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**DEVELOPMENT AND EVALUATION OF A
BREAST CANCER PREVENTION DECISION AID
TO ADDRESS THE NEEDS OF WOMEN AGED 50 AND OLDER
AT HIGH RISK FOR BREAST CANCER**

by

CAROLYN DAWN STACEY

**Thesis submitted to the
School of Graduate Studies and Research
in partial fulfillment of the requirements for the
degree of Master of Science in Nursing**

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Abstract

Objectives: To describe the support needs of high risk women; and to develop and evaluate a decision aid to meet their decision making needs. The Ottawa Decision Support Framework was the conceptual framework that guided the needs assessment and decision aid development and evaluation.

Setting: Urban breast health clinic for women at high risk of breast cancer.

Methods: The support needs of high risk women were identified using a self-assessment survey completed before and a satisfaction survey completed after a consultation visit with breast health practitioners. Guided by six key considerations for the development of decision aids, a breast cancer prevention decision aid was designed to address high risk women's informational and decisional support needs. The evaluation included a pre-test with 10 high risk women using the decision aid alone and a before/after study with 17 high risk women using the decision aid combined with decision support counselling.

Needs Assessment Findings: Before the consultation visit: a) informational needs included personal risk of breast cancer, healthy lifestyle practices, screening recommendations, decision making, and chemoprevention trials; and b) decision making needs included wanting information on options, benefits, and risks, and help clarifying personal values. In the post-visit survey, women were satisfied with the informational and emotional support they received, and their involvement in decision making.

Decision Aid Results: The aid alone and when combined with counselling significantly decreased some dimensions of decisional conflict, increased knowledge, and created more accurate risk perceptions. The aid with counselling, significantly reduced psychological distress, helped the uncertain become certain, and increased intentions to exercise regularly and eat more fruits and

vegetables. Women rated the aid as acceptable and both women and practitioners were satisfied with the effect of the decision aid on the consultation visit.

Conclusions: High risk women have important support needs that were assessed and provided the basis for developing a decision aid. This breast cancer prevention decision aid shows promise as a useful tool in preparing high risk women for discussion with breast health practitioners.

Further research is warranted to compare the decision aid with counselling to counselling alone or usual care.

Implications for Advanced Nursing Practice: Advanced practice nurses have a role in identifying decision making needs of high risk women, making decision aids available to women who are most likely to benefit from them, and addressing women's needs through program development, risk communication, behaviour modification interventions, and decision support counselling.

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List of Abbreviations

AICR	American Institute of Cancer Research
APN	Advanced Practice Nurse
BSE	Breast Self-examination
CBE	Clinical Breast Examination
CNA	Canadian Nurses Association
DSF	Decision Support Framework
HRBA	High Risk Breast Assessment
HRT	Hormone Replacement Therapy
IES	Impact of Event Scale
NCI	National Cancer Institute
NCIC	National Cancer Institute of Canada
NIH	National Institutes of Health
ONS	Oncology Nursing Society
RCT	Randomized Controlled Trial
SPSS	Statistical Package for the Social Sciences
STAR	Study of Tamoxifen and Raloxifene
WBHC	Women's Breast Health Centre

Chapter One

General Introduction

Breast cancer is an important health issue for women. It is the most common type of cancer occurring in women, with close to 20,000 new cases estimated for the year 2000 (National Cancer Institute of Canada, 2000). Women at high risk of developing breast cancer, hereafter called high risk women, represent about 21% of the adult female population (National Cancer Institute, 1999). The focus for high risk women is prevention. The challenge, however, is to help women understand their risk and decide on prevention strategies without increasing psychological distress. High levels of psychological distress have been associated negatively with women's ability to follow through with regular breast screening practices (Kash, Holland, Halper, & Miller, 1992; Lerman et al., 1993; Lerman, Kash, & Stefanek, 1994).

Recently, the Ottawa Regional Women's Breast Health Centre of the Ottawa Hospital established a High Risk Breast Assessment (HRBA) Clinic to address the needs of high risk women. A mandate of this Clinic is to provide supportive care that includes the provision of informational, emotional, and decisional support. A key to successful outcomes in this program lies in fully understanding women's decision making needs and providing decision support to address these needs. However, there is little published information on women's decision making needs. Previous research focused primarily on sub-groups of high risk women that were seeking genetic counselling (Audrain et al., 1998; Tessaro, Borstelmann, Regan, Rimer, & Winer, 1997). Moreover, even if women's needs are known, the degree to which breast health practitioners alone will address their needs with personal counselling is unclear. Therefore, effective tools are needed to prepare women for counselling. Decision aids have been shown to be efficacious

(O'Connor, Drake et al., 1999; O'Connor, Rostom et al., 1999), but none have been developed for women at high risk of developing breast cancer.

The objectives of this thesis are to: 1) describe the support needs of high risk women; and 2) develop and evaluate a decision aid to meet their decision making needs. The Ottawa Decision Support Framework (DSF) was chosen as the conceptual framework to guide the needs assessment and decision aid development and evaluation (O'Connor et al., 1998a). The research conducted, to accomplish these objectives, is summarized in the following papers.

First, a background paper on breast cancer-related decisions and steps necessary for guiding decision support was written for a clinical audience. This paper, "Nurses Guiding Breast Cancer-Related Decisions: A Decision Support Framework," is included in Appendix A to support the main focus of the thesis. It explored the clinical usefulness of the Ottawa DSF and available decision support tools in strengthening counselling for women making breast cancer-related decisions. Chapters 2 to 5 address the primary objectives of the thesis.

Chapter 2, "Support Needs of Women at High Risk of Breast Cancer: Implications for Advanced Practice Nurses," addresses the first objective of assessing support needs of high risk women. It contains a paper on a descriptive before/after survey of the support needs (informational, emotional, self-care, and decisional support) of women who were referred to the HRBA Clinic between July 1999 and May 2000.

Research to accomplish the second objective of the thesis is described in Chapters 3 and 4. A decision aid was developed to address the informational and decisional support needs identified by high risk women aged 50 and older. The main objectives of the decision aid were to assist women in preparing for their first consultation with breast health practitioners and to make a high quality decision about the use of tamoxifen as a chemopreventive agent. Chapter 3, "The

Development of a Breast Cancer Prevention Decision Aid for Women at High Risk of Breast Cancer,” contains a paper describing the necessary issues considered when developing the decision aid, “Making Choices: Options for Lowering my Risk of Breast Cancer”.

Chapter 4, “Evaluation of a Self-administered Breast Cancer Prevention Decision Aid for High Risk Women Considering Options to Lower their Risk”, contains a paper describing the evaluation of the decision aid in two phases. The main purpose of the first phase, with ten high risk women, was to determine acceptability and clarity of the information presented in the decision aid. Subsequently, in Phase II, the decision aid was evaluated in a before/after study with 17 women who used it in preparation for their first consultation at the HRBA Clinic.

Finally, chapter 5 provides a general discussion and conclusion that integrates the findings from all three main papers with implications for clinical nursing practice and further research.

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Chapter Two

This chapter is based on the following unpublished manuscript:

Stacey, D., DeGrasse, C., & Johnston, L. Support Needs of Women at High Risk of Breast Cancer: Implications for Advanced Practice Nurses. Submitted for publication to the Oncology Nursing Forum.

Contributions of Collaborators

There were three authors involved in this paper: Dawn Stacey (DS), Cathy DeGrasse (CD), and Lisa Johnston (LJ). DS wrote the first draft based on the needs of 20 women, aged 50 and older, seen in the High Risk Breast Assessment (HRBA) Clinic from July to December 1999, including results from five out of eight women on the satisfaction survey. DS and CD reviewed the draft determining the purpose and direction of the final paper. Subsequently, LJ pulled the data on all 97 women seen in the HRBA Clinic from July 1999 when it opened, to May 2000. DS revised the paper with the new findings. CD reviewed the paper for accurate representation of the HRBA Clinic and made editorial comments prior to its submission for publication.

Abstract

Purpose: To identify the informational, emotional, self-care, and decisional support needs of women at high risk of developing breast cancer and describe implications for the role of advanced practice nurses (APNs).

Design: Descriptive before/after survey.

Setting: Urban breast health clinic for women at high risk of breast cancer.

Sample: A consecutive sample of 97 high risk women: pre-menopausal, relative with breast cancer, confirmed breast cancer gene carrier, or 1.66% or greater five-year risk.

Methods: Self-administered health assessment questionnaire completed prior to the first consultation visit and a satisfaction survey completed post-visit.

Main Research Variables: Women's perceived informational, emotional, and decisional support needs; current self-care practices; and satisfaction.

Findings: At baseline, over half identified informational needs such as personal risk of breast cancer, healthy lifestyle practices, screening recommendations, decision making, and chemoprevention trials. Performing monthly breast self examination was the main self-care need. Seventy-five percent wanted information on options, benefits, and risks; and 62% wanted help in clarifying personal values. In the post-visit survey, most women's needs were met: 90% informational needs, 93% emotional needs, and 93% for their involvement in decision making.

Conclusions: Women at higher risk for breast cancer have important support needs that can be assessed, targeted for interventions, and evaluated against the care provided.

Implications for Advanced Nursing Practice: Advanced practice nurses are challenged to develop and administer evidence-based care to address the needs of high risk women. APNs

need specialized skills that include risk communication, behaviour modification interventions, and knowledge of guidance in decision making.

Support Needs of Women at High Risk of Breast Cancer: Implications for Advanced Practice Nurses

Breast health and breast cancer are important health issues for women. The high incidence of breast cancer, global breast health initiatives, and recent results of breast cancer chemoprevention trials have heightened public awareness of and concern about breast cancer risk. Most breast cancers occur in women over age 50, with only 22% occurring in women under age 50 (National Cancer Institute [NCI], 1999; National Cancer Institute of Canada [NCIC], 2000). In addition to increasing age, other major factors that place women at increased risk of breast cancer, hereafter called high risk women, include family history of breast cancer, prolonged menstrual history, and history of breast disease (Gail et al., 1989; Mahon, 1995). Primary and secondary prevention options for high risk women include changing lifestyle practices, using chemoprevention agents, having bilateral prophylactic mastectomies, and increasing breast cancer surveillance. There has been little investigation of the informational, emotional, self-care, and decisional support needs that impact on health-related decision making and actions. With the increasing complexity of knowledge and new technologies in breast cancer prevention, advanced practice nurses (APNs) are challenged to understand and address women's needs by maintaining a health focus that promotes health and prevents other illnesses. This paper will: 1) review research on the support needs of women at high risk of breast cancer; 2) describe the needs of women referred to a new high risk clinic; and 3) discuss implications for the role of the APN in addressing these needs.

Previous research on support needs

Support, according to Stewart (1995), is the provision of information, help, and emotional comfort to enhance coping and feelings of empowerment, make health related decisions,

minimize stress, and promote health, self-care, and appropriate use of health services. For the purposes of this paper, support includes addressing informational, emotional, self-care, and decision making needs.

Informational and emotional support needs. Support needs for high risk women reported in the literature have predominantly focused more narrowly on younger women referred for genetic counselling (Audrain et al., 1998; Hallowell, Murton, Statham, Green, & Richards, 1997; Hopwood et al., 1998; Lloyd et al., 1996; Tessaro et al., 1997). There was only one study that identified the needs of women with a family history of breast cancer, who were not seeking genetic counselling (Chalmers, Thomson, & Degner, 1995). In five of these six studies, interpretation of personal risk was identified as a need by the women (Audrain et al., 1998; Chalmers et al., 1995; Hallowell et al., 1997; Hopwood et al., 1998; Lloyd et al., 1996). In four of six studies, women identified informational needs about strategies for breast cancer detection and prevention (Audrain et al., 1998; Chalmers et al., 1995; Hallowell et al., 1997; Lloyd et al., 1996), as well as, the need for emotional support to help them cope with the psychological stress of being at risk (Audrain et al., 1998; Chalmers et al., 1995; Hopwood et al., 1998; Lloyd et al., 1996). Other needs included bereavement counselling to cope with breast cancer in a family member (Chalmers et al., 1995; Hopwood et al., 1998; Lloyd et al., 1996) and decision support for making the decision about genetic testing (Audrain et al., 1998; Tessaro et al., 1997).

Self-care support needs. Self-care behaviours important for high risk women are focused on primary and secondary breast cancer prevention. Primary prevention decreases risk of cancer by avoiding carcinogen exposure, promoting healthy practices, or using medical interventions such as chemoprevention or prophylactic mastectomy (Mahon, 1995). Primary prevention in breast cancer, that requires self-care, includes: a) limiting alcohol consumption (Longnecker,

1994); b), eating more fruits and vegetables (American Institute for Cancer Research [AICR], 1997); c) increasing physical activity (Friedenreich, Thune, Brinton, & Albanes, 1998); and d) specific to post-menopausal women, avoiding excess body weight (Trentham-Dietz et al., 1997). The AICR (1997) estimates that the risk of breast cancer can be reduced by one-third to one-half through health promotion efforts focused on healthful and sustainable lifestyle practices with the highest benefit seen in women who established healthy diets before puberty. However, it is unclear why more women do not undertake primary prevention measures to reduce their risk.

Secondary prevention employs strategies to identify persons at risk and screen to find cancer early (Mahon, 1995). There are several risk prediction models used to calculate breast cancer risk, each with inherent pros and cons (Armstrong, Eisen, & Weber, 2000). Major risk factors considered in many of these models include advancing age, family history of breast cancer, early menses, late menopause, nulliparous or delayed birth of first child to after age 30, and history of breast disease (Armstrong et al., 2000; Gail et al., 1989; Mahon, 1995). One definition of high risk, using the Breast Cancer Risk Assessment Tool, is a 1.66% or higher five-year risk of breast cancer (NCI, 1998). Risk assessment may also include assessing genetic susceptibility for women with a strong family history of cancer. The breast screening guidelines for women with a family history of breast cancer who are not necessarily eligible for genetic testing, include: a) breast self-examination (BSE) monthly; b) a clinical breast exam every 6 to 12 months; and c) a mammogram yearly in women aged 40 and older or starting ten years younger than the youngest affected relative, but not before 30 years of age (Ontario Cancer Genetics Network, 1999). Gail and Rimer (1998) recommend that women aged 40 to 49, with a risk of breast cancer equivalent to women aged 50 without risk factors, follow the mammography screening guidelines for women aged 50 and older. Although, these guidelines

are available, there is minimal research based-evidence to support them, especially in women under age 50, and they remain somewhat controversial. However, in women, aged 50 and older, routine screening mammograms lower mortality from breast cancer by one-third (Kerlikowske, Grady, Rubin, Sandrock, & Ernster, 1995) and women who practice BSE are 35% less likely to have advanced disease at the time of diagnosis (Mahon, 1995).

Decisional support needs. Primary and secondary prevention options that require careful decision-making, given their controversial nature, are new technologies such as chemoprevention agents, genetic testing, and prophylactic mastectomies (Fisher et al., 1998; Klijn, Janin, Cortes-Funes, & Colomer, 1997; Audrain et al., 1998). Enabling clients to participate in making health-related decisions is an example of empowerment. In a study of 98 healthy women attending genetic counselling, 95% wanted information on genetic benefits, limitations, and risks; 63% wanted advice and recommendations about whether or not to have genetic testing; and 50% wanted a discussion of their personal values (Audrain et al., 1998).

A new health service for high risk women

To address the needs of high risk women, the High Risk Breast Assessment (HRBA) Clinic at the Ottawa Regional Women's Breast Health Centre (WBHC) of the Ottawa Hospital began in July 1999. It is a comprehensive health service specifically targeted for high risk women. Women are eligible for this Clinic if they meet any of the absolute criteria: a) family history of breast or ovarian cancer in two or more first or second-degree relatives; b) breast cancer occurring in one first or second-degree relative, when bilateral or premenopausal in onset; c) atypical hyperplasia; d) lobular carcinoma in-situ; or e) positive genetic screen. Women are also eligible if they have cumulative risk factors resulting in a 1.66% or greater five-year risk of breast cancer using the Breast Cancer Risk Assessment Tool (NCI, 1998).

Services offered in the HRBA Clinic include: a) breast cancer risk assessment; b) options for breast cancer prevention and early detection, including genetic counselling and testing; c) supportive care (i.e. informational, emotional counselling, and guidance in decision making); d) clinical breast examination (CBE); e) diagnostic imaging; and f) clinical management recommendations sent to the primary care provider with ongoing surveillance offered within the clinic for the highest risk women. A multidisciplinary team of breast care experts including an APN, oncologists, surgeons, research coordinator, genetic counsellor, radiologists, radiology technologists, and a social worker collaborate to provide the necessary care and support to the high risk women with referral to other services as required.

An APN acts as the entry point to this Clinic, enhancing accessibility. Following telephone consultation with the APN and prior to their first appointment at the HRBA Clinic, women complete a self-assessment questionnaire (Appendix B). This questionnaire provides the multidisciplinary team with information to: a) permit risk calculation and determine whether the woman is a candidate for genetic counselling; b) identify individual support needs and expectations; and c) identify current lifestyle and screening practices. Therefore, specific proactive planning occurs prior to the scheduled appointment. Follow-up care is based on the woman's risk of developing breast cancer and tailored to a woman's individual choice selection of recommended health promotion and prevention strategies. Active client participation is encouraged at the HRBA Clinic through self-assessment, inviting women to ask questions as partners in their care, involving women in making health-related decisions, enabling women to take action in adopting healthy lifestyle practices, responding to a satisfaction survey, and participating as equal members on an accreditation team, aimed to ensure continuous quality improvement.

Purpose

This study had two purposes: a) to identify the informational, emotional, self-care, and decisional support needs of women at high risk of developing breast cancer; and b) to identify implications for the APN role in addressing these needs.

Methods

Two approaches were used to better understand the needs of a select group of high risk women seen in the HRBA Clinic. First, women's responses to their self-assessment questionnaires completed prior to the first clinic visit between July 1999 to May 2000 were analyzed. The purpose of this analysis was to describe their characteristics, pre-visit needs and expectations, and self-care behaviours. Secondly, a semi-structured satisfaction survey was mailed out in May 2000 with a self-addressed stamped return envelope to all women seen in this Clinic. The satisfaction survey was adapted from a current survey used in the WBHC Breast Diagnostic Clinic that was based on those developed by the Picker Institute (2000). The purpose of this survey was to ascertain women's satisfaction with having their needs met.

Results

Pre-clinic questionnaire. Ninety-seven women were seen in the HRBA Clinic between July 1999 and May 2000 (see Table 2.1). Of the 54 women under age 50, the typical woman who came to the Clinic was 40 years old, had a 1.5% five-year risk of breast cancer, and had a breast cancer family history with 78% having family histories that deemed them as eligible for genetic counselling. Of the 43 women aged 50 and older, the typical woman was 57 years old, had a 3.3% five-year risk of breast cancer, and had a family history of breast cancer with 54% having family histories that deemed them as eligible for genetic counselling. The majority of women were Caucasian, English-speaking, and had completed post-secondary education. The most

common reason for referral in both groups of women was having a family history of breast cancer. Another referral reason for women under age 50 was being a confirmed breast cancer gene carrier and for older women was wanting to find out about the current chemoprevention trial.

The most common informational needs identified, in order of importance, by more than half of the women in both groups were personal risk factors, lifestyle options, guidelines for breast screening, decision making, chemoprevention trial, hormone replacement therapy, genetic testing, and the use of tamoxifen (see Table 2.2). Very few women wanted information on prophylactic mastectomy. The high priority needs were similar for both groups of women with the main difference for medium priority needs being that women under age 50 wanted to know about hormone replacement therapy while older women wanted to know more about the chemoprevention trial. Seventy-five percent of all women identified that information (options, benefits, risks) would be most helpful in making breast health-related decisions, while, 62% identified needing guidance in how to consider personal values involved in the choice (see Table 2.3). Emotional needs were not solicited on the questionnaire nor identified on the comments section by women as personal needs.

The only difference between women of differing age groups in self-care and breast screening practices was reports of mammograms (see Table 2.4). Eighty-six percent of women, aged 50 and older, compared to 63% of women aged 40 to 49, and 29% of women under age 40, reported having had a mammogram within the previous year. For women under age 40 or age 50 plus, 83% reported having had a CBE within the last year compared to only 73% of women aged 40 to 49. About half of all women stated that they practiced monthly BSE, although they reported varying degrees of confidence with their ability. For all ages of women, 13% consumed

more than seven alcoholic drinks a week and 8% smoked (see Table 2.5). Physical activity, intake of fruits and vegetables, and body weight were not routinely documented, however, many women seen in the HRBA Clinic were anecdotally assessed to have had excess body weight.

Responses to post-clinic satisfaction survey. Sixty-one of these 97 women (63%), responded to the semi-structured satisfaction survey that included quantitative questions and an opportunity to provide general comments. Overall, the women were very satisfied that their needs were met. More specifically, women were satisfied with: a) their achieved level of decision making; b) the information provided; and c) the amount of emotional support (see Table 2.6). The high level of satisfaction was also obvious in the comments such as, *"This Clinic is exactly what I had been searching for after two immediate family members were diagnosed with breast cancer"* and *"My appointment there has set high expectations of how health care can be provided"*. Appreciation for the emotional support provided was also evident in several comments and exemplified in the following, *"I was very impressed by the emotional support which is given to a human being by very human beings"*.

Two themes emerging from the other comments included feeling part of the team and comfort with declining participation in the chemoprevention trial. Women's participation in the consultation process was clearly articulated by one woman who said, *"I felt that the team was working with me"* and another woman who stated, *"I felt very comfortable asking questions"*. Women who declined to participate in the chemoprevention trial expressed support in comments such as, *"I felt a bit guilty about my decision so put off calling about it and when I did, the response left me guilt-free"*.

Despite the women's high level of satisfaction, there were several suggestions for improvement. One woman asked for more *"alternative solutions to be available other than*

western-based medicine". Another woman commented, *"I was given excellent information and counselling and then sent on my way"*, but she was surprised that there was no planned follow-up, probably related to the Clinic's standard of referring lower risk women back to their family physician with primary and secondary prevention recommendations. One woman suggested that given the amount of information discussed at the visit, women should be given a take-home form of one's risk of getting breast cancer and recommendations. Finally, 100% of the women would recommend this Clinic to family and friends.

Discussion

Findings, reported by the high risk women in this study, have identified informational, emotional, self-care, and decision support needs. By addressing their needs, women can more accurately understand their risk, feel reassured and satisfied with their care, and take steps forward in health promotion.

Informational and emotional support needs. The common informational needs (e.g. personal risk of breast cancer, healthy lifestyle practices, screening guidelines, chemoprevention trials) are consistent with those identified in the literature by younger women seeking genetic counselling or women with a family history of breast cancer (Audrain et al., 1998; Chalmers et al., 1995; Hallowell et al., 1997; Hopwood et al., 1998; Lloyd et al., 1996; Tessaro et al., 1997). The results of this study indicate that the women were satisfied with the amount of informational and emotional support provided, however, emotional support needs and bereavement needs were not consistently measured. The literature described that emotional and bereavement support were common needs of high risk women and when these needs were not addressed women experienced higher levels of psychological distress (Hopwood et al., 1998; Kash, Holland, Osborne, & Miller, 1995; Lloyd et al., 1996). Anecdotally, some women seen in the Clinic were

assessed to have distress related to unresolved grief over a family diagnosis of breast cancer and consequently received emotional support and/or ongoing grief counselling. Further, the study by Kash and colleagues used a six-week group psycho-educational intervention to: a) provide education about personal risk, as well as breast cancer prevention and screening; b) facilitate problem solving by focusing on active coping; and c) provide emotional support.

Self-care and screening support needs. The high level of adherence to routine screening mammography for women aged 50 and older, observed in this study, is consistent for women who were seeking genetic counselling (Evans, Blair, Greenhalgh, Hopwood, & Howell, 1994; Lloyd et al., 1996). The appropriate use of mammography in women under age 50 would require further investigation to find out if it is consistent with risk-based recommendations (Gail & Rimer, 1998; Ontario Cancer Genetics Network, 1999). Health promotion and screening self-care needs for these women are in performing monthly BSE and establishing healthy body weight. A smaller number of women need to limit alcohol consumption. To date, women who are seen in the HRBA Clinic are verbally informed and given information about healthy lifestyle practices. Yet, the establishment and maintenance of a healthy lifestyle practice is a complex process with physical, psychological, social, and cultural implications (Pender, 1996).

Decisional support needs. Another need, identified by more than two-thirds of the women in this study, is guidance with decision-making. More specifically, women identified that to make a decision about breast cancer prevention options, they wanted information on the options, benefits and risks, and help in clarifying their personal values. These results are consistent with decisional support needs of women considering genetic testing (Audrain et al., 1998). After visiting the Clinic some of these needs were met in that, women did feel part of the team, comfortable asking questions, and satisfied with their involvement in decision making.

Limitations. There are several limitations in this study. First, the sample was limited to high risk women seen in the HRBA Clinic only and warrants further study with other high risk women. Possible ways of accessing these women are through mammography screening programs, breast cancer treatment centres, family practice settings, and community health centres. This study was dependent upon women accurately documenting their informational needs, lifestyle practices, and screening behaviours and as such, some women may have under or over estimated some practices like BSE. Another potential limitation was using a satisfaction survey. Women may have responded favorably based on having established a positive relationship with the health care professionals without necessarily having had their needs met. The generalizability of the findings are also limited given that most of the women were Caucasian, English speaking, and well-educated. Finally, the assessment was done within the first eleven months of opening the HRBA Clinic and several changes occurred that included adding more questions on lifestyle practices to the self-assessment questionnaire and refining clinic operations.

Implications for the APN role

High risk women have many support needs to enable them to make health-related decisions and take action. With the complexity of knowledge and skills required and the new technologies in breast cancer prevention, APNs are challenged to maintain a health focus through evidence-based practice when addressing the needs of high risk women. An oncology APN is a nurse, having graduate education, with expanded clinical, theoretical, and research-based knowledge, and skills that are used in the provision of care to individuals with an actual or potential diagnosis of cancer (Oncology Nursing Society, 1990; Spross & Heaney, 2000). While the competencies of APNs are grouped into five main areas (clinical practice, education,

collaboration/consultation, research, and leadership), it is the effective interaction, blending, and simultaneous execution of the identified skills, knowledge, judgement, and interpersonal attributes in highly complex practice environments and health care organizations that characterize advanced nursing practice (CNA, 1999; Hamric & Spross, 1989). Based on the results of this study, the APN role includes contributing to program development and evaluation, and partnering with high risk women to help them identify and meet their needs (see Table 2.7). Additional skills required, when caring for high risk women, include risk communication, behaviour modification, guidance in decision making, and public education.

Program development and evaluation. The APN, in collaboration with the multidisciplinary team, can provide leadership in the development, implementation, and evaluation of: a) a clinical program; b) evidence-based practice guidelines; and c) standards of care for high risk women.

Risk counselling. Helping women understand their risk of breast cancer is an important role for APNs (MacDonald, 1997). Risk perception is not routinely documented in the HRBA Clinic, although, other studies found that women who over-estimated their risk of breast cancer only contributed further to their emotional distress (Hopwood et al., 1998; Lloyd et al., 1996). Anecdotally, most women in the HRBA Clinic stated, they were relieved because their actual risk was less than their perceived risk. In another study, women had poor recall of their personal risk unless a letter was sent in follow-up to clinic counselling (Evans et al., 1994). To help women put risk in it's place, APNs need to clarify women's perception of risk and provide a written as well as a verbal explanation of the individual's risk. As well, APNs are in an ideal position to provide education about breast cancer susceptibility testing and in one study, proved to be equally effective when compared to genetic counsellors (Bernhardt, Geller, Doksum, &

Metz, 2000). Given the expanding scientific knowledge regarding breast cancer prevention, APNs can assist women in understanding research findings in the context of their individual situation.

Behaviour modification. APNs can enable women to identify their needs for action on lifestyle practices and support women to adopt healthy lifestyle practices. Specific areas that require consideration, are performing monthly BSE and weight management. Using behavioural modification theories, APNs could provide guidance in: a) assessing multiple factors impacting on health promotion and cancer prevention; b) providing appropriate counselling interventions; and c) evaluating outcomes through research (Bandura, 1997; Pender, 1996). In a review of studies by Lev (1997) that used the concept of self-efficacy in cancer prevention, several studies demonstrated that higher self-efficacy predicted increased confidence in performing BSE and participation in breast cancer screening. APNs should also consider the role of various others in addressing the needs of high risk women. For example, in a study by Zimmerman and Connor (1989), family members positively influenced the individuals in changing exercise and fat consumption behaviours. To fully understand the issues affecting high risk women, APNs using their research skills, should consider participatory action research to further explore the best methods for working with high risk women to adopt healthy lifestyle practices (Dickson, 1995).

Guidance in decision making. Using several of the sub-roles, APNs can consider what technologies would be most effective, interpret the new technologies for high risk women, enable these women to make informed decisions, and participate in research to evaluate their effect on health (Appendix A; Loescher, 2000). A theoretical approach that APNs could consider for guiding this population in decision making is the Ottawa Decision Support Framework (Appendix A; O'Connor et al., 1998a). Decisions about chemoprevention, genetic testing, and

prophylactic mastectomy fit well with this framework given these decisions have no clear right choice, uncertain outcomes, a value-laden nature, and involve more effort in deliberation than implementation.

Public education. Another important role for the APN is reaching out to the larger target population through individuals and groups. Currently, the APN, in the HRBA Clinic, provides education sessions on breast health as requested by women's groups in the community. Another option is to consider women, seen in the HRBA Clinic, as breast health messengers to target other women. This option is supported by findings of a strong sense of altruism that was seen in focus groups with women attending genetic counselling (Tessaro et al., 1997). To help these women be messengers, one suggestion is to create an informational resource on "What you can do?".

Conclusions

Given the controversial new technologies and informational, emotional, self-care, and decisional support needs of high risk women, breast cancer risk is an important but complex health issue. APNs working with high risk women or groups of women will continually be challenged to maintain a health focus. APNs, with their advanced knowledge and skills that include program development, risk communication, bereavement counselling, decision-making, and establishing healthy lifestyle practices have an important role in addressing the support needs of high risk women.

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Table 2.1

Demographics: Women Seen in the High Risk Breast Assessment Clinic

	Age 49 or under (n = 54)	50 & over (n = 43)
Age	40.5 median (range 25-49)	56.0 median (range 50-70)
<u>Reason for referral</u>		
Family history	44 (81.5%)	22 (51.2%)
Positive gene	6 (11.1%)	3 (7.0%)
Chemoprevention trial	2 (3.7%)	14 (32.6%)
Chemoprevention	0	1 (2.3%)
Lobular carcinoma in-situ	1 (1.9%)	2 (4.7%)
Other	1 (1.9%) unknown	1 (2.3%) ovarian cancer
Family history of breast cancer	52 (96.3%)	39 (90.7%)
Five-year risk using Breast Cancer Risk Assessment Tool (NCI, 1998)	1.15 median (range 0.1-4.0)	3.0 median (range 0.7-8.1)
Eligible for genetic counselling	42 (77.8%)	23 (53.5%)
Post-secondary school education	48 (88.9%)	35 (81.4%)
<u>Language spoken</u>		
English only	39 (72.2%)	31 (72.1%)
English & French	12 (22.2%)	9 (20.9%)
English & Italian	3 (5.6%)	2 (4.6%)
English & Spanish	0	1 (2.3%)
<u>Race</u>		
Caucasian	45 (83.3%)	42 (97.7%)
Jewish	2 (3.7%)	1 (2.3%)
Oriental/Asian	2 (3.7%)	0
Metis	4 (7.4%)	0
Black	1 (1.8%)	0

Table 2.2

Informational Support Needs: Women Seen in the High Risk Breast Assessment Clinic

Topics women wanted to discuss at their visit:	Both Groups N=97	Age 49 or under n=54	50 & over n=43
Personal risk of breast cancer	85 (87.6%) 1*	49 (90.7%) 2*	36 (83.7%) 1*
Breast screening	83 (85.6%) 2*	50 (92.6%) 1*	33 (76.7%) 3*
Lifestyle options	83 (85.6%) 2*	48 (88.9%) 3*	35 (81.4%) 2*
Decision making	66 (68.0%) 3*	37 (68.5%)	29 (67.4%)
Chemoprevention trial	63 (64.9%)	32 (59.5%)	31 (72.1%) 4*
Hormone replacement therapy	61 (62.9%)	38 (70.4%) 4*	23 (53.5%)
Genetic testing	56 (57.7%)	33 (61.1%)	23 (53.5%)
Tamoxifen	49 (50.5%)	28 (51.9%)	21 (48.8%)
Prophylactic mastectomy	27 (27.8%)	17 (31.5%)	10 (23.3%)

* Priority ranking

Table 2.3

Decisional Support Needs: Women Seen in the High Risk Breast Assessment Clinic

Topics women wanted discussed before making a decision about options to lower their risk of breast cancer	Both Groups n = 97	Age 49 or under n = 54	50 & over n = 43
Information on options, benefits and risks	73 (75.3%)	41 (75.9%)	32 (74.4%)
Guidance in values clarification	60 (61.9%)	32 (59.2%)	28 (65.1%)
Learning about sources of information and support	47 (48.5%)	28 (51.9%)	19 (44.2%)
Information on how others have made the decision	37 (38.1%)	20 (37.0%)	17 (39.5%)

Table 2.4

Self-care and Screening Practices: Women Seen in the High Risk Breast Assessment Clinic

	Age < 40 n = 24	Age 40-49 n = 30	50 & over n = 43
<u>Mammogram:</u>			
Within 1 year	7 (29.1%)	19 (63.3%)	37 (86.0%)
Within 2 years	11 (45.8%)	26 (86.7%)	42 (97.7%)
Never had one	10 (41.7%)	2 (6.7%)	0
Clinical breast exam within 1 year	20 (83.3%)	22 (73.3%)	36 (83.7%)
<u>Breast self-examination:</u>			
Monthly	10 (41.7%)	15 (50.0%)	20 (46.5%)
Every 2-6 months	9 (37.5%)	11 (36.7%)	15 (34.9%)
Every 7-11 months	0	2 (6.7%)	2 (4.7%)
Once a year	2 (8.3%)	0	3 (7.0%)
Never	3 (12.5%)	2 (6.7%)	3 (7.0%)

Table 2.5

Lifestyle Practices: Women Seen in the High Risk Breast Assessment Clinic

	Age 49 or under n=54	50 & over n=43
Alcohol > 7 drinks per week	7 (13.0%)	6 (14.0%)
Smokes	5 (9.3%)	3 (7.0%)

Table 2.6

Satisfaction: Women Seen in the High Risk Breast Assessment Clinic (n = 61)

	Yes, definitely/ completely	Yes, somewhat	No	No Answer
Informational needs met	55 (90%)	6 (10%)	0	0
Emotional needs met	57 (93%)	1 (2%)	0	3 (5%)
Involved in decision making	57 (93%)	2 (3%)	0	2 (3%)
Recommend clinic to others	59 (97%)	2 (3%)	0	0

	Excellent	Very Good	Good	Fair	Poor
Overall quality of care	43 (70%)	14 (23%)	2 (3%)	0	0

Table 2.7

APN Role in Addressing the Needs of High Risk Women using a Health Focus

	Women at High Risk of Breast Cancer (examples)	Advanced Practice Nurses (predominant sub-roles with examples)	Women's Identified Needs with Examples
Accessibility to Health Resources	• Self-referral or physician referral to breast health services • Educational resources • Cultural sensitivity	<u>Direct care</u> • Act as entry point • Collaborate with women to advocate for breast health • Develop educational resources that are appropriate culturally, socially, and educationally for the population • Develop programs in response to needs of high risk women	<u>Practical needs</u> • Written plan for follow-up and summary of options
Health Promotion & Illness Prevention	• Health promotion (i.e. eating fruits & vegetables, physical activity) • Avoiding carcinogens (i.e. alcohol, excess body weight, tobacco) • Chemopreventive agents (i.e. Tamoxifen, investigative therapy) • Surgical interventions (i.e. prophylactic mastectomy) • Risk identification (i.e. risk factors, genetic susceptibility) • Breast screening (i.e. breast self-exam, clinical breast exam, mammography)	<u>Direct care</u> • Assess factors impacting on healthy lifestyle practices. • Provide behavioral modification counselling • Promote self-efficacy • Encourage participation of significant others • Assess risk perception & risk • Determine genetic susceptibility • Provide pre-genetic testing education • Interpret risk tailored to each woman • Provide bereavement counselling, organize programs or groups <u>Educator</u> • Educate others on healthy lifestyle and screening guidelines based on level of risk <u>Researcher</u> • Evidence-based clinical practice • Participate in studies targeted at health promotion	<u>Priority of informational needs:</u> • Personal risk of breast cancer • Healthy lifestyle practice i.e. physical activity, weight loss, limiting alcohol • Breast screening i.e. Breast self-examination • Investigative agents

	Women at High Risk of Breast Cancer (examples)	Advanced Practice Nurses (predominant sub-roles with examples)	Women's Identified Needs with Examples
Appropriate use of Technology	• Chemopreventive agents • Surgical interventions • Genetic testing • Information & internet • Appropriate means to provide information to women	<u>Direct care</u> • Provide evidence-based verbal and written information to women • Interpret new technologies • Enable women to make informed choices • Guide in decision making <u>Educator</u> • Educate others on new technologies – risks, benefits, impact on care & health <u>Research</u> • Evaluate impact of new technologies on health • Participate in research (i.e. breast cancer prevention decision aid) <u>Leadership</u> • Professional development on new technologies	<u>Decisional support needs</u> • Information on options, benefits & risks • Help clarifying personal values • Guidance in decision making for health-related decisions such as chemoprevention, genetic testing, or prophylactic mastectomy
Participation of Consumers	• Identify needs • Self-help groups • Self-care • Clients planning and making health-related decisions	<u>Direct care</u> • Empower women to identify their needs • Use of Pre-visit self assessment questionnaire • Address their needs • Enable women to be active in planning and making health-related decisions <u>Collaborator</u> • Work with women to identify needs • Advocate for getting these needs met <u>Research</u> • Collate needs from pre-visit self-assessment • Administer a Satisfaction Survey • Facilitate focus groups • Conduct participatory action research • Perform a community assessment	<u>Emotional needs</u> • Support in coping with knowledge of being at high risk. <u>Practical needs</u> • To be able to help others by participating in research, encouraging women to attend breast health programs • Further explanation for the pre-visit self-assessment.

Chapter Three

This chapter is based on the following unpublished manuscript

**The Development of a Breast Cancer Prevention Decision Aid for Women at High Risk
of Breast Cancer.**

The Development of a Breast Cancer Prevention Decision Aid for Women at High Risk of Breast Cancer

Women who are concerned about their risk of breast cancer are faced with several options each with different benefit/risk profiles. One such option is the use of tamoxifen as a chemoprevention agent. In 1998, the results of the first three breast cancer prevention drug trials were inconsistent (Fisher et al., 1998; Powles et al., 1998; Veronesi et al., 1998). Common risks of taking tamoxifen, identified in these studies, were uterine cancer, cataracts, and thromboembolic events. Despite these controversial results, tamoxifen was approved for women at high risk of breast cancer. The American clinical practice guidelines clearly state that, women should carefully consider the risks and benefits of tamoxifen when making their decision (Chlebowski & Collyar, 1999). Given the potential benefits and serious risks, women at high risk for developing breast cancer faced with the decision to use tamoxifen are likely to experience difficulty in making this decision.

Decision aids are a formal approach that can be used to provide decision support for individuals considering health-related decisions. Decision aids, according to O'Connor, Fiset, and colleagues (1999), are structured "interventions designed to help people make specific and deliberative choices among options by providing (at a minimum) information on the options and outcomes relevant to the person's health status" (p. 67). A systematic review of 17 randomized trials with decision aids revealed that the use of decision aids improves knowledge of options and outcomes, reduces decisional conflict, and facilitates individuals to be more active in decision making with no effect on anxiety (O'Connor, Rostom et al., 1999). Currently there are no decision aids focused on chemoprevention for breast cancer.

There are six key considerations when developing a decision aid: 1) the need for a decision aid; 2) the feasibility of development; 3) its objectives; 4) the theoretical framework used to guide its development; 5) methods used within the aid to provide decision support; and 6) criteria for evaluation (O'Connor, Fiset et al., 1999). Guided by these six issues, the purpose of this paper is to describe the development of a decision aid for women, aged 50 and older at high risk of developing breast cancer, who are considering chemoprevention and other options to lower their risk of breast cancer.

1. The need

To establish the need for a breast cancer prevention decision aid, the following criteria needed to be examined: a) the magnitude of the issue; b) the availability of evidence for prevention options; c) the informational and decisional support needs of high risk women; and d) the availability of a breast cancer prevention decision aid.

a. Magnitude of the problem. Breast cancer is the most common type of cancer in women, affecting one in nine women during their lifetime and ranking second only to lung cancer as a cause of cancer-related deaths (National Cancer Institute of Canada [NCIC], 2000). More than two-thirds of breast cancers occur in women over age 50, with about half occurring in women aged 50 to 69. Women at high risk of breast cancer, hereafter called high risk women, may be defined as a 1.66% or greater five-year risk of developing breast cancer (Chlebowski & Collyar, 1999). This represents about 21% of the adult female population (National Cancer Institute [NCI], 1999).

b. Available evidence on breast cancer prevention options. Primary and secondary breast cancer prevention activities are aimed at developing and maintaining healthy lifestyle practices,

using chemopreventive agents, undergoing prophylactic mastectomy, and screening to find cancer early (Armstrong, Eisen, & Weber, 2000; Mahon, 1995).

The modifiable *lifestyle practices* most strongly linked to primary prevention of breast cancer are diet, exercise, alcohol use, and body weight. According to cohort and case control studies, women aged 50 and older can lower their risk of breast cancer by: a) limiting alcohol to one drink a day (Longnecker, 1994); b) maintaining a healthy body weight after menopause (Trentham-Dietz et al., 1997); c) consuming more fruits and vegetables (American Institute for Cancer Research [AICR], 1997); and d) exercising regularly (Friedenreich, Thune, Brinton, & Albanes, 1998). The results are less consistent among studies evaluating the benefits of fibre (Cline & Hughes, 1998) and lower fat (Boyd et al., 1997; Boyd, Martin, Noffel, Lockwood, & Trichter 1993; Holmes et al., 1999). Recent laboratory research of soy's effect on lowering the risk of breast cancer is suggesting promising results (Cline & Hughes, 1998). Overall, the AICR (1997) estimates that the risk of breast cancer in women can be reduced by one-third to one-half through health promotion efforts focusing on healthful and sustainable lifestyle practices. The American (1999a, b) and Canadian (1999a, b, c) Cancer Societies as well as the American Dietetic Associations and Dietitians of Canada (Affenito & Kerstetter, 1999) provide general recommendations for lifestyle choices that are consistent with these results (see Table 3.1).

The newest strategy in primary prevention of breast cancer is the use of *tamoxifen* as a chemopreventive agent. Tamoxifen, used as a hormone therapy for the treatment of breast cancer since the 1960's, works by binding to the estrogen receptors in tissues such as the breast and blocking the effects of estrogen (Gould, Gates, & Miaskowski, 1994). Three trials comparing tamoxifen to placebo have been reported. The Italian (Veronesi et al., 1998) and British (Powles et al., 1998) trials found no prevention benefit, but the larger North American trial (Fisher et al.,

1998) demonstrated a 45% reduction in the incidence of breast cancer (see Table 3.2). The British and Italian trials when compared to the North American trial had smaller sample sizes with fewer numbers of breast cancer events and allowed concurrent use of hormone replacement therapy. As well, in the Italian trial, women were at low risk for breast cancer and only 149 out of 5408 women completed the five years of treatment (Chlebowski & Collyar, 1999; Veronesi et al., 1998). The British women were younger with much stronger family histories of breast cancer occurring in premenopausal women and the length of intervention was eight years rather than the standard five years (Chlebowski & Collyar, 1999; Powles et al., 1998).

In addition to the estrogenic effects on breast cells, tamoxifen also affects the bones, endometrium, and vascular system resulting in both benefits and risks (see Table 3.2). The beneficial effect on the bone has resulted in a decrease in hip, radius, and vertebral fractures (Fisher et al., 1998). Previous studies with tamoxifen found lower levels of serum total cholesterol and low-density lipoprotein cholesterol (Grey, Stapleton, Evans, & Reid, 1995). However, in the North American prevention trial, no significant change in myocardial infarction rate was reported (Fisher et al., 1998). The serious health risks associated with tamoxifen use are increased risk of endometrial cancer and thromboembolic events such as deep vein thrombosis, stroke, and pulmonary embolism (Fisher et al., 1998; Day et al., 1999, Powles et al., 1998; Veronesi et al., 1998). These risks were particularly high in women aged 50 and older. The North American trial also reported an increase in cataracts, hot flashes, and vaginal symptoms among tamoxifen users (Day et al., 1999; Fisher et al., 1998). Further, women on tamoxifen experienced a small impact on sexual function causing decreased interest in sex, and difficulty becoming sexually aroused and having an orgasm (Day et al., 1999). There was no change in body weight or in frequency of depression between women who took tamoxifen and those who took a placebo

(Day et al., 1999). All of these benefits and risks must be weighed by high risk women, when making the decision about taking tamoxifen as a chemoprevention agent.

Another chemopreventive option is to participate in the clinical trial titled, "The Study of Tamoxifen and Raloxifene", better known as the *STAR Trial*. Raloxifene is a selective estrogen receptor modulator that is approved for use in the prevention and treatment of osteoporosis in postmenopausal women (Chlebowski & Collyar, 1999). Preliminary reports from the osteoporosis trials suggest that raloxifene may be associated with a lower risk of developing breast cancer (Cummings et al., 1999; Delmas et al., 1997; Ettinger et al., 1999). With raloxifene, the risk of thromboembolic events is similar to that of tamoxifen. Yet, there does not appear to be a risk of uterine cancer and hot flashes are potentially less severe with raloxifene. A side effect unique to raloxifene is leg cramps. Until further evidence emerges, raloxifene is only approved as a breast cancer preventive agent within a clinical trial setting (Chlebowski & Collyar, 1999).

Choosing to have a *prophylactic mastectomy* is an inherently difficult decision for high risk women. The decision requires weighing the risks of a major disfiguring surgery and the potential psychological distress against the benefit of lowering the risk of breast cancer by 90% to 95% (Klijn, Janin, Cortes-Funes, & Colomer, 1997). Prophylactic mastectomy is usually an option reserved for women who are confirmed to be breast cancer gene carriers (Armstrong et al., 2000).

High risk women also have the option of participating in more *intensive surveillance* for breast cancer that is tailored to their risk status. Screening guidelines for women aged 50 and older with a family history of breast cancer, but, not necessarily eligible for genetic testing, recommend that women perform breast self-examination monthly, have a clinical breast

examination every six to twelve months, and have a mammogram yearly (Ontario Cancer Genetics Network, 1999). However, these guidelines are controversial given that there is minimal research based-evidence to support them.

c. Decisional support needs. Three approaches used to determine the decisional support needs of high risk women were: a) a review of the self-assessment questionnaire completed by high risk women prior to attending a high risk breast assessment clinic; b) a review of the literature; and c) interviews with key informants. The first approach involved refining a self-assessment questionnaire specific to informational and decisional support needs of women referred to the Ottawa Regional Women's Breast Health Centre (WBHC) of the Ottawa Hospital, High Risk Breast Assessment (HRBA) Clinic. The questions were developed based on the risk factors associated with breast cancer, screening recommendations, related factors to general health status, and the Ottawa Decision Support Framework (Appendix A; O'Connor et al., 1998a). Of the 43 women aged 50 and older who completed the questionnaire, 67% wanted help in decision making (see Chapter 2). Additionally, 84% wanted to know their personal risk of breast cancer, 74% wanted information on the options, benefits and risks, 65% wanted help in clarifying their personal values, 44% wanted to learn about sources of information and support, and 40% wanted information on how others had made their decision. These results are consistent with a study that identified the decisional support needs of women considering genetic testing (Audrain et al., 1998).

In the literature review, as the second approach, there were no studies published on the process by which women make the decision to take tamoxifen as a chemopreventive agent. To further understand how women might make a decision about the use of tamoxifen, a literature review was completed for similar health-related decisions such as hormone replacement therapy

(HRT), participation in screening mammograms, testing for genetic susceptibility to breast cancer, and choices of breast cancer surgery options. From this review, it was determined that HRT was a health-related decision that was most similar to using tamoxifen as a chemopreventive agent. Both decisions involved healthy women deciding on the use of a medication to prevent potential disease. Women considering HRT, identified decision making needs that included: a) information on risk for heart disease or osteoporosis; b) opinions of others (i.e. experience of family members taking HRT, doctor's advice); c) acknowledgement of concerns about altering a natural body process; and d) knowledge of benefits including desired relief of menopausal symptoms (Andrist, 1998; Hunter, O'Dea, & Britten, 1997; Papaioannou et al., 1998; Saver, Taylor, & Woods, 1999). When comparing decision making for HRT to that of tamoxifen, the primary limiting factor is that many women motivated to use HRT do so in response to menopausal symptoms rather than for the purposes of disease prevention (Andrist, 1998; Hunter et al., 1997).

The third approach involved key informant interviews using structured interview questions that were developed using the Ottawa Decision Support Framework (Appendix A; O'Connor et al., 1998a). A convenience sample of seven key informants included: a nurse breast examiner working in a provincial breast screening program; medical oncologist; breast surgeon; breast health / breast cancer advanced practice nurse; breast cancer prevention research nurse; family physician; and two breast cancer survivors. The difficult decisions that were identified by more than half of the informants were lifestyle habits, early detection practices, and taking tamoxifen as a chemopreventive agent. The factors identified as impacting most on these difficult decisions were the lack of information and the need for guidance in weighing benefits and risks. Lifestyle changes were identified as the most difficult, as exemplified by one

participant who said, *"It is difficult to make a lifestyle change after 50 years"*. Regarding decision making, six of the seven participants stated that women should be the primary decision makers; while the other participant said that the decision making should be shared between the practitioner and the woman. Others who were identified most often as being involved in the decision making included family members and family physicians. Six of seven participants identified that women require access to health care professionals for counselling on their options for breast cancer prevention; while four of the seven identified access to peer support groups as necessary. All seven participants identified that women also required written information resources prepared by a team of experts.

d. Availability of decision aids. Several decision aids have been developed for health-related decisions but there are no decision aids specific to breast cancer prevention.

Summary of the need. The need for a decision aid was confirmed by establishing that the decision was common and important, and the evidence on efficacy of tamoxifen indicated that women needed to balance benefits against risks. However, decision support needs for high risk women aged 50 and older who are considering options to lower their risk of breast cancer are: a) realistic understanding of their personal risk of breast cancer; b) accurate information on healthy lifestyle practices, breast screening guidelines, risks and benefits of tamoxifen, and chemoprevention clinical trials; c) help in considering the opinions of others; d) clarification of personal values impacting on the decision; and e) guidance in making a decision. To help address these decisional support needs, women require access to health care professionals for counselling with supporting educational resources. A Breast Cancer Risk Assessment Tool (NCI, 1998) assesses risk but provides little information on options and outcomes of tamoxifen and no information on other strategies. There are no decision aids available for high risk women.

2. The feasibility

The development of a breast cancer prevention decision aid is feasible if there is evidence of the efficacy of prevention options, a risk assessment tool, access to expert practitioners, and an appropriate setting to disseminate the information.

Evidence for prevention options. Published evidence is available on healthy lifestyle practices for breast health (AICR, 1997), breast screening guidelines for high risk women (Ontario Cancer Genetics Network, 1999), outcomes of tamoxifen in a chemoprevention setting (Day et al., 1999; Fisher et al., 1998), and clinical practice guidelines on the use of tamoxifen (Chlebowski & Collyar, 1999).

Risk assessment tool. A decision aid, according to the definition, must provide information on outcomes relevant to the person's health status (O'Connor, Fiset et al., 1999). Many studies also tailor the probabilities of outcomes to patients' clinical risk. In breast cancer prevention, one must first determine an individual's risk to be able to individualize the options and potential outcomes. As well, 84% of high risk women want to know their personal risk of breast cancer (see Chapter 2). The revised Gail Model is the most commonly used risk assessment model (Armstrong et al., 2000; Gail et al., 1989). This model considers the women's current age, age of menarche, age at first full-term pregnancy, number of previous breast biopsies, personal history of atypical hyperplasia found on biopsy, race, and number of first-degree relatives with breast cancer to calculate her risk. For example, a white woman who is 50 years old, started her menses at age 11, had her first child at age 18, and has one first degree relative with breast cancer has a 2.0% five-year risk of breast cancer. The revised Gail Model is the basis for the Breast Cancer Risk Assessment Tool computer program (NCI, 1998) and can be ordered on-line free-of-charge at the NCI web site (NCI, 1999) or by calling 1-800-4-CANCER.

Limitations of this risk assessment tool are that family history is restricted to first-degree relatives only and it does not account for genetic testing results.

Access to expert practitioners. Feasibility also requires having access to experts for the development of the decision aid and for the provision of counselling on breast cancer prevention options. Practitioners who were accessible and interested in the development of such a decision aid included experts in: a) breast cancer prevention; b) the use of tamoxifen; c) patient education; and d) women's health issues such as osteoporosis and hormone replacement therapy. Some experts on this project had links to a provincial guideline development group (Cancer Care Ontario), whose task was the ongoing summary of evidence and dissemination of breast cancer-related information.

Setting to disseminate the decision aid. Finally, once a decision aid is developed, it is necessary to have a clinical setting in which the decision aid can be evaluated and counselling provided. In July 1999, the HRBA Clinic (see Figure 3.1) started with the purpose of providing a comprehensive breast health service specifically targeted to high risk women. The services include: a) breast cancer risk assessment; b) supportive care (i.e. informational, emotional counselling, and guidance in decision making); c) clinical breast examination; d) diagnostic imaging; e) options for breast cancer prevention; and f) clinical management recommendations sent to the primary care provider with ongoing surveillance offered within the Clinic for the highest risk women. This clinical setting also received approval in 1999 as a site for the STAR Trial.

3. The objective

The objective of the decision aid is to help high risk women, aged 50 and older who are considering options to lower their risk of breast cancer, prepare for consultation with a breast

health practitioner and make a high quality decision about the use of tamoxifen as a chemopreventive agent. A high quality decision is informed, consistent with personal values, acted on, and one in which the patient expresses satisfaction, not only with the decision itself but also with the process used to reach it (O'Connor et al., 1998a). More specifically, the aim of the decision aid is to directly improve the decision making in high risk women by:

- a) providing information on the options to lower the risk of breast cancer;
- b) describing potential outcomes of benefits and risks associated with and without tamoxifen tailored to the individual's risk status;
- c) clarifying personal values associated with outcomes related to tamoxifen; and
- d) guiding women in the process of making a decision.

3. The theoretical framework

The Ottawa Decision Support Framework (DSF) is the theoretical framework used to guide the development and evaluation of a breast cancer prevention decision aid (Appendix A; O'Connor et al., 1998a). It was chosen, given its fit with the decisional support needs of high risk women and previous use in guiding the development of decision aids. Decisions best suited for the Ottawa DSF are defined as ones in which: a) there is no clear right choice; b) it is stimulated by a new diagnosis; c) there are value-laden outcomes; and d) it requires more effort during deliberation with less effort during the implementation of the decision (O'Connor et al., 1998a). The decision to use tamoxifen as a chemopreventive agent fits with this definition. This framework also acknowledges other influences such as the shared experiences of other high risk women who have faced this decision or fears of taking a medication that will alter a natural body process.

The Ottawa DSF uses a three-step process to: a) assess client and practitioner determinants of decisions; b) provide decision support; and c) evaluate the decision process and outcomes (see Figure 3.2) (O'Connor et al., 1998a). Determinants of decisions are factors that influence decisions and when sub-optimal lead to poor decision making. Examples of sub-optimal determinants include: a) perceptions of the decisions (e.g. inadequate knowledge, unrealistic risk expectations, unclear values, or decisional conflict); b) perceptions of others (e.g. biased perceptions of variation in others' opinions, social pressures, inadequate support); and c) personal and external resources to make the decisions (e.g. limited skills in decision making, finances) (O'Connor, Fiset et al., 1999).

Decision aids are designed to address sub-optimal determinants by providing: accurate, balanced, and tailored information on options, benefits, and risks; clarifying patients' values; and enhancing decision making skills (O'Connor, Fiset et al., 1999). For example, with high risk women, knowledge may be improved by providing information on options with associated outcomes to lower their risk of breast cancer. Unrealistic risk expectations may be re-aligned by providing written and verbal explanations of probabilities of outcomes that are tailored to the woman's risk. Unclear values are addressed by helping the women judge the value of outcomes by describing them in familiar, simple, and experiential terms and by providing women the opportunity to rate the level of importance of the benefits and risks. Clarity regarding the perceptions of others' opinions may be achieved through the presentation of all options, and in some cases, the provision of examples with associated statistics of choices made by others. Decision making skills may be enhanced by guiding or coaching women in considering their personal issues involved in the choice and in communicating preferences. As a result of interventions targeted at sub-optimal determinants, patients may experience decreased decisional

conflict, become more certain about what to choose, and therefore, may be more likely to act upon their decisions (O'Connor, Fiset et al., 1999).

Several decision aids were developed and evaluated using the Ottawa DSF including one on HRT (O'Connor, Drake et al., 1999). Decision aids, based on the Ottawa DSF, were effective at: a) improving individuals' knowledge; b) creating more realistic expectations; c) lowering decisional conflict; d) improving certainty about choice; e) improving feelings of being informed; f) improving clarity of values; g) making individuals feel supported in their decision making; and h) helping the uncertain become certain in their choice (Drake, Engler-Todd, O'Connor, Surh, & Hunter, 1999; Fiset et al., 2000; Hing et al., 1999; O'Connor et al., 1998a,b).

5. The methods in the decision aid

Methods used in decision aids include: providing information on the clinical problem, options, and outcomes with or without tailored probabilities; implicit or explicit values clarification; information on others; coaching or guidance in deliberation, communication, and implementation of the decision; and mode of delivery (O'Connor, Fiset et al., 1999). Most of these strategies were used in the decision aid, "*Making Choices: Options for Lowering Your Risk of Breast Cancer*" to address the decisional support needs of high risk women. The decision aid is a self-administered audio-guided booklet and worksheet. The 24-page illustrated booklet provides bulleted information to allow women to visually follow along with the audiotape (Appendix C). The worksheet provides individualized breast cancer risk information and walks the woman through the steps in decision making with space to respond to checklists, to shade preferences, and to write down questions (Appendix D). The 35-minute audiocassette, recorded with an easy-listening female voice, tells the story (Appendix E). A musical sound signals the reader to turn the page. At the end of the decision aid, references to additional consumer breast

health information is listed that includes books, web sites, and toll-free telephone hotlines.

Credibility is assured by providing the list of members of the expert review panel and the supporting references for the decision aid. The specifics about each element in this decision aid are addressed below.

General information. In the breast cancer prevention decision aid, general information is provided on breast cancer, risk factors, and breast screening for high risk women. Proven lifestyle options, as well as those under investigation, are presented with the levels of evidence for each (Appendix C). The four levels of evidence are described using gold for randomized trials, silver for observational studies, bronze for expert opinion, and lab for laboratory research. Tamoxifen as a chemoprevention agent is presented with a gold rating. Risks, benefits, and side effects of tamoxifen are provided in a description format as well as numerically. Finally, the option of participating in the current chemoprevention trial is introduced.

Personal probabilities of outcome. Probabilities of potential outcomes, based on each woman's individual risk of breast cancer, are demonstrated using dots representing 1000 women. The individual's five-year risk of breast cancer is calculated using the Breast Cancer Risk Assessment Tool (NCI, 1998) and hand written onto the worksheet (Appendix D). The probabilities for outcomes associated with tamoxifen were calculated based on the results for women aged 50 and older from the North American breast cancer prevention trial (Fisher et al., 1998). Then, the potential reduction in breast cancers for the individual woman is calculated using her personal risk and the results from the North American trial with the number hand written on the worksheet.

Values clarification. Women are asked to weigh the benefits and risks of tamoxifen. The decision aid uses a balance scale to explicitly clarify values on a personal worksheet (Appendix

D). First, women are asked to add additional benefits or risks of tamoxifen. Next, the women are instructed to shade the boxes entirely for outcomes that are personally most important, partially shade boxes for outcomes of moderate importance, and not to shade outcomes of least importance. Finally, women are asked to mark their leaning along a 15-point line anchored by taking tamoxifen on one end, and not taking tamoxifen on the other end with unsure in the centre.

Guidance. The booklet and worksheet outline seven steps to guide women in making their decisions about lifestyle, breast screening, and chemoprevention. To demonstrate these steps, examples are provided of what two other women have done; one who chose to take tamoxifen and the other woman who chose not to take it. The audio-tape concludes with some suggestions on communicating preferences with the practitioner.

Format. Decision aids have been delivered using several formats including audiotape/workbooks, interactive videodisc, decision boards, posters, written vignettes, brochures, computer programs, and interview guides with tradeoff exercises (O'Connor, Fiset et al., 1999). The choice of format should consider consumer preference, effectiveness as a teaching strategy, cost, the way it is administered, literacy level, and equipment required. The most desirable methods for getting health-related information, in order of importance as identified by Canadians in a national survey, are booklets, physician counselling, Internet, CD-Roms, audio-tapes, and videos (O'Connor et al., 2000). However, in a meta-analysis of strategies for teaching patients, audio-tapes alone had the largest effect on teaching with an effect size of 0.58 compared to other types of instructional media (Theis & Johnson, 1995). In this same analysis, verbal instruction alone had the smallest effect size of 0.28.

To address the preferences of consumers while using an effective teaching strategy, it was decided to combine written, audio-cassettes, and verbal consultation. The take-home audio-guided booklet with a worksheet mode of delivery is easy to use, given the ability to be self-administered and the availability of equipment. The worksheet was designed as separate from the booklet to facilitate sharing it with the practitioner during consultation. Finally, the cost of producing and updating a booklet, worksheet, and audio-tape type of decision aid is considerably less than developing videos or computer programs (Treacy & Mayer, 2000). The booklet and worksheet were created on a personal computer with copies made on a colour printer. The audio-cassette was professionally recorded with the original duplicated as required.

6. The evaluation

There are several strategies to consider when planning the evaluation. These include using a development panel of experts, review panel of potential users, pilot studies using various designs (e.g. test-retest, before/after, post-test only), and either quasi experimental or randomized trials (O'Connor, Fiset et al., 1999). For the development of this decision aid, the first phase conducted was the development of the booklet, worksheet and audio-script that were drafted and redrafted by a panel of expert practitioners. The panel included medical oncologists, family physicians, a breast surgeon, a gynecologist specialized in menopause, a rheumatologist specialized in osteoporosis, a breast health / breast cancer advanced practice nurse, decision aid experts, a patient education specialist, and a career scientist focused on consumer decision making. This panel of experts evaluated the decision aid for accuracy, comprehensibility, and appropriateness of content.

The next phases in the evaluation process are to pre-test the decision aid for acceptability and clarity on high risk women who are potential users and then study the effectiveness of the

decision aid on women at the point of decision making in a before/after design. The Ottawa DSF can be used to guide the evaluation in a before/after study.

Conclusions

Women at high risk of developing breast cancer have several needs for decision support, that can be addressed using decision aids. A structured decision aid entitled "*Making Choices: Options for Lowering Your Risk of Breast Cancer*" was developed to inform and help prepare women for consultation with a breast health practitioner and subsequent decision making. However, further evaluation, to examine the acceptability as well as the decision aid's effect on the quality of decision making is required using the decision aid with high risk women.

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Table 3.1

Breast Health Recommendations by Organization

	Canadian Cancer Society www.cancer.ca		American Cancer Society www.cancer.org		American Dietetic Society & Dietitians of Canada
	All Cancers 2000a, b	Breast Cancer 2000c	All Cancers 1999a	Breast Cancer 1999b	Breast Cancer (Affenito & Kerstetter, 1999)
Regular Physical Activity	20-30 min 3x/week	Yes	30 min /day most days of week	Yes	-
Healthy Weight	Yes	Yes	Yes	Yes	Yes, BMI 20-25
Limit Alcohol	No more than 1/day	Yes	Yes	0-1/day	Yes, < 1.5/day
Eat more Fruits & Vegetables	Yes 5-10/day	Yes	Yes 5+/day	Yes	Yes
Eat higher fibre	Yes	-	-	-	Yes
Eat lower fat	Yes	Yes	Yes	Yes	-

Table 3.2

Benefits and Risks of Tamoxifen as a Chemopreventive Agent

	North American N = 13,388 (Fisher et al., 1998)	British N = 2471 (Powles et al., 1998)	Italian N = 3408 (Veronesi et al., 1998)
Invasive Breast Cancer	1.3% tamoxifen 2.6% placebo ($p < .00001$) RR = 0.51*	2.7% tamoxifen 2.9% placebo RR 1.06	0.7% tamoxifen 0.8% placebo
Non-invasive Breast cancer	0.52% tamoxifen 1% placebo ($p < .002$) RR = 0.50*		
Hip Fracture	0.18% tamoxifen 0.33% placebo RR = 0.55*	Not reported	Not reported
Spine Fracture	0.34% tamoxifen 0.46% placebo RR = 0.74*	Not reported	Not reported

	North American N = 13,388 (Fishel et al., 1998)	British N = 2471 (Powles et al., 1998)	Italian N = 5408 (Veronesi et al., 1998)
Radius, Colles' Fracture	0.21% tamoxifen 0.34% placebo RR = 0.61*	Not reported	Not reported
Uterine Cancer	0.53% tamoxifen 0.22% placebo RR = 2.53*	0.3% tamoxifen 0.08% placebo	98% had hysterectomies
Deep Vein Thrombosis	0.52% tamoxifen 0.32% placebo RR = 1.6*	0.32% tamoxifen 0.16% placebo	0.22% tamoxifen 0.11% placebo
Pulmonary Embolism	0.3% tamoxifen 0.09% placebo RR = 3.01*	0.24% tamoxifen 0.16% placebo	0.04% tamoxifen 0.04% placebo
Stroke	0.57% tamoxifen 0.36% placebo RR = 1.59*	Not reported	0.33% tamoxifen 0.18% placebo
Cataracts	9.4% tamoxifen 8.0% placebo RR = 1.14	Not reported	Not reported

* subgroup analysis also available for women under 50 years of age or 50 years of age and older.

Figure 3.1 High Risk Breast Assessment Clinic Flow

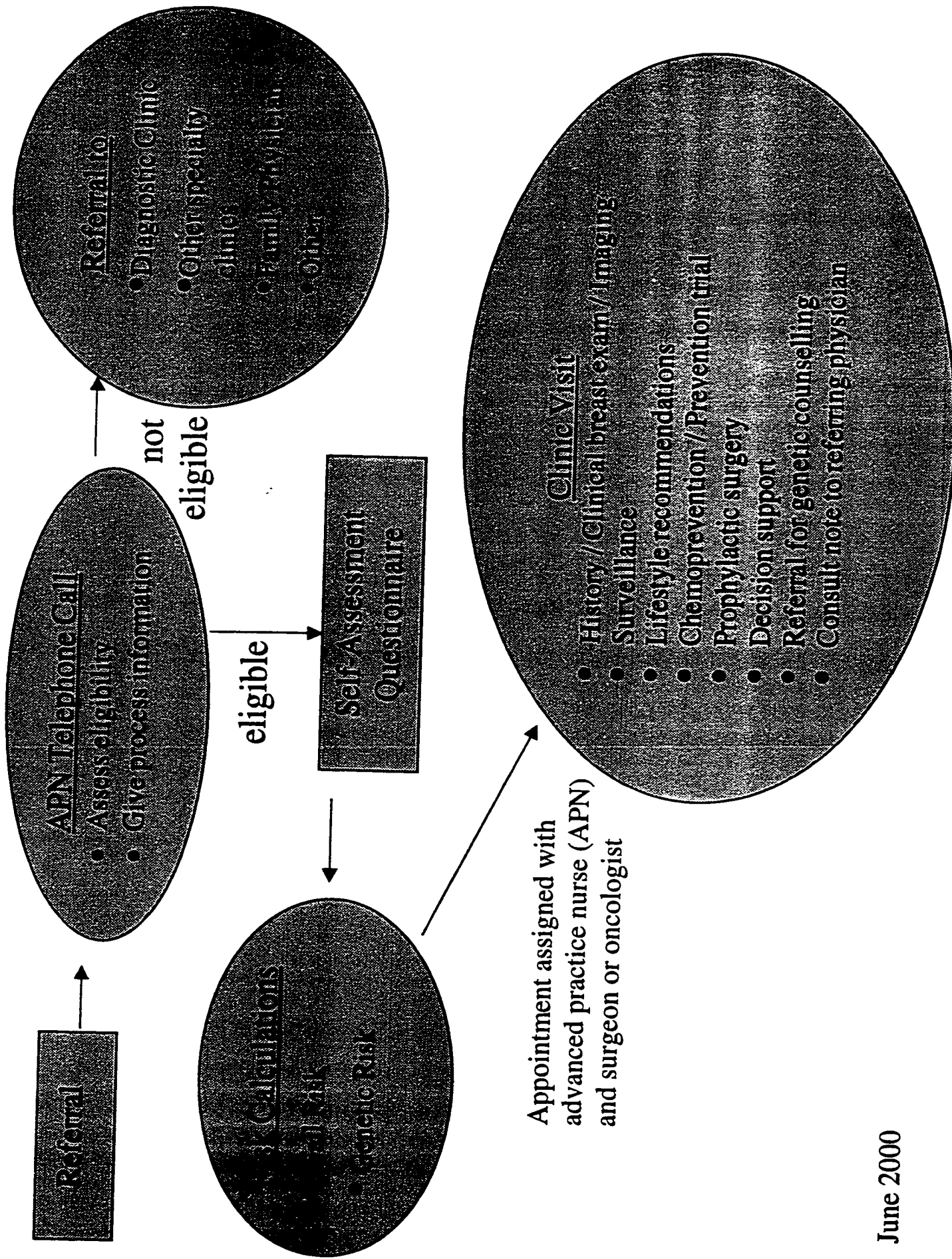


Figure 3.2 Ottawa Decision Support Framework

Assess Needs (Determinants of Decisions)	Provide Decision Support	Evaluate
Perceptions of the Decision Knowledge Expectations Values Decisional conflict Stage of decision making Perceptions of Others Perceptions of others' opinions & practices Support Pressures Roles in decision making Resources to Make Decision <u>Personal</u> Previous experience Self-confidence Motivation Skill in decision making <u>External</u> Support (information, advice, emotional, instrumental, financial, professional help) from social networks and agencies Characteristics <u>Client</u>: age, sex, marital status, education, occupation, culture, locale, medical diagnosis & duration, health status <u>Practitioner</u>: age, sex, education, specialty, culture, practice locale, experience, counseling style	Provide access to information Health situation Options Outcomes Other's opinions and choices Re-align expectations of outcomes Clarify personal values for outcomes Provide guidance/coaching in: Steps in decision making Communicating with others Handling pressure Accessing support & resources	Decision making Improved knowledge Realistic expectations & norms Clear values Agreement between values & choice Implementation of decision Satisfaction with decision making Outcomes of Decision Persistence with choice Improved quality of life Reduced distress Reduced regret Informed use of resources

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Chapter Four

This chapter is based on the following unpublished manuscript

**Evaluation of a Self-administered Breast Cancer Prevention Decision Aid
for High Risk Women Considering Options to Lower their Risk**

Abstract

Purpose: To evaluate the effectiveness of a decision aid for women aged 50 and older at higher risk of breast cancer in preparing for counselling about risk reduction options with a breast health practitioner.

Design: Phase I: Pre-test. Phase II: Before/after study.

Setting: Urban breast health clinic for women at high risk of breast cancer.

Sample: Phase I: Ten women aged 50 to 69, 1.66% or higher five-year risk of breast cancer, able to read and speak English, and no prior history of breast cancer. Phase II: 17 high risk women referred to the High Risk Breast Assessment Clinic.

Methods: Phase I: The women completed a questionnaire before and immediately after using the decision aid. Phase II: The women completed questionnaires at baseline and after receiving decision support (decision aid and counselling).

Main Research Variables: Women's decisional conflict; choice predisposition; knowledge of options and benefits and risks of tamoxifen; expectations of outcomes; psychological distress; and intentions to change unhealthy lifestyle practices.

Findings: The decision aid alone or combined with counselling significantly decreased some dimensions of decisional conflict ($p < 0.02$), increased knowledge ($p < 0.01$), and created more realistic expectations ($p < 0.01$). The aid with counselling, significantly reduced psychological distress ($p < 0.02$), helped the uncertain become certain ($p < 0.02$), and increased intentions to exercise regularly ($p < 0.03$) and eat more fruits and vegetables ($p < 0.02$). Women rated the aid as acceptable and both women and practitioners were satisfied with the effect it had on the counselling session.

Conclusions: The decision aid shows promise as a useful decision support tool in preparing high risk women for discussion with breast health practitioners. Further research should compare the decision aid's effect to counselling alone versus usual care.

Evaluation of a Self-administered Breast Cancer Prevention Decision Aid for High Risk Women Considering Options to Lower their Risk

Women at high risk for developing breast cancer want to be involved in their health care by finding out their individual risk of breast cancer, obtaining information about options to lower their risk, and learning decision making skills (see Chapter 2). The use of tamoxifen as a chemopreventive agent is a new option for high risk women. However, the decision to take tamoxifen involves carefully weighing the potential benefits and risks. Support for decision making can be obtained through counselling and may be supplemented by decision aids.

Currently, there are no decision aids to support women in their decision making related to breast cancer prevention. A systematic review of other patient decision aids revealed that decision aids were superior to usual care in increasing knowledge, reducing decisional conflict, and enhancing the level of participation in decision making without increasing anxiety (O'Connor, Rostom et al., 1999). However, decision aids have had no effect on patient satisfaction and a variable impact on the actual decisions. Several decision aids have been developed and evaluated using the Ottawa Decision Support Framework (DSF) (O'Connor, Drake et al., 1999). However, areas identified as requiring further research include: a) effects on persistence with choices and health outcomes; b) practitioners' views about decision aids and the effect on patient-doctor interactions; c) cost effectiveness; d) strategies for dissemination; and e) the influence of education, age, ethnicity, preference for decision making, and baseline choice predisposition on decision making (O'Connor, Drake et al., 1999; O'Connor, Fiset et al., 1999; O'Connor, Rostom et al., 1999).

To help women aged 50 and older make the decision about tamoxifen, a decision aid entitled, *"Making Choices: Options for Lowering My Risk of Breast Cancer"*, based on the

Ottawa DSF was developed (Chapter 3). In the decision aid, the options to lower the risk of breast cancer include: healthy lifestyle practices, more intense breast cancer surveillance, tamoxifen, and participating in a chemoprevention clinical trial. Although, the main decision is whether or not to take tamoxifen, lifestyle options were included to allow women other options than only medication. Women considering their options to lower their risk of breast cancer use the self-administered, audio-guided booklet and worksheet in preparation for consultation with high risk breast health practitioners.

Purpose

The main purpose of the study was to evaluate the effectiveness of a decision aid for women aged 50 and older at increased risk of developing breast cancer in preparing for counselling about risk reduction options with breast health practitioners.

Hypotheses

The decision aid was hypothesized to:

1. reduce decisional conflict;
2. help the undecided make a decision;
3. improve knowledge of the breast cancer prevention options, benefits, and risks;
4. create more realistic expectations of the likelihood of benefits and risks;
5. decrease the level of psychological distress; and
6. increase the intention to initiate a change in lifestyle practices.

Methodology

The decision aid was evaluated in two phases with the pre-test done using the decision aid alone and the second phase combining the decision aid with counselling in the High Risk Breast Assessment (HRBA) Clinic at the Ottawa–Regional Women’s Breast Health Centre,

Ottawa Hospital. The mandate of the Clinic is to provide a comprehensive breast health service specifically targeted to women at high risk of developing breast cancer. The services include a) assessing women's risk of developing breast cancer; b) providing information on options to lower her risk; c) encouraging the women to participate as partners in their care by completing a self-assessment questionnaire, asking questions, making health-related decisions, and taking action to adopt healthy lifestyle practices; d) supporting women in decision making; and e) clinical management recommendations sent to the primary care provider with ongoing surveillance offered within the clinic for the highest risk women. This clinic provided an appropriate setting to evaluate the "*Making Choices: Options for Lowering My Risk of Breast Cancer*" decision aid and the staff supported the project (Appendix F).

Phase I study. The decision aid was pre-tested on a convenience sample of female volunteers at high risk for developing breast cancer. The main purpose was to check for acceptability and clarity of the information presented in the aid. As well, the evaluation tools were pre-tested at this time. The participants completed a questionnaire before and immediately after using the decision aid to elicit knowledge, expectations, the decision about taking tamoxifen, decisional conflict, and preferred role in decision making.

Women personally known to the investigators and who expressed interest in the project were approached. Inclusion criteria were: a) female aged 50 to 69; b) 1.66% or higher five-year risk of breast cancer; c) able to read and speak English; d) no personal history of breast cancer; e) no prophylactic mastectomy; f) no prior history of cancer within the past ten years (except basal or squamous cell carcinoma of the skin or carcinoma in-situ of the cervix); and g) a performance status that does not restrict normal activity for a significant portion of each day (placing the woman at higher risk of thromboembolic disease). After confirming eligibility, all participants

signed a consent form (Appendix G) approved by the Ottawa Hospital Research Ethics Board, Ontario, Canada.

Phase II study. The decision aid was next evaluated in a before/after study design with seventeen high risk women. Eligibility criteria were identical to those for the Phase I study, however, in Phase II inclusion criteria included having a referral to the HRBA Clinic. The research coordinator at the Clinic invited eligible women to participate in the study at the time of their appointment booking (Appendix H). Those agreeing to participate were contacted by the research nurse within two weeks of their appointment to confirm eligibility and arrange a 30-minute meeting at a convenient location, usually the participant's home.

At this meeting, the study was explained and informed consent was obtained using a protocol approved by the Ottawa Hospital Research Ethics Board, Ontario, Canada (Appendix I). Participants then completed the baseline questionnaire that took approximately 15 minutes (Appendix J). The decision aid and acceptability questionnaire (Appendix K) were left with the participant. Participants were instructed to use the decision aid and complete the acceptability questionnaire in preparation for their first visit at the HRBA Clinic.

At the Clinic, women were assessed and counseled by an advanced practice nurse and one of four physicians (two medical oncologists, two breast surgeons). As part of the regular consultation visit, women were encouraged to share their worksheet, ask questions, clarify any concerns, and obtain support for information that was upsetting. After the visit, women handed in the acceptability questionnaire and then completed the participant satisfaction survey (Appendix L). Either the nurse or physician, involved in the participant's care, completed the practitioner satisfaction survey (Appendix M). Within a week after their consultation visit, the participants responded to a post decision support questionnaire via a telephone call with the

research nurse (Appendix N). Then, two months later, the research nurse telephoned the participants to find out if they had made any lifestyle changes and the outcome of their decision about tamoxifen (Appendix O).

Outcome Measures. The evaluation strategy was designed using the Ottawa DSF (Appendix A; O'Connor et al., 1998a). Self-administered questionnaires were used for the Phase I and II studies to elicit decisional conflict, knowledge, expectations of outcomes, the decision, and acceptability of the decision aid. In Phase II only, intention to make lifestyle change, psychological distress, participant satisfaction, practitioner satisfaction and two-month post decision were also included. All measures were evaluated before and after the intervention except acceptability and satisfaction that were only evaluated after decision support. A baseline demographics questionnaire was also used (Appendix P).

The participant's level of *decisional conflict* was measured with the Decisional Conflict Scale (O'Connor, 1995). This 16-item scale measures uncertainty in choosing an option, key determinants contributing to decisional conflict, and perceived quality of decision making. Responses to statements are chosen from a five-point scale ranging from strongly agree to strongly disagree with neither agree nor disagree in the middle. Scores for each item range from 1 (low decisional conflict) to 5 (high decisional conflict). The test-retest and alpha coefficients for this measure exceed 0.81. The measure is sensitive to change (Drake et al., 1999; Fiset et al., 2000; O'Connor et al., 1998a) and discriminates between different decision support interventions (Hing et al., 1999; O'Connor et al., 1998b).

The participant's *knowledge* was assessed using a 27-item questionnaire about lifestyle options and the benefits and risks of taking tamoxifen. The responses to statements included true, false, or unsure and were marked as correct or incorrect. The total possible scores ranged from 0

to 100% correct. Items in the questionnaire were reflective of the information contained within the decision aid and considered essential for informed decision-making. The content validity was established with an expert panel that included two medical oncologists, a breast surgeon, a breast health / breast cancer advanced practice nurse, and an expert in evaluation of decision aids.

Knowledge tests used in the evaluation of other decision aids have had good internal consistency, discriminated between interventions, and were sensitive to change (Drake et al., 1999; Fiset, 1998; Hing et al., 1999; O'Connor et al., 1998a)

Personal *expectations* of disease (breast cancer, uterine cancer, and blood clots) within the next five years with and without tamoxifen were elicited by asking each woman to quantify her risk. The possible responses were broken down into 29 groupings that ranged from 0 out of 1000 women with risk factors similar to themselves to 1000 out of 1000. The answers were rated as accurate, underestimated risk, or overestimated risk. The score for realistic expectations was the percent of accurate responses out of six questions. Test-retest coefficients for this measure exceed 0.80 and the scales are sensitive to change and discriminate between interventions (Hing et al., 1999; O'Connor et al., 1998a,b).

The participant's *choice predisposition* was measured by asking participants to mark along a 15-point scale anchored by not taking tamoxifen on one end and taking tamoxifen on the other, with unsure in the centre. Their decision was elicited with a direct choice question (accept tamoxifen, decline tamoxifen, or remain undecided) and reasons for their choice were asked. The test-retest reliability coefficients of these measures exceed 0.90, are correlated to personal values and expectations, and are sensitive to change (O'Connor, Tugwell, & Wells, 1994).

The *acceptability survey* used open and closed-ended questions to determine the acceptability of the decision aid. Closed-ended questions elicited feedback on amount, length,

clarity, and helpfulness of the information, degree to which the participant was upset by what they learned, how balanced and fair the information was presented, and whether or not they would recommend it to others. Open-ended questions asked what the participant liked and did not like about the decision aid, and prompted further comments regarding the closed-ended questions. These questions were based on a questionnaire evaluating the acceptability of the decision support programs produced by the Foundation for Informed Medical Decision Making (Barry, Fowler, Mulley, Henderson & Wennberg, 1995).

The participants current *lifestyle practices* (e.g. level of physical activity, fruit and vegetable intake, body weight, and alcohol intake) as well as their intentions to improve each lifestyle practice were measured. The intention to improve practices was measured using a seven-point scale that ranged from extremely likely on one end to extremely unlikely on the other end and not sure in the centre.

The Impact of Event Scale (IES) is a 15-item tool used to assess the *psychological distress* associated with a specific life event; in this case, high risk of breast cancer (Horowitz, Wilner, & Alvarez, 1979). Participants were asked to respond, on a four-point scale ranging from not at all, to often, to their level of agreement with statements of intrusiveness or avoidance of thoughts, feelings, or situations. In the original evaluation of the IES, the scale was administered immediately before and after brief therapy and proved to have good internal consistency (Cronback's $\alpha = 0.86$ for total score, 0.84 for intrusion, and 0.78 for avoidance sub-scales). The test-retest reliability scores were 0.87 for total stress score, 0.89 for intrusion sub-scale, and 0.79 for the avoidance sub-scale. The IES has also been shown to discriminate between those who received risk counselling regarding breast cancer risk and those who did not (Lerman et al., 1996).

Participants' and practitioners' *satisfaction* with preparation for the first visit at the HRBA Clinic, was assessed using nine and eleven questions respectively rated on a five-point scale ranging from 1 (low satisfaction) to 5 (high satisfaction). Patient and practitioner versions of the scale have high internal consistency ($\alpha > 0.90$) (O'Connor, 2000).

Data analysis. Data were entered and analyzed using the Statistical Package for the Social Sciences (SPSS for Windows- 7.5) (1996). Quantitative data were coded numerically and entered into the data file. All data were checked twice at entry and verified on printouts. In order to detect changes between baseline and post-intervention measures, Wilcoxon matched pairs signed ranks test and McNemar's test for change were used for interval scaled measures and for discrete measures respectfully. The responses on the acceptability survey, satisfaction questionnaires, rationale for their decision, and demographics were reported using descriptive statistics.

Sample Size. The primary outcome for this study was decisional conflict. The estimated sample size was calculated based on the paired t-test for comparing the means of the outcome 'decisional conflict' measured before and after decision support. For a level of significance $\alpha = 0.05$, power $(1-\beta) = 0.80$, a standard deviation of 0.6, and a correlation between before/after scores of 0.80, the sample size was estimated at 17 to detect a difference of 0.3 in the decisional conflict score, out of a possible score of one to five. Cohen (1977) defines this effect size as medium effect, one that would be apparent to an intelligent viewer. This effect size is clinically important in that it is commonly observed between those who make versus those who delay decisions (O'Connor et al., 1998b).

Results

Phase I results. Phase I was conducted in August to September 1999. Ten women participated in the pre-testing of the breast cancer prevention decision aid. As shown in Table

4.1, the participants varied in their age, marital status, primary language, education, and risk of developing breast cancer. The typical woman participating was 60 years old, married, Caucasian, English-speaking, with post-secondary education, having a mother with breast cancer, and a 2.8% median five-year risk of breast cancer. Eight out of ten participants preferred to make the final decision while the other two preferred to share the decision making with their practitioner.

The hypotheses that the decision aid would improve knowledge and realistic expectations, and decrease decisional conflict were supported. There was a statistically significant improvement in their knowledge scores (see Table 4.2), accuracy of expectation of outcomes associated with and without tamoxifen (see Table 4.3), and the informed sub-scale of the decisional conflict scale (see Table 4.4). At baseline, one participant was leaning toward tamoxifen, three were leaning toward no tamoxifen, and six were unsure what to choose. After the aid, four of the unsure made a choice and two remained unsure. Reasons cited for not choosing tamoxifen included concern about risk of uterine cancer and blood clots. In addition one woman said, *“I’m in reasonably good health so why interfere with my body’s natural processes”*.

Using the audio-guided booklet and completing the worksheet took, on average, 45 minutes. Overall, the women rated the decision aid highly for length and amount of information, and did not rate it as upsetting (see Table 4.5). Half of the participants rated it as balanced and fair, with some rating it as slanted to tamoxifen. All of the participants found it helpful in making the decision and would recommend the decision aid to other women. As one woman said, *“It was easy to follow and I was able to do it on my own, take my time, and think it out in a non-medical setting.”* One participant commented that, *“follow-up discussion between patients and*

professionals regarding choice is important” and she was subsequently referred to the HRBA Clinic.

Final revisions to the decision aid. The comments and suggestions of the ten women who participated in the Phase I pre-test study were considered and appropriate revisions made. The main revisions involved moving one page on the tamoxifen chemoprevention trials to an appendix.

Results: Phase II. From December 1999 to May 2000, women aged 50 and older referred for their first consultation at the HRBA Clinic were recruited. Of the 22 high risk women invited to participate in this study, 20 agreed, 19 completed the pre-decision support survey, and 17 completed the post-decision support survey (see Figure 1). The two women who declined participation stated that they already had enough information; however, one woman later expressed difficulty deciding about tamoxifen and requested the decision aid after her visit. Of the three women who agreed to participate but did not complete the study, one was too busy to meet prior to the first visit, one cancelled her HRBA Clinic consultation visit after using the decision aid, and the third woman had a language barrier.

The demographic characteristics of the women in the Phase II study are shown in Table 4.1. Their median age was 55 years, and the majority of them were Caucasian, post-secondary school educated, and married with a family history of breast cancer. Their median five-year risk of breast cancer was 2.6%. Most women wanted to be involved in the decision making.

Hypothesis 1. As hypothesized, there was a statistically significant improvement in the total *decision conflict* and all of the sub-scales except uncertainty (Table 4.4). The greatest improvements occurred on the informed and values clarity sub-scales.

Hypothesis 2. As shown in Table 4.6, there was significant reduction in the number of undecided participants from ten (65%) out of seventeen at baseline, to two (12%) out of seventeen two-months after receiving decision support. The main reason given for being unsure at baseline ($n = 6$) was that women wanted more information. Reasons given by the two women who chose to take tamoxifen immediately after decision support were, “*Feels like I am doing something to prevent it*” and “*Benefits outweigh the risks.*” The women who decided not to take tamoxifen immediately after decision support identified their decision as influenced by the side effects ($n = 9$) and the concern about taking medications ($n = 4$). Of the four women who remained unsure immediately after decision support, two were concerned about the side effects and two wanted to wait until after genetic counselling to make their decision.

At two months post-decision support, those women who made a decision were persisting with that decision (see Table 4.7). The two women who decided to take tamoxifen post-decision support, had started on the STAR trial. Of the four out of seventeen women who were unsure immediately after decision support, two continue to be unsure until they get further information about their risk of breast cancer (e.g. genetic testing), one decided to participate in the STAR trial, and one decided not to take tamoxifen.

Hypothesis 3. The participant’s *knowledge* scores before and after the decision support are summarized in Table 4.2. As hypothesized, there was a statistically significant ($p = 0.00$) improvement in the median knowledge scores from 41% to 89% with reductions in the number of incorrect and unsure responses.

Hypothesis 4. As hypothesized, there was a significant ($p = 0.00$) improvement in *realistic expectations* of disease outcomes (breast cancer, uterine cancer, and blood clots), with and without tamoxifen, from a median of 0% before to 83% after receiving decision support (see

Table 4.3). At baseline, most women either overestimated their risk of breast cancer ($n = 8$) or were unsure ($n = 6$). Most women ($n = 15$) were unsure of their risk of breast cancer, if they were to take tamoxifen for five years.

Hypothesis 5. Results of the *psychological distress* scores are described in Table 4.8. As hypothesized, the participants had a significantly lower level of total distress ($p = 0.02$) after receiving decision support.

Hypothesis 6. Table 4.9 describes the baseline *lifestyle practices* of the participants and Table 4.10 describes the effect the decision support had on the participant's intention to maintain or improve healthy lifestyle practices. The participant's intention to maintain or improve healthy lifestyle practices improved significantly for exercising ($p = 0.03$) and eating fruits and vegetables ($p = 0.02$) but not for alcohol use or healthy body weight. The most common reasons given for their choice related to eating fruits and vegetables, exercising regularly, and having a healthy body weight were: to feel better, to have a healthier lifestyle, and personal preference. For three of the seventeen women, health problems such as arthritis, back pain, and hypothyroidism interfered with their perceived ability to exercise and/or achieve a healthy body weight. Comments provided, by three of the seventeen women, indicated that action was being taken toward making a change and included joining a gym, starting to walk, and setting a goal of losing 25 pounds.

Both practitioners and participants were *satisfied* with the effect the decision aid had on the preparation for the counselling session (Tables 4.11, 4.12). The median scores across the items were uniformly high, with the exception of practitioners' ratings of the effect the decision aid had on the patient-physician relationship. In this study, the alpha coefficient of internal consistency of the participant scale was 0.94 and 0.86 for the practitioner scale.

The participant's ratings for *acceptability* of the decision aid are shown in Table 4.5. Overall, the participants found the aid to be acceptable in the amount, length, and clarity of information. As one woman said, "*Clear... precise... done for all walks of life.*" Only one of the seventeen participants felt somewhat upset by the information with no stated reason provided; all of her general comments were positive. Of the four women who provided comments in the section on feeling upset by the information, two said they were not upset and two were upset (e.g. by the reminders of having a relative with breast cancer and the fact that three out of ten women with breast cancer will die within ten years). The majority of women found it to be balanced and fair, and helpful in their decision making. All participants recommended the aid for others. Three participants commented positively on being able to see and hear the information, while, two women found that there was too much duplication between the audio-tape and booklet. Two women described it as too slow, which was exemplified by one of these women who said, "I can read faster than the speaker and found myself getting ahead of her". Finally, suggestions for improvement included: a) adding information on how to manage the side effects; b) explaining further the terms invasive versus non-invasive breast cancer; c) giving more details of actual deaths associated with the risks rather than just the occurrence of a disease; and d) providing more individualized information on personal risk of heart disease, osteoporosis, and cataracts. As one woman concluded, "*The tape and workbook don't answer all questions – but do provoke or raise questions that need personalized or individualized answers.*"

Discussion

As hypothesized, the decision aid used alone or combined with counselling decreased some dimensions of decisional conflict, increased knowledge, and created realistic expectations of outcomes. When the aid was used in combination with counselling, most of the women who

were uncertain at baseline made a decision with a shift away from using tamoxifen. At the same time, there were reductions in psychological distress and increased intentions to exercise regularly and eat five or more fruits and vegetables a day. Overall, the decision aid was very acceptable to participants who used the decision aid alone or in preparation for the consultation visit in the HRBA Clinic. Both participants and practitioners were satisfied with the effect it had on the counselling session.

The finding that decision support did not influence the participant's degree of uncertainty about the decision is probably a reflection of the inherent difficulty associated with the decision to take tamoxifen as a chemopreventive agent. Even though women made the decision, they continued to rate the decision as difficult to make. A similar effect was found in the evaluation of a hormone replacement therapy decision aid compared to a pamphlet (O'Connor et al., 1998b).

The results in this study are comparable to other studies with decision aids based on the Ottawa DSF. Participants in these studies were faced with decisions about hormone replacement therapy (O'Connor et al., 1998a,b), chemotherapy for advanced lung cancer (Fiset et al., 2000), medication therapy for atrial fibrillation (Hing et al., 1999), and prenatal testing (Drake et al., 1999). Following the use of decision aids, participants were more informed, had more realistic expectations of outcomes, decreased levels of decision conflict, and rated the decision aid as acceptable. In one study, by O'Connor, Jacobsen, and colleagues (2000) that evaluated satisfaction with preparation for decision making, participants and practitioners were satisfied with the decision making process.

There are four unique contributions of this study. First, a decision aid was developed in an area where no decision aids have been developed. Second, it included and evaluated healthy lifestyle practices as options along with medical intervention options, resulting in a shift in

intentions to exercise regularly and eat five or more fruits and vegetables. Third, insights were gained into the practitioner's acceptability of using decision aids in clinical practice. And finally, it was confirmed that the decision aid combined with counselling significantly decreased the participant's level of psychological distress resulting in a medium effect size, as defined by Cohen (1977).

Although, the evaluation revealed a shift in intentions to adopt healthy lifestyle practices, little is known about the impact their intentions will have on the implementation of or the longer-term adherence to lifestyle changes. Further research is needed in this area.

The decrease in psychological distress measured in this study within a week post decision support is consistent with another study, that used the IES at three months post counselling (Lerman et al., 1996). In this study, women with a family history of breast cancer who received risk counselling had lower levels of psychological distress compared to women offered usual care. In addition to risk counselling, the women who participated in our decision aid study also received structured information on options to lower their risk of breast cancer. One could hypothesize that the decreased distress following decision support was due to: a) decreased fear once women's exaggerated or uncertain perceptions of breast cancer risks were realigned; and b) reassurance that there were actions they could take to try to lower risks. Alternatively, the higher distress at baseline may have been due to the anticipated visit to the Clinic which naturally declined once the visit was over. To fully understand the mechanisms of this effect, a three-pronged randomized controlled trial (RCT) is needed to compare the decision aid combined with counselling to counselling alone to a control.

As with any study, there are limitations that restrict the interpretation of the findings and generalization to other populations and settings. First in the absence of a control group, one can

not attribute all of the observed effects to the decision support. This is particularly relevant to the decision, intention to change lifestyle practices, and psychological distress.

The decrease in distress levels could have been the result of a maturation effect, such that as time passed between the pre- and post- decision support evaluation, participants may have become more comfortable with knowing their risk of breast cancer. It is also difficult to assume that the degree of psychological distress was limited to knowing their risk of developing breast cancer and not related to other factors. While completing the pre-decision support survey, some women spoke about their recent experience with a friend or relative with breast cancer which was likely to have influenced their ratings on the IES. Finally, the change in distress levels may be attributed to the consultation with the breast health practitioners. To fully determine the effect of the decision aid would require a RCT.

Another main limitation is the generalizability of the results. The participants in this study cannot be assumed to be representative of all high risk women considering options to lower their risk. The decision aid was only evaluated in a small number of women who can read and understand English with the majority of women being Caucasian, married, and having post-secondary education. The aid was not evaluated for cultural sensitivity. As well, the Phase II study only involved women referred to the HRBA Clinic. Therefore, it is difficult to predict the generalizability to other groups of women and further evaluation with those groups is warranted.

In clinical practice, the decision aid was designed to prepare high risk women for consultation with practitioners and to support women in their desired role in decision making. However, the role of the practitioners was not well addressed in this study. There were two nurses and four physicians, each with their own beliefs and styles of practice, who provided consultation to the women on this study. It was assumed, given the practitioners' involvement in

the development of the decision aid, that they would know how to incorporate it into the consultation process; but, in reality this occurred through trial and error. It is unclear what styles of counselling were used by the practitioners and what effect the potential practice variations had on the decision support provided in consultation or the outcomes measured. Further research with decision aids should include preparation of practitioners as part of the procedure, monitoring of the consultation process, and comparison of the decision aid with counselling to counselling alone.

Although there was an improvement in the knowledge and realistic expectations, it is difficult to assume that this was entirely the effect of the decision aid and counselling and not influenced by co-intervention. During the study period, information was available from: a) a pamphlet on the “Study of Tamoxifen and Raloxifene” clinical trial; b) an article on tamoxifen as a chemopreventive agent in *Chatelaine Magazine* (Scott, 2000); c) the Internet; d) family members sharing their experiences with tamoxifen; e) a press release stating that tamoxifen was classified as a carcinogen or cancer causing agent (National Institutes of Health, 2000); and f) various sources cited within the decision aid. Some of these were identified by the participants and shared with the research nurse. However, a similar improvement in knowledge and realistic expectations was noted in the Phase I study with participants who used the decision aid alone. In this group, there was less time between the before and after surveys and, as a result, less chance of co-intervention. Moreover, other controlled trials have shown consistent effects on knowledge and expectations.

Future plans

The decision aid shows promise as a useful decision support tool in preparing women for discussion with breast health practitioners specialized in high risk counselling. Even though

women who used the decision aid were able to make a decision about tamoxifen, it is still an inherently difficult decision. In light of the observed benefits of the aid, its fit within the flow of the Clinic, and the satisfaction of users, the HRBA Clinic is considering further revisions based on women's suggestions and continued evaluation as part of standard care. As well, given the equal numbers of women under age 50 who visit the program (Chapter 2), consideration is being given to develop a similar decision aid for younger women.

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Figure 1

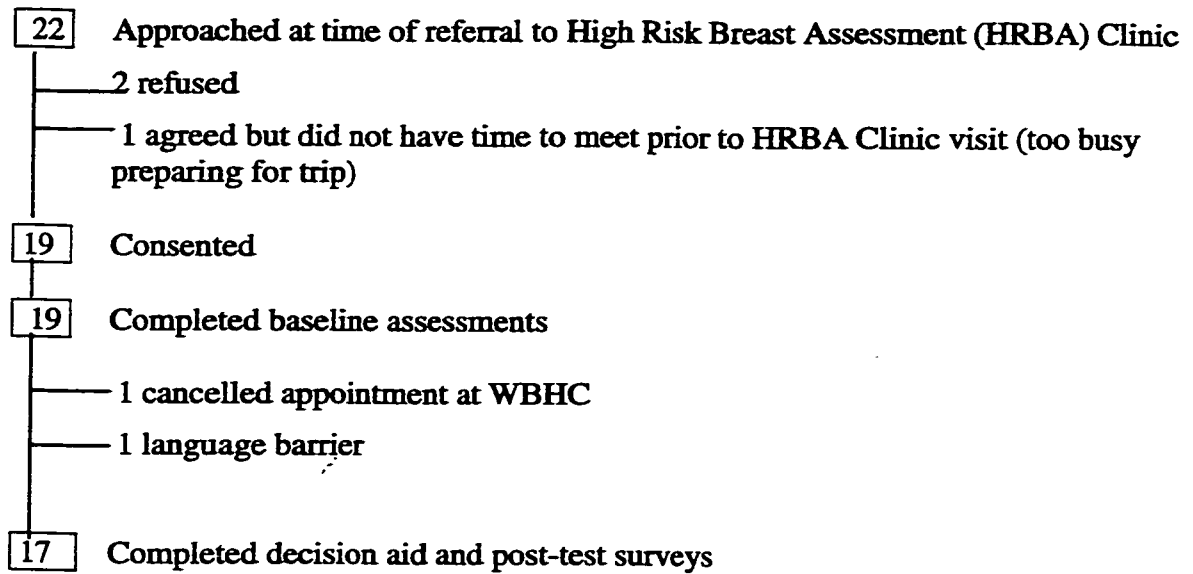
Phase II Decision Aid Evaluation Recruitment Summary

Table 4.1 Summary of Demographic Characteristics

	Phase I Decision Aid Only	Phase II Decision Aid & Counseling
	N=10	N=17
Age (in years)	median 59.5 (range 50-67)	median 55.0 (range 49-66)
50 to 54	2	8
55 to 59	3	6
60 to 64	4	2
65 to 69	1	1
Marital Status:		
Married, common law	8	15
Widowed	1	0
Divorced, separated	1	2
Primary Language Spoken/Read		
English	7	14
French	3	3
Education:		
High school diploma	2	2
Post secondary education	8	15
Age at first Menses	Median 12.0	Median 12.0
10-11	3	3
12-14	7	14
Age at birth of first child	Median 26.0	Median 24.0
No children	1	2
Child < 30	7	13
Child ≥ 30	2	2
Number of First Degree Relatives		
0	2	1
1	7	11
≥2	1	5
Number of Breast Biopsies		
0	8	11
1*	1	3
2*	1	3
* results all normal		
5-year risk of breast cancer	Median 2.8	Median 2.6
1.8 to 2.0 %	2	4
2.1 to 2.5 %	2	4
2.6 to 3.0 %	3	2
3.1 to 4.0 %	2	3
4.1 to 5.0%	1	1
5.5 to 6.0%	0	2
6.1 to 7.5%	0	1
Desired role in decision making		
Active	8	10
Shared	2	6
Delegate to Physician	0	1

Table 4.2

Knowledge Scores Before and After Decision Support

	Phase I Decision aid only (N=10)		Phase II Decision aid and counselling (N=17)	
	Correct Responses		Correct Responses	
	Pre	Post	Pre	Post
1. Options for lowering my risk of breast cancer are:				
Exercising regularly	6	10	16	17
Having a healthy weight	9	10	16	17
Drinking more alcohol	9	10	14	17
Eating 5 or more fruit & vegetables a day	7	10	15	17
Eating foods higher in fibre	2	3	2	4
Eating foods higher in fat	8	8	15	15
Taking tamoxifen every day	1	7	4	12
2. Tamoxifen can be given:				
To women with breast cancer	8	10	10	16
To healthy women who have a higher risk of breast cancer	6	10	14	17
For 5 years	6	10	5	17
3. Benefits of taking tamoxifen for healthy women who are at higher risk of breast cancer are:				
Lowers chance of breast cancer	5	10	10	17
Lowers chance of uterus cancer	3	10	4	17
Lowers chance of blood clots	4	10	1	16
Lowers chance of osteoporosis	2	10	4	17
Lowers blood levels of "bad" cholesterol	1	10	0	15
Lowers chance of cataracts	1	9	1	17
4. Risks of taking tamoxifen for healthy women who are at higher risk of breast cancer are:				
Increases chance of breast cancer	4	10	10	15
Increases chance of uterus cancer	3	10	4	17
Increases chance of blood clots	3	10	2	16
Increases chance of osteoporosis	1	10	3	17
Increases blood levels of "bad" cholesterol	1	10	1	16
Increases chance of cataracts	1	10	0	17
5. Some side effects of tamoxifen are:				
Hot flashes	5	10	7	17
Insomnia	0	5	14	6
Breast tenderness	0	4	14	7
Weight gain	0	5	1	10
Vaginal dryness	3	10	3	14
Median Score	40.5%	89%	41%	89%
Wilcoxon matched-pairs signed ranks test	z = -2.8 (p = 0.01*)		z = -3.6 (p = 0.00*)	

* Statistically significant

Table 4.3

Accuracy of Expectations of Outcomes Before and After Decision Support

	Phase I Decision aid only (N=10)		Phase II Decision aid and counselling (N=17)	
	Accurate Responses		Accurate Responses	
5-year risk of:	Pre	Post	Pre	Post
Breast cancer	0	8	0	13
Uterine cancer	3	8	7	12
Blood clots (brain, lungs, deep leg veins)	0	7	1	11
If taking tamoxifen, 5-year risk of				
Breast cancer	0	6	0	9
Uterine cancer	2	8	6	13
Blood clots (brain, lungs, deep leg veins)	0	7	0	10
Median Score	0%	83%	0%	83%
Wilcoxon matched-pairs signed ranks test	z = -2.7 (p=0.01*)		z = -3.3 (p=0.00)	

- statistically significant

Table 4.4

Decisional Conflict Before and After Decision Support

	Phase I (N=10)					Phase II (N=17)				
	Agree or Strongly Agree		z	p		Agree or Strongly Agree		z	p	
	Pre	Post				Pre	Post			
Total Decision Conflict (median)	2.6	2.2	-1.7	0.09		3.0	1.9	-3.1	0.00*	
Certainty Sub-scale (median) This decision is easy for me to make I'm sure what to do in this decision It's clear what choice is best for me	3.0	2.5	-0.6	0.58		3.0 6 7 6	2.0 11 12 11	-1.4	0.15	
Informed Sub-scale (median) I'm aware of the choices I have I feel I know benefits of taking tamoxifen I feel I know risks of taking tamoxifen	3.0	2.0	-2.3	0.02*		3.3 9 5 4	1.0 16 17 17	-3.6	0.00*	
Values clarity Sub-scale (median) I know how important benefits are to me I know how important risks are to me I know which is more important to me	2.7	2.0	-1.6	0.11		3.0 6 5 3	1.3 16 16 14	-3.1	0.00*	
Support/ Pressure Sub-scale (median) I am making this choice without pressure I have right amount of support from others I have enough advice about the choices	2.7	2.0	-1.7	0.09		2.3 16 10 2	1.3 17 17 12	-2.8	0.01*	
Satisfaction Sub-scale (median) I feel I have made informed choice My decision show what is important to me I expect to stick with my decision I am satisfied with my decision	2.6	2.5	-0.8	0.40		3.0 6 7 3 4	2.0 13 13 13 14	-2.4	0.02*	

* statistically significant

z scores were obtained from Wilcoxon matched-pairs signed ranks test

Table 4.5

Acceptability of the Decision Aid

	Phase I Frequency (N=10)	Phase II Frequency (N=17)
Amount of information?		
A lot more information	0	0
A little more than I needed	0	1
About the right amount of info	8	13
A little less than I needed	2	3
Much less than I needed	0	0
Was information upsetting?		
Not at all upsetting	10	10
A little upsetting	0	6
Somewhat upsetting	0	1
Very upsetting	0	0
Rating for length?		
Much too long	0	1
A little too long	1	2
Just about right	9	14
Should have been little longer	0	0
Should have been much longer	0	0
Rating for clarity?		
Everything was clear	6	12
Most things were clear	4	5
Some things were clear	0	0
Many things were unclear	0	0
Was it balanced & fair?		
Clearly slanted to tamoxifen	1	2
A little slanted to tamoxifen	2	5
Completely balanced	6	9
A little slanted to no tamoxifen	1	1
Clearly slanted to no tamoxifen	0	0
Helpful in making decision?		
Very helpful	5	6
Somewhat helpful	5	10
A little helpful	0	1
Not helpful	0	0
Would you recommend it?		
Definitely	8	12
Probably	2	5
Probably not	0	0
Definitely not	0	0

Table 4.6

Phase II Participant Certainty with the Decision Before and After Decision Support

Before Decision Aid & Counselling	After Decision Aid & Counselling		
	Yes, Tamoxifen (n=2)	Unsure (n=4)	No, Tamoxifen (n=11)
Yes, Tamoxifen (n=2)	1	0	1
Unsure (n =10)	1	2	7
No Tamoxifen (n=5)	0	2	3

McNemar Test binomial distribution ($p = 0.23$)

Table 4.7 Phase II Participant Predisposition to Tamoxifen Before versus Two-months After Decision Support

Before Decision Aid & Counselling	Two-months After Decision Aid & Counselling		
	Yes, Tamoxifen (n=3)	Unsure (n=2)	No, Tamoxifen (n=12)
Yes, Tamoxifen (n=2)	1	0	1
Unsure (n = 10)	2	1	7
No Tamoxifen (n=5)	0	1	4

McNemar Test binomial distribution ($p = 0.07$)

Before Decision Aid & Counselling	Two-months After Decision Aid & Counselling	
	Undecided (n=2)	Decided (n=15)
Undecided (n =10)	1	9
Decided (n = 7)	1	6

McNemar Test binomial distribution ($p = 0.02$)

Table 4.8 Phase II Psychological Distress Scores from Breast Cancer Risk Before and After Decision Support using the Impact of Event Scale

	Median Score (N = 17)		z score	p Value
	Pre	Post		
Total Impact ^a	26	21	-2.4	0.02*
Intrusive ^b	13	11	-1.5	0.15
Avoidance ^c	14	11	-1.4	0.18

*Statistically significant

z scores were obtained from Wilcoxon matched-pairs signed ranks test

^a scores range from 15 (low distress) to 60 (high distress) from breast cancer risk

^b intrusive sub-scale ranges from 7 (low intrusion of breast cancer risk on thoughts) to 28 (high intrusion).

^c avoidance sub-scale ranges from 8 (low avoidance of thinking about breast cancer risk) to 32 (high avoidance)

Table 4.9

Phase II Current Lifestyle Practices

	Frequency N = 17
Drink Alcohol?	
No	7
< 1 drink a day	7
occasionally more than 1/day	2
1 or more a day	1
Have a Healthy Body Weight?	
Yes	6
A little excess	7
No	4
Exercise 20-30 minutes most days a week?	
Yes, most days of the week	8
Yes, 3 days a week	2
Yes, occasionally	5
No	2
Eat 5 or more Fruits and Vegetables a day?	
Yes, most days	13
Occasionally	4

Table 4.10

Phase II Intention to Make a Lifestyle Change

N=17		Extremely likely	Somewhat likely	Slightly likely	Unsure	Extremely unlikely	Not Applicable	z score	p value
Drink 1 or less alcohol drinks a day	Pre	15	1	0	0	1	0	-1.9	0.06
	Post	16	0	0	0	1	0		
Start to have healthy Body Weight	Pre	5	2	2	2	0	6	-0.4	0.71
	Post	7	1	1	1	1	6		
Exercise for 20-30 minutes most day a wk	Pre	10	3	0	4	0	0	-2.2	0.03*
	Post	15	2	0	0	0	0		
5 or more Fruit & Vegetables a day	Pre	10	6	1	0	0	0	-2.3	0.02*
	Post	16	1	0	0	0	0		

* statistically significant

z scores were obtained from Wilcoxon matched-pairs signed ranks test

Table 4.11

Phase II Participant Satisfaction with Preparation for First Visit

	Not at all	A little	Some-what	A lot	A great deal	Median Scores
Help organizing your own thoughts about this decision	0	0	1	9	6	4
Help you consider what you think of the benefits and risks of each option	0	0	3	7	6	4
Help you identify the questions you need to ask	0	0	4	7	5	4
Help you to communicate your views to others	0	0	4	9	3	4
Help you to get more involved in decision making	0	0	3	8	5	4
Prepare you to make a better decision	0	0	3	9	4	4
Make the clinic visit run more smoothly	0	0	2	9	5	4
Improve the way time is spent during the clinic visit	0	0	4	5	7	4
Make you feel prepared for the clinic visit	0	0	4	6	6	4
Total						4

Scale scored from 1 (low satisfaction) to 5 (high satisfaction).
Alpha coefficient of internal consistency was 0.94

Table 4.12

Phase II Practitioner Satisfaction with the Participant Preparation for First Visit

	Not at all	A little	Some- what	A lot	A great deal	Median
Help her to fully understand the risks and benefits of tamoxifen	0	1	2	9	3	4
Help her identify the importance of the risks and benefits of tamoxifen	0	1	1	10	4	4
Prepare her for the consultation visit	0	0	3	8	5	4
Help her be as involved in the decision making process as she desired	0	1	0	11	4	4
Help her make a more informed decision	0	1	2	10	3	4
Help you to more fully understand the issues that are important to her	0	0	1	11	3	4
Help you tailor your counselling to her preference for participation	0	0	1	10	5	4
Facilitate the consultation visit	0	0	2	9	5	4
Affect the patient-physician relationship	0	1	6	7	0	3.5
Improve the way time was spent during the consultation visit	0	0	1	9	6	4
Improve the quality of the consultation visit	0	0	1	11	4	4
Total						4

Measured on scale of 1 (low satisfaction) to 5 (high satisfaction). Alpha coefficient of internal consistency was 0.86

Chapter Five

General Discussion & Conclusion

In this thesis, the support needs of women at high risk of developing breast cancer were determined, a breast cancer prevention decision aid to meet the needs of high risk women aged 50 and older was developed, and the effectiveness of this decision aid was evaluated. Women at risk of breast cancer are referred to the High Risk Breast Assessment (HRBA) Clinic primarily because of having a family history of breast cancer or an interest in the STAR chemoprevention clinical trial (Chapter 2). Further, these women have identified important informational, emotional, self-care, and decisional support needs, many of which can be addressed through counselling and supplemented by a decision aid. To address the needs of high risk women, the decision aid *"Making Choices: Options for Lowering My Risk of Breast Cancer"*, was developed using the Ottawa Decision Support Framework (DSF) (Appendix A; O'Connor et al., 1998).

Informational needs identified by high risk women, aged 50 and older who were referred to the HRBA Clinic, included wanting to know about their personal risk of breast cancer, healthy lifestyle practices, screening guidelines, and chemoprevention trials (Chapter 2). These needs are consistent with the needs reported in the literature for sub-groups of high risk women (Chapter 2) and those identified in the key informant interviews (Chapter 3). Women referred to the HRBA Clinic also identified decisional support needs that included information on options, benefits and risks, guidance in values clarification, and sources of information and support (Chapter 2).

Using research-based evidence published on options to lower the risk of breast cancer, we were able to incorporate this information into the decision aid and address many of the women's informational and decisional support needs. As well, the reviews of several decision aids, some of which were based on the Ottawa DSF, provided examples of methods to include in the breast

cancer prevention decision aid (Chapter 3). Those included were specifically chosen to address the women's identified decisional support needs. The evaluation showed that, after using the decision aid alone or in combination with decision support counselling, women scored significantly lower on some dimensions of decisional conflict ($p < 0.02$), were significantly more knowledgeable ($p < 0.01$), and had significantly more realistic expectations of risk of disease ($p < 0.01$) (Chapter 4). The decision aid combined with decision support counselling significantly helped the uncertain become certain. These results confirmed that the decision aid addressed their decisional support needs and further verified the support needs identified by the women. Positive responses to the acceptability and satisfaction questionnaires support the usefulness of a decision aid in addressing high risk women's support needs and in preparing them for counselling. However, further evaluation is needed to examine the influence practitioners had on the decision-making processes and outcomes.

Emotional support needs are not easily measured in clinical practice (Chapter 2), although, according to the HRBA Clinic satisfaction survey women's emotional needs were met. Moreover, improvements in psychological distress were noted following use of the decision aid combined with decision support counselling. However, it is unclear how these results would compare to the results of women who receive counselling alone.

The self-care needs identified in clinical practice included increased adherence to performing monthly breast self-examination and control of body weight (Chapter 2). The results of previous research revealed that women with higher levels of psychological distress were less likely to adhere to screening guidelines (Kash, Holland, Halper, & Miller, 1992; Lerman et al., 1993; Lerman, Kash, & Stefanek, 1994). Thus, breast screening practices, that were not assessed in the decision aid evaluation, should be included in subsequent research. The need to control

body weight was verified in the evaluation of the decision aid with more than half of the women identifying a need to lose weight. As well, in the evaluation, more than half of the women were not exercising enough and a quarter did not eat five or more servings of fruits and vegetables a day. Women's intention to improve their exercise habits and consumption of fruits and vegetables increased significantly. However, the effect intention to change has on actual behavioral changes as well as the potential difficulty associated with making a behavioral lifestyle change necessitate further evaluation. Research should focus on interventions for supporting women making such lifestyle changes and the longer-term adherence to continuing healthy lifestyle practices.

Several limitations were discussed in two of the papers (Chapters 2, 4). The main limitation is the generalizability given the small sample size of predominantly Caucasian, well-educated, married, English-speaking women.

Implications for nursing practice

Nurses have an important role in assessing the supportive needs, teaching, guiding, and advocating for high risk women. Several of the skills needed when working with high risk women require advanced nursing practice knowledge and skills such as program development and evaluation, risk communication, behaviour modification, and decision support counselling.

Most women at high risk of breast cancer want to take an active role in making breast cancer prevention-related decisions. Nurses with their expertise in patient teaching are well-positioned within the health care team to take an active role in supporting individuals with their decision making. The Ottawa DSF is a practical approach for guiding nurses in identifying determinants of decisions, addressing decisional support needs, developing decision aids, and evaluating the effectiveness of decision support strategies. Structured decision aids and decision

support counselling are two intervention options. Nurses can assess sub-optimal determinants of decisions and provide interventions such as helping women understand their options, creating more realistic expectations of outcomes, and guiding them in weighing values associated with the options and outcomes.

The use of decision aids requires identifying individuals who are most likely to benefit from them, making them available to such individuals, and ensuring follow-up consultation in an environment supportive of active patient involvement. Advanced practice nurses can also take a leadership role in the development and evaluation of decision aids. The development requires research skills, expertise in the design of educational resources for patients or public, and the ability to collaborate and communicate within an inter-disciplinary team of health care professionals.

Areas for further research

There are several areas to consider for further research with high risk women based on the results found in this thesis. These include emotional needs of high risk women, subsequent evaluation of the breast cancer prevention decision aid, and other decision aid research. At the HRBA Clinic, needs assessment should focus on identifying the emotional support needs of high risk women with evaluation of the effect of counselling alone on psychological distress. As well, further evaluation is required of interventions to support women in adopting and maintaining healthy lifestyle practices. The breast cancer prevention decision aid should be further evaluated in a RCT with monitoring of the women's longer-term persistence with their choice and related health outcomes, and expanding the evaluation to other groups of high risk women (e.g. non-dominant cultures, lower educational levels). Finally, further research in decision aids should explore web-based versions and the development of a decision aid for women under age 50.

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Appendix A

This appendix is reprinted with permission from the publisher and
is based on the following published manuscript:

Stacey, C. D., Jacobsen, M. J., & O'Connor, A. M. (1999). Nurses guiding breast cancer-related decisions: A Decision Support Framework. Innovations in Breast Cancer Care, 4 (3), 71-81.

Contributions of Collaborators

There were three authors involved in this paper: Dawn Stacey (DS), Mary Jane Jacobsen (MJJ), and Annette O'Connor (AOC). DS wrote the original draft based on her experience with women with breast cancer and a literature review on women at risk of breast cancer. MJJ, sharing her expertise with the Ottawa Decision Support Framework (DSF), worked collaboratively with DS to edit the draft and create the final paper. AOC reviewed the final paper prior to submitting for publication to ensure accuracy of the application of the Ottawa DSF and provided general editorial comments.

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Nurses Guiding Breast Cancer-Related Decisions: A Decision Support Framework

Prevention, screening, treatment, complementary therapies, lifestyle choices, and managing self-care—all have the potential to create difficult and complex decisions related to breast cancer. Some women are able to make a clear choice, whereas others experience decisional conflict. In general, oncology nurses have taken a supportive role in decision making by educating patients about their options. However, there is an opportunity for oncology nurses to take a more active role in providing decision support. The Ottawa Decision Support Framework can assist nurses in guiding women making decisions related to breast cancer.

Key Words

breast cancer
choice behavior
decision aids
decision making
decision support techniques
informed choice
patient education
patient participation

Historically, most health care decisions have been made by physicians; in some settings this is still the case. Physicians were once viewed as having all the medical knowledge and being responsible for making the appropriate choice. The advent of informed consent increased the emphasis on patient education but did not necessarily involve patients in choosing between options. The rise in patient consumerism, with its emphasis on informed choice, has had a major impact on health decision making.¹ Although in the past, patients rarely questioned their physician's judgment, today's patients—frequently armed with the latest information gleaned from personal research—are increasingly interested in participating actively in decisions influencing their health. Clinical practice guidelines and consensus statements support this direction and recommend that health care practitioners involve women with breast cancer in decision making about their treat-

ment.^{2,3} This article uses the Ottawa Decision Support Framework⁴ to explore the assessment of decision support needs related to breast cancer and to discuss strategies for interventions and evaluation in the clinical setting.

Breast Cancer-Related Decisions

Breast cancer is the most common type of cancer in women and ranks second only to lung cancer as a cause of cancer-related deaths. One in nine women will develop breast cancer at some point in her lifetime.⁵ Women face many decisions along the cancer care continuum, from prevention and screening through treatment and survivorship or palliation (Table 1, page 72). Consider, for example, M.T., a 58-year-old woman at increased risk for breast cancer who was offered the option of tamoxifen as a chemopreventive agent. M.T. was willing to take a medication to decrease her risk, but she was concerned about the increased risk of endometrial cancer, cataracts, and vascular events. She therefore had difficulty making this decision. Nurses need to be aware of such potentially difficult decisions and develop skills in supporting women experiencing decisional conflict.

Decisional Conflict and Manifestations

Decisional conflict, according to O'Connor,⁶ "is the uncertainty about which course of action to take when choice among competing actions involves risk, loss, regret, or challenge to personal life values." The oncology nurse can observe signs or manifestations of decisional conflict. The most obvious sign is a patient's stating her difficulty in making the decision. Other signs include expressing concern about possible poor results or outcomes, wavering between choices, putting off the decision, showing physical signs of stress, questioning what is important, being preoccupied with the decision, and feeling emotionally distressed by the decision. Monitoring for these signs can be incorporated into the routine nursing assessment of any patient confronting a potentially difficult decision.

Table 1.—Potentially Difficult Breast Cancer–Related Decisions

Cancer Care Continuum	Examples of Potentially Difficult Decisions
Prevention	Tamoxifen Randomized clinical trial of tamoxifen vs raloxifene Lifestyle options to lower risks Bilateral prophylactic mastectomies
Screening	Regular screening mammography Breast cancer genetic testing
Diagnostics	Type of biopsy Sentinel node surgery
Treatments	Lumpectomy with radiation therapy vs mastectomy Chemotherapy for node-negative breast cancer Adjuvant chemotherapy Clinical trial vs standard therapy Radiation therapy Tamoxifen for 5 y Supportive therapies Complementary therapies
Rehabilitation	Fitness program Breast reconstruction
Survivorship	Return to work Pregnancy vs use of birth control
Palliation	Dying at home vs in hospital

Consider another case, that of R.B., a 48-year-old married woman living on a farm about 90 minutes from the city, who was told that she has invasive breast cancer. She was given the choice of mastectomy, or lumpectomy followed by 5 weeks of radiation therapy. She was unable to make a decision right away, felt overwhelmed with the news of her breast cancer, and became teary eyed. The nurse recognized signs of decisional conflict in R.B.'s uncertainty about her choice and her signs of distress. Each choice has pros and cons, and R.B. has to decide which is best for her. Although this is a fundamentally tough decision, some factors contributing to its difficulty may be modifiable such as more knowledge about what is actually involved in the two choices, or access to resources for transportation for daily radiation therapy. Addressing these other factors may decrease a patient's decisional conflict.

Ottawa Decision Support Framework: Overview

The Ottawa Decision Support Framework⁴ is a practical, conceptual guide to decision support in clinical nursing practice. The framework was developed for health decisions that

- Have no clear choice that is "right" for everyone
- Are stimulated by a new diagnosis or life transition
- Require careful deliberation because of their uncertain outcomes or value-laden nature that necessitates benefit-risk trade-offs
- Require more effort during deliberation than during implementation

The theoretical basis for the framework includes concepts from general psychology,⁷ social psychology,⁸ decision analysis,⁹ decisional conflict,¹⁰ social support,^{11,12} and economics (concepts of expectations and values).¹³

The framework uses a three-step process that involves (1) assessing the determinants of decisions to identify needs, (2) providing support to meet those needs, and (3) evaluating the decision-making process and outcomes. This three-step process is similar to the assessment, intervention, and evaluation phases of the nursing process (Table 2).

Assessing Needs and Planning Decision Support: Determinants of Decisions

Determinants of decisions are factors that influence decisions and can pertain to patients or practitioners (see Table 2). One determinant is an individual's perception of a decision, including knowledge of the options, the expectation of benefit or risk, and the value or importance placed on the benefit or risk. Another is the individual's perceptions of others, that is, others involved in the decision, their opinions, their supportiveness or pressure to select a specific option, and the choice they would make in this situation. Yet another determinant is the resources to support decision making, such as personal resources (eg, motivation, self-confidence, and prior experience) and external resources (eg, finances and access to resources needed to implement the choice). Participant characteristics constitute another determinant. When determinants are suboptimal, they may create decisional conflict.

One of the primary determinants of the decision for a woman like M.T., who is considering tamoxifen for prevention, is her perception of the personal risk of breast cancer. If she perceives her risk to be low, she is unlikely to consider tamoxifen. A determinant for R.B., who was deciding on which breast cancer surgery to choose, was her access to resources. Her ability to arrange transportation for the frequent radiation treatments

Table 2.—Ottawa Decision Support Framework

Assess Needs (Determinants of Decisions)	Provide Decision Support	Evaluate
Perceptions of decision Knowledge Expectations Values Decisional conflict Stage of decision making	Provide access to information Health situation Options Outcomes Others' opinions and choices	Decision making Improved knowledge Realistic expectations and norms Clear values Agreement between values and choice Implementation of decision Satisfaction with decision making
Perceptions of others Perceptions of others' opinions and practices Support Pressures Roles in decision making	Realign expectations of outcomes Clarify personal values for outcomes	Outcomes of decision Persistence with choice Improved quality of life Reduced distress Reduced regret Informed use of resources Acted on Patient goals achieved
Resources to make decision <i>Personal resources:</i> previous experience, self-confidence, motivation, skill in decision making <i>External resources:</i> support from social networks and agencies; information; advice; emotional, instrumental, and financial help; professional help	Provide guidance or coaching in the following: Steps in decision making Communicating with others Handling pressure Accessing support and resources	
Characteristics <i>Client:</i> age, sex, marital status, education, occupation, culture, locale, medical diagnosis and duration, health status <i>Practitioner:</i> age, sex, education, specialty, culture, practice locale, experience, counseling style		

Adapted from O'Connor et al,⁴ with permission.

would influence her choice because she lives 90 minutes from the city.

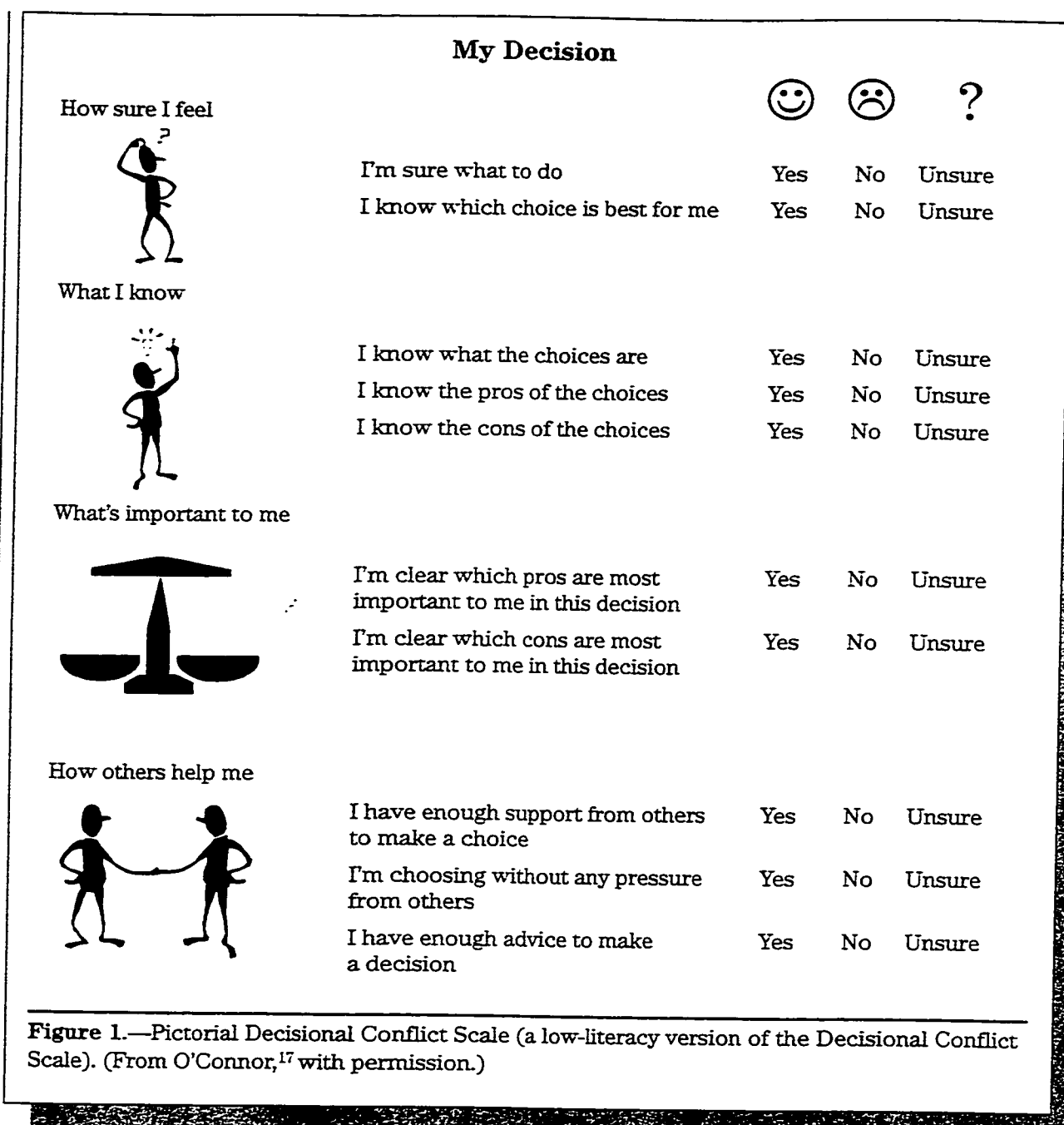
Assessing Needs and Planning Decision Support: The Tools

O'Connor et al¹⁴⁻¹⁶ has developed clinical practice tools and evaluation measures that the oncology nurse can use to screen for decisional conflict and assess the determinants of decisions with her patients. The purpose of this assessment is to identify determinants that are suboptimal (eg, lack of knowledge, unrealistic expectations, unclear val-

ues, lack of support, unwanted pressure, unclear perception of norms, inadequate resources) and to plan for decision support. Copies of these tools can be found on the Loeb Health Research Institute Web site, <http://www.lri.ca>, by selecting "OHDeC" (Ottawa Health Decision Centre).

The Decisional Conflict Scale

The Decisional Conflict Scale¹⁴⁻¹⁶ was developed to determine whether a patient is experiencing decisional conflict or uncertainty. The scale measures a patient's degree of uncertainty (ie, unsureness



about what to do or about which choice is best) and identifies some of the key determinants contributing to the decisional conflict (eg, feeling uninformed, unclear about values, unsupported in decision making). There are two versions of the scale, a long version, more suitable for research (available in English and French)¹⁵ and a simpler pictorial version (Figure 1), more suitable for use as a clinical practice tool (available in English and Spanish).¹⁷ The scale can be used to assess baseline needs and to monitor progress following interventions. Results can be interpreted at a glance. If decisional conflict is detected, the oncology nurse can proceed to use an interview guide, the Ottawa Guide for Decision

Assessment and Planning,¹⁴ to explore the details of the decision and plan interventions.

The Ottawa Guide for Decision Assessment and Planning

The Ottawa Guide for Decision Assessment and Planning, developed by O'Connor and Jacobsen,¹⁴ helps practitioners structure the assessment and planning stages according to the Ottawa Decision Support Framework. Part 1 of the guide (assessment) identifies the issues that the practitioner should address in exploring the determinants of the decision with the patient (Table 3). Probes and examples in the guide help the nurse explore the

decision from the patient's perspective, focus the patient on important factors influencing the decision, and identify determinants that might be suboptimal. The order in which information is obtained might vary from one situation to another. Part 2 of the guide (planning) summarizes the patient's characteristics, behavioral manifestations of decisional conflict, and suboptimal determinants of the decision. Patient goals are identified, and strategies are developed to address the suboptimal determinants. Evaluation criteria are outlined, including evaluation of the outcomes of the decision and the decision-making process.

From the assessment interview, the nurse should be able to obtain a clearer picture of the patient's decision support needs, which includes assessing the following decision determinants:

- Understanding the decision and options (knowledge)
- Perceiving the most likely pros and cons of the options (expectations)
- Knowing what is most personally important in making the choice (personal values)
- Considering perceptions of others involved in the decision (their opinions, support, or unwanted pressure)
- Identifying the desired level of participation in the decision-making process (role in decision making)
- Identifying strengths or needs in making or implementing the decision (resources)

The determinants of the decision found to be suboptimal provide the focus for decision support. In some situations, both assessment of needs and provision of decision support may occur during the assessment phase of the guided interview (eg, closing gaps in knowledge of options or realigning expectations about outcomes, benefits, or risks). In other cases, decision support requires planned interventions (eg, clarifying values, developing strategies to handle unwanted pressure, accessing support and resources).

Assessing Needs and Providing Decision Support: A Guided Interview

WHAT IS THE DECISION?—Asking the patient to articulate the decision ensures that the nurse and patient are congruent in identifying it. This also helps the patient focus on the decision being contemplated. For example, R.B. may think she is making a decision about mastectomy versus lumpectomy when she is actually deciding on mastectomy versus lumpectomy *plus* radiation therapy. The oncology nurse needs to clarify R.B.'s understanding of the options involved in this decision to enable R.B. to make an informed choice.

WHAT MAKES THIS A DIFFICULT DECISION?—Asking patients about their decision and what makes it difficult may bring out a wealth of information about their feelings and about factors contributing to the

Table 3.—Issues to Address When Assessing Decision Support Needs

Type of Issue	Specific Questions
Decision	What is the decision? What makes this a difficult decision?
Readiness	Is the patient ready for decision making? What stage of decision making is she in? When must the decision be made?
Options	What are the options, pros and cons? How likely are the pros and cons to occur? Which pros and cons are most important?
Other influences	Who is influential in the decision? What is the patient's preferred role in decision making? What resources are necessary?
Outcome	What is the desired outcome?

Adapted from O'Connor and Jacobsen,¹⁴ with permission.

decisional conflict. Early in the interview it may be best to simply acknowledge the difficulty and continue to explore the decision to obtain a more complete picture. Other contributing factors may become apparent as the interview proceeds.

IS THE PATIENT READY FOR DECISION MAKING?—Patients are less motivated to prepare to make a decision seen as far in the future; time pressure enhances the motivation but increases the difficulty of the decision making. Decision support is most effective for patients already considering their options. Prochaska and Velicer¹⁸ call this “contemplation phase” in the stages of change. Those in the precontemplation phase, who are not even thinking about the options, may benefit from some information to increase their awareness of the issues. For example, M.T., who was considering tamoxifen as a chemopreventive agent in the earlier scenario, may need to know that her lifelong risk of developing breast cancer is much higher than that of the average woman (ie, higher than one in nine) because of her family history and never having had children. Otherwise, she might remain in the precontemplation stage indefinitely.

WHEN MUST THE DECISION BE MADE?—Determining a deadline for making the decision is important. For some women, the deadlines may be externally imposed, for example, by the timing between surgery and the beginning of chemotherapy or by the schedule of a clinical trial. With externally imposed deadlines, the time pressure enhances the motivation but increases the difficulty of the decision making. Some patients may impose their own deadlines as a way of alleviating the anxiety and distress associated with decisional conflict.

WHAT ARE THE OPTIONS AND THEIR PROS AND CONS?—The patient first needs to learn about the available options and to have a realistic expectation of their outcomes. R.B., for example, needs to know that radiation therapy is a treatment given daily for several weeks after a lumpectomy. Sometimes patients are not even aware of all the available options. Consider, for example, a woman in the final stages of her battle with breast cancer who is trying to decide whether she wants to die at home or in the hospital. In talking with her, the oncology nurse realizes that she is not aware of a third option, dying in a local hospice. In general, one role of the nurse is to make patients aware of their options.

Patients need a realistic perception of the possible outcomes of the options and should know the pros and cons of each. Taking a few minutes to write down the pros and cons from the patient's

point of view helps the nurse assess the patient's knowledge, provides a visual stimulus, and facilitates discussion of the outcomes.

HOW LIKELY ARE THE PROS AND CONS TO OCCUR?—Sometimes it is appropriate to have the patient identify which pros and cons they think are most likely to occur. For example, M.T. wrote that taking tamoxifen will eliminate her chance of getting breast cancer and that this is her primary motivation for choosing that option. However, when the nurse clarified that tamoxifen may reduce her risk only by half,¹⁹ she became more interested in other options, such as lifestyle changes. The nurse needs to determine patients' perceptions and realign their expectations of outcomes as necessary.

WHICH PROS AND CONS ARE MOST IMPORTANT?—Many patients can clearly articulate their options, the pros and cons, and potential outcomes but are still unable to make a decision. Nurses encourage each patient to identify which pros and cons she thinks are most important. In this way, nurses actually have each patient clarify her personal values. There are several ways to help patients examine their personal values. For example, a patient can write the pros and cons in boxes and shade each box according to the item's level of importance in making the decision (Figure 2). Another approach is to ask the patient to rate the level of importance of an option's pro or con on a scale of 0 (not at all important) to 10 (extremely important).

For example, S.P., a 51-year-old woman who had a mastectomy and recently completed chemotherapy for early-stage breast cancer, went to see a plastic surgeon to discuss breast reconstruction surgery. S.P. identified the following advantages of breast reconstruction: (1) having a breast, (2) not needing a prosthesis, and (3) better-fitting clothes. The advantages of not having breast surgery were (1) avoiding risk of infection and (2) avoiding “going under the knife.” S.P. identified the most important benefit of reconstructive surgery as having the reconstructed breast resemble the other breast in shape, size, and appearance. The nurse intervened by showing S.P. pictures of surgically reconstructed breasts to help realign S.P.'s expectations. Next, S.P. re-evaluated the situation and concluded that having some breast was better than continuing to wear the prosthesis; she decided to proceed with the breast reconstruction after all.

WHO IS INFLUENTIAL IN THE DECISION?—Another factor that influences decision making is the opinions of others. Women have identified their physician,

other health care professionals, spouse, family, friends, and other women who have made the decision as important sources of information.^{21,22} Nurses can play a supportive role in encouraging each patient to identify individuals whose opinions are important to her in making her decision, facilitate her ability to obtain those opinions, and finally assist her in managing conflicting opinions.

Consider the case of T.W., a 43-year-old woman who completed chemotherapy 3 months ago for early-stage breast cancer. She continues to feel fatigued and is unsure of whether to return to work. At this point, she has spoken to her physician and husband. The nurse, knowing that there is variation in how patients make this

choice, offers to put T.W. in contact with other women who have made the decision.

The real challenge for nurses is helping women manage conflicting opinions. In this situation, the woman needs to identify whose opinion is most important and whether this person is placing unwanted pressure on her to make a specific decision. For example, after T.W. speaks with other women who have made the decision, she leans strongly toward staying home for another 6 months. However, her husband really wants her to return to work and get their lives "back to normal." The nurse verifies with T.W. that her husband's opinion is relevant and important to her, and coaches her in planning ways to communicate her values to him.

Step 1. What Is Important?

Lumpectomy, followed by radiation

Retain a nearly natural breast	No need for breast prosthesis or reconstructive surgery	I feel having only one breast will make me uneasy in intimate situations
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Mastectomy

High chance of avoiding side effects and inconveniences of radiation	Less worry about recurrence on the chest	
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Step 2. How Important Is It?

Lumpectomy, followed by radiation

Retain a nearly natural breast	No need for breast prosthesis or reconstructive surgery	I feel having only one breast will make me uneasy in intimate situations
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Mastectomy

High chance of avoiding side effects and inconveniences of radiation	Less worry about recurrence on the chest	
--	--	--

Step 3. Leaning

Leaning toward lumpectomy, followed by radiation

Leaning toward mastectomy

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Figure 2.—Sample values clarification exercise. Step 1: advantages and disadvantages of each procedure are listed; step 2: the personal importance of each point is indicated by shading; step 3: the "leaning" is indicated. (From Sawka et al,²⁰ with permission.)

WHAT IS THE PATIENT'S PREFERRED ROLE IN DECISION MAKING?—In considering the opinions of others, the patient needs to determine her preferred role in making the decision. The level of participation may vary from decision to decision and from one patient to another in a similar situation. For example, a patient may want to make the decision herself, delegate the decision making to her practitioner, or share in the decision making with her practitioner or significant others in her life. The nurse can guide the woman in identifying her desired preference for participating and can help her identify ways of communicating her preference to relevant others.

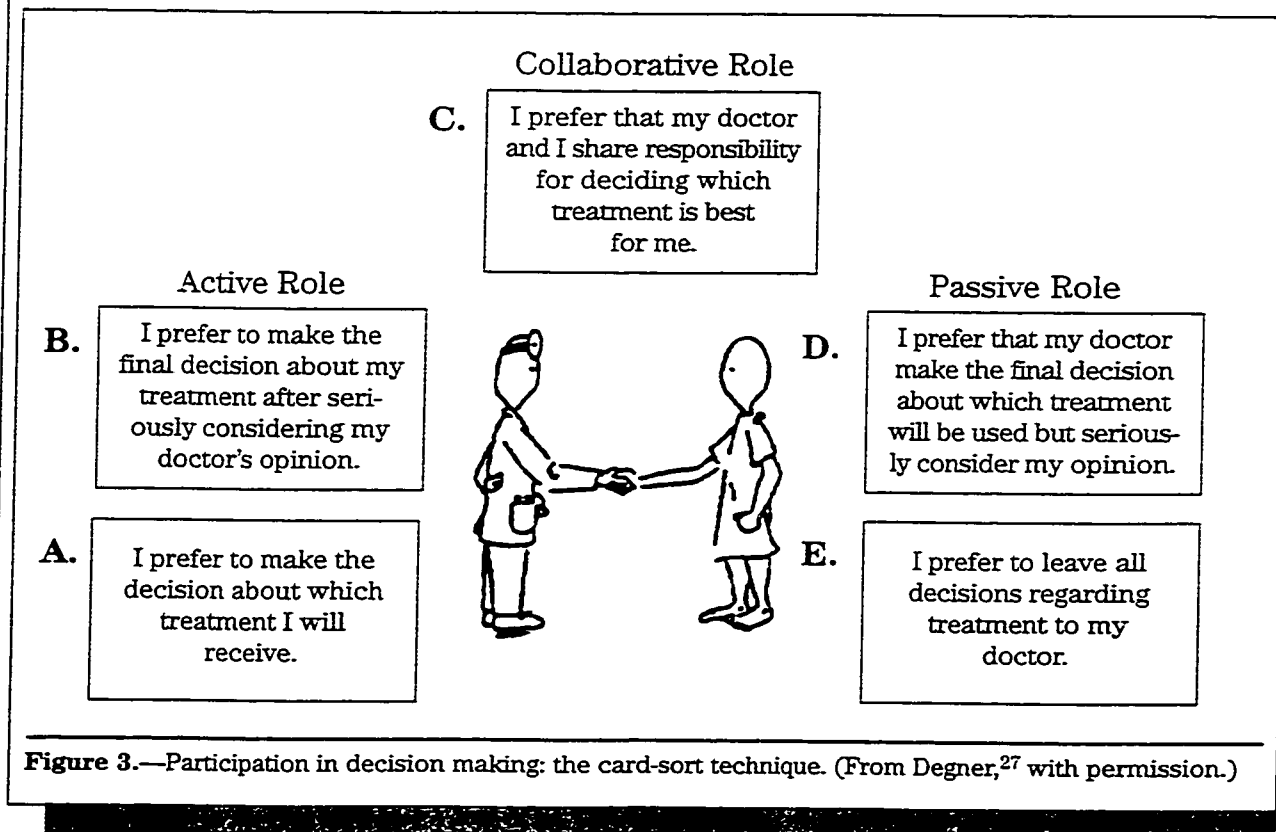
The majority of women with breast cancer prefer either an active or a collaborative role in decision making.²³⁻²⁶ However, the nurse cannot make assumptions about an individual's desired level of participation in decision making. In the largest study to date of decision preferences of women with breast cancer, Degner and colleagues²⁶ were unable to determine predictive factors. All women with breast cancer—regardless of age, education level, socioeconomic status, or desire for detailed information—should be assessed to determine their preferred role in decision making.

One way to determine a patient's desired level of participation is to use the Control Preferences Scale.²⁷ This card-sort technique is the one most consistently used to determine the preferences of

women with breast cancer for participation in treatment decisions (Figure 3). The woman considering a specific decision is presented with five cards representing different levels of participation. She is then asked to arrange the cards in an order representing her most-desired to least-desired level of participation.

WHAT RESOURCES ARE NECESSARY?—The final set of determinants that influence a patient's ability to make and implement a decision are personal and external resources. Personal resources include self-confidence, decision-making skills, experience with similar decisions, and motivation to make a decision. External resources for S.P., who is making the decision about breast reconstruction, could be the financial means to choose the surgery as an option. An external resource for T.W. was being able to speak with other women who had made the decision about going back to work by contacting a local breast cancer support group. An important factor affecting R.B.'s decision to have a mastectomy was the need to travel for daily radiation treatments over several weeks.

WHAT IS THE DESIRED OUTCOME?—Based on the assessment interview, the nurse should be able to identify the determinants of the decision that are suboptimal. In concluding the assessment interview, the nurse encourages



patients to identify their desired outcome. T.W., who is deciding whether to go back to work or stay home, set her goal as having her husband understand her values and support her in her choice.

For patients who have difficulty articulating their desired outcome, it is sometimes helpful to ask, "If you could wave a magic wand, what would you like to have happen?" According to the Ottawa Decision Support Framework, the fundamental goal in decision making is to help the patient achieve a high-quality decision. A high-quality decision is informed, consistent with personal values, acted on, and one in which the patient expresses satisfaction, not only with the decision itself but also with the process used to reach it.⁴

Provision of Decision Support

The second phase in the Ottawa Decision Support Framework is providing decision support interventions to enhance the quality of decision making by addressing modifiable determinants. Decision support includes providing information tailored to patient needs, realigning expectations, clarifying values, and helping patients develop decision-making skills. When providing decision support, it is also important to be aware of determinants that cannot be modified, such as education levels or cultural sensitivities, and ensure the decision support is individualized. Examples of some intervention strategies are provided in an earlier discussion ("Assessing Needs and Providing Decision Support: A Guided Interview," beginning on page 75).

Decision support can be done informally through counseling or more formally with decision aids. Decision aids are structured "interventions designed to help people make specific and deliberative choices among options by providing (at the minimum) information on the options and outcomes relevant to the person's health status."²⁸ Decision aids may also include information on the disease, expected outcomes tailored to the patient's risk factors, values clarification exercises, handling of others' opinions, and guidelines for decision making. Decision aids are developed in several formats, including audiotapes and workbooks, interactive videodiscs, decision boards, posters, written vignettes, brochures, computer programs, and interview guides with "trade-off" exercises.

A number of breast cancer-related decision aids are being developed and tested, but few are available for distribution (Table 4, page 80). The Ottawa Decision Support Framework has been used for the development of several breast cancer-related decision aids, including deciding about hormone replace-

ment therapy, the choice of breast cancer surgery,²⁰ and the options for lowering one's risk of breast cancer.²² Decision aids have been effective in improving patients' knowledge, creating more realistic expectations, decreasing decisional conflict, helping patients make decisions congruent with their values, and helping them feel supported in their decision making. A recent article reviews the evidence for using decision aids with patients in oncology.²⁵

Evaluation of Decision Support

Finally, the effectiveness of interventions requires evaluation. The evaluation focuses on whether the patient's goals were achieved and whether the goal of a high-quality decision was attained (see Table 2, page 73). During the evaluation and throughout the process, it is important to remember that there is no right or wrong decision. D.L., a 65-year-old woman with a history of deep vein thrombosis, recently received a diagnosis of noninvasive (in situ) breast cancer, found on a routine screening mammogram. D.L. was offered the choice of taking tamoxifen for 5 years after the surgery to reduce her risk of recurrence. After weighing the benefits and risks of her options and considering what was most important to her, D.L. decided not to take tamoxifen. She chose instead to have a mammogram and examination by a practitioner, both yearly. Some people may judge D.L.'s decision as wrong, but in fact it was informed, consistent with her values, and acted on, and she was satisfied with it—it was a high-quality decision.

Another option for evaluating the effectiveness of decision support is to readminister the Decisional Conflict Scale^{16,17} to determine whether the intervention lowered the patient's level of decisional conflict. The final four statements found on the long version of the scale measure the characteristics of a high-quality decision.

Conclusions

Nurses have an important role in teaching, supporting, guiding, and advocating for women making breast cancer-related decisions. The Ottawa Decision Support Framework is a practical approach for guiding oncology nurses in identifying and addressing decision support needs. It is evidence based and has been evaluated through research.^{16,28,30,31} This framework can be used to further develop nursing knowledge through clinical practice and research. The decision tools developed to date have been used and found to be effective in select populations but should also be evaluated in more diverse patient groups. More information on the Ottawa Decision Support

Table 4.—Examples of Breast Cancer Decision Aids

	Topic	Format	Location
Prevention	Making choices: options for lowering risk of breast cancer (in development) ²⁹	Workbook and audiotape	Loeb Health Research Institute, Ottawa Health Decision Centre, Ottawa, Ontario
	Making choices: hormones after menopause ¹ (includes information on breast cancer risk)	Workbook and audiotape	Loeb Health Research Institute, Ottawa Health Decision Centre, Ottawa, Ontario ¹⁴
Treatment: surgery	Lumpectomy vs mastectomy ³⁰	Decision board	Hamilton Regional Cancer Centre, Hamilton, Ontario
	Lumpectomy vs mastectomy ^{20,31}	Workbook and audiotape	Institute for Clinical Evaluative Science, Toronto, Ontario (distributed by Information Service, Canada)
	Lumpectomy vs mastectomy ³²	Interactive program (CD-ROM)	Academic Medical Centre, Amsterdam, the Netherlands
	Lumpectomy vs mastectomy ³³	Videotape or booklet	Foundation for Informed Decision Making, Dartmouth, NH
	Lumpectomy vs mastectomy ³⁴	Booklet or interactive computer program (CD-ROM)	Texas A&M University Health Science Center, Temple, Tex
Treatment: radiation therapy	Radiation vs no radiation after lumpectomy ³⁵	Decision board	Hamilton Regional Cancer Centre, Hamilton, Ontario
Treatment: chemotherapy	Chemotherapy vs no chemotherapy in women with node-negative breast cancer ³⁶	Decision board	Hamilton Regional Cancer Centre, Hamilton, Ontario
	Choices of adjuvant chemotherapy for women with breast cancer (in development)	Decision board	Hamilton Regional Cancer Centre, Hamilton, Ontario

Framework can be found on the Internet at <http://www.lri.ca> by following the links to OHDeC.

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Appendix B

Ottawa Regional Women's Breast Health Centre High Risk Breast Assessment Clinic Questionnaire

109a

**OTTAWA REGIONAL WOMEN'S BREAST HEALTH CENTRE
HIGH RISK BREAST ASSESSMENT
CLINIC QUESTIONNAIRE**

A. GENERAL INFORMATION

Name: _____ Date of Birth: _____ / _____ / _____
Year Month Day

Family Doctor - Name, Address and Phone Number:

Language:

Speak: ☐ English
☐ French
☐ Other → specify _____

Read: ☐ English
☐ French
☐ Other → specify _____

Education level (please indicate highest level you have completed.)

- ☐ Less than grade 9
- ☐ Some high school
- ☐ High school diploma
- ☐ Trade certificate/diploma
- ☐ Some college
- ☐ College diploma/degree
- ☐ Some university
- ☐ University degree

Race/Ethnic Background:

- ☐ White
 - ☐ Black
 - ☐ Oriental/Asian
 - ☐ Other → specify _____
-
-

High Risk Breast Assessment Clinic Questionnaire

B. REASON FOR APPOINTMENT:

We are interested in learning more about your *decision making needs* in preparation for your visit to the High Risk Breast Assessment Clinic at the Women's Breast Health Centre. For example, women who suspect they have a higher risk of breast cancer may be interested in discussing:

- ☆ their personal risk of breast cancer
- ☆ options to find breast cancer early
- ☆ options to lower the risk of breast cancer
- ☆ how to weigh the pros and cons of the options when making a personal choice.

The next set of questions will ask you about your *personal* decision making needs.

1. Which of the following topics are you interested in discussing at your visit?
(check (✓) all the boxes ☐ beside the items you are interested in discussing)

A. My personal risk of breast cancer

- ☐ Identifying my personal risk factors
- ☐ Finding out if I am a candidate for genetic testing

B. Detecting breast cancer early

- ☐ How often I should be screened for breast cancer

C. Options for lowering my risk of breast cancer

- ☐ Lifestyle choices (e.g. nutrition, exercise, alcohol, weight management)
- ☐ Tamoxifen
- ☐ Investigative therapies/prevention research (e.g. Raloxifene/STAR trial)
- ☐ Prophylactic mastectomy

D. Estrogen after menopause

- ☐ Whether or not I should avoid taking estrogen after menopause

E. Steps in decision making

- ☐ How to weigh the pros and cons of the options when making a personal choice

- ☐ other topics, please specify _____
- _____

High Risk Breast Assessment Clinic Questionnaire

2. Are there any decisions about breast health you are actively considering *right now*? _____

3. If you have listed more than one decision in the previous question, which decision is most important to you? _____

4. Now thinking about the decision you are actively considering, we would like to know whether you are having difficulty making this decision. Please place a check (✓) in the appropriate column depending on whether you would answer yes, no, or unsure to the question.

	YES	NO	UNSURE
I'm sure what to do in this decision.			
It's clear which choice is best for me.			
I am aware of the choices I have.			
I know the pros (advantages) of the choices.			
I know the cons (disadvantages) of the choices.			
It's clear which pros are most important to me.			
It's clear which cons are most important to me.			
I have enough support from others to make a choice.			
I'm choosing without any pressure from others.			
I have enough advice to make a choice.			

5. What role would you like to take in making your decision? (check (✓) only one)
- ☐ I prefer to make the final decision after considering my health practitioners' opinion
 - ☐ I prefer that my health practitioner and I share responsibility for deciding what is best for me.
 - ☐ I prefer that my health practitioner makes the final decision but seriously considers my opinions.

Is there anyone else who you would like to be involved in this decision?

High Risk Breast Assessment Clinic Questionnaire

6. What would you find helpful in making this decision? (check (✓) all the boxes ☐ that apply)

- ☐ Information on the options, their benefits and risks
- ☐ Guidance in how to consider the personal issues involved in the choice
- ☐ Information on how others decide about the options
- ☐ Learning about sources of support and resources
- ☐ Other, please specify _____

C. PAST MEDICAL HISTORY:

1. Do you have, or have you ever had, any of the following medical problems?

NO YES UNSURE

- | | | | | |
|----|--------------------------|--------------------------|--------------------------|--|
| a. | ☐ | ☐ | ☐ | Angina (chest pains) |
| b. | ☐ | ☐ | ☐ | Atrial fibrillation |
| c. | ☐ | ☐ | ☐ | Heart attack |
| d. | ☐ | ☐ | ☐ | Osteoporosis |
| e. | ☐ | ☐ | ☐ | High blood pressure (hypertension) |
| | | | | If YES, is the hypertension currently controlled? ☐ Yes ☐ No |
| f. | ☐ | ☐ | ☐ | Diabetes |
| | | | | If YES, is the diabetes currently controlled? ☐ Yes ☐ No |
| g. | ☐ | ☐ | ☐ | Stroke |
| h. | ☐ | ☐ | ☐ | Mini stroke (TIA) |
| i. | ☐ | ☐ | ☐ | Blood clots - ☐ legs (deep vein thrombosis - DVT)
☐ lungs (pulmonary embolism - PE) |
| j. | ☐ | ☐ | ☐ | Mental health problems |
| k. | ☐ | ☐ | ☐ | Cataracts |
| l. | ☐ | ☐ | ☐ | Thyroid or other hormone problems |
| m. | ☐ | ☐ | ☐ | Bleeding disorder |
| n. | ☐ | ☐ | ☐ | Liver disease, yellow jaundice, hepatitis, cirrhosis |
| o. | ☐ | ☐ | ☐ | Other → specify _____ |

2. Do you have any allergies?

☐ No

☐ Yes → specify _____

3. Do you smoke?

☐ No

☐ Yes → specify _____ cigarettes/week

4. Do you use alcohol?

☐ No

☐ Yes → specify _____ drinks/week

5. Have you ever had any medical problems with your breasts?

☐ no

☐ yes

→ if yes, what kind of problems have you had?

☐ cyst or lump

☐ tumour (not cancerous)

☐ pain/swelling

☐ nipple discharge

☐ breast infection/abscess

☐ abnormal mammogram

☐ other → specify _____

6. Have you ever had a breast biopsy?

☐ no

☐ yes

→ if yes, ☐ needle core biopsy

→ findings 1. _____

2. _____

3. _____

☐ fine needle aspiration (FNA) for solid lump not cyst

→ findings 1. _____

2. _____

3. _____

7. Have you ever had breast surgery?

☐ no

☐ yes

→ yes, specify type and date of surgery _____

8. Are you currently experiencing any problem with your breast(s)?

- ☐ no
☐ yes

→ yes, specify _____

9a. Are you currently taking any prescription medications?

☐ No

☐ Yes → specify

1. _____	5. _____
2. _____	6. _____
3. _____	7. _____
4. _____	8. _____

9b. Are you currently taking over-the-counter medication? (e.g. aspirin, vitamins, herbs)

☐ No

☐ Yes → specify

1. _____	5. _____
2. _____	6. _____
3. _____	7. _____
4. _____	8. _____

D. REPRODUCTIVE HISTORY:

Regarding your reproductive history, please answer the following questions:

- At what age did you start your menstrual period? _____ years
- Have you ever used the birth control pill?
☐ no
☐ yes → how long _____ months?
- Number of pregnancies _____
- Number of live births _____
- Age at first live birth _____ years.

High Risk Breast Assessment Clinic Questionnaire

109g

6. Did you ever breast feed?

☐ no

☐ yes → how long _____ months?

7. Did you use hormones (Diethylstilbestrol - DES) during your pregnancy?

☐ no

☐ yes

8. Are you still menstruating?

☐ regularly

☐ irregularly

☐ not at all

9. First day of last menstrual period _____ / _____ / _____
Year Month Day

10. Have you had a hysterectomy?

☐ no

☐ yes → specify year _____

11. Do you have both your ovaries?

☐ yes

☐ no

12. Have you used hormone replacement therapy?

☐ Never

☐ Previously

☐ Current

→ if previously, what type

☐ Estrogen (Premarin, Estrace)

☐ pill ☐ patch ☐ cream ☐ injection

☐ Progesterone (Provera)

☐ Both

☐ Other → specify _____

For how long? _____ months

109;

☐ less than 12 months ago → specify date _____

☐ more than 2 years ago

2. Why did you have the most recent mammogram?

☐ breast problem (diagnosic) → specify _____

☐ **yes**

☐ less than 12 months ago → date of examination / /

year month day

☐ more than 2 years ago☐ **yes**

☐ other → specify _____

☐ don't know

High Risk Breast Assessment Clinic Questionnaire

109j

6. How often do you examine your breast for lumps or irregularities?

Would you say:

- ☐ once a month
- ☐ every 2-6 months
- ☐ every 7-11 months
- ☐ once a year or less often
- ☐ never

F. FAMILY HISTORY:

Please provide as much information as you know about your family history on the following 3 pages. Information on all family members is required whether they have had cancer or not.

The family history is divided into 3 sections:

- 1) Immediate family members
- 2) Extended family - Maternal
- 3) Extended family - Paternal

Please Enter Information On all Family Members Whether They Have Had Cancer or Not

IMMEDIATE FAMILY

	NAME first & last (maiden name)	Date of Birth	Date of Death (or Age)	Diagnosed with Cancer	Type of Cancer	Date of Diagnosis (or Age)	Hospital of Diagnosis (name & province)	Bilateral Cancer for breast/ovarian (yes or no)	Type of Surgery
Example	Jane Smith	1-Jan-66	####	Yes	Breast	12-Apr-96	Ottawa Hospital, Ont.	Yes	mastectomy
YOU									
Your Sister(s)	1.								
	2.								
	3.								
	4.								
	5.								
Your Daughter(s)	1.								
	2.								
	3.								
	4.								
	5.								
Your Son(s)	1.								
	2.								
	3.								
	4.								
	5.								
Your Brothers	1.								
	2.								
	3.								
	4.								
	5.								
Husband/ Partner									

Please Enter Information On all Family Members Whether They Have Had Cancer or Not

MATERNAL FAMILY

[illegible]

Please Enter Information On all Family Members Whether They Have Had Cancer or Not

PATERNAL FAMILY

	NAME first & last (maiden name)	Date of Birth	Date of Death (Age)	Diagnosed with Cancer	Type of Cancer	Date of Diagnosis (or Age)	Hospital of Diagnosis (name & province)	Bilateral Cancer for Breast/Ovarian (yes or no)	Type of Surgery
Example	Jane Smith	1-Jan-66	####	Yes	Breast	12-Apr-96	Ottawa Hospital, Ont.	Yes	mastectomy
Father									
Grandmother (father's mother)									
Aunt(s) (father's sisters)									
Grandfather (father's father)									
Uncle(s) (father's brothers)									
Other family members with cancer (name relationship & name of parent)									

Appendix C

Decision Aid Booklet

Making Choices:
Options for Lowering My Risk
of Breast Cancer



A Decision Aid for Women 50
Years Old and Older

© O'Connor, DeGrasse, Stacey, Verma 1999

University of Ottawa

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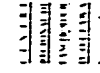
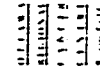
1053 Carling Avenue

Ottawa, ON K1Y 4E9

Phone: 613-761-5499

Fax: 613-761-5492

Email: krobertson@LRI.ca



Welcome!

This workbook and cassette tape prepare you to meet with your practitioner to discuss options for lowering your risk of breast cancer.

Instructions:

1. Set aside 30-40 minutes.
2. Have a pencil ready
3. Place the cassette in a tape recorder, press the play button
4. Stay on the page until you are asked to turn to the next page

Please Note:

Research studies that support the information provided are referenced by numbers such as "1". The complete list of references is at the back of this workbook.

This workbook is for you if...

Breast cancer

Major risk factors & screening tests

Ranking studies that test ways to lower risk of breast cancer

Lifestyle options

Tamoxifen option

Research trial: Raloxifene option

Steps in considering my options

Molly and Sally's situation

Appendix

For more information

References

1

2

3

4

5

7

11

12

13

17

18

21

You will learn about

- You are a woman 50 years old or older
- You do not have breast cancer
- You want to consider options to lower your risk of getting breast cancer

- Breast cancer risks and options to lower your risk of breast cancer



- The benefits and risks of each option

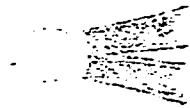
- How to weigh the benefits and risks in your situation



1/10c

Ranking Studies That Test Ways to Lower Risk of Breast Cancer^{10,11}

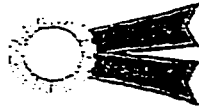
Gold #1



Randomized Trials

- Treatment chosen by tossing a coin. Participants studied closely.
- More confident about the results because users are more comparable to non-users

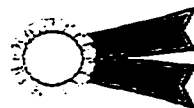
Silver #2



Observation Studies

- "Circumstantial" evidence
- Compares those who choose to use an option with those who don't
- Less confident about the results because users may be different from non-users (e.g. healthier, wealthier, better health habits)

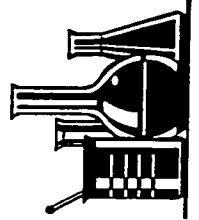
Bronze #3



Expert Opinion

- Based on experience, case studies, or reports of expert committees.

Lab Studies



- Based on lab experiments with human breast cells in a test tube or non-humans
- Not sure how a woman will respond to the option.

Lifestyle Options to Lower the Risk of Breast Cancer

May cut risk by one third to one half



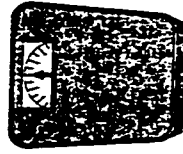
- Exercise regularly
- aim for about 20-30 minutes most days of the week.

Silver #2



16/21 Studies¹²

- Maintain a healthy weight after menopause



Healthy weight range¹³ ;

5'0" = up to 124 Lbs

5'5" = up to 145 Lbs

5'10" = up to 168 Lbs

Silver #2

14, 15, 16

3/3 studies

- Limit alcohol to one drink per day¹⁷
One drink is a 12 oz. beer, a 6 oz glass of wine, or 1 oz of liquor



Silver #2

32/39 studies¹⁷

- Eat 5 or more fruits and vegetables a day.



- choose carrots and green leafy vegetables (like cauliflower, broccoli and cabbage)

- Fruit and vegetables are a good source of vitamins, minerals, and fibre

Silver #2

15/22 studies¹⁸

Lifestyle Options Under Investigation ^{6,7}

- High fibre foods

(whole wheat, bran, fruits, vegetables, legumes, prunes, blackberries)



Silver #2 ¹⁹
4/5 studies



- Lower fat foods (lean meat, poultry with skin removed, low fat and skim milk products) and vegetable-based oils (olive, canola, peanut)



Olive oil

Silver #2 ^{20,21,22}
15/24 studies



- Phytoestrogens

- Soy (found in soymilk, tofu, tempeh, miso)
- Flaxseed



Lab studies only ²³

Tamoxifen Option ^{24,25}

- Tamoxifen is an anti-estrogen that is used in some healthy women at higher risk of breast cancer
- Tamoxifen binds to receptors for estrogen and prevents the action of estrogen on the cell
- Because many breast cancers are very sensitive to estrogen, stopping the estrogen from getting into the cell is a treatment for breast cancer
- Tamoxifen has been used for more than 20 years in women who already have breast cancer

Gold #1

1/3 studies ^{24,25,26}

- It is a pill taken every day for 5 years

- Three randomized trials have been completed testing Tamoxifen in women who don't have breast cancer.

- Two very small Italian and British studies have shown no benefit with Tamoxifen in women with normal risk or in younger women with family history of breast cancer. ^{24,25}

- One very large study of American and Canadian women showed that Tamoxifen cut the risk in half in women who were at high risk either because they were older (over 60 yrs) or had other risk factors such as a family history. ²⁶

See Appendix for more detail on the studies

Results from the North American Tamoxifen Research Study ^{20,28}



Benefits

- Lower risk of breast cancer
- Lower risk of broken bones (hip, spine, wrist) from osteoporosis
- Lower blood level of bad cholesterol (LDL) ^{29,30}



Risks

- Increased risk of cancer in the uterus
- Increased risk of blood clots (leg veins, lung, brain)
- Increased risk of cataracts
- Side effects included hot flashes and vaginal changes (dryness, discharge, itching)
- A small chance of having sexual problems



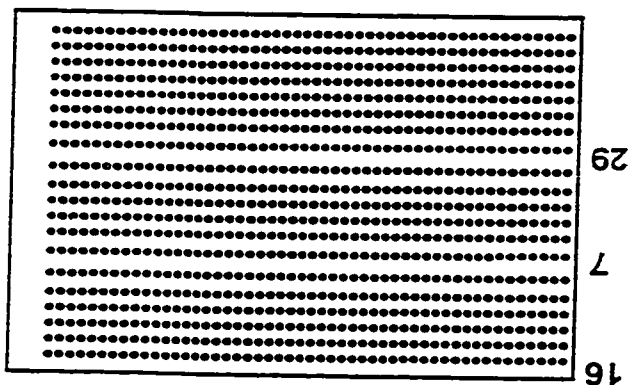
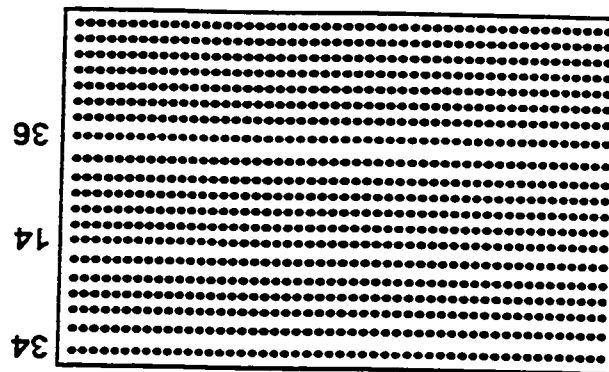
No difference

- No significant difference was found between those taking Tamoxifen and those who did not in terms of weight gain or depression.

Benefits of Tamoxifen for every 1000 women who took it in the North American Study ²⁵



Women 50 years old and older who took the placebo over 5 years

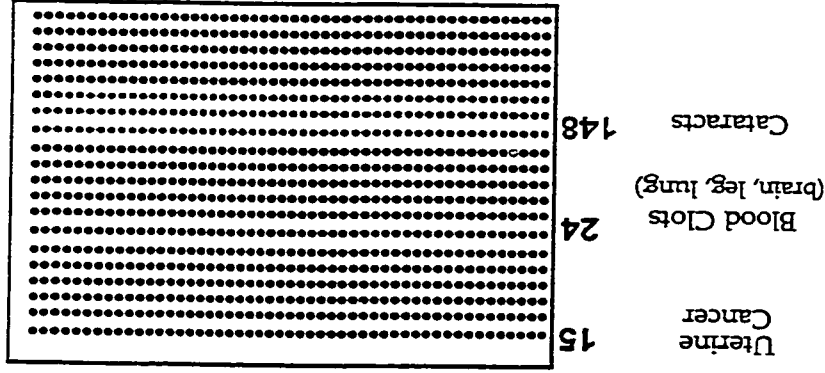


Women 50 years old and older who took Tamoxifen over 5 years

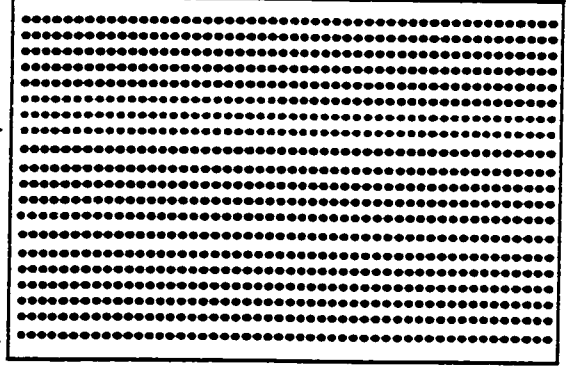
Risks of Tamoxifen for every 1000 women who took it in

26

Women 50 years old and older who took Tamoxifen over 5 years



Women 50 years old and older took the placebo over 5 years



Research Trial: Raloxifene Option

31,32,33

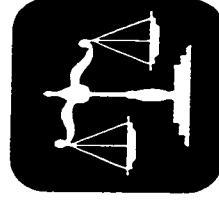
- Raloxifene is a Selective Estrogen Receptor Modulator (SERM) that is very similar to Tamoxifen.

- It is approved for use in women who are post-menopausal for preventing and treating osteoporosis



- Women who took Raloxifene did not seem to have as high a risk of cancer of the uterus, when compared to women who took Tamoxifen, but more studies are needed.

- Side effects include mild leg cramps, an increased risk of blood clots similar to Tamoxifen, and an increase in hot flashes, but possibly not as common as with Tamoxifen.



- If you are at increased risk of breast cancer, you may be asked to join a study comparing Tamoxifen to Raloxifene. The purpose of the study is to find out which drug is better at preventing breast cancer.

- If you are interested in finding out more about this study, ask your practitioner.



What is my personal risk of breast cancer ?



What am I doing to lower my risk of breast cancer ?



What do I think of the possible benefits and risks of Tamoxifen ?



What am I doing for early detection ?



Do I want to consider a research study comparing Raloxifene to Tamoxifen ?



Who should decide about Tamoxifen ?



What questions do I need answered before deciding ?



What is my personal risk of breast cancer ?

My personal risk of breast cancer in the next 5 years is: 23 out of 1000.

}

(For women Molly's age with no risk factors, the risk is 8 out of 1000.)



What am I doing to lower my risk of breast cancer ?

- I try to exercise regularly
- I try to eat more fruits and vegetables
- I limit alcohol
- I need to lose weight



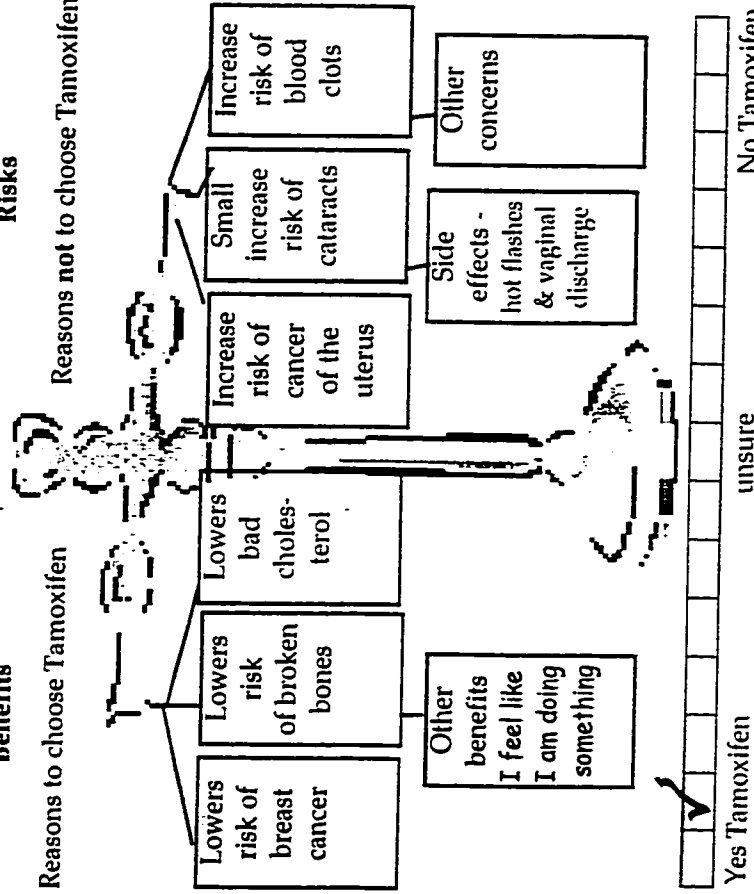
What do I think of the possible benefits and risks of Tamoxifen ?

Benefits

Reasons to choose Tamoxifen

Risks

Reasons **not** to choose Tamoxifen





What am I doing for early detection ?

- I examine my breasts some months
- a nurse examines my breasts every 2 years
- I have a mammogram every 2 years



Do I want to consider a research study comparing Raloxifene to Tamoxifen ?

- I am not sure



Who should decide about Tamoxifen ?

- My practitioner and I together



What questions do I need answered before deciding ?

- How often will I have doctor's visits ?
- Is there something else I should be doing ?



What is my personal risk of breast cancer ?

My personal risk of breast cancer in the next 5 years is :34 out of 1000 women. (for women Sally's age with no risk factors, the risk is 10 out of 1000 women.)



What am I doing to lower my risk of breast cancer ?

- I exercise regularly
- I am trying to eat more fruits and vegetables
- I am trying to maintain a healthy weight



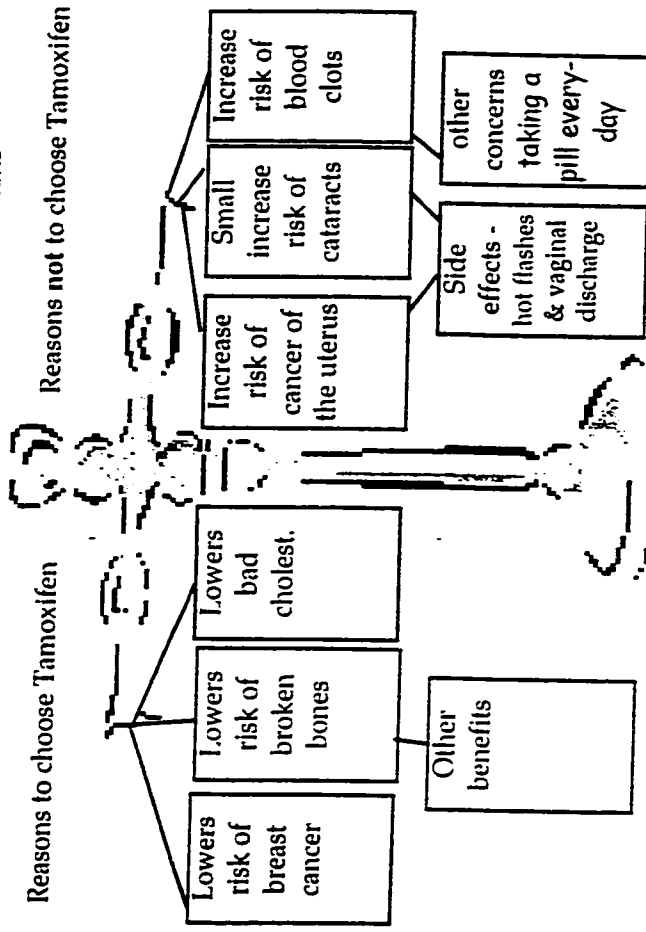
What do I think of the possible benefits and risks of Tamoxifen ?

Benefits

Reasons to choose Tamoxifen

Risks

Reasons not to choose Tamoxifen



☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	-------------------------------------

Yes Tamoxifen

Unsure

No Tamoxifen

Sally's Situation



What am I doing for early detection ?

- my doctor examines my breasts every 2 years
- I have had a mammogram done



Do I want to consider a research study comparing Raloxifene to Tamoxifen ?

- No, I do not want to join a research study



Who should decide about Tamoxifen ?

- I should, after considering my options



What questions do I need answered before deciding ?

- Do I have to give up drinking 2 glasses of wine with dinner every night ?
- I am not comfortable examining my own breasts so should I have a mammogram more often ?

Appendix

There have been 3 gold ranked studies done testing Tamoxifen in women who do not have breast cancer.

North American Study:²⁶

- Found 45% decrease in the number of breast cancers in the premenopausal and postmenopausal women who took tamoxifen.
- It included 13,388 American and Canadian women who were 35 to over 70 years old and were at higher risk for breast cancer because of being over 60 years old or other risk factors such as family history.

British Study:²⁷

- Found no decrease in the number of breast cancers in the women who took tamoxifen.
- It included 2471 British women who had a strong family history of breast cancer.

Italian Study:²⁸

- Found no decrease in the number of breast cancers in the women who took tamoxifen.
- It included 5408 healthy Italian women who had recently had a hysterectomy and were at a normal risk for breast cancer.

There were several reasons why the decrease was only seen in the North American study:

- When compared to the Italian study, the North American women were at higher risk of getting breast cancer and were more likely to have taken the Tamoxifen as prescribed. More of the Italian women stopped taking the Tamoxifen early.
- When compared to the British study, the North American women were older, less likely to have an inherited type of breast cancer, and there were differences in the length of treatment with women in the British study taking Tamoxifen for 8 years.

Presently, there is another international study underway testing Tamoxifen in women at increased risk of breast cancer.

For More Information Books

Altman, Roberta. *Every Woman's Handbook for Preventing Cancer: More than 100 Simple Ways to Reduce Your Risk.* Toronto: Pocket Books, 1996.

A medical journalist and breast cancer survivor shares many ways that women can change to help prevent cancer.

American College of Sports Medicine. *ACSM Fitness Book.* 1998

A guide for what exercises to do, when to do them and how to execute them properly. After a four-item fitness test, there are step-by-step instructions to create an exercise program that is perfectly suited to you. The ACSM is dedicated to promoting healthier lifestyles for people around the world.

American Institute for Cancer Research's Program for Cancer Prevention. *Stopping Cancer Before it Starts.* New York: Golden Books, 1999.

Helps the reader understand the cancer process, presents some of the most important science behind the new recommendations to prevent cancer, provides practical tools to make changes to lower cancer risk, and shares some recipes for a healthier you. Primary focus on nutrition and exercise. The AICR conducts research and education programs.

Canadian Cancer Society. *Healthy Eating: Reducing Your Risk of Cancer.* Toronto: The Author, 1996.

A free information booklet with healthy eating tips that include: what foods to buy, how best to prepare the foods, and what to eat.

Love, Susan and Lindsey, Karen . *Dr. Susan Love's Breast Book.* Don Mills, Ontario: Addison-Wesley Publishing Co, 1995

A resource book with information on breast care, screening, diagnosis, treatment, and research. The section on causes of breast cancer covers genes, and environment, risk factors (genetic, hormonal, external), pre-cancerous conditions, prevention, and screening.

Michnovicz, JJ and Klein, DS. *How to Reduce Your Risk of Breast Cancer.* New York: Warner Books, Inc., 1994.

The latest scientific information about breast cancer - who gets it and how to prevent it. Steps are given that you can take to help guard yourself and your family's health. Information is provided on low fat diet, phytochemicals, antioxidants, aerobic exercise, body shape, types of dietary fibre that eliminate estrogen from your body, soybeans, cabbage,... and more.

For More Information Books

Potter, John, F. *How to Improve Your Odds Against Cancer.* Lifetime Books Inc. 1998

A health guide for the lay person on prevention strategies and techniques of early detection. Prevention focuses on changing your patterns of living addressing the risk of developing cancer with tobacco use, excessive alcohol ingestion, dietary factors, excessive exposure to sunlight, chemicals, drugs, sexually transmitted diseases, and X-ray's. Dr. Potter is a professor of surgery.

Sharkey, Brian. *Fitness and Health..* 1997.

Explains in plain English how the body responds to physical activity, why physical activity is so important to health and how best to become physically active. Sharkey is past president of the American College of Sports Medicine and a world renowned fitness authority.

Winawer, Sidney and Shike, M. *Cancer Free: The Comprehensive Cancer Prevention Program.* New York: Fireside Book/ Simon and Schuster, 1995.

Two physicians from Memorial Sloan-Kettering Cancer Center give guidelines to help people design a personal program to increase their odds of staying cancer free. Information on assessing your cancer risk, understanding the link between the mind and cancer, re-evaluating your diet and lifestyle, and designing your personal prevention program is discussed.

Websites

American Cancer Society
<http://www.cancer.org>

American Dietetic Association & Canadian Dietetic Association
position on Women's health and nutrition
<http://www.eatright.org/awomenshealth.html>

American National Cancer Institute
<http://cancernet.nci.nih.gov>

Canadian Cancer Society
<http://www.cancer.ca>

University of Pennsylvania Cancer Centre
<http://oncolink.com>

Toll-Free Telephone Numbers

American Cancer Society
1-800-ACS-2345

Cancer Information Service - Canadian
1-888-939-3333

National Cancer Institute Cancer Information Service- U.S.A.
1-800-4-Cancer

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6. Canadian Cancer Society, 1999 www.cancer.ca
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Desktop publishing of this booklet was done at the
Loeb Health Research Institute by Kim Robertson

Appendix D

Decision Aid Worksheet



What am I doing for early detection ?

Practitioner
recommendations

I have a mammogram done every 1 to 2 years ☐ Yes, every 1-2 years ☐ Yes, have had one ☐ No _____

I have my breasts examined by a doctor or nurse every year ☐ Yes, every 1-2 years ☐ No _____

I examine my breasts every month ☐ Yes, every month ☐ Yes, some months ☐ No _____



Do I want to consider a research study comparing Raloxifene to Tamoxifen ?

- ☐ Yes, I am interested in finding out more about the study
- ☐ I am not sure
- ☐ No, I do not want to join a research study



Who should decide about Tamoxifen ?

- ☐ I should, after considering my practitioner's opinion
- ☐ My practitioner and I together
- ☐ My practitioner
- ☐ I am not sure



What questions do I need answered before deciding ?

Steps in Considering My Options for Lowering My Risk of Breast Cancer

Appendix E

Decision Aid Audio-script

**Decision Aid Audio-Script for
"Making Choices: Options for Lowering My Risk of Breast Cancer"**

Hello, My name is Pam and I know what it's like to make decisions about lowering the risk of breast cancer. It can be confusing, emotional, and many women feel there is a lot to learn. That is why this program was developed.

I will be your guide for this workbook that prepares you for an informed discussion with your practitioner about your own situation and the options for lowering your risk of breast cancer. Your practitioner may be a doctor or nurse specialized in options for lowering your risk of breast cancer.

When you hear the following sound:.

****SOUNDS****

Please turn to the next page of your workbook. You can stop the tape at any time if you are not ready to continue on to the next page or you can rewind the tape to re-listen to a section.

Let's start by looking at page number 1: "This workbook is for you":

PAUSE to find page

This workbook was created for women aged 50 or older who do not have breast cancer and want to consider options to lower their risk of getting breast cancer.

In this workbook, you will learn about:

- what puts women at increased risk for breast cancer;
- the options for lowering your risk of breast cancer, and
- the benefits and the risks or pros and cons of each option.

Then you can use this information to weigh the benefits and risks in your own situation.

Let's start by talking about breast cancer:

****SOUNDS****

Breast cancer occurs when a normal cell in the breast becomes abnormal and grows out of control.

There are two types of breast cancer: invasive and non-invasive.

Invasive breast cancer occurs when the breast cancer grows into a lump in the breast and it can spread to other places in the body such as the bones, liver, lungs, and brain.

Non-invasive breast cancer is also called "in situ" breast cancer. It grows only in the breast and does not spread to other parts of the body.

Unfortunately, of those who get invasive breast cancer, 3 out of 10 women will die within 10 years.

Some women have described the effects of breast cancer as a change in their appearance after breast surgery.

If they had chemotherapy, they have described temporary side effects such as nausea, vomiting, fatigue, hair loss, and an increased risk of getting an infection.

If they had radiation therapy, they have described temporary side effects such as fatigue and a skin reaction in the treatment area.

Emotionally, some women have felt:

- worried, down or depressed;
- fearful that the cancer will return or spread or
- fearful of dying from breast cancer.

Sometimes breast cancer made women feel like they were the only ones suffering, and they felt very alone. In other situations, the breast cancer affected other family members.

Some women were concerned about how their breast cancer might affect their sexuality.

PAUSE to next page

Now, let's talk about the major risk factors for breast cancer and options for screening.

The main factors that put you at higher risk of getting breast cancer are

- being female,
- increasing age (the risk of breast cancer is higher in women aged 50 or older)
- having a family history of breast cancer in a mother, sister, or daughter, or
- having had previous breast biopsies showing abnormal cells.

A woman's risk of breast cancer is also increased by these other risk factors:

- never having children;
- having your first child after 30;
- starting your menstrual periods earlier than 12 years of age; or
- going through menopause after 55 years of age.

As you can see from this list, it is often impossible to change these risk factors.

The next step is to consider what screening tests you are doing. The screening tests are divided into breast screening or genetic testing.

Breast Screening finds breast cancer early and is the best way to increase the chances of being cured of breast cancer. These practices will help you find a breast lump when it is small and before it has the chance to spread.

All women 50 years or older should:

- have a mammogram every 1 to 2 years;
- have their breasts examined every year by a nurse or doctor trained in breast exams; and
- should examine their breasts every month.

Some women with breast cancer in their family, may want to know more about genetic testing. Genetic tests can tell if a woman has a high risk of inherited breast cancer or breast cancer that runs from generation to generation in a family. Genetic testing is not for everyone as very few breast cancers are inherited. Only, 5 out of 100 breast cancers are inherited.

For more information, you can talk to your practitioner about the usefulness of genetic testing in your situation.

****SOUNDS****

Before we move on to talk about the options for lowering your risk of breast cancer, let's talk for a minute about how we rank or judge the quality of the research studies on lowering the risk of breast cancer.

We have chosen to use 4 categories to rank the studies:

The Gold or #1 ranking is given to randomized research trials. This means that the treatment tested was chosen by tossing a coin and the people who joined in the study did not have a choice of which treatment they would get. As well, they were watched very closely throughout the entire study. We can feel more confident about the results of these gold ranked studies because the people who used the treatment are more comparable to the ones who did not use it.

The silver or #2 ranking is given to observational studies. This means that the results are more circumstantial or depend upon the individual situation. People who joined in these studies were able to choose the treatment option they wanted. We are not as confident with these results compared to those of gold ranked studies because the people who used the treatment may be different than the ones who did not use it. For example, they may have been healthier, had more money, or had better health habits such as doing breast exams every month.

The bronze or #3 ranking is given to information based on expert opinion. Expert opinion may come from experience, individual case studies, or reports from expert committees.

The lab studies ranking is based on the results learned in laboratory experiments. These experiments may be done on human breast cells in a test tube or non-humans. It is not known how women will respond to the treatment option.

PAUSE to next page

Now let's discuss the **lifestyle options for lowering your risk of breast cancer**. We have grouped them into lifestyle options that are proven and those options that are still being investigated.

Women who **exercise regularly, maintain a healthy weight, limit alcoholic drinks and eat more fruits and vegetables** may lower their **risk** of breast cancer **by one-third (1/3) to one-half (1/2)**.

Now for the specifics of what you would have to do to lower your risk of breast cancer:

You need to exercise for **20 to 30 minutes most days of the week**. 16 out of 21 silver ranking studies have proven that regular exercise lowers the risk of breast cancer. Exercise includes walking, biking, running, swimming, golfing or doing similar activities.

You need to keep a **healthy weight after menopause**. All the silver ranking studies have proven that body weight is linked with risk of post-menopausal breast cancer. We have given you the upper limit of a healthy weight range according to 3 levels of height. Consider your height and look at these weights to see if you have a healthy weight. (PAUSE)

Next you need to **limit the number of alcoholic drinks to 1 a day**. For every additional 1 drink of alcohol a day, the risk of breast cancer increases. 32 out of 39 silver ranking studies confirmed the link between drinking alcohol and risk of breast cancer.

As well, you need to **eat 5 or more fruits and vegetables a day**. In 15 out of 22 silver ranked studies, the risk of breast cancer was lower in women who ate a diet high in fruits and vegetables. The results are more consistent for women who ate more vegetables, specifically **carrots and leafy green vegetables such as cauliflower, broccoli and cabbage**. **Fruits and vegetables are also a good source of vitamins, minerals, and fibre.**

****SOUNDS****

Other **lifestyle options that are under investigation** include:

- **eating foods high in fibre,**
- **limiting the amount of fat in your diet, and**
- **eating foods high in phytoestrogens.**

These options have inconsistent results on the risk of breast cancer.

Eating foods high in fibre and choosing lower fat foods have not been proven to lower your risk of breast cancer. However, they are linked with better health and lowering your risk of other types of diseases such as colon cancer and heart disease.

Phytoestrogens such as Soy or flaxseed, have mostly been studied in laboratories for their effects on heart disease, cancer, osteoporosis, and menopause symptoms. **Soy is found in soymilk, tofu, tempeh, and miso,** and flaxseed is found in special breads at the bakery or can be bought as flax seed oil.

PAUSE to next page

Another option for lowering your risk of breast cancer is with a medicine called Tamoxifen.

Tamoxifen is an anti-estrogen that is used in some healthy women who are at higher risk of getting breast cancer. Estrogen is a female hormone in the body that can stimulate breast cancer cells.

Tamoxifen binds to receptors for estrogen to prevent the estrogen from having an effect on the cell. We have estrogen receptors in different parts of our body such as our breasts, uterus, and bones.

Because many breast cancers are very sensitive to estrogen, stopping the estrogen from getting into the cell is a treatment for breast cancer.

Tamoxifen has been used for more than 20 years in women who already have breast cancer.

Tamoxifen is taken in the form of a pill every day for 5 years.

Because research has proven that tamoxifen prevented breast cancer from returning in women who had breast cancer, further research was done to find out if it would prevent breast cancer from starting in healthy women who did **not** have breast cancer.

There have been 3 gold ranked studies done testing Tamoxifen in women who don't have breast cancer.

Two very small Italian and British studies have shown no benefit with tamoxifen taken by women with normal risk, or in younger women with a strong family history of breast cancer.

One very large study done with American and Canadian women showed that tamoxifen cut the risk in half. In this study, the women were at higher risk either because they were older - meaning that they were over 60 years of age, or the women had other risk factors such as a family history of breast cancer.

All three studies showed there were risks and side effects from taking Tamoxifen.

For more information on these studies, look in the appendix at the back of the booklet.

****SOUNDS****

So now let's look specifically at what Benefits and Risks were found in the North American Tamoxifen research study. In this randomized research study, some women took Tamoxifen while others took a placebo or "fake" pill. The women in the two groups were similar in all respects, except that one group of women was taking Tamoxifen. In this study, strong evidence was found about Tamoxifen's benefits and risks.

In the women who took tamoxifen, the risk of invasive and non-invasive breast cancer was lower.

The women who took tamoxifen also had a lower risk of osteoporosis. Osteoporosis is a condition of weak, brittle bones that break very easily. Broken bones or fractures are most often in the hip, spine, or wrist. Osteoporosis is more common in women after menopause when there is a natural drop in a woman's estrogen. The Tamoxifen binds to the estrogen receptors in the bones to make the bones stronger.

According to other studies, women who took Tamoxifen had lower blood levels of bad cholesterol or LDL. Higher blood levels of bad cholesterol are linked to an increased risk of heart disease.

The women who took Tamoxifen had an increased risk of some rare but serious problems that included cancer of the uterus, blood clots, and cataracts.

Women, in the study, were followed more closely for early signs of pre-cancer changes in the uterus such as unusual vaginal bleeding. The cancers of the uterus that were found in these women were found early and were curable. Women who had their uterus removed did not need to be concerned about getting cancer of the uterus.

The risk of blood clots was higher for women taking Tamoxifen. Blood clots can occur in the leg veins. Sometimes the clot can travel:

- to the lungs causing chest pain and difficulty breathing, or
- to the brain causing a stroke.

Blood clots are more likely to occur in women who are less physically active.

There was an increased risk of vision changes from cataracts (or clouding of the lens inside the eye) for the women who took Tamoxifen.

These women were also more likely to experience side effects such as hot flashes and vaginal changes. The vaginal changes included dryness, discharge, and itching.

Women who took Tamoxifen compared to women taking the placebo had a small chance of sexual problems such as feeling less interested in sex and taking longer to become sexually aroused or to reach an orgasm.

In the North American research study, there was no significant difference between those taking tamoxifen and those who did not in terms of weight gain, feeling depressed, or sad.

PAUSE to next page

Now let's consider the benefits of Tamoxifen:

On this page you can see what happened, over 5 years, to women aged 50 and older who took tamoxifen compared to those who took placebo.

There are two sets of blocks of 1000 circles on this page that represent 1000 women who did not take tamoxifen on the left and 1000 women who took tamoxifen on the right.

Looking at the top of each block of circles, the shaded circles to the left represent 34 post-menopausal women out of 1000 who did not take Tamoxifen and who got invasive breast cancer.

Looking at the block on the right, you will notice that only 16 out of 1000 post-menopausal women who took tamoxifen got invasive breast cancer. With Tamoxifen, half as many women got breast cancer.

Now let's look at the risk of non-invasive breast cancer. Looking at the second set of shaded circles from the top, the shaded circles to the left represent 14 women out of 1000 who did not take Tamoxifen and who got non-invasive breast cancer. Looking at the block on the right, you will notice that only 7 out of 1000 women who took Tamoxifen got non-invasive breast cancer. Again with Tamoxifen, half as many women got non-invasive breast cancer.

The risk of broken bones, such as at the hip, spine, or wrist, decreased from 36 to 29 out of 1000 post-menopausal women. This is a decrease of a little less than one-quarter.

****SOUNDS****

On this page we will consider the risks of tamoxifen.

Now looking at the first set of shaded circles at the top. Cancer of the uterus occurred in 4 post-menopausal women out of 1000 who took a placebo and 15 out of 1000 post-menopausal women who took tamoxifen. This is an increase of almost 4 times.

The risk of blood clots increased from 12 to 24 out of 1000 post-menopausal women. This is twice as many. About half of these clots went to the brain resulting in a stroke and the rest were found in the legs or lungs.

The risk of cataracts increased from 124 to 148 out of 1000 women. This is a small increase of 20% or about one fifth.

As you can see there are several benefits and risks that need to be considered when thinking about taking tamoxifen to lower your risk of breast cancer.

PAUSE to next page

Another option for potentially lowering your risk of breast cancer is to consider joining a research trial testing Raloxifene.

Raloxifene is a Selective Estrogen Receptor Modulator, also called a SERM for short, that is very similar to Tamoxifen.

Raloxifene has recently been approved for use in post-menopausal women for preventing osteoporosis, or as a treatment in women who have osteoporosis to prevent broken bones.

Women who took Raloxifene did not seem to have as high a risk of cancer of the uterus compared to women who took tamoxifen. More studies are needed and women who take Raloxifene still need to be watched closely.

The side effects of Raloxifene include mild leg cramps, an increased risk of blood clots similar to Tamoxifen, and an increase in hot flashes but the hot flashes may not occur as often, as with Tamoxifen.

If you are at increased risk of breast cancer you may be asked to join a study comparing Tamoxifen to Raloxifene. The purpose of the study is to find out which drug is better at preventing breast cancer. If you decide to join the study, the choice of which medicine you would take, Tamoxifen or Raloxifene, would be decided randomly.

If you are interested in finding out more about this study, ask your practitioner.

****SOUNDS****

Now it is time to **consider your options** for lowering your risk of breast cancer. On the next page I will review the 7 steps with some questions you need to ask yourself; then I will show you how two other women have answered these questions for themselves. Finally, you will get a chance to consider the 7 steps using a personal worksheet.

Step 1 asks you to find out your personal risk of breast cancer.

Step 2 asks: What are you doing to lower your risk of breast cancer?

Step 3 asks: What do you think of the possible benefits and risks of Tamoxifen?

Step 4 asks: What are you doing for early detection of breast cancer?

Step 5 asks: Do you want to consider a research study comparing Raloxifene to Tamoxifen?

Step 6 asks: Who should decide about Tamoxifen?

Step 7 asks you to list any questions that need answering before you decide.

It may help to hear how other women have answered these questions before we complete your personal worksheet. I will describe two women's decisions and the factors that were important to them.

PAUSE to next page

Molly is a 55 year old women, who started her menstrual periods when she was 12. Her first child was born when she was 28 years old. Her mother had breast cancer.

Molly was concerned about her chance of getting breast cancer. Her risk of breast cancer over the next 5 years was 23 out of 1000. The risk of breast cancer for women the same age as Molly with no risk factors was 8 out of 1000. Any score over 17 is considered to be high risk.

In Step 2, Molly considered what she was doing to lower her risk of breast cancer. She identified that she was:

- trying to exercise regularly,
- eat 5 or more fruit or vegetables daily, and
- does not routinely have more than 1 drink a day.

She did however, weigh more than she should. Overall, she identified that there was room to improve on her lifestyle practices.

In step 3, Molly looked at the weigh scale showing reasons to choose tamoxifen (or benefits) on the left and reasons not to choose tamoxifen (or risks) on the right.. She added another benefit of taking Tamoxifen to the scale. Molly felt that taking Tamoxifen would make her feel like she was doing something. She did not think of any additional concerns to add to the boxes on the scale.

Next, Molly filled in the weigh scale boxes with a pencil to show her values. In each box, Molly filled in the amount that showed how important each benefit and risk was to her. She filled in a large portion of the box if the factor was very important, and only a small part if it was less important. Those factors that were not at all important, she left blank.

For benefits, she thought that lowering her risk of breast cancer from 23 to 12 out of a 1000 was very important. Molly was very concerned that she would get breast cancer and wanted to feel like she is doing something to lower her risk. She also identified that lowering her risk of osteoporosis was very important. Lowering her blood level of bad cholesterol was not that important.

On the risk side, she was very concerned about increasing her risk of cancer of the uterus. The increased risk of cataracts, blood clots, and side effects were not that important to her.

At the end of this step, Molly placed her check mark on the row of boxes to show her overall leaning after considering all the risks and benefits and how important they were for her. She was strongly leaning towards taking Tamoxifen.

****SOUNDS****

In step 4, she considered her current practices for early detection of breast cancer. She identified that she examined her breast every few months when she remembered and that she could improve by doing this more often. She was having her breasts examined by a trained nurse every 2 years at the same time as having a mammogram.

For the 5th step, Molly identified that she was not sure if she wanted to join the research study testing Raloxifene. She was going to ask her practitioner a few more questions about the study first.

Step 6 is where Molly thought about who should make the decision. She felt most comfortable sharing the decision making with her practitioner.

In the final step, Molly wanted to ask her practitioner two questions:

*How often she would have doctor's visits if she chooses Tamoxifen, and
If there was something else that she should be doing.*

PAUSE to next page

On the next page is Sally's situation. Sally was a 61 year old woman, who started her menstrual periods when she was 13. Her first child was born when she was 23 years old. Her sister had breast cancer and Sally had 1 breast biopsy done a year earlier.

Based on these risk factors, Sally's estimated risk of breast cancer over the next 5 years was 34 out of 1000. For women Sally's age with no risk factors, the risk of breast cancer was 10 out of 1000.

In Step 2, Sally considered what she was doing to lower her risk of breast cancer. She identified that she exercised everyday all year round. She tried to eat 5 or more fruit and vegetables a day. She did however, weigh more than she should and enjoyed 2 glasses of wine at dinner every evening. Based on her lifestyle practices, she agreed that she could make changes to lower her risk of breast cancer.

In Step 3, Sally first identified that another concern about taking Tamoxifen was that she did not want to take a pill every day that would interfere with her natural body processes. She did not think of any additional benefits.

Next, Sally filled in the weigh scale boxes with a pencil to show her values. On the benefit side, she thought that lowering her risk of breast cancer from 34 to 16 out of 1000 was very important. The extra protection from osteoporosis and lower levels of bad cholesterol was not important.

On the risk side, she was very concerned about the increased risk of cancer of the uterus from 4 to 15 out of 1000, blood clots from 12 to 24 out of 1000, side effects of Tamoxifen, and the need to take a pill everyday. She shaded all of these to show their importance to her.

At the end of this step, Sally placed her check mark on the row of boxes to show her overall leaning after considering all the risks and benefits and how important they were for her. She was strongly leaning towards **not** taking Tamoxifen.

****SOUNDS****

In step 4, Sally considered her current practices for early detection of breast cancer. She identified that she does have her breasts examined by her family doctor every 2 years and she has had a mammogram done. She does not examine her own breasts.

For the 5th step, Sally identified that she was not interested in joining the research study testing Raloxifene.

Step 6 is where Sally thought about who should make the decision. She felt very strongly that she would make the decision herself.

In the final step, Sally wanted to ask her practitioner:

If she needed to give up drinking 2 glasses of wine with dinner every night, and

If she needed to have a mammogram done more often because she does not examine her own breasts.

PAUSE to next page

Now it is time for you to complete **your own personal worksheet**. This worksheet will help you to consider all the issues and may be a helpful summary to show your practitioner. Please pull out your worksheet and have a pencil in hand.

PAUSE

I will help you complete this personal worksheet by describing what to do in each step. If you have not completed a step by the time I've finished reviewing it, I will remind you to stop the tape until you are ready to go on. Also, if you have questions, you can write them down on the back of the worksheet.

Let's start with step 1 called "What is my personal risk of breast cancer?" By now you should have been given your personal risk of breast cancer over the next 5 years. A woman with a value of less than 17 out of 1000 over 5 years is considered to be at normal risk of breast cancer. If your value is higher than 17 it means you are at higher risk. This information will be used again in Step 3.

In step 2, you need to consider what you are doing to lower your risk of breast cancer. For each of the lifestyle choices, place a check mark in the box that best describes what you are doing. You have four choices:

- you can choose yes, you are doing it;
- yes, you are trying to do it;
- no, you are not doing it; or
- you are thinking about doing it.

Put a question mark in the box if you are unsure.

The first lifestyle option is exercising for 20-30 minutes most days of the week,
 Next rate if you are eating 5 or more fruits and vegetables a day,
 Mark if you limit your alcohol drinks to 1 or fewer a day, and
 Finally, do you have a healthy weight?
 You may stop the tape if you need more time to complete this section (PAUSE).

For the 3rd step ask yourself to think of all the possible benefits and risks of Tamoxifen. On the left side of the page you will see a list of reasons to choose Tamoxifen and on the right side, reasons not to choose Tamoxifen. Over five years, 1000 women like you who take Tamoxifen will have: fewer breast cancers, seven fewer broken bones, and lower levels of bad cholesterol. Over five years, 1000 women like you who take Tamoxifen will have: 11 more cancers of the uterus, 24 more cataracts, and 12 more blood clots (5 of which will occur in the brain causing a stroke and the rest occurring in the lungs or legs). There are also side effects such as hot flashes and vaginal changes.

Now lets move on to the weigh scale. Look at the empty boxes for other benefits and other risks. Take a few minutes to add in any other reasons you might have to choose Tamoxifen or reasons not to choose Tamoxifen if there is something that you identified that is not in the boxes.

You may want to stop the tape now until you are ready to move on to the next step. (PAUSE)

Now take your pencil and shade in the boxes on the weigh scale to show how important each of the benefits and risks are to you. Fill in the whole box if it's very important, part of the box if it's somewhat important, or leave it blank if it's not at all important. There are no right or wrong ratings of importance, this is your personal opinion about each of the benefits and risks. You can stop the tape until you are finished shading the weigh scale boxes. (PAUSE)

At the end of step 3 in "my leaning", you can show where you are leaning in your decision. Check close to the left if you are leaning towards taking tamoxifen, close to the right if you are leaning toward not taking tamoxifen, or close to the middle if you are not sure. Again, there is no right or wrong answer, it is your opinion based on everything you know about tamoxifen.

In step 4 you need to think about what you are doing for early detection: Place a check mark in the box that best describes your answer. Put a question mark in the box, if you are unsure.

- The first question asks if you have a mammogram done every 1 to 2 years; or have you had one done at some time?
- The next question asks if you have your breasts examined by a doctor or nurse every year, every 1 to 2 years, or if you do not have them examined.
- And finally, do you examine your own breasts every month, some months, or you do not examine them.

You may stop the tape if you need more time to complete this section (PAUSE).

In step 5, you are asked if you want to join a study comparing Raloxifene and Tamoxifen. Check the box that best identifies how you feel about this question:

- yes, you are interested and want to find out more about the study;
- you are not sure; or
- no, you do not want to join a research study.

In step 6, you can show who should make the decision about tamoxifen. You may answer that:

- you would prefer to make the decision on your own after considering your practitioner's opinion;
- you prefer to make the decision together with your practitioner;
- you prefer to have your practitioner decide for you; or
- you can check the last box if you are not sure.

In step 7 called "My questions", note any questions that you may have for your practitioner. At this point you may want to stop the tape to add your questions (PAUSE).

The personal worksheet you have just completed will help you and your practitioner discuss your options for lowering your risk of breast cancer. Bring the worksheet with you when you go to your next visit.

****PAUSE****

This completes the last part of the workbook.

Here are four suggestions you may want to consider for the next visit with your practitioner when you share the personal worksheet you have just completed:

First, review possible benefits and risks by asking your practitioner to look over Step 3 of your personal worksheet to fill in gaps of information and to verify your benefits and risks.

Second, clarify your personal importance of the benefits and risks by showing your practitioner your weigh scale. You may wish to adjust your opinions, if you receive new information that changes your views.

Third, discuss your decision about choosing, not choosing, or remaining unsure about tamoxifen.

Finally, talk to your practitioner about helping you with healthy lifestyle changes and clarifying the breast screening you should be doing?

If you are interested in reading more about options for lowering your risk of breast cancer, there is a list at the back of the workbook. You can also find more detailed information about the 3 studies done on women who took Tamoxifen to prevent breast cancer.

The references to the studies we mentioned are also found at the end of the workbook.

Inside the front cover is a list of all the members of the research team who participated in making this workbook.

Good luck with your decision making and I hope that you have found this helpful in preparing for a discussion with your practitioner.

(~ 35 minutes to read)

Appendix F

Letter of Support



**Ottawa Regional
WOMEN'S BREAST HEALTH CENTRE**

Ottawa Civic Hospital
Grimes Lodge, 5th Floor
200 Melrose Avenue
Ottawa, ON K1Y 4K7
Tel: (613) 761-4400
Fax: (613) 761-4405

113a

July 14, 1999

Dawn Stacey, RN, BScN, OCN (R)
Graduate Student
University of Ottawa
Master of Nursing Program

Dear Dawn:

It is with great pleasure that we provide you with this letter of support for your thesis project entitled, "Development and Evaluation of a Decision Aid for Women Considering Options to Lower Their Risk of Breast Cancer". We are extremely excited and pleased to support this research project at a time when we are launching our new High Risk Breast Assessment Clinic. We feel that this type of research is extremely important to assist us in evaluating how we can help women in managing their risk of developing breast cancer.

We look forward to working with you on this project and intend to support your work through to completion.

Sincerely,

Cathy De Grasse, RN, MScN, OCN (R)
Program Coordinator, Clinical Services

D.J. Mirsky, MDCM, FRCS(C), FACS
Program Coordinator, Medical Services

Appendix G

Consent Forms



Ottawa Regional
WOMEN'S BREAST HEALTH CENTRE
The Ottawa Hospital – Civic Campus
Grimes Lodge, 5th Floor
200 Melrose Avenue
Ottawa, ON K1Y 4K7
Tel: (613) 761-4400
Fax: (613) 761-4405

114a

Consent Form – Phase I

Evaluating the Effectiveness of a Decision Support Program for Post-menopausal Women at Increased Risk of Breast Cancer Considering their Options to Lower their Risk:

Pre-Test of the Decision Aid

Research Team:

Annette O'Connor, RN, PhD, Professor, Faculty of Nursing, University of Ottawa
Cathy DeGrasse, RN, MScN, Administrator, Ottawa Regional Women's Breast Health Centre
Shailendra Verma, MD, Medical Oncologist, Ottawa Regional Cancer Centre
Eva Tomiak, MD, Medical Oncologist, Ottawa Regional Cancer Centre
Elaine Jolly, MD, Gynecologist, Ottawa Hospital – General Campus
Douglas Mirsky, MD, Surgeon, Ottawa Regional Women's Breast Health Centre
Ann Cranney, MD, Rheumatologist, Ottawa Hospital – Civic Campus
Lisa Moore, MD, Family Physician, Family Medicine Centre, Ottawa Hospital – Civic

Purpose:

The purpose of this research study is to find out what women think about educational materials for women making decisions about their options to lower their risk of breast cancer. What we learn from this study will help doctors and nurses in the future to provide better support to women who are making these decisions. As a woman who is post-menopausal, we are asking for your opinion on the educational materials. Your comments and suggestions will be used to improve them.

Procedure:

The following are the steps in the procedure:

1. You will be asked to complete a survey telling us a bit about yourself, what you know about lowering your risk of breast cancer, and how difficult the decision is for you. This survey will take about 15 minutes to complete.
2. You will then be given a workbook and audiotape that will give you information about options for lowering your risk of breast cancer. As well, the workbook guides you through an exercise that will help you to think about what is most important for you in deciding on your options. The workbook will take about 30 to 45 minutes to use.
3. After you have used the workbook and audiotape, you will be asked to complete a survey with questions similar to those in the first survey. As well we want you to tell us your opinions about the workbook. This will take about 15 minutes.

Risks and Benefits:

There are no known risks of taking part in this study. You may find the information in the workbook and audiotape upsetting. If you feel upset, you can discuss your feelings with a doctor or nurse at the Women's Breast Health Centre. The possible benefits of the study are:

- The workbook and audiotape may help you make a decision about ways of lowering your risk of breast cancer.
- What we learn from this study may help other women who will have to make decisions about options to lower their risk of breast cancer.

Confidentiality:

The information collected during this study from your surveys will be kept confidential. A code number will be used to identify the information so your name will not appear on any papers. All relevant information and surveys obtained while you are on this study will only be made available to the research team and, if requested, to the Research Ethics Committee at the Ottawa Hospital – Civic Campus. If the results of the study are published, you will not be identifiable on any documentation leaving this site.

Voluntary Participation:

Joining this study is your choice. You are under no obligation to take part in the study, and you may withdraw from the study at any time.

Consent:

I have read the above information and understand this consent form. I have also had the chance to ask questions and they have been answered to my satisfaction. I agree to take part in this study.

Name _____

Date _____

Witness _____

You will receive a copy of this consent form. If you have any questions about this study, you can telephone the researcher, her supervisor, or the director of the research institute:

Dawn Stacey, RN, Master of Science in Nursing Student, University of Ottawa, telephone number: 737-7700 ext. 6852.

or

Annette O'Connor, RN, PhD, Professor, Faculty of Nursing, University of Ottawa, telephone number: 798-5555 ext. 7582

or

Andreas Laupacis, Director of the Clinical Epidemiology Unit, Loeb Health Research Institute, Ottawa Hospital – Civic Campus



The Ottawa Hospital—Civic Campus
Grimes Lodge, 5th Floor
200 Melrose Avenue
Ottawa, ON K1Y 4K7
Tel: (613) 761-4400
Fax: (613) 761-4405

114c

Evaluating the Effectiveness of a Decision Support Program for Post-menopausal Women at Increased Risk of Breast Cancer Considering their Options to Lower their Risk

Research Team:

Annette O'Connor, RN, PhD, Professor, Faculty of Nursing, University of Ottawa
Cathy DeGrasse, RN, MScN, Administrator, Ottawa Regional Women's Breast Health Centre
Shailendra Verma, MD, Medical Oncologist, Ottawa Regional Cancer Centre
Eva Tomiak, MD, Medical Oncologist, Ottawa Regional Cancer Centre
Elaine Jolly, MD, Gynecologist, Ottawa Hospital – General Campus
Douglas Mirsky, MD, Surgeon, Ottawa Regional Women's Breast Health Centre
Ann Cranney, MD, Rheumatologist, Ottawa Hospital – Civic Campus
Lisa Moore, MD, Family Physician, Family Medicine Centre, Ottawa Hospital – Civic

Purpose:

The purpose of this study is to evaluate how women respond to educational materials for women making decisions about their options to lower their risk of breast cancer. What we learn from this study will help doctors and nurses provide better support to women making this decision in the future. As a woman who has been referred to the Women's Breast Health Centre, you are being asked to take part in this study.

Procedure:

The following are the steps in the procedure:

1. You will be asked to complete a survey telling us a bit about yourself, what you know about lowering your risk of breast cancer, and how difficult the decision is for you. This survey will take about 15 minutes to complete.
2. You will then be given a workbook and audiotape that will give you information about options for lowering your risk of breast cancer. As well, the audiotape guides you through an exercise that will help you to think about what is most important for you in deciding on your options. The audiotape and workbook can be used at home, and will take about 30 to 45 minutes to use. The audiotape and booklet are supposed to help you prepare for your first visit to the Women's Breast Health Centre.
3. You will meet with a nurse and doctor at the Women's Breast Health Centre to discuss questions you may have from the workbook and decision aid as well as talk about your options for lowering your risk of breast cancer. After this visit, we will ask you to complete a new survey telling us how satisfied you were with the decision support you received both from the workbook/audio-tape and the clinic staff. This survey will take about 10 minutes.
4. About 3 days after your visit to the Women's Breast Health Centre, the research nurse will telephone you to ask you questions similar to those in the first survey. You will have a copy of the survey to follow along, when the nurse is asking the questions. This survey will take about 15 minutes to complete.

5. About 2 months later, the research nurse will telephone you to find out if you have started doing anything new to lower your risk of breast cancer.

Risks and Benefits:

There are no known risks of taking part in this study. You may find the information in the workbook and audiotape upsetting. If you feel upset, you can discuss your feelings with a doctor or nurse at the Women's Breast Health Centre. The possible benefits of the study are:

- The audiotape and workbook may help you make a decision about ways of lowering your risk of breast cancer
- What we learn from this study may help other women who will have to make decisions about options to lower their risk of breast cancer.

Confidentiality:

The information collected during this study from your health record and surveys will be kept confidential. A code number will be used to identify the information so your name will not appear on any papers. All relevant information and surveys obtained while you are on this study will only be made available to the research team and, if requested, to the Ottawa Hospital Research Ethics Board. If the results of the study are published, you will not be identifiable on any documentation leaving this site.

Voluntary Participation:

Joining this study is your choice. You are under no obligation to take part in the study, and you may withdraw from the study at any time. Whether or not you decide to participate will have no effect on the care you would normally receive at the Women's Breast Health Centre. Using the decision aid is in addition to any support and information you receive from the physicians and nurses at the Women's Breast Health Centre.

Consent:

I have read the above information and understand this consent form. I have also had the chance to ask questions and they have been answered to my satisfaction. I agree to take part in this study.

Name _____

Date _____

Witness _____

You will receive a copy of this consent form. If you have any questions about this study, you can telephone the researcher, her supervisor, or the director of the research institute:

Dawn Stacey, RN, Master of Science in Nursing Student, University of Ottawa, telephone number: 737-7700 ext. 6852.

Or Annette O'Connor, RN, PhD, Professor, Faculty of Nursing, University of Ottawa, telephone number: 798-5555 ext. 7582

Or Andreas Laupacis, Director of the Clinical Epidemiology Unit, Loeb Health Research Institute, Ottawa Hospital – Civic Campus

Appendix H

Telephone Script to Introduce the Study

**Decision Aid Study for Women aged 50 or older
at Risk of Breast Cancer**

Contact: Dawn Stacey RN, BScN, OCN
Masters in Nursing Student, University of Ottawa,
(613) 737-7700 ext. 6852 or at home 837-5356
dawn.stacey@orcc.on.ca or bdoucet@cyberus.ca

A nurse, working on her Master's degree in nursing, is doing a project with women who are being seen in the Breast Cancer Risk Assessment clinic at the Ottawa Regional Women's Breast Health Centre. The project involves using a workbook and audiotape of information on the options for women at risk of breast cancer and is suppose to help prepare women for discussion with their practitioner at the Centre. It involves meeting with the nurse either in your home or at the Centre for about 30 minutes. She will discuss the project with you and give you the workbook and audiotape before your appointment at the Centre.

If you are interested in this project, I will have the nurse give you a call.

I will be assessing for eligibility but the main criteria are:

- ☐ Female Gender
- ☐ Age 50 – 69
- ☐ Referral to the Ottawa Regional Women's Breast Health Centre (self/practitioner)
- ☐ 5-year risk of breast cancer at least 1.66, actual 5-year risk
- ☐ Ability to read and speak English

Appendix I

Research Ethics Approval

**Loeb Health Research Institute
at the Ottawa Hospital - Civic Campus
725 Parkdale Avenue
Ottawa, Ontario
K1Y 4K9**

18 May, 1999

Dr. Annette O'Connor
Loeb Health Research Institute
Clinical Epidemiology Unit
C4
Ottawa Hospital - Civic Campus

Dear Dr. O'Connor:

Re: Protocol # 1999078-01H

**Development and Pilot Testing of a Decision Support Program
Regarding Chemo-Prevention Options for Post-Menopausal
Women at High Risk for Breast Cancer**

Protocol approval valid until -

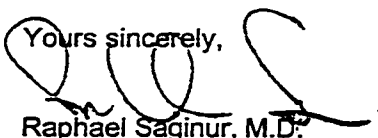
17 May, 2000

Thank you for your letter dated May 10, 1999. I am pleased to inform you that your protocol (listed above) has been reviewed by the Research Ethics Board and approved. No changes, amendments or addenda may be made in the protocol or the consent form without the Research Ethics Board review and approval.

The validation date should be indicated on the bottom of all consent forms and information sheets (see copy attached). Approximately one month prior to that time, a single renewal form should be sent to Research Services.

Medical Research Council guidelines require a greater involvement of the Research Ethics Board in studies over the course of their execution. You must maintain as part of your records copies of the signed consent form. As well, you must inform the Board of adverse events encountered during the study, here or elsewhere, or of significant new information which becomes available after the Board review, either of which may impinge on the ethics of continuing the study. The REB will review the new information to determine if the protocol should be modified, discontinued, or should continue as originally approved.

Yours sincerely,


Raphael Saginur, M.D.
Chairman
Research Ethics Board

Encl.

Appendix J

Baseline Questionnaire

Date: _____
Day / Month / Year

Study #: _____



Women's Opinion Survey
About the Options
to Lower their Risk of Breast Cancer
Pre Decision Support



A. How much I think or avoid thoughts about my risk of breast cancer

Below is a list of comments made by women who are being assessed for their risk of breast cancer. Please circle each item, indicating how frequently these comments were true for you DURING THE PAST SEVEN (7) DAYS. If they did not occur during that time, please circle in the "not at all" column.

1. I thought about my risk of breast cancer when I didn't mean to.	1 Not at all	2 Rarely	3 Sometimes	4 Often
2. I avoided letting myself get upset when I thought about it or was reminded of it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
3. I tried to remove it from memory.	1 Not at all	2 Rarely	3 Sometimes	4 Often
4. I had trouble falling asleep or staying asleep because of pictures or thoughts about it that came into my mind.	1 Not at all	2 Rarely	3 Sometimes	4 Often
5. I had waves of strong feelings about it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
6. I had dreams about it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
7. I stayed away from reminders of it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
8. I felt as if it hadn't happened or it wasn't real.	1 Not at all	2 Rarely	3 Sometimes	4 Often
9. I tried not to talk about it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
10. Pictures about it popped into my mind.	1 Not at all	2 Rarely	3 Sometimes	4 Often
11. Other things kept making me think about it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	1 Not at all	2 Rarely	3 Sometimes	4 Often
13. I tried not to think about it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
14. Any reminder brought back feelings about it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
15. My feelings about it were kind of numb.	1 Not at all	2 Rarely	3 Sometimes	4 Often

Adapted from Horowitz et al (1979). Impact of Event Scale.

B. What I know about options for lowering my risk of breast cancer

We would like to know how much you know about options for lowering your risk of breast cancer, before you use the workbook and audiotape.

Below are listed some statements about options for lowering your risk of breast cancer. Please mark if you think they are true, false or you are not sure by circling your answer.

1. Options for lowering my risk of breast cancer are:

Exercising regularly	True	False	Unsure
Having a healthy weight	True	False	Unsure
Drinking more alcohol	True	False	Unsure
Eating 5 or more fruit & vegetables a day	True	False	Unsure
Eating foods higher in fibre	True	False	Unsure
Eating foods higher in fat	True	False	Unsure
Taking Tamoxifen every day	True	False	Unsure

2. Tamoxifen can be given:

To women with breast cancer	True	False	Unsure
To healthy women who have a higher risk of breast cancer	True	False	Unsure
For 5 years	True	False	Unsure

3. Benefits (pros) of taking Tamoxifen for healthy women who are at higher risk of breast cancer are:

Lowers chance of breast cancer	True	False	Unsure
Lowers chance of cancer of the uterus	True	False	Unsure
Lowers chance of blood clots	True	False	Unsure
Lowers chance of osteoporosis	True	False	Unsure
Lowers blood levels of "bad" cholesterol	True	False	Unsure
Lowers chance of cataracts	True	False	Unsure

4. Risks (cons) of taking Tamoxifen for healthy women who are at higher risk of breast cancer are:

Increases chance of breast cancer	True	False	Unsure
Increases chance of cancer of the uterus	True	False	Unsure
Increases chance of blood clots	True	False	Unsure
Increases chance of osteoporosis	True	False	Unsure
Increases blood levels of "bad" cholesterol	True	False	Unsure
Increases chance of cataracts	True	False	Unsure

5. Some side effects of Tamoxifen are:

Hot flashes	True	False	Unsure
Insomnia	True	False	Unsure
Breast tenderness	True	False	Unsure
Weight gain	True	False	Unsure
Vaginal dryness	True	False	Unsure

C. My chances of disease in the next 5 years.

Now we are interested in your opinion about your chances of breast cancer, cancer of the uterus, and blood clots in the next 5 years.

Breast Cancer

Do you consider yourself to be: Check ☒ one

- ☐ Low risk for breast cancer
- ☐ Average risk for breast cancer
- ☐ High risk for breast cancer

For women at the same risk as you (your age, your risk factors), how many women out of 1000 will have breast cancer in the next 5 years?

- ☐ I don't know
- ☐ 0 out of 1000; Nobody like me will have breast cancer.
- ☐ 1 to 5 out of 1000
- ☐ 6 to 10 out of 1000
- ☐ 11 to 15 out of 1000
- ☐ 16 to 20 out of 1000
- ☐ 21 to 25 out of 1000
- ☐ 26 to 30 out of 1000
- ☐ 31 to 35 out of 1000
- ☐ 36 to 40 out of 1000
- ☐ 41 to 45 out of 1000
- ☐ 46 to 50 out of 1000
- ☐ 51 to 60 out of 1000
- ☐ 61 to 75 out of 1000
- ☐ 76 to 100 out of 1000
- ☐ 101 to 150 out of 1000
- ☐ 151 to 200 out of 1000
- ☐ 201 to 250 out of 1000
- ☐ 251 to 300 out of 1000; One quarter of the women like me will have breast cancer.
- ☐ 301 to 350 out of 1000
- ☐ 351 to 400 out of 1000
- ☐ 401 to 450 out of 1000
- ☐ 451 to 500 out of 1000
- ☐ 501 to 550 out of 1000; Half of the women like me will have breast cancer.
- ☐ 551 to 600 out of 1000
- ☐ 601 to 700 out of 1000
- ☐ 701 to 800 out of 1000; Three quarters of women like me will have breast cancer.
- ☐ 801 to 900 out of 1000
- ☐ 901 to 999 out of 1000
- ☐ 1000 out of 1000; Everybody like me will have breast cancer.

Cancer of the Uterus

For women at the same age as you, how many women out of 1000 will have cancer of the uterus in the next 5 years?

- ☐ I don't know
- ☐ 0 out of 1000; Nobody like me will have cancer of the uterus.
- ☐ 1 to 5 out of 1000
- ☐ 6 to 10 out of 1000
- ☐ 11 to 15 out of 1000
- ☐ 16 to 20 out of 1000
- ☐ 21 to 25 out of 1000
- ☐ 26 to 30 out of 1000
- ☐ 31 to 35 out of 1000
- ☐ 36 to 40 out of 1000
- ☐ 41 to 45 out of 1000
- ☐ 46 to 50 out of 1000
- ☐ 51 to 60 out of 1000
- ☐ 61 to 75 out of 1000
- ☐ 76 to 100 out of 1000
- ☐ 101 to 150 out of 1000
- ☐ 151 to 200 out of 1000
- ☐ 201 to 250 out of 1000
- ☐ 251 to 300 out of 1000; One quarter of the women like me will have cancer of the uterus.
- ☐ 301 to 350 out of 1000
- ☐ 351 to 400 out of 1000
- ☐ 401 to 450 out of 1000
- ☐ 451 to 500 out of 1000
- ☐ 501 to 550 out of 1000; Half of the women like me will have cancer of the uterus.
- ☐ 551 to 600 out of 1000
- ☐ 601 to 700 out of 1000
- ☐ 701 to 800 out of 1000; Three quarters of women like me will have cancer of the uterus.
- ☐ 801 to 900 out of 1000
- ☐ 901 to 999 out of 1000
- ☐ 1000 out of 1000; Everybody like me will have cancer of the uterus.

Blood Clots

For women at the same age as you, how many women out of 1000 will have blood clots (in deep leg veins, lungs, or brain) in the next 5 years?

- ☐ I don't know
- ☐ 0 out of 1000; Nobody like me will have blood clots.
- ☐ 1 to 5 out of 1000
- ☐ 6 to 10 out of 1000
- ☐ 11 to 15 out of 1000
- ☐ 16 to 20 out of 1000
- ☐ 21 to 25 out of 1000
- ☐ 26 to 30 out of 1000
- ☐ 31 to 35 out of 1000
- ☐ 36 to 40 out of 1000
- ☐ 41 to 45 out of 1000
- ☐ 46 to 50 out of 1000
- ☐ 51 to 60 out of 1000
- ☐ 61 to 75 out of 1000
- ☐ 76 to 100 out of 1000
- ☐ 101 to 150 out of 1000
- ☐ 151 to 200 out of 1000
- ☐ 201 to 250 out of 1000
- ☐ 251 to 300 out of 1000; One quarter of the women like me will have blood clots.
- ☐ 301 to 350 out of 1000
- ☐ 351 to 400 out of 1000
- ☐ 401 to 450 out of 1000
- ☐ 451 to 500 out of 1000
- ☐ 501 to 550 out of 1000; Half of the women like me will have blood clots.
- ☐ 551 to 600 out of 1000
- ☐ 601 to 700 out of 1000
- ☐ 701 to 800 out of 1000; Three quarters of women like me will have blood clots.
- ☐ 801 to 900 out of 1000
- ☐ 901 to 999 out of 1000
- ☐ 1000 out of 1000; Everybody like me will have blood clots.

D. My chances of disease with taking Tamoxifen

117h

Now we are interested in your opinion on how much Tamoxifen will affect your chances of developing breast cancer, cancer of the uterus, and blood clots.

Breast Cancer

For women at the same risk as you (your age, your risk factors) who take Tamoxifen for 5 years, how many women out of 1000 will have breast cancer in the next 5 years?

- ☐ I don't know
- ☐ 0 out of 1000; Nobody like me will have breast cancer.
- ☐ 1 to 5 out of 1000
- ☐ 6 to 10 out of 1000
- ☐ 11 to 15 out of 1000
- ☐ 16 to 20 out of 1000
- ☐ 21 to 25 out of 1000
- ☐ 26 to 30 out of 1000
- ☐ 31 to 35 out of 1000
- ☐ 36 to 40 out of 1000
- ☐ 41 to 45 out of 1000
- ☐ 46 to 50 out of 1000
- ☐ 51 to 60 out of 1000
- ☐ 61 to 75 out of 1000
- ☐ 76 to 100 out of 1000
- ☐ 101 to 150 out of 1000
- ☐ 151 to 200 out of 1000
- ☐ 201 to 250 out of 1000
- ☐ 251 to 300 out of 1000; One quarter of the women like me will have breast cancer.
- ☐ 301 to 350 out of 1000
- ☐ 351 to 400 out of 1000
- ☐ 401 to 450 out of 1000
- ☐ 451 to 500 out of 1000
- ☐ 501 to 550 out of 1000; Half of the women like me will have breast cancer.
- ☐ 551 to 600 out of 1000
- ☐ 601 to 700 out of 1000
- ☐ 701 to 800 out of 1000; Three quarters of women like me will have breast cancer.
- ☐ 801 to 900 out of 1000
- ☐ 901 to 999 out of 1000
- ☐ 1000 out of 1000; Everybody like me will have breast cancer.

Cancer of the Uterus

For women at the same age as you who take Tamoxifen for 5 years, how many women out of 1000 will have cancer of the uterus in the next 5 years?

- ☐ I don't know
- ☐ 0 out of 1000; Nobody like me will have cancer of the uterus.
- ☐ 1 to 5 out of 1000
- ☐ 6 to 10 out of 1000
- ☐ 11 to 15 out of 1000
- ☐ 16 to 20 out of 1000
- ☐ 21 to 25 out of 1000
- ☐ 26 to 30 out of 1000
- ☐ 31 to 35 out of 1000
- ☐ 36 to 40 out of 1000
- ☐ 41 to 45 out of 1000
- ☐ 46 to 50 out of 1000
- ☐ 51 to 60 out of 1000
- ☐ 61 to 75 out of 1000
- ☐ 76 to 100 out of 1000
- ☐ 101 to 150 out of 1000
- ☐ 151 to 200 out of 1000
- ☐ 201 to 250 out of 1000
- ☐ 251 to 300 out of 1000; One quarter of the women like me will have cancer of the uterus.
- ☐ 301 to 350 out of 1000
- ☐ 351 to 400 out of 1000
- ☐ 401 to 450 out of 1000
- ☐ 451 to 500 out of 1000
- ☐ 501 to 550 out of 1000; Half of the women like me will have cancer of the uterus.
- ☐ 551 to 600 out of 1000
- ☐ 601 to 700 out of 1000
- ☐ 701 to 800 out of 1000; Three quarters of women like me will have cancer of the uterus.
- ☐ 801 to 900 out of 1000
- ☐ 901 to 999 out of 1000
- ☐ 1000 out of 1000; Everybody like me will have cancer of the uterus.

Blood Clots

For women at the same age as you who take Tamoxifen for 5 years, how many women out of 1000 will have blood clots (in deep leg veins, lungs, or brain) in the next 5 years?

- ☐ I don't know
- ☐ 0 out of 1000; Nobody like me will have blood clots.
- ☐ 1 to 5 out of 1000
- ☐ 6 to 10 out of 1000
- ☐ 11 to 15 out of 1000
- ☐ 16 to 20 out of 1000
- ☐ 21 to 25 out of 1000
- ☐ 26 to 30 out of 1000
- ☐ 31 to 35 out of 1000
- ☐ 36 to 40 out of 1000
- ☐ 41 to 45 out of 1000
- ☐ 46 to 50 out of 1000
- ☐ 51 to 60 out of 1000
- ☐ 61 to 75 out of 1000
- ☐ 76 to 100 out of 1000
- ☐ 101 to 150 out of 1000
- ☐ 151 to 200 out of 1000
- ☐ 201 to 250 out of 1000
- ☐ 251 to 300 out of 1000; One quarter of the women like me will have blood clots.
- ☐ 301 to 350 out of 1000
- ☐ 351 to 400 out of 1000
- ☐ 401 to 450 out of 1000
- ☐ 451 to 500 out of 1000
- ☐ 501 to 550 out of 1000; Half of the women like me will have blood clots.
- ☐ 551 to 600 out of 1000
- ☐ 601 to 700 out of 1000
- ☐ 701 to 800 out of 1000; Three quarters of women like me will have blood clots.
- ☐ 801 to 900 out of 1000
- ☐ 901 to 999 out of 1000
- ☐ 1000 out of 1000; Everybody like me will have blood clots.

E. My Opinion about Lifestyle Change

117k

We want to know your opinion about making a lifestyle change.

Eating Fruits and Vegetables

1. Do you currently eat 5 or more fruits and vegetables per day?
 - ☐ Yes, most days
 - ☐ Yes, occasionally
 - ☐ No
2. If you were asked right now to eat 5 or more fruits and vegetables each day, how likely are you to do so in the next month:
 - ☐ Extremely likely
 - ☐ Somewhat likely
 - ☐ Slightly likely
 - ☐ Unsure
 - ☐ Slightly unlikely
 - ☐ Somewhat unlikely
 - ☐ Extremely unlikely
3. Please explain the reasons for your choice:

Exercising Regularly

4. Do you currently exercise for 20 to 30 minutes most days of the week?
 - ☐ Yes, most days (skip to question 7)
 - ☐ Yes, 3 days a week
 - ☐ Yes, occasionally
 - ☐ No
5. If you were asked right now to exercise for 20 to 30 minutes most days of the week, how likely are you to do so in the next month:
 - ☐ Extremely likely
 - ☐ Somewhat likely
 - ☐ Slightly likely
 - ☐ Unsure
 - ☐ Slightly unlikely
 - ☐ Somewhat unlikely
 - ☐ Extremely unlikely
6. Please explain the reasons for your choice:

Healthy Body Weight

7. Do you currently have a healthy body weight?

- ☐ Yes (skip to question 10)
- ☐ I am underweight (skip to question 10)
- ☐ I have a little excess weight
- ☐ No

8. Are you presently doing anything to change your weight?

- ☐ Yes, I am watching what I eat _____
- ☐ Yes, I am exercising
- ☐ I am planning on doing something
- ☐ No

9. If you were asked right now to lose weight with the goal of reaching a healthy body weight, how likely are you to start to do so in the next month:

- ☐ Extremely likely
- ☐ Somewhat likely
- ☐ Slightly likely
- ☐ Unsure
- ☐ Slightly unlikely
- ☐ Somewhat unlikely
- ☐ Extremely unlikely

10. Please explain the reasons for your choice:

Limit Alcohol

11. Do you drink alcohol?

- ☐ No (skip to the next page)
- ☐ Yes, less than 1 drink a day (skip to the next page)
- ☐ Yes, occasionally more than one drink a day
- ☐ Yes, I usually drink 1 or more drinks a day

12. If you were asked right now to limit your alcohol to 1 drink a day, how likely are you to do so in the next month:

- ☐ Extremely likely
- ☐ Somewhat likely
- ☐ Slightly likely
- ☐ Unsure
- ☐ Slightly unlikely
- ☐ Somewhat unlikely
- ☐ Extremely unlikely

13. Please explain the reasons for your choice:

F. My Opinion about Tamoxifen

We want to know what your opinion is of Tamoxifen.

1. If you were asked right now to make a choice about taking Tamoxifen, please show where you would be on the scale below, by placing a check in the box ☒.

If you want to take Tamoxifen, you would check ☒ far to the left.

If you do not want to take Tamoxifen, you would check ☒ far to the right.

If you are not sure, you would check ☒ in the middle.

Yes Tamoxifen					Unsure					No Tamoxifen					

2. If you were asked whether or not you wanted to take Tamoxifen, with what you know now, check ☒ which choice looks the best for you:

☐ Taking Tamoxifen,
reason for this choice

☐ Not taking Tamoxifen
reason for this choice

☐ I'm not sure
reason for this choice

G. My difficulty in making this Choice

117n

Now think about your choice of taking or not taking Tamoxifen. Please show how strongly you agree or disagree with these statements by circling the number from 1 (strongly agree) to 5 (strongly disagree) that best shows how you feel about your decision.

This decision is easy for me to make	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I'm sure what to do in this decision	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
It's clear what choice is best for me	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I'm aware of the choices I have to lower the risk of breast cancer	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I feel I know the benefits of taking Tamoxifen	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I feel I know the risks of taking Tamoxifen	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I know how important the Benefits are to me in this decision	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I know how important the risks are to me in this decision	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree

I know which is more Important to me (the benefits or the risks)	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I am making this choice Without any pressure from Others	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I have the right amount of support from others in making this choice	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I have enough advice about the choices	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I feel I have made an informed choice	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
My decision shows what is important to me	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I expect to stick with my decision	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I am satisfied with my decision	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree

H. How much do you want to be involved in making the decision about Tamoxifen?

Some women want to make their own decision about taking Tamoxifen to lower their risk of breast cancer. Other women want their doctor to make the decision for them. Still others want to share the decision with their doctor. Who do you think should make the decision about Tamoxifen?

Please check ☒ the one box that shows your opinion. There is no right or wrong answer, we want to know what you prefer.

- ☐ I prefer to make the final decision about Tamoxifen.
- ☐ I prefer to make the final decision about Tamoxifen after seriously considering my doctor's opinion.
- ☐ I prefer that my doctor and I share responsibility for making the final decision about Tamoxifen.
- ☐ I prefer that my doctor makes the final decision about Tamoxifen, but seriously considers my opinion.
- ☐ I prefer to leave the decision about Tamoxifen to my doctor.

(Adapted from Degner, Sloan, & Venkatesh, 1997)

Appendix K

Acceptability Questionnaire

Study # _____

My Thoughts on the Workbook & Audiotape
“Making Choices: Options for Lowering My Risk of Breast Cancer”

1. What did you like most about the workbook and audiotape?
2. What did you not like about the workbook and audiotape?
3. How would you rate the amount of information in the workbook and audiotape? Please check ☒ one.
 - ☐ Much less than I needed
 - ☐ Little less than I needed
 - ☐ About the right amount of information
 - ☐ A little more information than I needed
 - ☐ A lot more information than I needed
4. Did you find the information in the workbook and audiotape upsetting? Please check ☒ one.
 - ☐ Not at all upsetting
 - ☐ A little upsetting
 - ☐ Somewhat upsetting
 - ☐ Very upsettingPlease comment: _____
5. How would you rate the length of the workbook and audiotape? Please check ☒ one.
 - ☐ Much too long
 - ☐ A little too long
 - ☐ Just about right
 - ☐ Should have been a little longer
 - ☐ Should have been much longer

6. How **clear** was the information in the workbook and audiotape? Please check ☒ one.
- ☐ Everything was clear
 - ☐ Most things were clear
 - ☐ Some things were clear
 - ☐ Many things were unclear
7. How **balanced and fair** did you find the workbook and audiotape? Please check ☒ one.
- ☐ Clearly slanted to tamoxifen
 - ☐ A little slanted to tamoxifen
 - ☐ Completely balanced
 - ☐ A little slanted to no tamoxifen
 - ☐ Clearly slanted to no tamoxifen
8. How **helpful** is the workbook and audiotape in helping you make a decision about tamoxifen? Please check ☒ one.
- ☐ Very helpful
 - ☐ Somewhat helpful
 - ☐ A little helpful
 - ☐ Not helpful
9. Would you **recommend** this workbook and audiotape to other people who are facing choices for lowering their risk of breast cancer? Please check ☒ one.
- ☐ I would definitely recommend it
 - ☐ I would probably recommend it
 - ☐ I would probably not recommend it
 - ☐ I would definitely not recommend it
10. Do you have any **other comments** about the workbook and audiotape?

Appendix L

Participant Satisfaction with Preparation for Consultation

Date: _____
day / month / year

Study # _____ 119a

My satisfaction with my preparation for decision making

The following questions refer to the audiotape, workbook, and personal worksheet you used in preparing for your clinic visit at the Women's Breast Health Centre. Please give your opinion about how the educational material prepared you for the clinic visit by circling the number that shows how much it helped you.

A '0' means it did not help at all and a '4' means it helped a great deal.

How much did the audiotape, workbook, and personal worksheet

- | | | | | | |
|--|-----------------|---------------|---------------|------------|-------------------|
| 1. Help you to organize your own thoughts about this decision? | 1
Not at all | 2
A Little | 3
Somewhat | 4
A lot | 5
A great deal |
| 2. Help you to consider what you think of the benefits and risks of each option? | 1
Not at all | 2
A Little | 3
Somewhat | 4
A lot | 5
A great deal |
| 3. Help you to identify the questions you need to ask? | 1
Not at all | 2
A Little | 3
Somewhat | 4
A lot | 5
A great deal |
| 4. Help you to communicate your views to others? | 1
Not at all | 2
A Little | 3
Somewhat | 4
A lot | 5
A great deal |
| 5. Help you to get more involved in decision making? | 1
Not at all | 2
A Little | 3
Somewhat | 4
A lot | 5
A great deal |
| 6. Prepare you to make a better decision? | 1
Not at all | 2
A Little | 3
Somewhat | 4
A lot | 5
A great deal |
| 7. Make the clinic visit run more smoothly? | 1
Not at all | 2
A Little | 3
Somewhat | 4
A lot | 5
A great deal |
| 8. Improve the way time is spent during the clinic visit? | 1
Not at all | 2
A Little | 3
Somewhat | 4
A lot | 5
A great deal |
| 9. Make you feel prepared for the clinic visit? | 1
Not at all | 2
A Little | 3
Somewhat | 4
A lot | 5
A great deal |

(Adapted from Graham & O'Connor, 1996, University of Ottawa)

November, 1999

Appendix M

Practitioner Satisfaction with Participant Preparation for Consultation

Date: _____
day / month / year

Study # 120a

Practitioner's Satisfaction Survey

The following questions refer to the audiotape, workbook, and the patient's personal worksheet, "Making Choices: Options for Lowering My Risk of Breast Cancer" that was given to your patient prior to the consultation visit at the Women's Breast Health Centre.

To what extent did the use of the audio-booklet and worksheet by your patient:

	Not at all	A little	Some- what	A lot	A great deal
1. Help her to fully understand the risks and benefits of Tamoxifen?	1	2	3	4	5
2. Help her identify the importance she places on the risks and benefits of Tamoxifen?	1	2	3	4	5
3. Prepare her for the consultation visit?	1	2	3	4	5
4. Help her be as involved in the decision making process as she desired?	1	2	3	4	5
5. Help her make a more informed decision?	1	2	3	4	5
6. Help you to more fully understand the issues that are most important to her?	1	2	3	4	5
7. Help you tailor your counseling to her preference for decision participation?	1	2	3	4	5
8. Facilitate the consultation visit?	1	2	3	4	5
9. Affect the patient-physician relationship?	1	2	3	4	5
10. Improve the way time was spent during the consultation visit?	1	2	3	4	5
11. Improve the quality of the consultation visit?	1	2	3	4	5

(Adapted from Graham & O'Connor, 1996, University of Ottawa)

July, 1999

Appendix N

Post-Decision Support Questionnaire

Date: _____
Day / Month / Year

Study #: _____



Women's Opinion Survey
About the Options
to Lower their Risk of Breast Cancer
Post Decision Support



A. How much I think or avoid thoughts about my risk of breast cancer

Below is a list of comments made by women who are being assessed for their risk of breast cancer. Please circle each item, indicating how frequently these comments were true for you DURING THE PAST SEVEN (7) DAYS. If they did not occur during that time, please circle in the "not at all" column.

1. I thought about my risk of breast cancer when I didn't mean to.	1 Not at all	2 Rarely	3 Sometimes	4 Often
2. I avoided letting myself get upset when I thought about it or was reminded of it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
3. I tried to remove it from memory.	1 Not at all	2 Rarely	3 Sometimes	4 Often
4. I had trouble falling asleep or staying asleep because of pictures or thoughts about it that came into my mind.	1 Not at all	2 Rarely	3 Sometimes	4 Often
5. I had waves of strong feelings about it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
6. I had dreams about it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
7. I stayed away from reminders of it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
8. I felt as if it hadn't happened or it wasn't real.	1 Not at all	2 Rarely	3 Sometimes	4 Often
9. I tried not to talk about it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
10. Pictures about it popped into my mind.	1 Not at all	2 Rarely	3 Sometimes	4 Often
11. Other things kept making me think about it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	1 Not at all	2 Rarely	3 Sometimes	4 Often
13. I tried not to think about it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
14. Any reminder brought back feelings about it.	1 Not at all	2 Rarely	3 Sometimes	4 Often
15. My feelings about it were kind of numb.	1 Not at all	2 Rarely	3 Sometimes	4 Often

Adapted from Horowitz et al (1979). Impact of Event Scale.

B. What I know about options for lowering my risk of breast cancer

We would like to know how much you know about options for lowering your risk of breast cancer after you have used the workbook and audiotape. Don't worry if you can not remember everything ... we did not expect you to memorize the information you received. But it would help us learn what things impressed you enough that you can recall them easily. If you wish, you can refer back to the audiotape and workbook.

Below are listed some statements about options for lowering your risk of breast cancer. Please mark if you think they are true, false or you are not sure by circling your answer.

1. Options for lowering my risk of breast cancer are:

Exercising regularly	True	False	Unsure
Having a healthy weight	True	False	Unsure
Drinking more alcohol	True	False	Unsure
Eating 5 or more fruit & vegetables a day	True	False	Unsure
Eating foods higher in fibre	True	False	Unsure
Eating foods higher in fat	True	False	Unsure
Taking Tamoxifen every day	True	False	Unsure

2. Tamoxifen can be given:

To women with breast cancer	True	False	Unsure
To healthy women who have a higher risk of breast cancer	True	False	Unsure
For 5 years	True	False	Unsure

3. Benefits (pros) of taking Tamoxifen for healthy women who are at higher risk of breast cancer are:

Lowers chance of breast cancer	True	False	Unsure
Lowers chance of cancer of the uterus	True	False	Unsure
Lowers chance of blood clots	True	False	Unsure
Lowers chance of osteoporosis	True	False	Unsure
Lowers blood levels of "bad" cholesterol	True	False	Unsure
Lowers chance of cataracts	True	False	Unsure

4. Risks (cons) of taking Tamoxifen for healthy women who are at higher risk of breast cancer are:

Increases chance of breast cancer	True	False	Unsure
Increases chance of cancer of the uterus	True	False	Unsure
Increases chance of blood clots	True	False	Unsure
Increases chance of osteoporosis	True	False	Unsure
Increases blood levels of "bad" cholesterol	True	False	Unsure
Increases chance of cataracts	True	False	Unsure

5. Some side effects of Tamoxifen are:

Hot flashes	True	False	Unsure
Insomnia	True	False	Unsure
Breast tenderness	True	False	Unsure
Weight gain	True	False	Unsure
Vaginal dryness	True	False	Unsure

C. My chances of disease in the next 5 years.

Now we are interested in your opinion about your chances of breast cancer, cancer of the uterus, and blood clots in the next 5 years.

Breast Cancer

Do you consider yourself to be: Check ☒ one

- ☐ Low risk for breast cancer
- ☐ Average risk for breast cancer
- ☐ High risk for breast cancer

For women at the same risk as you (your age, your risk factors), how many women out of 1000 will have breast cancer in the next 5 years?

- ☐ I don't know
- ☐ 0 out of 1000; Nobody like me will have breast cancer.
- ☐ 1 to 5 out of 1000
- ☐ 6 to 10 out of 1000
- ☐ 11 to 15 out of 1000
- ☐ 16 to 20 out of 1000
- ☐ 21 to 25 out of 1000
- ☐ 26 to 30 out of 1000
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- ☐ 41 to 45 out of 1000
- ☐ 46 to 50 out of 1000
- ☐ 51 to 60 out of 1000
- ☐ 61 to 75 out of 1000
- ☐ 76 to 100 out of 1000
- ☐ 101 to 150 out of 1000
- ☐ 151 to 200 out of 1000
- ☐ 201 to 250 out of 1000
- ☐ 251 to 300 out of 1000; One quarter of the women like me will have breast cancer.
- ☐ 301 to 350 out of 1000
- ☐ 351 to 400 out of 1000
- ☐ 401 to 450 out of 1000
- ☐ 451 to 500 out of 1000
- ☐ 501 to 550 out of 1000; Half of the women like me will have breast cancer.
- ☐ 551 to 600 out of 1000
- ☐ 601 to 700 out of 1000
- ☐ 701 to 800 out of 1000; Three quarters of women like me will have breast cancer.
- ☐ 801 to 900 out of 1000
- ☐ 901 to 999 out of 1000
- ☐ 1000 out of 1000; Everybody like me will have breast cancer.

Cancer of the Uterus

For women at the same age as you, how many women out of 1000 will have cancer of the uterus in the next 5 years?

- ☐ I don't know
- ☐ 0 out of 1000; Nobody like me will have cancer of the uterus.
- ☐ 1 to 5 out of 1000
- ☐ 6 to 10 out of 1000
- ☐ 11 to 15 out of 1000
- ☐ 16 to 20 out of 1000
- ☐ 21 to 25 out of 1000
- ☐ 26 to 30 out of 1000
- ☐ 31 to 35 out of 1000
- ☐ 36 to 40 out of 1000
- ☐ 41 to 45 out of 1000
- ☐ 46 to 50 out of 1000
- ☐ 51 to 60 out of 1000
- ☐ 61 to 75 out of 1000
- ☐ 76 to 100 out of 1000
- ☐ 101 to 150 out of 1000
- ☐ 151 to 200 out of 1000
- ☐ 201 to 250 out of 1000
- ☐ 251 to 300 out of 1000; One quarter of the women like me will have cancer of the uterus.
- ☐ 301 to 350 out of 1000
- ☐ 351 to 400 out of 1000
- ☐ 401 to 450 out of 1000
- ☐ 451 to 500 out of 1000
- ☐ 501 to 550 out of 1000; Half of the women like me will have cancer of the uterus.
- ☐ 551 to 600 out of 1000
- ☐ 601 to 700 out of 1000
- ☐ 701 to 800 out of 1000; Three quarters of women like me will have cancer of the uterus.
- ☐ 801 to 900 out of 1000
- ☐ 901 to 999 out of 1000
- ☐ 1000 out of 1000; Everybody like me will have cancer of the uterus.

Blood Clots

For women at the same age as you, how many women out of 1000 will have blood clots (in deep leg veins, lungs, or head) in the next 5 years?

- ☐ I don't know
- ☐ 0 out of 1000; Nobody like me will have blood clots.
- ☐ 1 to 5 out of 1000
- ☐ 6 to 10 out of 1000
- ☐ 11 to 15 out of 1000
- ☐ 16 to 20 out of 1000
- ☐ 21 to 25 out of 1000
- ☐ 26 to 30 out of 1000
- ☐ 31 to 35 out of 1000
- ☐ 36 to 40 out of 1000
- ☐ 41 to 45 out of 1000
- ☐ 46 to 50 out of 1000
- ☐ 51 to 60 out of 1000
- ☐ 61 to 75 out of 1000
- ☐ 76 to 100 out of 1000
- ☐ 101 to 150 out of 1000
- ☐ 151 to 200 out of 1000
- ☐ 201 to 250 out of 1000
- ☐ 251 to 300 out of 1000; One quarter of the women like me will have blood clots.
- ☐ 301 to 350 out of 1000
- ☐ 351 to 400 out of 1000
- ☐ 401 to 450 out of 1000
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- ☐ 501 to 550 out of 1000; Half of the women like me will have blood clots.
- ☐ 551 to 600 out of 1000
- ☐ 601 to 700 out of 1000
- ☐ 701 to 800 out of 1000; Three quarters of women like me will have blood clots.
- ☐ 801 to 900 out of 1000
- ☐ 901 to 999 out of 1000
- ☐ 1000 out of 1000; Everybody like me will have blood clots.

D. My chances of disease with taking Tamoxifen

Now we are interested in your opinion on how much Tamoxifen will affect your chances of developing breast cancer, cancer of the uterus, and blood clots.

Breast Cancer

For women at the same risk as you (your age, your risk factors) who take Tamoxifen for 5 years, how many women out of 1000 will have breast cancer in the next 5 years?

- ☐ I don't know
- ☐ 0 out of 1000; Nobody like me will have breast cancer.
- ☐ 1 to 5 out of 1000
- ☐ 6 to 10 out of 1000
- ☐ 11 to 15 out of 1000
- ☐ 16 to 20 out of 1000
- ☐ 21 to 25 out of 1000
- ☐ 26 to 30 out of 1000
- ☐ 31 to 35 out of 1000
- ☐ 36 to 40 out of 1000
- ☐ 41 to 45 out of 1000
- ☐ 46 to 50 out of 1000
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- ☐ 76 to 100 out of 1000
- ☐ 101 to 150 out of 1000
- ☐ 151 to 200 out of 1000
- ☐ 201 to 250 out of 1000
- ☐ 251 to 300 out of 1000; One quarter of the women like me will have breast cancer.
- ☐ 301 to 350 out of 1000
- ☐ 351 to 400 out of 1000
- ☐ 401 to 450 out of 1000
- ☐ 451 to 500 out of 1000
- ☐ 501 to 550 out of 1000; Half of the women like me will have breast cancer.
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- ☐ 701 to 800 out of 1000; Three quarters of women like me will have breast cancer.
- ☐ 801 to 900 out of 1000
- ☐ 901 to 999 out of 1000
- ☐ 1000 out of 1000; Everybody like me will have breast cancer.

Cancer of the Uterus

For women at the same age as you who take Tamoxifen for 5 years, how many women out of 1000 will have cancer of the uterus in the next 5 years?

- ☐ I don't know
- ☐ 0 out of 1000; Nobody like me will have cancer of the uterus.
- ☐ 1 to 5 out of 1000
- ☐ 6 to 10 out of 1000
- ☐ 11 to 15 out of 1000
- ☐ 16 to 20 out of 1000
- ☐ 21 to 25 out of 1000
- ☐ 26 to 30 out of 1000
- ☐ 31 to 35 out of 1000
- ☐ 36 to 40 out of 1000
- ☐ 41 to 45 out of 1000
- ☐ 46 to 50 out of 1000
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- ☐ 76 to 100 out of 1000
- ☐ 101 to 150 out of 1000
- ☐ 151 to 200 out of 1000
- ☐ 201 to 250 out of 1000
- ☐ 251 to 300 out of 1000; One quarter of the women like me will have cancer of the uterus.
- ☐ 301 to 350 out of 1000
- ☐ 351 to 400 out of 1000
- ☐ 401 to 450 out of 1000
- ☐ 451 to 500 out of 1000
- ☐ 501 to 550 out of 1000; Half of the women like me will have cancer of the uterus.
- ☐ 551 to 600 out of 1000
- ☐ 601 to 700 out of 1000
- ☐ 701 to 800 out of 1000; Three quarters of women like me will have cancer of the uterus.
- ☐ 801 to 900 out of 1000
- ☐ 901 to 999 out of 1000
- ☐ 1000 out of 1000; Everybody like me will have cancer of the uterus.

Blood Clots

For women at the same age as you who take Tamoxifen for 5 years, how many women out of 1000 will have blood clots (in deep leg veins, lungs, or head) in the next 5 years?

- ☐ I don't know
- ☐ 0 out of 1000; Nobody like me will have blood clots.
- ☐ 1 to 5 out of 1000
- ☐ 6 to 10 out of 1000
- ☐ 11 to 15 out of 1000
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- ☐ 21 to 25 out of 1000
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- ☐ 101 to 150 out of 1000
- ☐ 151 to 200 out of 1000
- ☐ 201 to 250 out of 1000
- ☐ 251 to 300 out of 1000; One quarter of the women like me will have blood clots.
- ☐ 301 to 350 out of 1000
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- ☐ 401 to 450 out of 1000
- ☐ 451 to 500 out of 1000
- ☐ 501 to 550 out of 1000; Half of the women like me will have blood clots.
- ☐ 551 to 600 out of 1000
- ☐ 601 to 700 out of 1000
- ☐ 701 to 800 out of 1000; Three quarters of women like me will have blood clots.
- ☐ 801 to 900 out of 1000
- ☐ 901 to 999 out of 1000
- ☐ 1000 out of 1000; Everybody like me will have blood clots.

E. My Opinion about Lifestyle Change

We want to know your opinion about making a lifestyle change.

Eating Fruits and Vegetables

1. If you do not eat 5 or more fruits and vegetables a day and were asked right now start eating them every day, how likely are you to do so in the next month:
 - ☐ Extremely likely
 - ☐ Somewhat likely
 - ☐ Slightly likely
 - ☐ Unsure
 - ☐ Slightly unlikely
 - ☐ Somewhat unlikely
 - ☐ Extremely unlikely
2. Please explain the reasons for your choice:

Exercising Regularly

3. If you do not exercise regularly and were asked right now to exercise for 20 to 30 minutes most days of the week, how likely are you to do so in the next month:
 - ☐ Extremely likely
 - ☐ Somewhat likely
 - ☐ Slightly likely
 - ☐ Unsure
 - ☐ Slightly unlikely
 - ☐ Somewhat unlikely
 - ☐ Extremely unlikely
4. Please explain the reasons for your choice:

Healthy Body Weight

5. Have you started to do anything to change your weight?

- ☐ Yes, I am watching what I eat _____
- ☐ Yes, I am exercising
- ☐ I am planning on doing something
- ☐ No

6. If you have excess weight and were asked right now to lose weight with the goal of reaching a healthy body weight, how likely are you to start to do so in the next month:

- ☐ Extremely likely
- ☐ Somewhat likely
- ☐ Slightly likely
- ☐ Unsure
- ☐ Slightly unlikely
- ☐ Somewhat unlikely
- ☐ Extremely unlikely
- ☐ Not applicable

7. Please explain the reasons for your choice:

Limit Alcohol

8. If you drink more than 1 alcohol drink a day and were asked right now to limit your alcohol to 1 drink a day, how likely are you to do so in the next month:

- ☐ Extremely likely
- ☐ Somewhat likely
- ☐ Slightly likely
- ☐ Unsure
- ☐ Slightly unlikely
- ☐ Somewhat unlikely
- ☐ Extremely unlikely

9. Please explain the reasons for your choice:

F. My Opinion about Tamoxifen

We want to know what your opinion is of Tamoxifen.

1. If you were asked right now to make a choice about taking Tamoxifen, please show where you would be on the scale below, by placing a check in the box ☒.

If you want to take Tamoxifen, you would check ☒ far to the left.

If you did not want to take Tamoxifen, you would check ☒ far to the right.

If you are not sure, you would check ☒ in the middle.

Yes Tamoxifen				Unsure				No Tamoxifen							

2. If you were asked whether or not you wanted to take Tamoxifen, with the information you now have, check ☒ which choice looks the best for you:

☐ Taking Tamoxifen,
reason for this choice

☐ Not taking Tamoxifen
reason for this choice

☐ I'm not sure
reason for this choice

G. My difficulty in making this Choice

Now think about your choice of taking or not taking Tamoxifen. Please show how strongly you agree or disagree with these statements by circling the number from 1 (strongly agree) to 5 (strongly disagree) that best shows how you feel about your decision.

This decision is easy for me to make	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I'm sure what to do in this decision	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
It's clear what choice is best for me	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I'm aware of the choices I have to lower the risk of breast cancer	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I feel I know the benefits of taking Tamoxifen	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I feel I know the risks of taking Tamoxifen	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I know how important the Benefits are to me in this decision	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I know how important the risks are to me in this decision	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree

I know which is more Important to me (the benefits or the risks)	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I am making this choice Without any pressure from Others	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I have the right amount of support from others in making this choice	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I have enough advice about the choices	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I feel I have made an informed choice	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
My decision shows what is important to me	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I expect to stick with my decision	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
I am satisfied with my decision	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree

H. How much were you involved in making the decision about Tamoxifen?

Please check ☒ the one box that best describes how much you were involved in making the decision about Tamoxifen.

- ☐ I made the final decision about Tamoxifen.
- ☐ I made the final decision about Tamoxifen after seriously considering my doctor's opinion.
- ☐ My doctor and I shared responsibility for making the final decision about Tamoxifen.
- ☐ My doctor made the final decision about Tamoxifen after seriously considering my opinion.
- ☐ My doctor made the final decision.

(Adapted from Degner, Sloan, & Venkatesh, 1997)

Appendix O

Two-month Post Intervention Telephone Assessment

Date: _____
day / month / year

Study # _____ 122a

2-Month Post-Intervention Telephone Assessment

Chart Audit

Were there any prescriptions for tamoxifen or STAR trial medication on the health record?

☐ No

☐ Yes Date: _____

Was there a progress note within the health record, after the initial consultation visit, to indicate implementation of the decision?

☐ No

☐ Yes, If yes, please explain:

Self-report Telephone call 2-months after Consultation:

1. Tell me what you are currently doing to promote good health and decrease your risk of breast cancer.

Reason for this change:

2. Some practices are associated with promoting good health and decreasing your risk of breast cancer. Which of the following are you doing or planning to do?

Date: _____

Study # _____

day / month / year

Eating 5 or more fruits and vegetables a day	<u>Results at Pre-Survey</u> ☐ Yes, most days ☐ Yes, occasionally ☐ No ☐ Pre-Survey: How likely are you to do so in the next month: _____ ☐ Post-Survey: How likely are you to do so in the next month: _____	<u>Results at 2 Month Post-Survey</u> ☐ If yes most days on pre/post, are you continuing to eat 5+ fruits & vegetables a day ☐ Yes ☐ No ☐ Last time you said ..., have you started to eat more fruits and veg a day? ☐ Yes, most days ☐ Yes, occasionally ☐ No, thinking about it ☐ No
<u>Comments:</u>		
Exercise for 20 to 30 minutes most days of the week	<u>Results at Pre-Survey</u> ☐ Yes, most days ☐ Yes, 3 days a week ☐ Yes, occasionally ☐ No ☐ Pre-survey: How likely are you to do so in the next month: _____ ☐ Post-survey: How likely are you to do so in the next month: _____	<u>Results at 2 Month Post-Survey</u> ☐ If yes, are you continuing to exercise most days of the week ☐ Yes ☐ No ☐ Last time you said ..., have you started to exercise more often? ☐ Yes, most days ☐ Yes, 3 days a week ☐ No, I am thinking about it ☐ No
<u>Comments:</u>		

Date: _____
 day / month / year

Study # _____

122c

Having a healthy body weight	<u>Results at Pre-Survey</u> ☐ Yes ☐ I am a little underweight ☐ I have a little excess weight ☐ No Are you doing anything? ☐ Yes, I am watching what I eat ☐ Yes, I am exercising ☐ I am planning on doing something ☐ I am thinking about doing something ☐ No ☐ Pre-Survey: How likely are you to start to lose weight in the next month: _____ ☐ Post-Survey: How likely are you to start to lose weight in the next month: _____	<u>Results at 2 Month Post-Survey</u> ☐ If yes on pre/post, are you continuing to maintain a healthy weight ☐ Yes ☐ No ☐ Last time you said you were...., have you started doing anything to change your weight? ☐ Yes, I am watching what I eat ☐ Yes, I am exercising ☐ I am planning on doing something ☐ No
<u>Comments:</u>		
Do you drink alcohol?	<u>Results at Pre-Survey</u> ☐ No ☐ Yes, less than 1 drink a day ☐ Yes, occasionally more than one drink a day ☐ Yes, I usually drink 1 or more drinks a day ☐ Pre-Survey: How likely are you to limit alcohol in the next month: _____ ☐ Post-Survey: How likely are you to limit alcohol in the next month: _____	<u>Results at 2 Month Post-Survey</u> ☐ If yes, are you continuing to not drink or limit your alcohol ☐ Yes ☐ No ☐ Last time you said, are doing anything to change how much you drink? ☐ Yes, limit to 1 drink or less a day ☐ Yes, but occasionally more than 1 drink a day ☐ No I am not limiting what I drink

Date: _____

Study # _____

1222

day / month / year

Comments:**Chemoprevention****Decision made 3 days after
consultation visit:**

- ☐ Agreed to start on Tamoxifen
for 5 years
- ☐ Agreed to start on STAR Trial
- ☐ Refused to take tamoxifen or
STAR Trial
- ☐ Undecided

**Last time you said have you
started taking any medicine aimed at
decreasing your risk of breast cancer
such as tamoxifen or STAR Study
medication?**

- ☐ Yes → If yes, please explain
- ☐ No
- ☐ Haven't decided yet
- ☐ Plan to get prescription
- ☐ Plan to fill prescription

Comments:**3. Final comments:**

Appendix P

Clinical and Demographic Questionnaire

Date: _____
day/month/year

Study # _____ 123a

Development and Evaluation of a Decision Aid for Women Considering Options
to Lower Their Risk of Breast Cancer

Clinical and Demographic Questionnaire

Risk Assessment

- Genetic Risk _____
- Actual age _____ years
- Age at first menstrual period _____ years
- Age at birth of 1st child _____ years
- Number of 1st degree relatives with breast cancer (mother, sister, daughter) _____
Relationship to relative _____
- Number of breast biopsies _____
Results _____
- No personal history of breast cancer (invasive or in situ)
- Race __ White, __ Black, __ Asian
- 5-year risk of breast cancer for participant: _____ (to be used on worksheet)
- 5-year risk of breast cancer for women same age with no risk factors: _____ (to be used on worksheet)
- Number of fewer breast cancers with Tamoxifen _____ (to be used on worksheet)

Eligibility Form

- ☐ Female aged 50 – 69 years
- ☐ Referral to the Ottawa Regional Women's Breast Health Centre (self/practitioner)
- ☐ 5-year risk of breast cancer at least 1.66, actual 5-year risk
- ☐ Ability to read and speak English
- ☐ No prophylactic mastectomy
- ☐ No prior history of cancer within the past 10 years (except basal or squamous cell carcinoma of the skin, or carcinoma in situ of the cervix)
- ☐ Performance status that does not restrict normal activity for a significant portion of each day.

Date: _____
day/month/year

Study # _____

123b

Personal Characteristics

1. Marital Status:
☐ married, common law
☐ widowed
☐ single
☐ divorced/separated
2. Language most frequently spoken:
☐ English
☐ Other: _____
☐ French
3. Language most frequently read:
☐ English
☐ Other: _____
☐ French
4. Highest grade or level of education completed:
☐ less than grade 9
☐ high school diploma
☐ some college
☐ some university
☐ some high school
☐ trade certificate / diploma
☐ college diploma / degree
☐ university degree

Relevant Medical History

History of:

- ☐ hysterectomy
- ☐ treatment for osteoporosis
- ☐ other: _____

Topics women wanted to discuss at their visit:

- ☐ General risk assessment
- ☐ Screening recommendations
- ☐ Lifestyle information
- ☐ Chemoprevention
- ☐ Prophylactic mastectomy
- ☐ Decision making
- ☐ Prevention research (ie. STAR)
- ☐ Genetic Counseling/testing
- ☐ HRT information
- ☐ Other: _____

Date: _____
day/month/year

Study # _____

123C

Breast Cancer Prevention Decision Aid Cohort Study
"Making Choices: Options for Lowering my Risk of Breast Cancer"

Completed Date	Form	Timing
☐	Clinical and Demographic Questionnaire	Complete at WBHC
☐	Consent Form	Completed at baseline with woman
☐	Pre-Decision Support Survey	Completed at baseline with woman Collected at 1 st Visit to WBHC
☐	My Thoughts on the Workbook & Audiotape	Given out with the Decision Aid and to be returned at 1 st Visit to WBHC
☐	My Satisfaction with my Preparation for Decision Making	Given out at 1 st Visit and to be called to elicit responses
☐	Post-Decision Support Survey	Given out at 1 st Visit and to be called to elicit responses
☐	Practitioner Satisfaction Survey	Given out at 1 st Visit and to be completed at WBHC
☐	2-Months Post-Survey	Telephone call to elicit responses