fourth, study invitations were mailed to potential eligible women identified through clinic- and registry-based databases. Women were invited to correspond with the research team via telephone or email if they were interested in participation in the study.

The research team conducted telephone screenings to determine if potential participants met inclusion criteria. Fifty-three women telephoned the author (PhD candidate) to express interest but two could not be contacted again. Among the remaining 51 women, 17 (33%) were not eligible because they had previous diagnosis of breast cancer (n=3), were not ER+ (n=1), received initial OET prescription greater than 24 months ago (n=4), had no side effects (n=5), did not initiate OET (n=3), and were still receiving primary therapy (n=1). The remaining 34 women completed the interview but three were ineligible due the lack of side effects (n=1) or previous diagnosis of breast cancer (n=2). The final sample of 31 participants represented 58% of the initial pool of women who expressed interest in the study.

Data collection

After obtaining consent, the researchers interviewed participants in a semi-structured interview using the interview guide created by the research team. It began with the question:

> "Think back to when you first became aware that the tamoxifen or aromatase inhibitors would be part of your treatment for breast cancer. Tell me as much as you can about this time, including where the information came from, what type of information you received, and whether or not you were informed about potential side effects."

The team then asked more structured questions about the participants' experiences with OET, side effects, and their needs and supports for making decisions about OET. Upon completion of the interview, participants created a timeline to validate the chronology of events discussed. Participants received a $35 dollar gift card to compensate for their time. Interviews were audio-recorded and transcribed by a professional transcriptionist.

3.3 Data Analysis

Data analysis began as soon as the first interview was transcribed and verified. All three authors (nurse scientists) were involved in the data analysis. Constant comparative analysis was used to discover common patterns and variation in the data, and grounded theory coding principles were followed (Charmaz, 2006).[3.2] The procedures included initial, focused, axial, and theoretical coding (Charmaz, 2006).[3.2] Initial coding, which is the labeling of all important facts and ideas in the transcripts, was conducted by the first author and verified by the others. Focused coding is the examination of initial codes for the presence of significant or recurring codes that are then grouped together to form categories. The first author proposed potential categories that were reviewed, discussed, and modified by the other authors. Axial coding involves returning to the data to define the attributes and characteristics of the generated categories, and theoretical coding is the identification of the potential relationships

among the generated categories. Theoretical sampling, defined as sampling to collect specific information needed to develop categories or enhance the theoretical framework, was done during theoretical coding (Charmaz, 2006).[3.2] Due to the highly interpretive nature of axial and theoretical coding, the authors met biweekly to discuss findings and develop the final framework.

3.4 Results

Sample

The average age of the participants was 55 (SD=8.35, range=42-70 years). Twenty-six were White (83.8%), 2 were Hispanic (6.5%), 2 were African American (5.5%), and 1 was multi-racial (3.2%). All participants had at least a high school education (100%), the majority were employed full-time (51%), and only 2 reported difficulty in paying for housing and food (6.4%). Twenty-five participants (80.6%) reported taking herbal supplements or vitamins. At the time of the interview, 12 participants were on original tamoxifen (38.7%), 1 was on tamoxifen after switching from AI (3.2%), 8 were on their original AI prescription (25.0%), 2 were now on AI after switching from Tamoxifen (6.5%), 3 were on a different AI after switching from another AI (9.6%), 4 stopped after original OET and did not switch to another (12.9%), and 1 participant stopped after switching OET (3.2%).

Framework

The framework described below reflects a social process through which women's experiences with OET unfolded over time. Commonalities in the participants' narratives suggested that this process included four stages. The authors labeled the four stages as follows: *being told what I need to do to live, doing what I need to do to live, enduring what I need to do to live,* and *deciding how I want to live*.

Because the four-stage framework is a conceptual rendering of a common process, it does not necessarily capture the full heterogeneity of the participants' experiences. For example, while many of the participants experienced the stages chronologically as described below, not all participants experienced each stage, and some experienced the stages in a different sequence or for differing lengths of time. The framework nonetheless represents a typical trajectory for women who are prescribed OET and who experience side effects.

Being told what I need to do to live

Because participants described being informed about OET as a necessary rather than possible treatment option, the authors labeled this first stage as *being told what I need to do to live*. All participants described that they first learned of the OET prescription early in their treatment of breast cancer. Few participants were surprised when informed about needing OET, and most expected it to be part of their treatment. Providers told the participants that taking OET markedly decreased their chances of recurrence and thus improved their odds of living longer. One 49-year-old American woman said,

> "My general surgeon had my test results and showed me that in fact I definitely needed to take some sort of an estrogen inhibitor, and there just wasn't any option. I had to take it."

Some participants were informed about OET by their surgeon when they were initially diagnosed with breast cancer, whereas others were informed later when discussing treatment plans with their oncologist. For example, one 43-year-old woman stated,

> "I was told about it when I first met with my oncologist and she was laying out the chemo, kind of the overall plan for me after my surgery."

In a few instances, surgeons informed participants about OET, but oncologists prescribed it.

Providers emphasized the life-saving potential of OET in a number of different ways. Some providers shared detailed facts about OET, and others showed complex figures and graphs. Some providers explained risks of recurrence and benefits of OET by using a website with information tailored to the participants' disease. One 42-year-old woman explained:

> She [oncologist] plugged in all the numbers based on what I had and stage or whatever she plugged in, and there was a 7% chance of it coming back if I stayed on the drug for at least five years, at least that's what I was told, but if I didn't take the drug, it was a 14.4% chance of it returning within ten years.

Other participants were simply told that taking OET would definitely reduce the chance of recurrence because their cancer was "hormone fed" or "so estrogen" and were not provided specific facts and figures. Regardless of how the life-saving potential of OET was presented, not taking OET initially seemed unfathomable to the participants. One 44-year-old woman stated,

> "It seemed to me - it didn't seem like a choice to us [she and her husband]. If there was a drug that was going to significantly reduce my risk of recurrence up to 50%, then it didn't seem like a choice to us."

While providers explained the benefits of OET, they did not always tell participants about potential side effects. Some providers mentioned possible side effects, whereas others did not. A 48-year-old woman stated,

> "He [surgeon] gave me a pamphlet. It was about four pages long and he said, 'Here's your prescription.' Really no warning from him about side effects at all."

Several providers stressed that the benefits of OET would outweigh the side effects or that the side effects could be addressed if and when they occurred.

In some cases, the initial unquestioning acceptance of the need for OET was related to the high degree of trust participants had in their providers. When providers indicated that OET was necessary, most participants did not question the providers

because they were “well educated and highly trained” experts in cancer treatment. In addition, some participants simply believed that their provider had their best interests in mind. A 46-year-old woman stated,

> “I highly trust my oncologist, and she’s making the best decisions for me, so I don’t question her opinion or her directive to take these medicines.”

Doing what I need to do to live

Because the participants saw OET as life-saving and accepted their providers’ recommendations to take OET without much question, the authors labeled the second stage as *doing what I needed to do to live.* This stage included deciding to take OET, getting the prescription filled, and initiating OET. During this stage, the majority of participants were ready do whatever they needed to do to have their best chance for survival. For example, one 60-year-old woman said,

> “So I went to the pharmacy and I got the exemestane. Looked at the price and was horrified and started taking the exemestane.”

Deciding to take OET

Most participants readily decided to take OET. One 57-year-old woman said, “That [tamoxifen] was just the next stage.” Because participants feared a recurrence of breast cancer, most were motivated ‘without question’ to take OET, and none seriously considered not taking it. One 48-year-old woman said,

> “At that point, there was no question. This is cancer. This is a huge deal. If that’s the medicine it takes to deal with it, then that’s what we’re going to do.”

Another 46-year-old woman said,

> “The alternative would be not to do anything or not take it, and the alternative didn’t make sense either. Why not do anything when you can actually have this medication that helps.”

These women thus filled their prescriptions soon after receiving them.

The few participants who were more hesitant about taking OET delayed getting their prescriptions filled until they had more information regarding possible side effects or more information on how OET worked. One 53-year-old woman said:

> "I told her [oncologist] I wanted to research it and see what the side effects were and everything and decide. She gave me the prescription, then I came home and researched, and I seen (saw) there were a lot more side effects than what she had told me. I called the nurse back, and all she told me was not everybody has those side effects and I should go ahead and try it. I went ahead and tried it."

During this delay, these women weighed the benefits and potential risks. One 44-year-old woman said,

> "I figured that my decision to take it was the risk of it recurring. I would rather take the side effects and feel confident that I wouldn't have a recurring cancer."

Getting the prescription filled

Most participants did not feel that getting their prescriptions filled was a significant event. The pharmacists told the participants very little about the potential side effects of OET, although some provided written information in the form of printouts or pamphlets. Some pharmacists gave brief verbal instructions to participants such as "take it on an empty stomach" or "try and take it at the same time each day," but did not provide detailed instructions or engage in in-depth discussions about the potential side effects. One 43-year-old woman said:

> [Did not receive information] from the pharmacist. They [pharmacist] didn't give me anything. It [information] was just on the bottle to take it. There was no pamphlet from the pharmacy. You know sometimes you get those things about medication and side effects? There was nothing about that one [Tamoxifen].

The participants also did not receive information from their pharmacists about potential drug interactions. A few participants were concerned about the likely interactions of OET with other medications such as insulin or thyroid medication but did not ask their

pharmacists. Instead, they sought this information independently. For example, one 56-year-old woman said:

> When I got my prescription filled, I didn't read the side effects. I was just more concerned about the interaction with my thyroid medication, and I found out that there really shouldn't be any problem that would affect my thyroid medication. That was about the limit of what I checked [using Google™].

A few participants considered the cost of OET when getting their prescription filled. However, even when cost was a consideration, participants continued to be willing to do whatever it took to get OET. One 52-year-old woman said:

> I have insurance, but for people that don't this is a very expensive drug. Even with my insurance, I pay quite a bit for it. It's $300 a month, and that's for the generic. Luckily I had made my deductible, so I wasn't really paying for it at the time. At the beginning of the year it might have been a little bit tough coming up with that money. I would have done it if I needed to.

Initiating OET

Most participants initiated the OET soon after getting their prescriptions filled. The fear of cancer recurrence motivated these participants to start their medication right away. Participants felt as if starting the medication was "something [they] should do." A 51-year-old woman stated, "I took the prescription, I filled it, and I took it." Another 68-year-old woman said,

> "I felt like I was aware of the potential [for side effects], but I went ahead and decided I was going to give it a try."

Most participants immediately initiated the OET because they knew their cancer was ER+ and that OET could block estrogen in the body. One 63-year-old woman said,

> "Well, just to know that the cancer was hormone fed and that I needed something to stop those hormones. That was the only thing in my head that I didn't think there was any question that I should take it [Tamoxifen]."

Although most participants initiated OET almost immediately after getting the prescription filled, some delayed initiating OET. A 46-year-old woman said,

> "I picked it up, and I didn't even take it. I had it in my little pantry thing where I keep my medicine, and it was another two weeks after that that I started taking it."

A 60-year-old woman said,

> "I had it [anastrazole] in hand in its little prescription bag for three days before I made the decision to start taking the pills."

Enduring what I need to do to live

Because all participants experienced side effects from OET and tried their best to bear them, the authors labeled the third stage as *enduring what I need to do to live.* The participants experienced a wide variety of side effects that varied based on the OET type. Some participants experienced side effects immediately, whereas others experienced a delay in the onset of the side effects. Most participants attributed the side effects to OET, whereas others questioned whether the side effects were due to OET or other causes. Most of the side effects were life-altering, and the participants tried a variety of management strategies to help with the side effects, sometimes trying various things to experience some relief.

Experiencing the side effects

All participants experienced side effects that varied by the OET type prescribed. Participants who took tamoxifen experienced hot flashes, fatigue, stiffness, constipation, alterations in taste and vision, memory loss, sweating, difficulty sleeping, changes in mood, changes in appetite, hair loss, vaginal dryness, and diminished sex drive. Participants who took AIs experienced hot flashes, headache, joint pain, muscle aches, gastro-intestinal upset, vaginal pain, neuropathy, memory loss, difficulty concentrating, and difficulty sleeping. Most of the side effects that the participants experienced were life altering as they were severe, caused considerable suffering, and interfered with the

women's daily activities. One 63-year-old woman was "surprised by the severity" of her side effects. A 40-year-old woman said:

> When I started taking Tamoxifen, I immediately had issues with hot flashes that were just crazy hot flashes. I had already had some hot flashes because I had started through menopause, but the Tamoxifen hot flashes, I went like 36 hours without sleeping because every time I would lay my head down I was just like…..it was like my blood was boiling.

The onset of side effects varied among participants. Some experienced side effects almost immediately after initiating OET whereas others experienced them later in their treatment.

Determining the cause of the side effects

Participants' recognition of the onset of side effects was affected by variations in onset and presentation. Some participants were uncertain whether their side effects were directly related to OET or a result of something else such as cancer recurrence, the residual effects of cancer, chemotherapy, or radiation. Some participants who had vague or ambiguous symptoms, such as difficulty with memory or localized pain in wrists or feet, had an especially difficult time determining if their symptoms were due to OET. One 43-year old woman said,

> "At the beginning, I didn't know how many of these side effects had to do with the end of radiation or the beginning of Tamoxifen."

Another 44-year-old woman said, "I didn't really connect it at that point it was the Tamoxifen." These participants did a number of things to determine whether their side effects were OET-induced. Some participants, either independently or in consultation with their providers, ceased taking OET for a period-of-time to monitor if side effects would stop and then restarted OET to monitor if the side effects returned. One 68-year-old woman said:

> I had a lot of GI tract upset. When I went off of it [Aromasin], within three days my system was completely totally back to what I would consider normal before this happened, so we [oncologist and I] concluded it was the Aromasin.

Other participants looked up information on the internet to see if their side effects were common and were experienced by others. One 43-year-old woman said,

> "I guess in some ways it [the Internet] is helpful. I did see that there were other people who might be suffering from hair loss from Tamoxifen."

Some women got opinions from family and peers about whether the side effects were related to OET. Some family members made the connection between OET and side effects for the participants. One 44-year-old woman said:

> That's when…. I didn't really connect it [the way I was feeling] at that point it was the Tamoxifen. Because it had been so long since I had started taking it, I just thought I wasn't going to have side effects until my husband mentioned it to me. It was probably about two months in. He said, 'maybe that's what they were talking about. Maybe these were the side effects they [oncologist] were talking about'.

Trying to manage the side effects

The participants tried a variety of strategies to manage their side effects and to feel better. Participants who were certain their side effects were from OET found ways to treat or manage them almost immediately. For example, one 60-year-old woman said:

> Within three days of that first pill, I took it in the morning and went to bed that night three days after I had started it with a vague unusual headache because I never have headaches. So then for a week I tried taking anastrazole at night figuring well I could sleep with my sleeping pill and not be aware of the headache and then tomorrow would be better.

Others did not engage in management strategies until they were convinced that OET was causing the side effects. To manage their side effects, participants followed their providers' recommendations, switched from one OET to another, or tried to manage the side effects on their own.

Following provider recommendations for the side effects

Many of the participants discussed their side effects with their providers who suggested different approaches for management. The providers consulted by the participants were those who prescribed the OET, the radiation oncologist or surgeon.

Providers prescribed medications such as Lexapro or Neurontin, nutraceuticals such as vitamin E or magnesium, behavioral strategies such as exercise or dividing the dose of the OET, or integrative therapies such as Reiki. Participants experienced varying degrees of relief by following these recommendations. For example, one 44-year old woman said,

> "I'm on Lexapro now, and it immediately changed how I'm able to function with the side effects from the Tamoxifen."

Alternatively, a 54-year-ol woman said,

> "She [oncologist] put me on an antidepressant. It made things worse I think. I stopped taking it recently."

Some participants received referrals to providers not directly involved in the cancer treatment for management of their side effects. Sometimes the referrals were for one-time consultations, such as to a sleep specialist, and sometimes referrals resulted in additional referrals. One 67-year-old woman described her experience when she started having pain, numbness, and tingling in her wrist:

> I went to my GP [general practitioner], and she thought that I had carpal tunnel. She sent me to a neurologist for testing of carpal tunnel. He said, 'Yes, you have carpal tunnel.' I went to an orthopedic doctor. He said, 'Yes, you have carpal tunnel, and we can fix it right way.' He said 'You can have surgery, and you can have it fixed right away.' I said 'I don't think I'm bad enough for surgery.' I saw my oncologist for my regular checkup soon after that. She said 'That is crazy because tendonitis is a fairly common side effect of Aromasin, and you would still have tendonitis even if they gave you surgery for carpal tunnel.'

Switching from one OET to another

Some providers recommended that the participants switch their OET in an attempt to alleviate side effects. This recommendation was often in response to severe or adverse side effects such as an anaphylactic reaction or a thrombolytic event. In some cases, the recommendation followed less severe side effects such as headaches, gastrointestinal upset, and diarrhea. Even though participants switched from Tamoxifen

to AIs or from one AI to another, they did not always experience relief. One 70-year-old woman said,

> "He [oncologist] said 'there are some properties in one [aromatase inhibitor] that might not be in the other, and it might lessen your joint pain.'… I have not found that to be true at all."

Some participants, however, did find the switch to be helpful. One 68-year-old woman said:

> I started taking it [Letrozole] and didn't experience much for the first few weeks, and then I started having the same kind of joint stiffness, hot flashes, and a little bit of GI problems, nothing like what I experienced with the Aromasin, but a little bit. By that I mean I might have a couple of episodes two or three times a week where it'll just kind of hit me and I'll need to be in a bathroom.

Managing side effects on one's own

Many of the participants tried to manage their side effects on their own, prior to or without consulting their providers. Some tried nutraceuticals for relief that included switching from magnesium citrate prescribed by the oncologist to magnesium glycinate for hot flash relief, vitamin B for concentration and memory, vitamin E for hot flash relief, increasing vegetable and fiber intake for constipation, and eating bananas and drinking coconut water for leg cramps. One provider, however, determined that a participant's nutraceutical strategy for hot flashes was potentially harmful. A 54-year-old woman explained:

> I talked to my coworkers, and they said that they took something off the shelf from [the pharmacy]. I tried that [supplement], and my oncologist told me that was not good because they [supplement] had hormones in them. I said I didn't know that, so I stopped it immediately.

Some participants tried behavioral strategies and found relief from exercise, yoga, and meditation. Others reported relief from using ice packs and wet wipes to cool during hot flashes. Other successful strategies including taking OET on a full stomach to avoid

nausea, avoiding foods that tasted funny, or writing things down to help with difficulty concentrating or remembering. A few participants found relief from Reiki.

Combining a variety of strategies

Participants combined the strategies described above in several different ways. Very few tried just a single strategy. Several tried strategies sequentially; they tried one strategy, waited a while to see if it would work, and then tried another. Others tried one strategy after another in a desperate attempt to feel better. Some tried several strategies concurrently to see if they could land on something that worked. Some first attempted their own strategies and then contacted their providers when their own efforts were unsuccessful.

One 61-year-old woman's experiences revealed the complexities of managing OET side effects:

> The doctor suggested verbally I take some glucosamine and some Celebrex. Unbeknownst to me, until I read the label, the glucosamine has shell-fish in it, and even though it's a small amount that was what was initially making me sick because I'm allergic to shell-fish. I felt really bad ….it was totally unbearable. The pain was affecting my sleeping. I was provided with some sleeping medication, but it wasn't really helping. I was sent to a sleep specialist who prescribed the generic form of Ambien and that helped quite a bit. Oddly, the thing that helped absolutely the most is …. Reiki…. when I had the reiki it calmed everything down and made me sleep so much better… As I worked with the sleep doctor getting better sleep, I think that also helped with the healing. Then the pain finally just started resting in [one area]…I was sent to a doctor who looked at it if there was some kind of mechanical problem... It was that doctor who recommended a sugar-free diet, and that helped the inflammation a lot. My oncologist in June also recommended an anti-inflammatory diet, but this other doctor actually recommended a book that was medical-based that had really good information on things that you can do to inflame pain in the joints….I also during that time started working out quite a bit, about 150 minutes of exercise…

Deciding how I want to live

Because many participants experienced a point-in-time where they decided whether the suffering from the side effects was worth the benefits of continuing OET, the authors labeled the fourth stage as *deciding how I want to live*. The participants had to decide if they could best live with the side effects or best live without the side effects but with the knowledge that their cancer would more likely return. The decision represented a pivotal moment for many of the participants. To make this decision, many sought additional information or advice from their providers, family, or friends. Some participants decided to continue the OET to live as long as possible, some decided to continue the OET for now, and some decided to discontinue the OET because they could not, or did not wish to, live with the side effects any longer.

Deciding to continue OET

Some participants decided to continue OET as long as needed. Most of these participants were certain they would continue OET for the recommended time of 5 or 10 years. One 67-year-old woman said,

> "My commitment to it [Aromasin] is pretty strong to stick with it for the five years…I've read how good these work, the Aromasin, the aromatase inhibitors, if people stay on them."

Many participants had talked at length with providers, peers, and family and had carefully considered the risks and benefits of OET. The fear of recurrence was particularly strong in some of these participants. The support of family, friends, and faith helped sustain many of these participants. Some did not want to face the regret of going off the OET only to have their cancer return. One 54-year old woman said,

> "Then all I can think is OK, I don't take this and I was told to and it may come back and bite me later I only have myself to blame."

Deciding to continue OET "for now"

At the time of the interview, some participants were still on OET but were not certain they would continue treatment for the recommended time. These participants were considering whether the benefit of OET was worth tolerating the side effects. One 56-year-old woman said:

> "I guess ultimately I need to talk to the doctor and do more research and decide what's going to be better for me. What I'll feel more comfortable doing, stop taking the medicine, praying it [breast cancer] doesn't come back, or just try to manage the symptoms and stick it out for four more years….I don't know if I can go another four years, especially if I'm not going to start feeling any better, but then on the other hand I'm kind of afraid that if I stop taking it [Tamoxifen] my cancer will come back."

Deciding to stop OET

Several participants had decided to stop OET and most of these were confident they had made the right decision. Similar to how participants who had made the decision to continue OET, participants who decided to stop it thoughtfully contemplated if the burden of the side effects outweighed the risk of their cancer recurrence. These women sought the advice of providers, families, or friends. One 52-year-old woman said,

> "My next visit I told her [oncologist], and she made it my choice whether I wanted to stop…she said if it was causing me problems, it probably would be best to go ahead and stop, so that's what I did." The one thing that all participants who had stopped taking OET had in common was that they felt like they could no longer live with the side effects. One 70-year-old woman said, "I decided I wasn't going to live like that the rest of my life."

3.5 Discussion

The purpose of this study was to develop a theoretical framework that reflects the social process through which women's experiences with OET unfolded over time. Using grounded theory methods, we analyzed 31 interviews from women who had experienced OET side effects. The framework includes four stages that we labeled *being told what to*

do to live, *doing what is needed to live*, *enduring what is needed to live*, and *deciding how to live*. The framework reflects the major finding that women readily agreed to take OET when their providers stressed on its life-saving potential but re-evaluated its risks and benefits after experiencing life-altering side effects, causing some to terminate the therapy. Thus far, most studies measured only the presence, frequency, or severity of OET side effects but did not explore women's personal experiences with these side effects. Unlike these studies, our study was an in-depth qualitative inquiry of the experiences of women on OET.

Our study nonetheless confirmed some findings from previous research. Similar to our findings that women do not have in-depth discussions with providers and pharmacists on the potential side effects before beginning OET, a previous study also found that very few patients asked to speak to a pharmacist about their medications. Our finding that women often initially struggled to determine if a bothersome side effect was in fact caused by OET confirms a finding by Wouters et al. (2013) that providers and women often experience uncertainty on whether their symptoms are related to menopause, prior chemotherapy, or OET. [3.11] Mao et al. (2013) and Stanton, et al (2014) found that when women fail to find relief from side effects after attempting a variety of treatment or management strategies, they try switching to a different type of OET therapy.[3.7,3.10] This finding is consistent with our study. Similarly, our finding that switching does not often bring lasting relief was also reported supported by a previous study that switching often does not prevent further side effects or decisions to interrupt or stop OET.

The framework we developed should be considered in light of previous theories applied to this issue. For example, Goldophin (2009) theorized that shared decision-making is the crux of patient-centered care and improved the quality of healthcare. The

most important attribute of patient-centered care is the active engagement of patients in making health care decisions.[3.5] Our finding that shared decision-making was often absent in early discussions on OET may be likely due to providers being highly invested in preventing breast cancer recurrence above all else. This is substantiated by the findings of Morrow et al (2011) that the desire to adhere to published treatment guidelines inhibited shared decision making. Understanding our findings in the context of this theory therefore raises questions about how shared decision-making during the first OET prescription can influence women's experiences managing their side effects if and when they occur.

Another theory that can interpret our framework is the Transactional Model of Stress and Coping.[3.6] According to this theory, the stress induced by an event or situation is mediated by the individual's appraisal of the stressor. Persons appraise the event/situation as well their resources and ability to manage or cope with it. Once coping strategies are implemented, they reappraise the stressor. This process can result in adaptation to the stressor or changes in their responses, including engaging in specific health behaviors. Among our participants, the initial stressor was the diagnosis of ER+BC and the threat of reoccurrence. This threat motivated women to initiate OET without much question and initially endure the side effects. Some women found their efforts to manage or withstand the side effects to be unsuccessful and reappraised the side effects as being unbearable. This reappraisal led to their decision to stop OET or have the possibility of stopping OET in the future. The Transactional Model of Stress and Coping, therefore, can frame the key dilemma experienced by our participants – the tension between the desire to live longer and the desire to live well – as a shifting of appraisals. The women continually reappraised the threat of breast cancer reoccurrence,

threats posed by OET, and their own coping strategies and resources. The intricacies of these reappraisals resulted in their decisions to continue or discontinue OET.

3.6 Limitations

Some limitations in this study should be noted. First, the interviews conducted for this study required retrospective recall of events, which could cause participants to focus only on their most salient experiences, limiting the details they could provide on more routine experiences. For example, participants might have focused on the most memorable negative aspects of their OET experiences rather than “everyday” management strategies. In addition, not having contemporaneous details on the women’s thought processes to make on-going decisions about OET, such as a diary, limited our evaluation of nuances like making multitude decisions on OET on a daily basis. Nonetheless, the women’s narratives provided enough robust data to meet the study goals.

Second, most participants were from a single clinic and thus the nature of their healthcare encounters may have been influenced by the culture of that clinic. Most of the participants were insured and able to afford their medication. Thus, it is possible that the unfolding of their OET experiences could differ in important ways from women who are less resourced. The later group’s processes, for example, might be more driven by the cost of the medication that lacks in our sample. Last, despite the author’s efforts to oversample minority women, there was not enough diversity in the final sample to determine if race and/or ethnicity influenced how the participants managed OET symptoms. Because non-Hispanic Black women have the highest rate of triple negative breast cancer and breast cancer diagnosed at advanced stages, many of these women treated in our recruitment sites were not eligible for the study.[9] The minority women who were included in the sample, however, reported experiences similar to non-Hispanic

white women and thus the findings represent experiences that are likely to be common to all groups.

3.7 Implications for Practice

Despite limitations, the framework contributes to a better understanding of the experiences of OET in women diagnosed with ER+BC. Providers can use this framework to guide conversations with women who have received an OET prescription following a diagnosis of ER+BC. The framework suggests that these women might benefit from a clearer understanding of the benefits, risks, and side effects of OET early on, more assistance in managing the side effects, and more decision support in the form of intentional discussions about decisions to continue OET or to suspend it. Nurse Navigators or Clinical Nurse Specialists are well positioned to assist survivors in the adjuvant phase of breast cancer treatment in this way, perhaps resulting in an increase in the number of survivors who choose to take OET for the recommended duration. The findings of this study can alert providers to the difficult and fundamental choice some survivors must make between living longer and living well so providers routinely engage survivors in meaningful discussions and provide support as they make this life-altering decision.

3.8 Future Research

Further development of the framework using a longitudinal design with a larger and more diverse sample is recommended. A longitudinal study that follows women from the time they are prescribed OET until they discontinue it or complete the therapy is also needed. Encouraging women to maintain a contemporaneous record of their symptoms, their responses to the symptoms, and their on-going decisions about OET will allow a more in-depth understanding of the factors that most influence women to discontinue OET. Future research studies should also include more racially and demographically

diverse participants to allow determination of the influence of racial and socioeconomic factors on the experience of OET. Such a sample would reveal whether the experiences of low-resourced women differ from women with both financial resources and strong social support.

3.9 Conclusion

Adverse side effects from OET are a common experience shared by women treated for ER+BC. The framework depicts a four stage process that reflects a social process through which women's experiences with OET unfold over time. A key finding was that women experience a dilemma between wanting to live longer and wanting to live well and they attempt to resolve this by deciding the course of their OET treatment. The framework adds to the current knowledge, an in-depth description of the challenges that women experience while taking OET and the difficult choices they face. Further development of the framework using longitudinal design to obtain narrative data about the OET experiences as they unfold over time is recommended. Despite limitations, clinicians can use the framework to guide assessment and management of OET side effects and to initiate or guide conversations throughout the duration of OET.

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Chapter 4

This chapter presents a typology of the decisional needs and supports in women with ER+breast cancer experiencing OET side effects.

4.1 Background

Millions of women worldwide take oral endocrine therapy (OET) as standard therapy for estrogen receptor-positive breast cancer (ER+BC).[4.1] OET is prescribed for breast cancer survivors (BCS) to prevent reoccurrence by blocking certain hormones that fuel cancer growth. OET side effects are common and vary by type of OET prescribed. Tamoxifen side effects may include hot flashes, weight gain, loss of libido, and/or thromboembolic disease or endometrial pathologies.[4.2] Aromatase inhibitor (AI) side effects may include hot flashes, arthralgias, fractures, rashes, and/or gastrointestinal upset.[4.2] Women who report experiencing OET side effects are two to four times more likely to discontinue OET earlier than the recommended five year period than women who do not report side effects.[4.3-4.7] To date, most studies have measured the presence, frequency, or severity of OET side effects but have not explored women's personal experiences with these side effects, including their decisions to continue or discontinue the therapy as a result.[4.10] A better understanding of how women make such decisions is needed.

The Ottowa Decision Support Framework (ODSF) is an evidence-based, practical, mid-range theory for guiding patients in making such important health-related decisions.[4.8] The framework considers all persons (e.g., individual, family, couple, provider) involved in the decision-making. According to the framework, quality decisions occur when persons' decisional needs are met and appropriate decisional supports are provided.[4.8] Decisional needs are what persons require to make quality decisions, such

as an understanding of all options; information about the side effects, risks, and benefits of each option; clarification of values and priorities; and an awareness of available resources. Decisional supports include sources of help available to persons faced with making health-related decisions. Supports can provide facts or probabilities, help clarify persons' values and needs, and facilitate their progress.[4.8] External decisional supports are resources in the person's environment that provide help with decision making. Such supports can include clinical counseling, decision aids, and coaching. The quality of persons' health-related decisions affects their actions or behavior, their health outcomes, and their use of health services.

Designing strategies to support ER+BCS in continuing OET for the recommended length of time requires information about their decisional needs and supports regarding continuing or discontinuing the therapy. Such strategies could help women identify, enlist and/or leverage sources of external decisional support to improve the quality of their decision-making. The purpose of this qualitative study was therefore to describe decisional needs and external decisional supports among ER+BCS who reported experiencing side effects due to OET.

4.2 Methods

Basic qualitative description methods as described by Sandelowski (2000) guided the study.[4.9] This method was selected because it allowed for a straightforward description of a phenomenon of interest.[4.9]Qualitative description uses low-inference analysis to provide a comprehensive summary of a narrative data set in everyday language. Because the study purpose was to provide a comprehensive description of the types of common decisional needs and external decisional supports in ER+BCS, rather than a highly interpretive or theoretical rendering of data, qualitative description was the most applicable method to meet the study aims.

Following both Institutional and Scientific Review Board approvals, the research team recruited women through community and provider-supported methods. Some methods used for recruitment included strategically placing study fliers in areas where women who were diagnosed with cancer were likely to frequent (e.g., clinic waiting rooms), creating a Facebook study page and sharing the page with BCS groups, using Facebook paid advertising, and sending study information via mail to potentially eligible women identified through clinic- and registry-based databases.

Potential participants were invited to call a phone number or email study staff if they were interested in participating and were screened for eligibility by the first author. Women were eligible for participation if they were between the ages 40 and 75 years, had a first time diagnosis of ER+BC, had completed primary therapy, had initiated OET 6-24 months prior, and were able to read, speak, and understand English. Women were not eligible for participation if they had a health proxy or guardian that made decisions on their behalf, reported a diagnosis of a current or previous serious mental disorder such as psychosis or dementia, or were unable to recall their OET decision-making over time.

An interview was scheduled with eligible participants. Before the interviews started, participants provided consent to participate. They also provided demographic information and information about their BC treatment history. A semi-structured interview guide was developed. The guide asked participants to describe decisions they had made about their OET, what needs they had to make these decisions, and what supports they had received or desired in making the decisions. All interviews were tape recorded and transcribed verbatim for analysis. Participants received a $35.00 gift card in recognition of their time and effort.

4.3 Analysis

The research team analyzed interview narratives with standard content analytic procedures. The research team included four doctoral-prepared nurse scientists and a psychologist. Three team members read all transcribed interviews in their entirety. The first author (PhD candidate) highlighted all text units (words, phrases, sentences) that were related to OET decisions, decisional needs, and external decisional supports discussed by the participants. These text units were coded with a label that captured the essential meaning of the text unit. Using a series of data display tables to group similar codes together, three team members divided the codes into categories. The categories were then organized in a two-by-two table to display the categories reflecting the decisional needs revealed by the participants and categories reflecting the kinds of external supports they believed that could met those needs. The entire team reached consensus on the categories through discussion occurring at regular team meetings, frequent reexamination of the data, and review of findings. The final analytic product was a typology reflecting four kinds of decisional needs and six types of external supports.

4.4 Results

Sample

The final sample included 31 ER+BCS, 58% of the initial pool of interested women (Figure 4.1). The type of OET prescribed for the women varied, and the sample included those who continued OET, switched to a new type of OET, or discontinued OET (Figure 4.1). Demographic characteristics are shown in Table 4.1. The mean age of the participants was 55.39 years old (SD = 8.57, range 42-70 years).

Typology

All participants discussed a variety of decisions about OET, including whether to begin the therapy, how to manage the side effects, and whether to continue the therapy as prescribed.[4.10] They identified four needs they had while making these decisions: (1) information about OET and its side effects, (2) in-depth discussions about side effects, (3) help in managing side effects, and (4) emotional support. The participants also identified six sources of external decisional supports who/that helped them meet these needs: (1) healthcare providers, (2) husbands, (3) other BCS, (4) friends and family, (5) the internet and other media sources, and (6) God. The resulting typology is shown in Table 4.2. Below, we describe how each source of external decisional support met, or in some cases failed to meet, one or more of the participants' four decisional needs.

Healthcare Providers

Many participants identified healthcare providers as sources of support for their decision-making about OET. Providers included nurses, physicians (e.g., surgeons, radiation oncologists, medical oncologists), pharmacists, and social workers. Healthcare providers were involved in meeting all decisional needs.

Information about OET and its side effects. Participants often looked to healthcare providers for information about OET and its side effects in order to make decisions about their therapy. Most providers routinely gave this information in pamphlets or printouts that included descriptions about the types of OET and the possible side effects of each type. The participants generally found such information helpful. For example, one 53-year-old participant said,

> "It [printed information] was helpful…. It was nice because it was in written form, and that way because sometimes when you're in the office it's overwhelming, and then you can go home and look at it at your leisure…."

Some participants, however, found the information they received to be inadequate, and some women did not receive any printed information at all. These participants suggested that a printout or pamphlet that described the benefits and risks of OET would have been useful. For example, one 51-year-old participant said,

> "It would be kind of helpful to have something that you could read about the pros and cons of some of the different choices maybe just to have as a reference… and even to have a doctor give it to you."

In-depth discussions about OET side effects. Some providers did not simply provide information but rather engaged in in-depth discussions with participants about the side effects of OET, and this aided women's decision-making. Several providers, for example, talked at length with participants about the different types of side effects that could occur with different types of OET. One 52-year-old participant said,

> "She [the oncologist] pretty much told me what I could expect or if I had these side effects that's one of the things that the drug could cause."

Another 44-year-old participant said,

> "She [the oncologist] really did inform me well about what side effects she had witnessed personally in her practice."

Other providers initiated in-depth discussions on how OET works generally in preventing reoccurrence. These discussions helped participants decide to continue with OET despite its side effects by increasing their awareness of the life-saving potential of the therapy.

Other providers did not have in-depth discussions about side effects and this left the participants feeling uncertainty about whether the side effects they experienced were from the OET, another cancer, breast cancer treatment, or aging. One 56-year-old participant said,

> "Since I've been taking this for a while now and the last visit that I had, I am kind of questioning whether some of the things that I'm experiencing is because of the medication."

Also, in the absence of these discussions some participants questioned whether or not they could endure the OET for the duration of time it was prescribed. One 56-year-old participant stated,

> "I feel like I can't make a very good decision one way or the other if I want to continue this. I guess the only way to find out if it's the medication [making me feel this way] is to stop taking the medication [OET] and see if I feel better."

Help managing side effects. Some participants looked to their providers not just for discussions about their side effects but for help in managing them. Several providers prescribed medications such as clonidine or Effexor for hot flashes. Others recommended supplements such vitamin E or magnesium or behavioral strategies such as using a fan while sleeping or a cooling gel pillow for hot flashes. One 49-year-old said,

> "That was when she [oncologist] said we can do something about that, and so she prescribed the clonidine."

Another 53-year-old said,

> "The oncologist told me we're going to block your estrogen. There's a chance that you'll get hot flashes. A lot of people experience hot flashes taking the medication. If they get horrible, we'll try some things."

Some providers offered a variety of approaches for managing the side effects. A 58-year-old participant said:

> "I saw her [oncologist] a month later, and she asked me how I was doing on it [Tamoxifen], and I told her it was terrible. I hated it. It gave me night sweats. I didn't sleep well. It was not a good thing. I felt like I was complaining. She said you don't have to suffer. Let's just split the pill into two."

Receiving such helped support the participants' decisions to continue their OET by providing hope that there were ways the side effects could be eliminated, lessened, or tolerated.

Not all participants, however, received help from their providers in managing their side effects. One 60-year-old participant said,

> “I called her [oncologist] for something because I knew I was battling this anxiety. I don’t remember what the question was. I called and left a message on her voice machine and she never called me back.” She said, “I wish there had been an agreed-upon symptom management plan spelled out or handed to me on a sheet.”

Emotional support. The participants also welcomed emotional support from their providers and found that this aided their decision to continue their OET despite side effects. These providers listened to the participants, were accessible outside of patient visits, and were attentive to their concerns. For example, one 61-year-old participant described her providers as

> “encouraging people who really listen to your concerns and take them seriously, understanding that my body is different than other peoples and treat me like a person, a whole person.”

Another 68-year-old participant said,

> “There's always been follow through. When I've been told I'll get a phone call back, I'll get a phone call back. Questions have been answered.”

Some participants, however, did not receive emotional support from their providers, especially when they voiced concerns about their side effects. For example, one 53-year-old participant said,

> “I just feel like she [Oncologist] didn’t really listen to me, take time to really listen to me about my side effects, so I decided to look for another oncologist.” Another 46-year-old participant said, “I felt like the support wasn't really there that I needed.”

Husbands

Many participants identified their husbands as important sources of support for their decision-making related to OET. We suspect other types of stable partners would also offer support in similar ways but the participants in our study only mentioned their husbands. The participants discussed some ways in which all four decisional needs could be met by their husbands.

Information about OET and its side effects. Several husbands provided support by encouraging participants to seek additional information about OET and its side effects. For example, one 44-year old participant said, “My husband – it’s all about ‘Let’s get the information. Let’s get all the details.’” Other husbands helped participants understand information given by providers. A 51-year old participant said,

> “Sometimes it was difficult to read through those studies because they were pretty technical, medical jargon, but my husband helped me understand those.”

In-depth discussions about side effects. Several participants relied on discussions with their husbands to make decisions about their OET. Some couples discussed whether or not the participants should switch to a different OET because of side effects. For example, one 59-year old participant said

> “When making the decision to switch….My husband was there too, and we were like yeah, we feel more comfortable doing that so that’s why we switched to the Arimidex.”

Another 53-year old participant had discussions with her husband about her side effects that encouraged her to continue with the OET:

> “My husband said, ‘Give it some time. It’ll level off. Just give it some time. Your body has been through a lot. It’s all new.’”

Help managing side effects. The husbands provided help in managing the participants’ side effects in several ways. Some husbands recalled details of side effect management strategies given by the provider during visits that participants might have forgotten. Others recognized the participants’ side effects before they did and encouraged them to report these side effects to their providers. For example, one 58-year old participant said,

> “When I talked to her [oncologist] the next month, I was kind of reluctant because I thought I was being a big baby to talk to her about it, but my husband was right there with me. He encouraged me to say I just really don’t like the way it makes me feel at all.”

Some husbands helped manage the participants' side effects in practical ways. A 60-year old participant revealed,

> "During bad bouts of lupus flair [from OET] my husband was hoisting me out of a chair and helping me out of the bathtub. Raising my legs in the bed at night. And asking me 'What do you need me to do for you?'"

Emotional support. One major way that husbands provided support to the participants as they made decisions about OET was by "being there" for them. Many husbands accompanied their wives to their doctors' appointments, and the participants felt encouraged by this. Husbands provided emotional support by reminding participants to take their OET. A 48-year old participant said, "Then my husband was asking me did you take the [OET] prescription?" Husbands were also supportive by being generally caring and attentive. One 44-year old said, "My husband is a very strong support to me."

Other BCS

The participants also identified other BCS as sources of support for decision-making on OET. The other survivors could be friends, coworkers, or strangers encountered through social media. The participants indicated that all four decisional needs could be met in some fashion by other BCS. Participants who were unable to share their OET experience with another survivor indicated that it may have been helpful to talk with someone who had experienced what they were going through.

Information about OET and its side effects. Participants found that information from other survivors available on the internet to be helpful as it provided some insight into whether or not the side effects experienced by the participants were related to OET. For example, one 59-year old participant said,

> "I looked up a lot of blogs on the internet to see if other people were experiencing those, if they had those symptoms. Some people seem to have those symptoms."

In-depth discussions about side effects. Participants and other breast cancer survivors discussed their OET experiences, commiserated over their side effects, and shared how they made decisions about continuing or discontinuing the treatment. For example, one 49-year old participant said,

> "They [friends with breast cancer] would listen to me. They would give me their story. They would tell me how they came to their decisions [about OET]."

Another 57-year old shared,

> "There was a lady I remember from the breast center I met when getting radiation who said, 'I've taken this [OET] for six years and it doesn't bother me. I have zero side effects. It's fine. You'll be fine'."

Help managing side effects. Other survivors also provided support by sharing specific strategies they had used to manage their side effects. The participants found it helpful to speak with others who knew what might really work. For example, one 57-year old participant shared,

> "Because I had people that had gone through this that I talked to, at least three or four women, seriously talked to about what can ease all of these side effects. I took what they said and did it."

Another 68-year old participant shared:

> "Just talking with someone who was coming from a little bit less of a medical perspective and her explaining to me some of the things that she had tried as far as helping with the hot flashes and helping with the energy and those kinds of things was really helpful."

Emotional support. Other survivors provided emotional support by encouraging the participants to endure the side effects of OET because it was so important in preventing reoccurrence. These survivors gave reassurance that taking OET would be worth it and provided hope for the participants. For example, one 48-year old participant shared,

> "I go to a support group periodically, and the ladies there have been very supportive of you need to do this [tamoxifen]. You don't need to give up. You don't need to quit when it's so important."

Another 49-year old shared a conversation with her coworker who had been diagnosed with cancer:

> "She [coworker also diagnosed with cancer] just wanted somebody [me] to tell her it was okay to feel whatever she was feeling. I had had all of these other women who had done that for me and their willingness to talk about their experience, to talk about their feelings, to be vulnerable again, but to be vulnerable again so it would help somebody, which was me."

Friends and Family

Some participants identified friends and family as sources of support for decision-making related to OET. These persons could be anyone who was close to and cared about the participant's well-being. The participants discussed ways in which the external decisional need of emotional support could be meet by friends and family.

Emotional support. Friends and family provided emotional support by being available to participants in times of need. One 50-year old shared,

> "And I have a good friend that I tell her… She is not a cancer survivor or anything but I'll be like everybody thinks I am just fine and I am just not."

In addition, family and friends gave referrals for providers. For example, one participant 53-year old participant shared, "He's [coworker] the one who helped me find my oncologist."

Not all friends and family, however, provided support. One 53-year-old participant revealed,

> "I would say I'm having really bad side effects from this, and then she [daughter] would say, 'Well, at least you didn't go through chemo, Mom. Just keep thinking that you've only got to take this for three more years or whatever.' She would always say that. That's why I just try to push through hoping it will get better."

The Internet and Other Media Sources

Several participants indicated that the internet and other media sources such as books, research articles, and printed reports served as a source of support for decision-making related to OET. The participants discussed ways in which two decisional needs

could be meet by these sources: information about OET and its side effects, and help in managing side effects.

Information about OET and its side effects. Participants often obtained general information about OET and its side effects from the internet by "Googling" their questions. For example, one 50-year old said,

> "I had read [on the internet] something that was one of the most effective parts of the whole treatment was taking something like that [OET], especially if you were estrogen receptor positive…."

Participants obtained information on what types of OET were available, why different types of OET are prescribed, and how OET works to decrease the risk of breast cancer reoccurrence from the internet and other informational sources. For example, one 53-year old said, "For me, seeing the research knowing that this was the best option was helpful." One 63-year old participant revealed how much a particular book had helped her because it had so much information in it.

Management of side effects. Participants also obtained information about managing side effects from the internet and other informational sources. For some participants, this information was particularly helpful because it came from a source that they deemed credible. Some strategies obtained from the internet included how to manage nausea, hot flashes, and interruptions in sleep. One 48-year old shared,

> "I talked to Dr. Google about it some and found out there's things with Tamoxifen that you can take it at night, and I had been taking it in the morning."

God

A few participants indicated that God served as a source of support for decision-making related to OET. These participants discussed ways by which their faith provided emotional support while they made decisions about their OET.

Emotional support. Some participants found solace in the belief that God would assure that they made the right decisions about their OET. One 60-year old shared,

> "And underlying everything is my strong Christian faith and belief in a God whose plan for me is never wrong."

Another 46-year old participant said,

> "I believe in God, and I believe there's a higher power. I know ultimately he has all the answers."

4.5 Discussion

Because OET might be prescribed for as long as a 10 year period, and is accompanied by a myriad of troublesome side effects, women need to make many decisions about their therapy over a long period of time. Due to the life-saving nature of the therapy, the most critical decision is whether or not to continue the therapy.[4.11]Our study revealed that women who take OET had several decisional needs and found external decisional supports from a number of different sources. Their needs ranged from practical information about side effects and how to manage them to the emotional support of providers and close family and friends who listened to them and expressed their understanding of what they were experiencing.

Decisional needs

Our findings regarding the types of decisional needs identified by ER+BCS resonated with several prior studies. For example, a study by Kahn et al. revealed that OET communication that included discussion of OET side effects was a positive predictor of patient adherence.[4.7] This finding was supported by the narratives of our participants who claimed that having clear information about side effects and how to manage them helped them continue on OET despite the aversive and life altering side effects. Our findings about instances when ER+BCS did not have their decision needs meet by their providers are similar to the findings by Kimmick et al. (2015).[4.12] These

researchers reported that women's difficult-to-manage OET side effects are rarely adequately addressed by providers even with regular follow-up after breast cancer treatment.[4.12] Our findings extend the knowledge on what is known about the decisional needs of ER+BCS by revealing that these needs often extend beyond the need for information and management strategies and at times include the need for in-depth discussions about the side effects and the support of others who appreciate the extent of their suffering due to the side effects they experience.

External decisional supports

Our finding on the external decisional supports of ER+BCS also is consistent with prior research. Our finding, for example, that the internet is an important external support was also reported by Fogel et al. (2002). These researchers found that many cancer patients use the internet to make informed choices often because they find it more comfortable to seek information over the internet rather than use traditional cancer support services.[4.14]

However, our findings on the role of family and friends as external supports differed from the findings of Van London (2014).[4.13]In that study, women described receiving little understanding and support about symptoms from family and friends and felt husbands only wanted to hear about OET experiences for a limited amount of time,[4.13] whereas our results revealed that husbands and family and friends were strong sources of decisional support. Our findings extend the work of previous researchers by delineating multiple sources of external support and demonstrating how different sources of support meet, or fail to meet, a variety of needs in different ways.

4.6 Limitations

Limitations of this research should be considered. First, the majority of participants were highly resourced with income, insurance status, and social support. This may have resulted in an identification of needs and supports that were more similar than dissimilar. For example, the decisional needs of our sample were typically met by one of the sources they identified, whereas a lower resourced sample might have provided a more robust discussion of unmet needs. All patients in this study came from one clinic, which might have limited our findings especially to variations in the decisional supports received from healthcare providers. Women not treated in an academic health center, for example, may experience different types of provider supports. Because our sample was fairly homogeneous in terms of race, we were not able to compare needs and supports across racial groups. In addition, our interviews did not include specific structured questions about how each decisional need was met or unmet by each source and therefore some sources may have provided supports that were not captured in the interviews.

4.7 Implications for practice

Our study highlights the important role of healthcare providers in providing external decisional support for ER+BCS. Our findings suggest that providers need to be mindful that information alone may not be enough for some ER+BCS, and many may need significant and on-going support from providers if the women are to continue OET for the recommended duration. Providers need to not only provide information about the potential side effects of OET but to thoroughly and thoughtfully discuss them with ER+BCS. Some women will likely only continue OET if their provider is actively involved in helping them understand, manage, and eliminate or tolerate the side effects for the recommended duration. Providers need to convey to women that they understand that

the experience of the side effects can be life-altering and that they appreciate that the management of the side effects can be an on-going and arduous process.

Our finding that women use a variety of external supports when making decisions about OET might prompt providers to inquire about the sources of external support available to each woman in order to guide referrals. For example, providers might recommend a local support group if a woman desires to receive or give support to other survivors. Similarly, providers might recommend legitimate internet sources or help women determine which sources are reliable. Providers might also inquire whether women have the support they need from important others in their lives to withstand the side effects.

This typology thus can be used as a springboard to prompt conversations about OET decisions and to assess the needs and supports women have or may desire to have while make decisions about OET, especially whether to continue or discontinue the therapy. Findings can also provide foundational informational to develop decision aids that address decisional needs and provide new or capitalize on existing sources of external decisional supports.

4.8 Conclusion

The decisional needs and supports of ER+BCS who experience OET side effects and who are thus faced with making decisions about whether or not to continue OET are varied. The findings of this study can alert providers to the decisional needs of this group of women. In addition, findings can help providers ascertain the best ways they might provide decisional supports to enable women to continue the therapy for the recommended period of time and thus experience its potentially life-saving benefits.

Figure 4.1. Participant Accrual and Prescribed Oral Endocrine Therapy

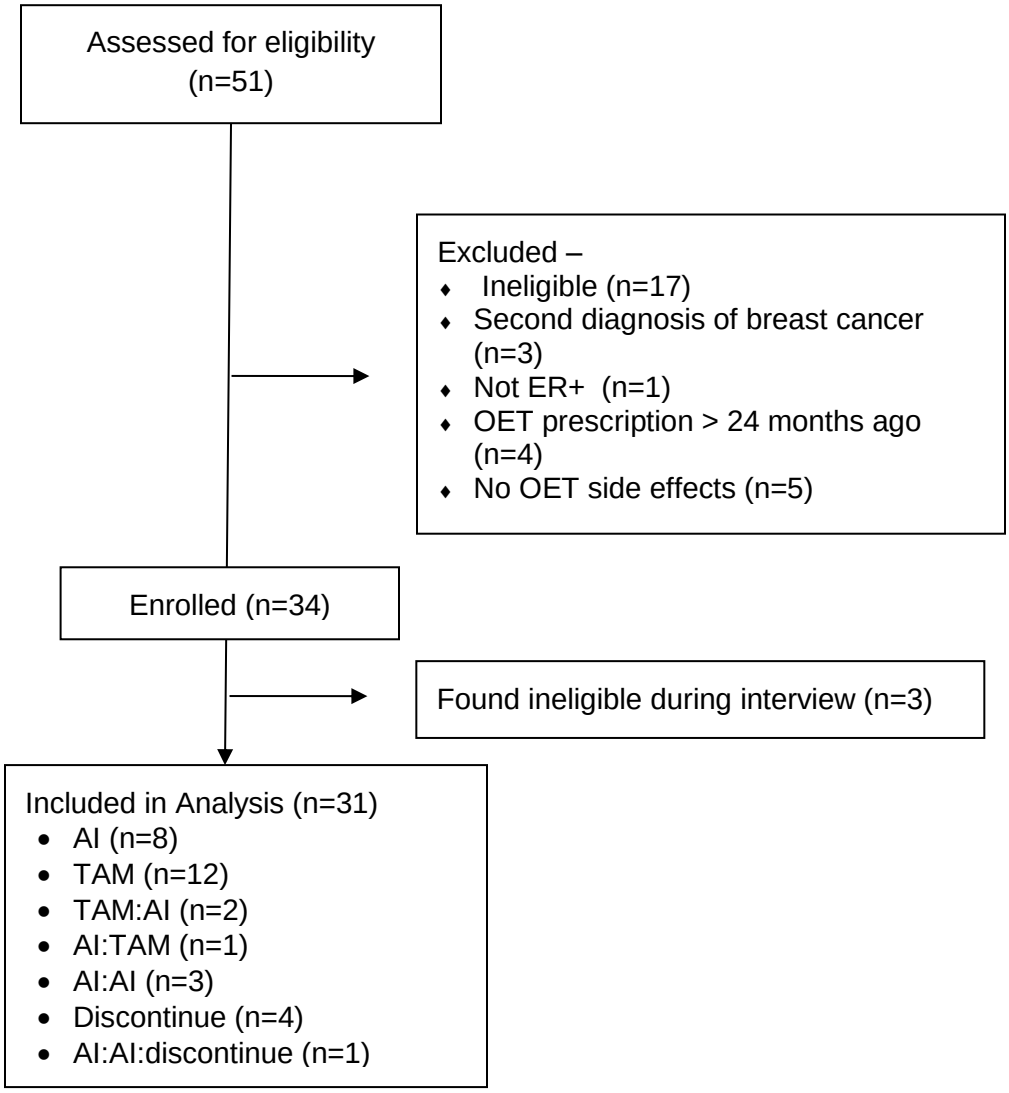

Figure 4.1. Study accrual of participants from screening through analysis including reasons for exclusion and type of oral endocrine therapy (OET). N=number of participants. Of the 31 participants included in the analysis, 8 were taking their initially recommended Aromatase Inhibitor (AI) prescription, 12 were taking their initially recommended Tamoxifen (TAM) prescription, 2 participants had switched from TAM to AI (TAM:AI), 1 participant had switched from AI to TAM (AI:TAM), 3 had switched from one AI to another AI (AI:AI), 4 participants had stopped OET, and one participant had stopped OET after switching from one AI to another AI (AI:AI:discontinue).

Table 4.1: Sociodemographic and Breast Cancer Treatment Characteristics of the 31 Participants

Race/Ethnicity	N (%)
White, non Hispanic or Latino	26 (90.3%)
White, Hispanic or Latino	2 (6.5%)
African American, non Hispanic or Latino	2 (6.5%)
More than one race, non Hispanic or Latino	1 (3.2%)
Marital status	
Single	2 (6.5%)
Married	28 (90.3%)
Widowed	1(3.2%)
Employment status	
Employed full-time	17 (54.8%)
Employed part-time	5 (16.1%)
Homemaker	4 (12.9%)
Retired	5 (16.1%)
Other (self-employed)	1 (3.2%)
Income (able to pay for things like housing and food)	
Difficulty	2 (6.5%)
No difficulty	29 (93.5%)

Table 4.2. Typology of Decisional Needs.

Decisional Needs					
		Information about OET and its side effects	In-depth discussions about side effects	Help managing side effects	Emotional Support
External Decisional Supports	Healthcare providers	X	X	X	X
	Husbands	X	X	X	X
	Other breast cancer survivors		X	X	X
	Friends and Family				X
	Internet/other media sources	X		X	
	God				X

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Chapter 5

5.1 Summary of Dissertation Project

Oral endocrine therapy (OET) is standard therapy for millions of estrogen receptor-positive breast cancer survivors (ER+BCS). OET significantly reduces BC recurrence, mortality, and metastasis. ER+BCS often do not take their OET as recommended due to adverse side effects.

The purpose of this dissertation was to develop an explanatory framework of decision making by women with ER+BC who reported experiencing side effects from OET. This project comprised two components and resulted in three manuscripts.

The first component was a systematic review with three main findings: (1) Side effects negatively impact OET non-adherence; (2) absence of decisional supports provided to or available for ER+BCS who are experiencing OET side effects was observed; and (3) ER+BCS likely have unmet decisional needs on OET. This manuscript is presented in Chapter 2 and was accepted for publication in Cancer Nursing.[1]

The second component was a grounded theory study of 31 ER+BCS who reported OET side effects. During a single semi-structured interview, participants described their experiences with OET over time. Specific aims of the grounded theory study were the following:

Aim 1: Describe responses to OET side effects among women with ER+ BC.

Aim 2: Identify common decisional needs of women with ER+ BC who report experiencing OET side effects.

Aim 3: Identify common decisional supports sought by and provided to women with ER+ BC who report experiencing OET side effects.

Aim 4: Describe how women with ER+BCS who report experiencing OET side effects make decisions about initiating, continuing, switching, and/or discontinuing OET.

This study produced two qualitatively derived products. The first product was a theoretical framework that depicted four stages through which the experience of OET decision making unfolded. The stages were (1) *being told what I need to do to live*, (2) *doing what I need to do to live*, (3) *enduring what I need to do to live*, and (4) *deciding how I want to live*. This framework is presented in Chapter 3.

The second qualitatively derived product was a typology that depicted six sources of external decisional supports (healthcare providers, husbands, other breast cancer survivors, friends and family, the internet and other media sources, and God) that met four types of decisional needs (information about OET and its side effects, in-depth discussions about side effects, help in managing side effects, and emotional support). This typology is presented in Chapter 4.

5.2 Synthesis of Key Findings

The first key finding was the need for nurses to conduct more research into the decision making process of ER+BCS who reported experiencing OET side effects. The main findings of the review paper were: (1) OET side effects can lead to ER+BCS stopping OET before the recommended duration, and (2) ER+BCS have decisional needs related to OET. The review published in Cancer Nursing (Chapter 2) identified gaps in knowledge that provided the impetus to conduct the dissertation research. This review showed that most existing studies measured only the presence, frequency, or severity of OET side effects but did not explore women's personal experiences of these side effects, and that there was no existing in-depth qualitative inquiry of the experiences of women on OET.

The second key finding was the grounded theory framework. The framework emerged from grounded theory analysis of data collected for Aims 1 and 4 (see pages 6, 7 or 95, 69).The framework reflects a social process through which women's experiences with OET unfolded over time. Commonalities in the participants' narratives suggest that this process included four stages. Because the four-stage framework is a conceptual rendering of a common process, it does not necessarily capture the full heterogeneity of the participants' experiences. For example, while many of the participants experienced these stages chronologically as described below, not all participants experienced each stage, and some experienced the stages in a different sequence or for differing lengths of time. The framework nonetheless represents a typical trajectory for women who are prescribed OET and who experience side effects. The framework reflects the major finding that women readily agreed to take OET when their providers stressed its life-saving potential but re-evaluated its risks and benefits after experiencing life-altering side effects, causing some to terminate the therapy.

The third key dissertation finding was the typology of needs and supports. The typology emerged from content analysis of data collected for Aims 2 and 3 (see pages 6,7 or 95). The typology was organized according to the source of potential external decisional support by decisional needs. Six sources of external decisional support and four decisional needs were identified. Because OET might be prescribed for as long as a 10 year period, and is accompanied by a myriad of troublesome side effects, women need to make many decisions about their therapy over a long period of time. Due to the life-saving nature of the therapy, the most critical decision is whether or not to continue the therapy. The findings of this study revealed that women who take OET have several decisional needs and found external decisional support from a number of different sources. Their needs ranged from practical information about side effects and how to

manage them to the emotional support of providers and close family and friends who understood what they were experiencing.

5.3 Strengths of Dissertation

A strength of this dissertation is its ability to address existing gaps in previous research by providing an in depth description of women's OET decision making experiences. To my knowledge, this is the first study to generate an explanatory framework for decision making by women with ER+BC who reported experiencing side effects. Although we have known that side effects contribute to women's decisions to stop OET, this study has clearly described women receiving insufficient information about side effects from providers, and their desire to seek additional information. This is the first study to clearly unravel the details of the decision making process of OET adherence by ER+BCS. Thus, the dissertation findings contribute new information to nursing, medicine, oncology, and symptom science by expanding the understanding of how OET side effects contribute to non-adherence and poor patient outcomes. Findings from this in-depth qualitative study can be used to develop interventions, such as decision aids, to promote quality decision making and improve the quality of health outcomes of breast cancer survivors taking OET.

5.4 Limitations of Dissertation

Our findings should be understood in the context of several study limitations. First, the interviews conducted for this study required retrospective recall of events and this could cause participants to focus only their most salient experiences and limit the amount of details they could provide about their more routine experiences. For example, participants might have focused on the most memorable negative aspects of their OET experiences rather than on the "everyday" ways they tried to manage the side effects.

Not having contemporaneous details about the thought processes the women used to make on-going decisions about OET, such as those that may be available in a diary, limited us in explicating the nuanced processes likely to be involved in the multitude of decisions the women needed to make about OET on a daily basis. Nonetheless, the women's narrative accounts provided enough robust data to meet the study goals.

Second, most participants were from a single clinic and thus the nature of their healthcare encounters may have been influenced by the culture of that clinic. As a result, most of the participants were insured and able to afford their medication and it is possible that the unfolding of their OET experiences could differ in important ways from women with fewer resources. The latter group's processes, for example, might be more driven by the cost of the medication and lack of support in comparison with our sample. In addition, this may have resulted in an identification of needs and supports that were more similar than dissimilar. For example, the decisional needs of our sample were typically met by one of the sources they identified; whereas a lower resourced sample might provide a more robust discussion of unmet needs.

Third, despite the team's effort to oversample minority women, including contacting all minority women within the available population, there was not enough diversity in the final sample to determine if race and/or ethnicity influenced how the participants managed OET symptoms. Because non-Hispanic Black women have the highest rate of triple negative breast cancer and breast cancer diagnosed at advanced stages, many of these women treated in our recruitment sites were not eligible for study. The minority women who were included in the sample, however, reported very similar experiences to Caucasian women and thus the findings represent experiences that are likely to be common to all groups.

5.5 Summary of Recommendations for Future Research

Further development of the framework presented in this dissertation using a longitudinal design with a larger and more diverse sample is recommended. A longitudinal study that follows women from the time they are prescribed OET until they discontinue it or complete the therapy is also needed. Encouraging women to maintain a contemporaneous record of their symptoms, their responses to the symptoms, and their on-going decisions about OET will allow a more in-depth understanding of the factors that may most influence women to discontinue OET. Future research studies should also include more racially and demographically diverse participants to allow determination of the influence of culture and socioeconomic factors on the experience of OET. Such a sample would reveal whether the experiences of low-resourced women differ from women with both financial resources and strong social support.

Additional recommendations for future research are to use these innovative findings for future intervention research. The narrative accounts provided during the interviews provide descriptive information that can be used to generate interventions to improve quality decision making. For example, findings about decisional needs and supports can be used to develop a decision aid. Next steps in this research would be to use the identified information decisional needs and their requirements for decisional supports to develop a draft of a decision aid. Then, after review of the decision aid by stakeholders of patient and provider groups, revisions would be made from recommendations prior to conducting field tests with patients. Findings of field testing would then be peer reviewed or appraised by individuals not involved in its development.

5.6 Summary of Practice Implications

Despite limitations, the framework and typology developed from the study contribute to a better understanding of the experiences of OET in women diagnosed with ER+BC. Providers can use the framework and typology to guide conversations with women who have received a prescription for OET following a diagnosis of ER+BC. Both the framework and typology suggest that women might benefit from a clearer understanding of the benefits, risks, and side effects of OET early on, and obtaining more assistance in managing the side effects, and more decision support in the form of intentional discussions about decisions to continue OET or to suspend it.

Findings from the dissertation are immediately translatable into practice in the following ways. First, providers are now aware of the difficult and fundamental choice some survivors must make between living longer and the quality of their lives. Therefore, they now can routinely engage survivors in meaningful discussions and provide support as they make this life-altering decision. Second, providers know now that types, sources, and content of OET information can impact the quality of decisions women with ER+ breast cancer make about their OET. Therefore, providers should be prepared with numerous types, sources, and content of OET information that has been verified and that can be trusted in order to ensure that the patient makes a quality decision. Third, although several sources of support are able to meet needs identified by this population, only the sources of provider and husbands are able to meet all needs identified by study participants. Therefore, providers need to be mindful that while information alone may be enough for some ER+BCS, most ER+BCS will need more significant interactions with providers if they are to continue OET for the recommended duration.

5.7 Conclusion

Adverse side effects from OET are a common experience shared by women with ER+BC. The stories provided by the participants reflect the significance of the experience of OET side effects in these women and how their experience compromises quality health outcomes. The study serves as a call to action for healthcare providers to provide side effect management strategies and decisional support to ER+BCS throughout their OET experience.

References

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Dissertation Appendices

Demographic and treatment form

Interview guide

Letters of support

SRC approval

DEMOGRAPHIC and TREATMENT FORM

How old are you today? ____

Are you Hispanic or Latina?

No _____ (1)
Yes _____ (2)

What is your marital status?

single _____ (1)
single, living with partner _____ (2)
married _____ (3)
widowed _____ (4)
other _____ (5)

Do you consider yourself….?

White/Caucasian _____(1)
Black/African American _____(2)
Asian _____(3)
American Indian/Alaskan Native _____(4)
Native Hawaiian/Pacific Islander _____(5)
More than one race _____(6)

Which of the following best describes your current work status?

employed full time _____(1)
employed part time _____(2)
homemaker _____(3)
retired _____(4)
unemployed _____(5)
other _____(6)

How much difficulty do you have paying for basics, like housing and food?

No difficulty _____ (1)
Some difficulty _____ (2)
A lot of difficulty _____ (3)

Please circle the highest grade of education you completed.

1 2 3 4 5 6 7 8
9 10 11 12 (high school)
13 14 15 16 (college)
17 18 (master's degree)
19 20 (doctorate)

Current medications (please list): _____

DATE OF DIAGNOSIS: ____-____-____

Location: __ left (1) __ right (2) __ bilat (3)

Stage:

0 _____ (1)
I _____ (2)
IIA _____ (3)
IIB _____ (4)
IIIA _____ (5)
IIIB _____ (6)

Her2 status _____ (+ or -)
ER status _____ (+ or -)
PR status _____ (+ or -)

CHEMOTHERAPY
_____ none (0)
_____ some (1), # cycles received? _____

Begin date: ____-____-____
End date: ____-____-____

Complete Treatment Received:
_____ surgery alone (1)
_____ surgery + XRT (2)
_____ surgery + chemo (3)
_____ surgery + XRT + chemo (4)

DATE OF SURGERY: ___-___-___

Type of surgery:

_____ lumpectomy (1)
_____ MRM (2)
_____ RM (3)
_____ other (4)

RADIATION THERAPY

_____ none (0)
_____ some (1)

Begin date: ____-____-____
End date: ____-____-____

TAMOXIFEN

___ never used (0)
___ yes, currently using (1)
___ used in past, no current use (2)
___ don't know (3)

Begin date: ____-____-____
End date: ____-____-____

AROMATASE INHIBITORS

___ never used (0)
___ yes, currently using (1)
___ used in past, no current use (2)
___ don't know (3)

Begin date: ____-____-____
End date: ____-____-____

Date of last treatment

____-____-____

Interview Guide

I am interested in understanding how women who are prescribed oral endocrine therapy (tamoxifen or aromatase inhibitors) make decisions about the therapy – whether to begin it, whether to take the medication daily as it is prescribed, and whether to continue it or not based on severe side effects. I am particularly interested in how women make these decisions when they experience the medication's side effects. I would like to hear about any side effects you have had, and the decisions you have made from the time you first started the medication until now. I will ask you several open-ended questions. If you don't want to answer a question, let me know. You can stop the interview at any time.

…….Think back to when you first became aware that the tamoxifen or aromatase inhibitors would be part of your treatment for breast cancer. Tell me as much as you can about this time, including where the information came from, what type of information (verbal, print, resources) you received, and whether or not you were informed about potential side effects

Aim 1 Topic/question guide *(responses to side effects)*

- Tell me about any side effects you have had. When did they occur (timing)?
- Describe to me what happened after you started experiencing each side effect.
- Were the side effects expected or unexpected?
- What did you do when you started having side effects?
- Did you seek or receive any additional information after you started experiencing side effects? How did you use this information?
- Did you receive any help or support in managing the side effects?

Aim 2 Topic/question guide (*decisional needs*)-no support language

- Tell me about any decisional needs you may have had regarding your (tamoxifen or aromatase inhibitor) (will probe for decisions related to initiation, continuation, switching, discontinuation).
- Tell me how the side effects you were experiencing influenced those needs, if at all.
- What were the things you were unsure about regarding your decision for therapy?
- Did you receive any information that you didn't understand?
- Was there anything you were uncertain about regarding your decisions? Did you need anything else to make your decision?

Aim 3 Topic/question guide (*decisional support*) no need language

- Let's go back to the major decisions you made regarding your (tamoxifen or aromatase inhibitor) and the help or support you had or would have liked to have made those decisions.
    - Tell me about the help or support you actually received when you were making important decisions about your medication (probe based on answers to questions above).
    - Tell me about the help or support you would have liked to have received.
- Sometimes when we make decisions, things can happen that we do not find helpful. We might not get the information we need, we might get inaccurate information, we might not have anyone to talk to about our decisions, and things

like that… Tell me about things that might have happened, if any, that got in the way of your decision making.

Aim 4 Topic/question guide (*process over time*)

- Now, I would like to construct a timeline with you in which we plot the information you have given me over the time from when you have been prescribed OET until now.
- Let's begin with when you were first aware you would be prescribed OET…. (Construct the timeline for each critical decision. For each critical decision, review the decisional needs and decisional supports that the participant said accompanied each decision. For each decision, ask "Have we forgotten anything?" or "Shall we add anything here?")
- Eventually, we would like to develop strategies that would help women make decisions about their OET. What might these strategies include? What might have been (would be) helpful for you?

INDIANA UNIVERSITY

MELVIN AND BREN SIMON
CANCER CENTER

October 13, 2014

Jennifer Milata, MSN, RN, ACNS-BC
Pre-doctoral fellow
Indiana University School of Nursing
1111 Middle Drive
Indianapolis, IN 46220

Dear Mrs. Milata:

This letter is to provide my strong support for the submission for your R36 application "The oral endocrine therapy decision making process in women with breast cancer". Specifically, I can help you in troubleshooting any difficulties in accessing that patient population, including patients seen at Eskenazi Health. Your sponsor, Janet Carpenter, PhD, RN, FAAN is a Full Member of the cancer center with access to patients and clinician colleagues.

Best wishes,

Kathy D. Miller, MD
Ballve' Lantero Scholar in Oncology
Co-Director of the IU Simon Cancer Center Breast Cancer Program
Associate Professor of Medicine
Department of Personalized Medicine
Division of Hematology/Oncology
IU School of Medicine

cc: Janet S. Carpenter, PhD, RN, FAAN carpentj@iu.edu

MELVIN AND BREN SIMON CANCER CENTER

INDIANA UNIVERSITY

January 12, 2015

Jennifer Milata, MSN, RN, ACNS-BC
Pre-doctoral Fellow
Indiana University School of Nursing
1111 Middle Drive
Indianapolis, IN 46220

Dear Mrs. Milata,

This letter is to provide my strong support for the submission of your R36 application, "The Oral Endocrine Therapy Decision Making Process in Women with Breast Cancer". Our breast cancer survivors can have significant difficulties adhering to oral endocrine therapy and your proposed work in this area fits well with the IU Melvin and Bren Simon Cancer Center.

Dr. Janet Carpenter, your sponsor, is a Full Member of the cancer center with access to patients for collecting data and to clinicians for verifying the theoretical framework that develops from your findings.

I understand that patients will be recruited from the following sources: targeted mailings, flyers placed in the community, support group newsletters, the IUSCC tumor registry, and the I-CTSI recruitment services, and that your protocol has received approval from Dr. Champion, Associate Director of the Cancer Prevention and Control Program. In addition, I understand that you are planning to share your findings with local providers, including IUSCC oncologists. I am fully supportive of your plans and wish you continued success in your doctoral studies. Please let me know how I can be of further assistance in supporting your training and research.

SCIENTIFIC REVIEW COMMITTEE

Indiana University Melvin and Bren Simon Cancer Center

OUTCOME REPORT

Meeting Date: 7/18/2014

SRC Submission#: 13609 **Protocol#:** IUCRO-0477

Title: Responses to Recommendations for Oral Endocrine Therapy for Breast Cancer

Janet Carpenter
Sponsor: IU

Result (**bold type**): **Reviewed, comments listed below**

1.	**Approved (may require some secretarial changes) for submission to IRE**
2.	Provisionally approved, pending specifically requested changes and/or questions/concerns that need to be addressed. Return to SRC for expedited review by Primary Reviewer(s).
3.	Tabled. Return to SRC for full review at monthly SRC meeting.
4.	Disapproved. May not be re-submitted to the SRC in its present form without major revisions.

***All responses to the SRC for Provisional Approvals and Tabled Protocols must include:**

1. **A line by line response to the issues raised in the SRC outcome report.**
2. **Provide a modified protocol with tracked changes.**

Curriculum Vitae

Jennifer Lynn Milata

EDUCATION

	Place	Degree	Dates
GRADUATE:	Indiana University Indianapolis, IN	PhD, Nursing Science	2017
	Indiana University Indianapolis, IN	MSN, Adult Nursing CNS	2006-2009
UNDERGRADUATE:	Indiana University Indianapolis, IN	BSN, Nursing	1998-2001

ACADEMIC APPOINTMENTS

Place	Title/Rank	Dates
Indiana University Indianapolis, IN	Clinical Adjunct Faculty Clinical Capstone Practicum	Spring, 2016
Indiana University Indianapolis, IN	Teaching Assistant Scientific Basis of Clinical Nurse Specialist Practice	Spring, 2015
IvyTech Community College Indianapolis, IN	Director, Systematic Evaluation and Quality Improvement-Nursing	2011-2012
Indiana University Indianapolis, IN	Research Associate, School of Nursing	2009-2011
Indiana University Indianapolis, IN	Project Manager, School of Nursing	2005-2011

CLINICAL APPOINTMENTS

Place	Title	Dates
Cook Research Incorporated West Lafayette, Indiana	Clinical Project Manager	2016- current
Indiana University, Indianapolis, IN	Staff Nurse, Clinical Research Center, PRN	2015-2016
Indiana University, Indianapolis, IN	Clinical Nurse Manager, Clinical Research Center	2004-2005
Indiana University, Indianapolis, IN	Staff Nurse, Clinical Research Center	2003-2004
St. Vincent Hospital, Indianapolis, IN	Staff Nurse, Adult ICU	2001-2003

CONSULTATIONS

Place	Reason	Dates
National Council State Boards of Nursing (NCSBN)	Clinical Simulation Evaluation, Clinical Simulation Study	2012
St. Vincent WellCare Ascension Health, Indpls, IN	Consultant health behavior assessment and monitoring proposals	2012
Lilly Research Laboratories, Eli Lilly & Co., Indianapolis, IN	Hot flash measurement in clinical trial of new drug	2007

LICENSURE

Type	State/Organization	Dates
Registered Nurse	State of Indiana	2003-Present

CERTIFICATION

Type	State/Organization	Dates
Board Certified Adult Clinical Nurse Specialist	National / American Nursing Credentialing Center	2011-2016
Certified Clinical Research Coordinator	National / Association of Clinical Research Professionals	2005-current

PROFESSIONAL ORGANIZATIONS

Oncology Nursing Society	2013-Present
Sigma Theta Tau International Honor Society of Nursing	2001- Present
Midwest Nursing Research Society	2008-Present
Association Clinical Research Professionals	2005-Present

HONORS AND AWARDS

IUPUI Elite 50 Graduate Student	2015
Emily Holmquist Distinguished Pre-Doctoral Nursing Student Award	2014

GRANTS, FELLOWSHIPS, SCHOLARSHIPS

Grants

2015-2016, AHRQ R36 HS 024241-01. AHRQ Dissertation Research Award (Milata, PI), total ($ 42,895)

Fellowships

2012-2015, NINR 2T32 NR007066 (21-26) Indiana University: Training in Behavioral Nursing (Rawl, PI). Fellow. ($ 22,500/year)

2012-2016, Research Incentive Fund (RIF). Indiana University School of Nursing ($10,000/year)

Scholarships
2015, Jesse Cross Scholarship. ($1,500)
2014 Oncology Nursing Society Pre-Doctoral Research Scholarship. ($3,000)

PUBLICATIONS
1. **Milata, J.L.,** Draucker, C.B., & Carpenter, J.S. Under Review. The experience of oral endocrine therapy. *European Journal of Oncology Nursing*. In Press.
2. **Milata, J.L**, Otte, J.E., Carpenter, J.S. (2016). Oral endocrine therapy non-adherence, adverse effects, decisional support, and decisional needs in women with breast cancer. Cancer Nursing. {epub ahead of print}..
3. Carpenter, J. S., & **Milata,** J. L. (2014). Do Menopausal Symptoms Continue after Oral Endocrine Therapy for Breast Cancer? [invited editorial] *Menopause.* Oct;21(10):1035. doi: 10.1097/GME.0000000000000298.
4. Carpenter, J. S., Newton, K. N., Sternfeld, B. S., Joffe, H. Reed, S. R., Ensrud, K. E., & **Milata, J.** (2012). Laboratory and ambulatory evaluation of vasomotor symptom monitors from the Menopause Strategies Finding Lasting Answers for Symptoms and Health network. *Menopause,* 19 (6), 664-671. PMCID PMC3326209.
5. Von Ah, D., Skaar, T, Unverzagt, F., Yu, M., Wu, J., Schneider, B., Storniolo, A. M., Moser, L., Ryker, K., **Milata, J**., & Carpenter, J.S. (2012). Evaluating the role of serotonin on neuropsychological function after breast cancer using acute tryptophan depletion. *Biological Research for Nurses*, 14(1) 5-16.
6. Carpenter, J. S., Yu, M., Wu, J., Von Ah, D., **Milata, J.,** Otte, J. L., Johns, S., Schneider, B., Storniolo, A. M., Salomon, R., Desta, Z., Cao, J., Jin, Y., Philips, S., & Skaar, T. (2009). Evaluating the role of serotonin in hot flashes after breast cancer using acute tryptophan depletion. *Menopause,* 16(4), 644-652. PCMID: PMC2714664.

PRESENTATIONS
Research (Peer Reviewed)
1 **Milata, J.L.,** Draucker, C.B. & Carpenter J.S., (2016). The oral endocrine therapy decision making process in women with breast cancer. Poster presented at IUPUI Student Research Day. Indianapolis, IN.
2 **Milata**, **J.L.** & Carpenter J.S. (2014). Communication as a factor associated with non-adherence to oral endocrine therapy in breast cancer. Poster presented at AACH: American Academy on Communication in Healthcare 2014 Research and Teaching Forum. Orlando FL.
3 **Milata**, **J.L.** & Carpenter, J.S. (2014) Systematic review of interventions to improve adherence to oral chemotherapy. Poster presented at MNRS: Midwest Nursing Research Society. St. Louis MO.
4 **Milata, J.L**. & Carpenter, J.S. (November, 2013). Review of Methodological Issues in Studying Adherence to Oral Endocrine Therapy in Breast Cancer. Poster presented at ONS 2013 Connections: Advancing Care Through Science Conference. Dallas, TX.
5 **Milata, J.L**. & Carpenter, J.S. (November, 2013). How visual rhetoric creates knowledge of breast cancer: A rhetorical analysis of pink ribbon images. ONS 2013 Connections: Advancing Care Through Science Conference. Dallas, TX.
6 **Milata, J.L**. & Carpenter J.S. (April, 2013). A Review of Adherence to Oral Endocrine Therapy for Breast Cancer. IUPUI Student Research Day. Indianapolis, IN.

7 **Milata, J.L.** & Carpenter J.S. (May, 2009). Characteristics that describe women who biobank for breast health. IUPUI Student Research Day. Indianapolis, IN.

Clinical

1 **Milata, J.L.** (2008). Improving safe handling procedures during investigational chemotherapy administration. Clinical Research Center, Indiana University. Indianapolis, IN.

2 **Milata, J.L.** (2008). Sleep hygiene protocols in hospitalized cancer patients. Unit Based Presentation. St. Vincent Hosptial, Ascension Health. Indianapolis, IN.

3 **Milata, J.L.** (2007). Music for distraction during bone marrow biopsy. Unit Based Presentation. University Hospital, Clarian Health. Indianapolis, IN.

SERVICE

2014-2016	Abstract review, Oncology Nursing Society Congress Conference
2011-current	Girl Scout Troop Leader, Central Indiana Girl Scouts
2012-current	Susan G. Komen Biobank Volunteer
2012	Ad hoc review, Western Journal of Nursing Research