Development and Alpha Testing of a Fertility Decision Aid for Young Canadians Diagnosed with Breast Cancer at Risk of Infertility Following Cancer Treatment

by

Brittany Speller

A thesis submitted in conformity with the requirements for the degree of Master of Science
Institute of Health Policy, Management and Evaluation
University of Toronto

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2017

Abstract

Young women (45 years of age or younger) diagnosed with breast cancer are at risk of treatment-related infertility. Even with established fertility preservation options available in Canada, women feel as though they have limited support and access to resources. This thesis aimed to develop a Canadian decision aid to assist young women in making value-based fertility preservation decisions prior to breast cancer treatment. The development process was guided by the Ottawa Decision Support Framework and International Patient Decision Aids Standards criteria including an evaluation of existing decision support resources, initial paper prototype development and content expert review, end user engagement at a one-day meeting, development of an online decision aid, and alpha testing. The final paper and online decision aid will be pilot tested and disseminated across Canada to help young breast cancer patients make informed fertility decisions in partnership with their health care providers prior to treatment.
Acknowledgments

Gratitude goes to the many individuals who were a vital part in the creation of this decision aid.

I would first like to sincerely thank my thesis supervisor, Dr. Nancy Baxter for supporting me and giving me the opportunity to complete my thesis on this important project. Your continual guidance and valuable insights on all aspects of my thesis has been very much appreciated. It has been a pleasure to learn from you. My experience working on this project and with you has allowed me to grow my skills and confidence as a researcher and for that I am truly thankful.

Thank you to my committee members Dr. Erin Kennedy and Dr. Kelly Metcalfe. My learning experience has been enhanced by your expertise and continual involvement throughout the decision aid development. Thank you for your support and insights to strengthen this thesis. Additionally, Dr. Marcia Facey – I greatly appreciate the guidance and education you have provided in regards to qualitative research. Thank you for your patience and detailed feedback to enhance my work.

This study would not have been possible without the support from the multitude of survivors, health care providers, cancer organizations, and advocacy groups who were instrumental in the development of the decision aid. Thank you for helping with recruitment, committing your time to provide iterative reviews, and for sharing your experience with me to develop the decision aid.

Special thanks go to Dr. Baxter’s research team. I consider myself fortunate to have been able to complete my graduate work with others who share the same passion for research. A huge thank you to Corinne, Anne, Amanda, Andrea, and Tari for your help throughout the project.

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<th>Definition</th>
</tr>
</thead>
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<tr>
<td>Amenorrhea</td>
<td>The absence of a menstrual period for 3 cycles in a row. Amenorrhea may be temporary or permanent during chemotherapy. However, the absence or presence of a menstrual cycle is not a reliable predictor of fertility.(^1)</td>
</tr>
<tr>
<td>Congenital Defects</td>
<td>Structural or functional anomalies that occur to a fetus before birth.(^2)</td>
</tr>
<tr>
<td>Ovarian Cortical Fibrosis</td>
<td>Thickening of the outer layer of the ovary that can result in lower ovarian functioning.(^3)</td>
</tr>
<tr>
<td>Decision Quality</td>
<td>The extent that patients are informed about the health condition they are facing and receive care that reflects their goals and preferences regardless of the outcome.(^4)</td>
</tr>
<tr>
<td>Decisional Conflict</td>
<td>The uncertainty experienced when the choices for the course of action involve risk, regret, loss or challenge personal values. (^5)</td>
</tr>
<tr>
<td>Follicles</td>
<td>Small cavities in the ovary that each contain one immature egg.(^6)</td>
</tr>
<tr>
<td>Gonadotoxic</td>
<td>Having a harmful effect to the gonads (organ that produces reproductive cells called gametes for males and females).(^7)</td>
</tr>
<tr>
<td>Menopause</td>
<td>Time in life when periods stop permanently and natural pregnancy is no longer possible. Women reach menopause when they stop having a menstrual period for 12 cycles in a row.(^8)</td>
</tr>
<tr>
<td>Menarche</td>
<td>The start of a woman’s reproductive cycle.(^9)</td>
</tr>
<tr>
<td>Oncology health care providers</td>
<td>A broad definition of medical professionals who provide care to cancer patients including surgical oncologists, medical oncologists, radiation oncologists, nurses, and social workers.</td>
</tr>
<tr>
<td>Premature menopause</td>
<td>When menstrual periods stop and menopause is reached before the natural menopause period in life. Natural pregnancy is no longer possible when menopause is reached.(^10)</td>
</tr>
<tr>
<td>Premature ovarian failure</td>
<td>Loss of the normal function of ovaries before the age of 40. Failure of ovaries results in inadequate amounts of estrogen being produced and the infrequent release of eggs commonly leading to infertility. Women may experience infrequent periods for many years and may be able to get pregnant during this time.(^10)</td>
</tr>
<tr>
<td>Woman</td>
<td>The term woman is used throughout this thesis to refer to any individual born with ovaries.</td>
</tr>
</tbody>
</table>
Chapter 1
Introduction

This introduction describes an overview of the thesis and brief rationale for the development of a fertility decision aid for young breast cancer patients (18 to 45 years of age) in Canada. The previous work completed as part of a larger study on improving the quality of fertility decision-making in young women diagnosed with breast cancer is also described. The chapter ends by presenting the specific research objectives for this thesis.

1.1 Thesis overview

The overall objective of the thesis is to develop a decision aid on the fertility options for young breast cancer patients in Canada, entitled “Begin Exploring Fertility Options, Risks and Expectations (BEFORE) – A decision aid for young breast cancer patients in Canada” (herein referred to as the BEFORE decision aid). The online and downloadable paper version of the BEFORE decision aid is accessible through www.before.offtomarket.ca (indirect link). The rationale for targeting the BEFORE decision aid to young breast cancer patients was that breast cancer is the most common cancer in young women, the fertility risks from breast cancer treatment are higher, and the pregnancy rates of breast cancer survivors are the lowest among all cancer survivors.\(^{11,12}\)

The purpose of the BEFORE decision aid is to provide young breast cancer patients in Canada with fertility-related information, to ensure they feel prepared to make informed and value-based fertility decisions in partnership with health-care providers prior to treatment that may adversely impact fertility. To achieve the purpose, we aimed to develop a decision aid that achieves the following three goals:

1. To provide information to young breast cancer patients on the available fertility options prior to treatment that may cause infertility in survivorship;

2. To assist young breast cancer patients in making fertility-related decisions that align with their values; and

3. To act as an adjunct to consultation and help young breast cancer patients and health-care providers discuss treatment-related fertility risks and make fertility preservation decisions more effectively.
This thesis project is based on previous work that aims to improve fertility care for young cancer patients in Canada. The project includes seven steps (Figure 1.1) and the current thesis focuses on evaluating existing fertility decision support resources, developing the BEFORE decision aid, and conducting alpha testing (Step 3, Step 4, and Step 5). Previous work shown in Step 1 and Step 2 (Figure 1.1) included systematic reviews on existing fertility decision support resources for young cancer patients and the barriers and facilitators to fertility decision-making among patients and health care providers. In addition, needs assessment interviews were completed with multi-disciplinary health care providers across Canada and cancer survivors to understand their experiences with fertility discussions and decision-making. Future work to pilot test the decision aid and complete wider dissemination across Canada is also planned (Step 6 and Step 7, Figure 1.1), building on the work presented in this thesis.

Figure 1.1 Project steps
Following this introduction, Chapter 2 presents a comprehensive literature review on the impact of breast cancer treatment on fertility, fertility options, barriers and facilitators to fertility discussions, and best practices for decision aid development. Chapter 3 describes the methods and results of an evaluation on existing fertility decision support resources with breast cancer survivors and health care providers to determine informational needs. In Chapter 4, the development of the BEFORE decision aid is outlined through a systematic process involving iterative expert review and user engagement. Chapter 5 presents the methods and results of alpha testing on the BEFORE decision aid with breast cancer survivors and health care providers. In Chapter 6, the key findings, strengths and limitations, and next steps for the study are discussed and used to conclude the thesis.

1.2 Research objectives

The overall aim of this study was to develop a decision aid for young Canadian women diagnosed with breast cancer who are at risk of infertility following cancer treatment. The specific research objectives were to:

1. Identify the aspects of existing fertility decision resources that breast cancer survivors and health care providers find valuable to include in the BEFORE decision aid.

2. To co-develop the BEFORE decision aid based on current best practices for decision aid development with breast cancer survivors, health care providers who treat young breast cancer patients and infertility in cancer patients, cancer organizations, advocacy groups, patient education specialists, and decision-making experts.

3. Conduct usability, comprehensibility, and acceptability (alpha) testing of the BEFORE decision aid (paper and online prototypes) with breast cancer survivors and health care providers.
Chapter 2
Literature Review

This chapter presents the rationale for developing the BEFORE decision aid by describing the background of breast cancer among young women in Canada, highlighting the relationship between breast cancer and fertility, and reviewing the barriers and facilitators to fertility discussions and decision-making. The history of decision aids and best practices for decision aid development are reviewed including the frameworks and criteria available to guide developers and the key components of decision aids. The chapter concludes with a justification for the development of the BEFORE decision aid and the conceptual framework chosen to guide development.

2.1 Breast cancer in Canada

Breast cancer is the most common cancer diagnosis among Canadian women with an estimated 25,700 new cases in 2016.\textsuperscript{13} Even as the leading cancer diagnosis, the death rate from breast cancer has declined since the mid-1980s due to advances in screening allowing for the detection of earlier stage cancer and improvements in breast cancer treatments.\textsuperscript{13}

2.1.1 Breast cancer in young adults

Most breast cancer cases in Canada occur in women over the age of 50. However, an estimated 1195 women between 0-39 years of age and 3,300 women between 40-49 years of age were diagnosed with breast cancer in 2016.\textsuperscript{13} Although the age range considered to represent “young” women of childbearing age varies in the literature,\textsuperscript{14} for the purposes of this thesis, young women are those between the ages of 18 and 45. This age range was chosen since it encompasses young women who are of childbearing age.

Young women face distinct burdens when they are diagnosed with breast cancer. Specifically, they have to make quick decisions surrounding fertility preservation if their family-building is not complete.\textsuperscript{15} Although young women generally have more aggressive cancer compared to older women, the 5-year survival rates for young women with breast cancer has risen from 81% in 2004-2006 to 85% in 2015.\textsuperscript{13} As a result of the higher survival rates, focus has shifted to considering aspects of survivorship including fertility preservation.\textsuperscript{15}

2.2 Cancer and fertility

In 2007, Dr. Teresa Woodruff first described oncofertility as an “interdisciplinary field bridging biomedical, social sciences and examines issues regarding an individual's fertility options, choice
and goals in light of cancer diagnosis, treatment and survivorship.” The emerging field of oncofertility has grown in the past decade due to the higher survival rates among cancer survivors and progress in reproductive technologies. In addition, there is heightened awareness of the complications associated with cancer treatment and the impact of infertility on the quality of life among survivors.

2.2.1 Female fertility
At the time of birth, women have approximately one to two million follicles that contain immature eggs in their ovaries. The number of follicles decrease as women age with 300,000-400,000 remaining at the time of menarche. Women reach reproductive age when menstruation occurs each month. At the beginning of the menstrual cycle hormones called follicle-stimulating hormone (FSH) and luteinizing hormone (LH) stimulates the ovaries and cause one egg to mature from the immature eggs contained in the follicles. The mature egg is then released into the fallopian tubes in a process called ovulation. The remaining stimulated follicles will stop growing and degenerate, causing a decrease of approximately 1000 follicles each month. If the mature egg is fertilized by sperm it will result in a pregnancy and if the egg is not fertilized menstruation will occur. This cycle is repeated each month until there are few to no follicles remaining in the ovaries.

As the number of follicles decrease with age the ability to become pregnant (or fertility) also decreases. The decrease in fertility is accelerated after the age of 37-38 when approximately 25,000 follicles remain. The decline continues for 10-13 additional years in a process called perimenopausal transition until the follicles are depleted and women reach menopause. Women reach menopause once they have not had a menstrual cycle for one full year. The average age of menopause, age 51, has remained consistent for centuries.

Infertility occurs when women are no longer able to become pregnant due to factors other than natural menopause. There are a variety of reasons for infertility including low egg quality or a low number of eggs in the ovaries.

2.2.2 Impact of breast cancer treatment on fertility
Cancer treatments have potential gonadotoxic effects and can compromise the reproduction abilities of women diagnosed with breast cancer. The treatment for breast cancer varies for each women based on prognostic and clinical factors. Generally, a multi-modal treatment regimen is recommended by the healthcare team that may include surgery, radiation, chemotherapy, hormone
and biologic therapy.\textsuperscript{23} Table 2.1 includes the description and impact of common cancer treatments in relation to fertility.

**Table 2.1 Breast cancer treatments impact on fertility\textsuperscript{22,23}**

<table>
<thead>
<tr>
<th>Breast Cancer Treatments</th>
<th>Description</th>
<th>Recommended</th>
<th>Impact on Fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No Impact to Fertility</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast surgery</td>
<td>Surgically removing the tumour from the breast. Woman have the option of lumpectomy or modified radical mastectomy. Axillary lymph node dissection or sentinel lymph node biopsy may also be completed</td>
<td>In most breast cancer cases</td>
<td>Surgery to the breast does not have an impact on fertility</td>
</tr>
<tr>
<td>Breast radiation</td>
<td>Destroys the remaining tumour cells in the breast and axillary node region to reduce the risk of a local recurrence or shrink the tumour before surgery</td>
<td>When breast-conserving surgery is chosen, and may be given after a mastectomy in cases with a high risk of recurrence</td>
<td>Radiation to the breast does not have an impact on fertility</td>
</tr>
<tr>
<td><strong>Possible Impact to Fertility</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemotherapy – (e.g., cyclophosphamide)</td>
<td>Treatment given orally or intravenously to stop the growth of cancer cells in the breast. It reduces the risk of recurrence or shrinks the tumour before surgery</td>
<td>In locally advanced, advanced, or early-stage breast cancer cases with a high risk of recurrence</td>
<td>Alkylating chemotherapy agents (e.g., cyclophosphamide) may have a significant impact on fertility by decreasing the number and quality of eggs</td>
</tr>
<tr>
<td>Hormone therapy</td>
<td>Treatment used to stop the growth of cancer cells and prevent the return of breast cancer (after surgery and radiation) or to shrink the tumour before surgery</td>
<td>Hormone-receptor positive breast cancer (ER/PR+)</td>
<td>Hormone therapy may have an indirect impact on fertility because women should not become pregnant while receiving treatment and age-related declines in fertility will occur during that time.</td>
</tr>
<tr>
<td>Biologic therapy – (e.g., Trastuzumab (Herceptin®))</td>
<td>Treatment given intravenously to stop the growth of HER2-positive cancer cells in the breast</td>
<td>In HER2-positive breast cancer cases</td>
<td>Trastezumab may have an indirect impact on fertility because during the approximately one year women are on treatment they should not become pregnant and age-related declines in fertility will occur during that time.</td>
</tr>
</tbody>
</table>

ER–Estrogen Receptor, PR–Progesterone Receptor, HER2–Human Epidermal growth factor Receptor 2
The information in the table is adapted from the treatment information presented by the Canadian Cancer Society and National Cancer Institute.

Breast surgery and breast radiation do not impact the fertility of women.\textsuperscript{23} In contrast, chemotherapy has a variable effect on fertility for each woman, yet this treatment modality can cause temporary or permanent amenorrhea, premature menopause, premature ovarian failure, or permanent infertility.\textsuperscript{24}
Even if menstruation returns following treatment, fertility may still be compromised in women due to a decrease in the number and quality of eggs (although temporary amenorrhea after treatment does not necessarily indicate women are infertile). The factors that affect post-treatment fertility include age, ovarian reserve prior to treatment, and the chemotherapeutic agents used. The exact impact of chemotherapy on fertility is challenging to determine as each woman possesses different factors that will impede or enable their fertility in survivorship. However, cyclophosphamide (an alkylating agent commonly used in chemotherapy protocols to treat breast cancer in young women) has been reported to reduce the mass of ovarian follicles by 90% shortly after administration. Alkylating agents cause direct damage to eggs in the ovaries through the reduction in follicles and in some cases cause ovarian blood-vessel damage and cortical fibrosis. The infertility risks from alkylating agents increases as women age due to the reduced number of follicles in their ovaries from the natural aging process. The American Society of Clinical Oncology (ASCO) has described the risk of permanent amenorrhea following chemotherapy regimens that include cyclophosphamide as low for women under 30 years of age (20% risk), intermediate for those 30-39 years of age (40% risk), and high for those over 40 years of age (80% risk).

Hormone and biologic therapies have an indirect impact on fertility due to the duration of time that they are recommended after surgery, radiation, and chemotherapy. As part of standard treatment, women with human epidermal growth factor receptor 2 (HER2) positive breast cancer are given Trastuzumab (Herceptin®) over approximately one year. Women who are hormone receptor positive (estrogen and/or progesterone receptor positive) are recommended to receive hormone therapy. While most breast cancers are hormone receptor positive (74%), younger premenopausal women tend to have more aggressive cancers that are triple negative (estrogen, progesterone, and HER2 negative). Although the duration of recommended therapy varies, in general women with hormone receptor positive cancers are treated with hormonal therapy for 5-10 years. Pregnancy while taking hormone or biologic therapy increases the risk of congenital defects and early cessation of therapy may increase the chance of cancer recurrence. Therefore, women are counselled to take hormone therapy after treatment and to not attempt pregnancy while on treatment. Since the chances of reproducing and having a healthy pregnancy decline with age, women who have required a long treatment course will experience natural declines in fertility as they age and may face challenges becoming pregnant after treatment.
2.2.3 Fertility preservation options for females in Canada

Established and experimental fertility preservation options are available for women with breast cancer in Canada. Established methods that are effective forms of preserving fertility include embryo cryopreservation (embryo freezing) and oocyte cryopreservation (egg freezing).30 Experimental methods that are available and require more research include ovarian suppression during treatment with gonadotropin-releasing hormone analogues (GnRH agonist), ovarian tissue banking, and in vitro maturation.30 The descriptions and availability of the fertility preservation options in Canada are outlined in Table 2.2. Women with breast cancer also have the option to forgo any established or experimental fertility preservation options and choose to proceed with the planned treatment regimen and “wait and see” if treatment compromises their fertility.16

<table>
<thead>
<tr>
<th>Fertility Preservation Options</th>
<th>General Description</th>
<th>Availability in Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Established Fertility Preservation Options</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Embryo cryopreservation (embryo freezing)</td>
<td>Mature eggs are retrieved from the ovary and fertilized with sperm to create embryos. The embryos are frozen until treatment is completed and then they are thawed, and implanted into the uterus.</td>
<td>Available in all fertility clinics across Canada</td>
</tr>
<tr>
<td>Oocyte cryopreservation (egg freezing)</td>
<td>Mature eggs are retrieved from the ovary and frozen until treatment is completed. After treatment, the eggs are thawed, fertilized with sperm, and implanted into the uterus.</td>
<td>Available in most fertility clinics across Canada</td>
</tr>
<tr>
<td><strong>Experimental Fertility Preservation Options</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GnRH agonist (ovarian suppression)</td>
<td>Monthly drugs that are given throughout the course of gonadotoxic chemotherapy to stop the ovaries from making estrogen (putting the woman in menopause during treatment).</td>
<td>Available across Canada</td>
</tr>
<tr>
<td>Ovarian tissue banking</td>
<td>Part of the ovary is surgically removed and frozen until treatment is complete. After treatment, the ovary is thawed and transferred back into the woman.</td>
<td>Less widely available</td>
</tr>
<tr>
<td>In vitro maturation</td>
<td>Immature eggs are retrieved from the ovary, matured in a lab and frozen until treatment is completed. After treatment, the mature eggs are thawed, fertilized with sperm, and implanted into the uterus.</td>
<td>Less widely available</td>
</tr>
</tbody>
</table>

The information in the table is based on the established and experimental fertility preservation options in the original 2006 and updated 2013 American Society of Clinical Oncology Clinical Practice Guidelines on Fertility Preservation for Patients with Cancer. Availability of services is based on fertility clinic websites across Canada and verbal communication with fertility clinics.

The fertility preservation options are not mutually exclusive. For example, young women can choose to freeze both embryos and eggs prior to treatment as well as use an GnRH agonist during treatment.31 Additional parenthood options are available to women after treatment including egg or embryo donation, adoption, and surrogacy.30 The decision to complete one or multiple fertility
preservation options should be made with consideration towards patient age, treatment regimen, natural fertility status without treatment, and social and personal situation.¹²

### 2.2.4 Consequences of infertility for young cancer patients

Fertility concerns are high among younger cancer patients and can influence treatment decisions.³² A survey of female cancer survivors (n=204) found that those with high levels of fertility concerns were more likely to experience moderate or severe depression in survivorship, which may be due to unmet informational needs.³³ In a review by Penrose et al., individuals with infertility secondary to their cancer treatment experienced negative emotional responses, leading to strain in relationships.³⁴ Canada and Schover also found that women 10-years post treatment who became infertile had lower satisfaction with their relationships than their counterparts who remained fertile.³⁵ The authors also found that fear of rejection by future partners is prevalent among single women who are infertile following treatment.³⁵ Treatment-related infertility can have a long-term impact on psychosocial distress and the quality of life in survivors.³⁴⁻³⁶ In particular, Wenzel et al. found that among women (n=231) who were five years post treatment, those who experienced treatment-related infertility reported significantly more distress, lower mental health, and lower overall psychological and physical well-being compared to women who remained fertile.³⁶ The authors also found that among infertile women, 6% felt “like less of a woman” and 8% were less satisfied with their life as a whole.³⁶ Canada and Schover found survivors (n=239) had greater stress about infertility using the Reproductive Concerns Scale that measures distress relating to infertility among female cancer survivors and found survivors were more likely to manage their distress through avoidance strategies.³⁵ Through the assessment of cancer survivors in these studies, the challenges experienced as a result of treatment-related infertility are evident.

### 2.2.5 Fertility preservation guidelines for cancer patients

In Canada, a guideline by the advocacy group Rethink Breast Cancer targeted to young breast cancer patients has one recommendation focusing on fertility.³⁷ The Care Guideline for Young Women with Breast Cancer was created in 2015 through consultations with breast cancer patients and multi-disciplinary health care providers in oncology, nursing, and psychosocial support. The guideline aims to compliment Canadian clinical practice guidelines from Health Canada and the Canadian Medical Association for the treatment and care of breast cancer.³⁷ The guideline states that health care providers should always communicate the possible impact of treatment on fertility and the fertility-related options to patients.³⁷
In addition to this Canadian guideline by Rethink Breast Cancer, there are multiple guidelines across jurisdictions created for fertility preservation in cancer patients of reproductive age. A recent systematic review found seven guidelines on fertility preservation for young cancer patients from American, European, and International organizations (Table 2.3).38

**Table 2.3 Fertility preservation guidelines for cancer patients of reproductive age**38

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Country</th>
<th>Year</th>
<th>Patient population</th>
<th>Included fertility options for women with breast cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Society of Clinical Oncology</td>
<td>United States of America</td>
<td>2006 and updated in 2013</td>
<td>All cancer patients of reproductive age</td>
<td>− Embryo freezing</td>
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<td></td>
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<td>− Egg freezing</td>
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<td>− Ovarian tissue freezing</td>
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<td></td>
<td>− Ovarian suppression</td>
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<td></td>
<td>− Donor eggs/embryos</td>
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<td></td>
<td></td>
<td>− Gestational carrier (surrogate)</td>
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<td>− Adoption</td>
</tr>
<tr>
<td>European Society of Breast Cancer Specialists</td>
<td>Europe</td>
<td>2010</td>
<td>All cancer patients of reproductive age</td>
<td>− Embryo freezing</td>
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<td>− Egg freezing</td>
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<td></td>
<td>− Ovarian suppression</td>
</tr>
<tr>
<td>International Society for Fertility Preservation (general for cancer patients)</td>
<td>International</td>
<td>2012</td>
<td>All cancer patients of reproductive age</td>
<td>− Embryo freezing</td>
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<td>− Ovarian tissue freezing</td>
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<td>− Ovarian suppression</td>
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<tr>
<td>International Society for Fertility Preservation (specific for breast cancer)</td>
<td>International</td>
<td>2012</td>
<td>Breast cancer patients</td>
<td>− Embryo freezing</td>
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<td>− Ovarian tissue freezing</td>
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<td>− Ovarian suppression</td>
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<tr>
<td>National Comprehensive Cancer Network</td>
<td>United States</td>
<td>2012</td>
<td>All cancer patients of reproductive age</td>
<td>− Embryo freezing</td>
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<tr>
<td>FertiPROTEKT</td>
<td>Germany</td>
<td>2011</td>
<td>All cancer patients of reproductive age</td>
<td>− Embryo freezing</td>
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<td>− Ovarian suppression</td>
</tr>
<tr>
<td>St Gallen International Expert Consensus</td>
<td>International recommendations</td>
<td>2009</td>
<td>All cancer patients of reproductive age</td>
<td>− Embryo freezing</td>
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<td>− Ovarian suppression</td>
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</tbody>
</table>

The information in the table is the synthesis of fertility preservation guidelines found in a systematic review by Haddadi et al., for young patients with breast cancer from 2003-2013.

The seven guidelines had varying final recommendations and ranged in quality when assessed by the authors using the Appraisal of Guidelines for Research & Evaluation (AGREE II) Instrument. The highest rated guideline was from ASCO (68% score using AGREE II) and was released in 2006 with an update in 2013.24,30,38 The ASCO guideline recommends that provider-patient communication on
fertility should occur as early as possible and patients should be provided with appropriate referrals to fertility specialists.\textsuperscript{24} Most of the guidelines (6 of 7, 85.7\%) were directed towards individuals of reproductive age with any cancer types and all included embryo, egg and ovarian tissue freezing as available fertility options. All but one guideline recommended ovarian suppression as an experimental fertility option. The ASCO guideline was the sole guideline to outline after treatment parenthood options (e.g., donor eggs, adoption, and surrogacy).\textsuperscript{38}

\textbf{2.2.6 Barriers to fertility preservation decision-making}

Despite consistent recommendations in guidelines for fertility discussions, there are numerous barriers to fertility preservation discussions and decision-making including both oncology health care provider and patient factors.\textsuperscript{39}

\textbf{Oncology health care provider factors impacting fertility discussions}

Oncology health care providers play a fundamental role in delivering fertility services and act as gatekeepers, referral initiators to fertility specialists, knowledge brokers, and facilitators in supporting patient fertility decision-making.\textsuperscript{40} However, many barriers can hinder oncology health care providers from discussing fertility with breast cancer patients. A key barrier is the lack of domain knowledge on fertility.\textsuperscript{41-43} In particular, Ronn and Holzer describe the lack of information provision and patient education in Canada as a problem that “begins with knowledge awareness.”\textsuperscript{44} A survey by Yee \textit{et al.}, of Canadian oncologists (n=152) found that many were not able to correctly answer a 6-item assessment on cancer-related infertility and fertility preservation.\textsuperscript{45} In the survey, fertility knowledge also varied by specialty with gynecologic oncologists scoring the highest and radiation oncologists scoring the lowest, however surgical oncologists were not included in the sample population. The survey also found that oncology health care providers in community non-teaching hospital settings were significantly less knowledgeable on fertility than their colleagues who practiced at teaching hospitals. Similar to the Canadian findings, a qualitative study with oncologists in the United States found that a main barrier to fertility discussions was lack of fertility knowledge.\textsuperscript{41} While many oncologists believe they have adequate fertility knowledge, a 2010 survey (n=249) in the United States found that only 17\% had experience with fertility preservation techniques.\textsuperscript{42} The survey also found that 97\% of oncologists agreed with the ASCO guidelines and 75\% expressed interest in attending educational sessions on fertility preservation. These results indicate that although a lack of knowledge is a barrier, there is interest among oncology health care providers to improve their fertility knowledge.\textsuperscript{42}
Oncofertility is a relatively new area and in Canada there is a lack of consistent collaborative initiatives among oncology health care providers and fertility specialists. Ideally a patient should receive proactive discussions and information surrounding fertility in addition to a fertility specialist referral if they are interested in learning more about the fertility options available. However, there is role confusion on who is responsible for discussing fertility with patients and with a diverse multidisciplinary care team this can lead to less information provided to patients or conflicting responses. Additionally, there is a lack of resource awareness as 45% of respondents in the survey by Yee et al. did not know where to refer women for fertility preservation. Most fertility clinics in Canada report low referral rates for cancer patients and the issue of fertility is often inadequately discussed in oncology clinical settings. Low referral rates are especially problematic as a recent needs assessment survey of young breast cancer patients (n=574) in Canada found that 84% of patients aged 20-29 and 47% of patients aged 30-39 had fertility concerns. Additional factors influencing referrals to fertility specialists were the length of time an oncology health care provider was practicing (younger providers were more likely to refer than older providers) and the specialty (medical oncologists more likely than surgical oncologists to discuss fertility). The low referral rates may be due to the perceptions among oncology health care providers of the low efficacy and high cost of fertility preservation, and/or that fertility preservation may delay starting cancer treatment. While there is no consensus on the “appropriate” patient for a fertility preservation consultation, Mersereau states that fertility risks should be communicated with women who are premenopausal regardless of their age or disease characteristics. Early communication and subsequent referrals to fertility specialists for counselling and information are especially important due to the long-term negative impacts of treatment-related infertility among cancer survivors.

Patient factors impacting fertility discussions

Patients lack knowledge on the extent of age-related fertility decline and the impact of cancer treatments on future fertility. In Canada, a survey of childless women between the ages of 20-50 found that the women had moderate knowledge on fertility but lacked knowledge on the implications of delaying childbearing and specific aspects of fertility preservation including cost and eligibility. In addition to the lack of knowledge, breast cancer survivors in multiple studies felt they were not provided with adequate information, education, counselling, or resources to make fertility decisions. A qualitative study of breast cancer survivors from Australia (n=18) found that while not all younger women wanted information, those who did want information often received inadequate, conflicting, and inconsistent fertility information that was not directed towards young
women.\textsuperscript{52} In Canada, women with breast cancer report similar ineffective fertility communication with oncology health care providers and lack resources to help make fertility preservation decisions.\textsuperscript{47} As a result, breast cancer patients report experiencing decision conflict surrounding fertility preservation due to poor knowledge on the resources and services available.\textsuperscript{54,55} Additionally, a study by Yee found that women were significantly more likely to have a fertility discussion if they did not have children at the time of diagnosis, were younger at the time of diagnosis, and if they initiated and raised fertility concerns.\textsuperscript{40}

Cost of fertility preservation and insurance coverage for fertility medications may also be a perceived barrier for accessing fertility preservation prior to treatment.\textsuperscript{54,55} Currently in Canada, one cycle of \textit{in vitro} fertilization and oocyte freezing (not including the cost of fertility drugs) is covered in Ontario for cancer patients under the age of 43. Additionally, in Quebec fertility preservation and drugs are covered for cancer patients.\textsuperscript{56,57} However, the remaining provinces and territories in Canada do not have coverage and patients must seek out alternate sources of funding to help alleviate the cost of fertility preservation or pay for the preservation themselves. The cost of fertility preservation averages between $10,000 and $20,000 but can vary based on the number of egg retrieval cycles required, medications, and annual storage fees.\textsuperscript{44} In contrast, a recent study by Gotz \textit{et al.}, at Mount Sinai Hospital in Toronto, Ontario found that cost may not be a main barrier to fertility preservation as they found no increase in fertility preservation utilization following the coverage in Ontario for cancer patients under the age of 43.\textsuperscript{58} The authors report that other factors may be more influential when patients make fertility decisions such as the impact on prognosis and concern surrounding the delay of treatment.\textsuperscript{58}

The lack of knowledge on the efficacy of fertility preservation, prognosis of breast cancer as well as the urgency for treatment to begin can create a conflict of priorities in patients. Without adequate information and discussion, the conflict may cause distress and regret in survivorship.\textsuperscript{34}

### 2.2.7 Facilitators to fertility preservation discussions

A range of strategies are used across Canada and internationally to facilitate discussions and provide fertility information to young women diagnosed with cancer including:

- Collaboration of an online fertility knowledge network and referral system to fertility clinics who accept oncology fertility referrals in Canada by the Cancer Knowledge Network (\texttt{www.cancerkn.com}) and United States through FERTILITY SCOUT\textsuperscript{TM} (\texttt{www.allianceforfertilitypreservation.org}).\textsuperscript{12} The FERTILITY SCOUT\textsuperscript{TM} is an online tool
that allows cancer patients and oncology health care providers to locate fertility clinics in the area. Oncology health care providers can also send referrals to fertility specialists through the online system.59

- Formal hospital-based cancer programs for young cancer patients such as the Sunnybrook Health Sciences Centre in Toronto, Ontario with the PYNK: Breast Cancer Program for Young Women developed in 2008,60 and the Cancer and Fertility Program at Memorial Sloan Kettering Cancer Center developed in 2009.61 Both programs depend on a nurse navigator/fertility clinical nurse specialist to guide young patients through the care journey and support oncology health care providers in providing fertility information. The programs also have dedicated information resources to specifically address the needs of younger cancer patients and resources for patients to assist them with fertility decision-making and emotional needs.60,61 Additionally, the Cancer and Fertility Program has resources for oncology health care providers that outline a clear referral process to fertility specialists and ongoing fertility education.61

- Development of organizations providing information, support, and financial resources for patients and health care providers on fertility such as Fertile Future in Canada (www.fertilefuture.ca), LIVESTRONG (www.livestrong.org), and the Oncofertility Consortium in the United States (www.oncofertility.northwestern.edu).

- Increased focus and understanding of the need for multi-disciplinary approaches to treatment for young cancer patients. For example, the Moffitt Cancer Centre in the United States formally involved and recognized fertility specialists and genetic counselors as members of their oncology care team that also included medical, surgical and radiation oncologists, nurses or nurse navigators, and social workers.62

- Training programs for oncology health care providers. For example, an eLearning training program, entitled Educating Nurses about Reproductive Issues in Cancer Healthcare (ENRICH), has been developed in the United States for oncology nurses to educate them on a breadth of fertility topics over 10-weeks.63

- Development of patient education materials. For example, in Australia and the Netherlands decision aids have been created to inform young breast cancer patients on their fertility
2.2.8 Limitations of existing fertility educational materials

While fertility decision aids and educational materials exist, there are a lack of Canadian specific resources for young cancer patients prompting recommendations for the development of Canadian resources to promote fertility discussions. Existing decision aids from Australia and the Netherlands contain information that is context specific to the environments (e.g., funding sources and coverage of fertility preservation, resources for patients to access more information, and commonly available fertility options). Since these factors are important in fertility decision-making, they need to be in a Canadian context for accurate use and interpretation by Canadian patients. Additionally, the online decision aid created in the Netherlands is currently only available in Dutch. Therefore, no fertility decision aids are currently available online in English or French for use by Canadian breast cancer patients. Additionally, both the Australian and Dutch decision aids contain varying levels and depth of information on the fertility options, present success rates and natural pregnancy rates after treatment in different formats, do not separate the fertility options success rates by age, and include different values clarification method formats. However, despite the differences, evaluations of both decision aids have shown that patients were satisfied and had increased knowledge on fertility information and the fertility options after using them. As such, it is challenging to determine which decision aid format would be best to adapt for Canadian patients. Fertility educational materials such as brochures and educational websites also exist in the United States. However, these resources vary from decision aids as they do not aim to help patients clarify the value they place on the different fertility options. In addition, there are variances between the available resources, available fertility options, and funding and coverage of fertility preservation between Canada and the United States. For example, altruistic and paid surrogacy is permitted in the United States, however, in Canada paid surrogacy is not permitted and only altruistic surrogacy is allowed. Therefore, while fertility resources exist in other jurisdictions a fertility decision aid is needed in the Canadian context for young breast cancer patients to assist them in making informed fertility decisions prior to treatment.
2.3 Decision aids

The International Patient Decision Aids Standards (IPDAS) define decision aids as “tools designed to help people participate in decision making about health care options. They provide information on the options and help patients clarify and communicate the personal value they associate with different features of the options.” Decision aids are commonly developed for decisions with no “best” option and explicitly state the decision under consideration then provide personalized information on the various options and the associated outcomes. Decision aids are not a substitute to consultation from health care providers but aim to assist patients in understanding the scientific uncertainties in the options, clarify the personal values they associate with each option, and present the benefits and harms in an unbiased format to allow for effective communication with health care providers and subsequent preference-sensitive decision-making. Decision aids therefore differ from other patient education materials that provide general information but do not focus on preparing patients for decision-making.

2.3.1 Shared decision-making and decision aids

Shared decision-making (SDM) has four key characteristics as defined by Charles et al.:

(1) explicitly identifies different analytic steps in the treatment decision-making process; (2) provides a dynamic view of treatment decision-making by recognizing that the approach adopted at the outset of a medical encounter may change as the interaction evolves; (3) identifies decision-making approaches which lie between the three predominant models (paternalistic, shared and informed); and (4) has practical applications for clinical practice, research and medical education.

While many health care providers believe they are engaging in SDM, there is a gap in understanding of what SDM entails, the time and skills required, and the level of involvement each patient wants in the decision-making process. SDM also requires that health care providers are knowledgeable about the medical decision and share their knowledge in a way that supports patients in deliberation and decision-making. The preferred role a patient has in their care impacts SDM. Singh et al., report that among cancer patients (n=3491), 25% wanted a passive role, 26% wanted an active role, and most (49%) wanted a collaborative role in treatment decision-making. Women were found to take a more passive role compared to men but young patients were less likely to take a passive role in the decision-making when compared to older adults.
Decision aids may be used to help support SDM by describing the health condition and outlining the choices. Since the information provided in clinical discussions can impact patient preference, information through decision aids can help patients become active and informed if they prefer that role. Following the increase in research and interest in decision support interventions, over 500 decision aids have been developed covering an array of health conditions. While no decision aid guarantees SDM occurs between health care providers and patients in clinical practice, decision aids have been designed to work in the clinical environment to allow for SDM to occur when used in consultation. The challenge is that there is generally low uptake of decision aids that require shared completion between health care providers and patients in consultations.

2.3.2 Decision-making process using decision aids

Decision aids help structure the decision-making process between two or more options allowing for a more deliberate decision. Decision-making is easier when there is relative certainty about the facts and values of the decision and when people know what they want and know the outcomes of their decision. In contrast, decision-making is challenging when there is uncertainty surrounding what people want to happen and when there is uncertainty in the outcomes of a decision. Many health decisions have no single “best” choice and thus patients may be faced with uncertainty surrounding the outcomes for each choice and what the best decision is for them. Decision aids therefore aim to provide patients with information on an explicit health condition in a format that allows them to weight the risks and benefits for each option thereby allowing them to make more informed decisions that are consistent with their values.

The dual process theory on decision-making states that there are two ways decisions are made: (1) intuitive mode (fast, autonomous, drawing on past experiences, and frugal); and (2) analytic thinking (deliberate reasoning, slower, and more resource intensive). Analytic thinking aligns with the aim of decision aids as it helps people slow down their thinking and allows them to go through deliberate reasoning prior to making the final decision, which can help minimize cognitive biases. The prospect theory by Kahneman and Tversky also emphasizes how heuristics and systematic biases play a role in decision-making including certainty effect, reflection effect, probabilistic insurance, isolation effect, values function, and weighting function. Sepucha et al., suggest that if decision aids follow more analytical thinking then more reasoned decisions can be made and choices will be more informed and based on values, ultimately resulting in a higher quality decision.
In addition to the process of decision-making, Bekker et al. found that decision-making among women (n=117) deciding whether to have a prenatal diagnostic test following a positive screen for Down’s syndrome was impacted by cognitive strategies and emotions. In particular, they found women who used a decision aid used more cognitive and abstract terms while evaluating information surrounding the options available (both positive and negative). While a higher number of women at the time of decision-making expressed more negative emotion words, the emotion words allowed for the verbalization of feelings related to the decision. Overall, the researchers concluded that decision aids were effective because of the generation and evaluation of cognition and emotions that are not normally seen in routine clinical discussions. Emotion can have an influential role in decision-making; patients faced with a new diagnosis that requires quick treatment decision-making can lead to strong emotional responses and may result in feelings of conflict. However, with the use of decision aids the decisions can be made based on complete information allowing for patients to generate more positive and negative reasons for the options in line with their values and beliefs.

2.3.3 Effectiveness of decision aids

In 1983, the first randomized control trial was completed to evaluate a decision aid. There have now been over 100 trials that show decision aids are effective in improving the decision-making process and other outcomes of patients. Studies assessing the effectiveness of decision aids have mainly focused on evaluating the decision-making process and/or decision quality. However, there is no standardization or consensus on the best measures to assess the effectiveness of decision aids. The change in decisional conflict is the most common measure used to evaluate decision aids. Studies also measure patients’ knowledge, satisfaction, anxiety, decision-making process, and have begun to evaluate if decisions made with the use of decision aids are more consistent with patients’ values. Few studies have evaluated knowledge retention and the long-term impact of decision aids on quality of life or other health outcomes. Decision aids can also impact the treatment decision. In a randomized control trial, Whelan et al., found individuals diagnosed with breast cancer who used a decision board (n=94) were more likely to choose breast conserving surgery over mastectomy compared to those receiving usual care. The decision board also improved communication and resulted in users having lower decisional conflict, higher satisfaction with their decision-making and higher knowledge. Additional measures beyond decision quality and decision-making process include cost-effectiveness, utilization of services, treatment rates, and inequalities and disparities in health; however, the impact on these outcomes has not been well studied.
A recently updated Cochrane review of 105 studies that examined 50 decisions involving 31,043 participants was completed to assess the effects of decision aids on treatment and screening decisions. The review found a high risk of bias in 12 of the 105 studies (11.4%). The decision aids encompassed diverse medical conditions with the most common on screening for prostate cancer (n=14), screening for colon cancer (n=10), diabetes medication (n=4), and genetic testing for breast cancer (n=4). The decision aids were designed using a variety of formats and most reported on the clinical problem and probabilities of the possible health outcomes. All studies provided implicit values clarification and over half (57.1%) included explicit values clarification. Few decision aids provided personal stories (41%) and steps to help with decision-making (65.7%). Among the primary outcomes the review found that decision aids used in preparation or during consultation were effective in increasing knowledge (high quality evidence) and risk perceptions when expressed probabilities for the health outcomes were included (moderate quality evidence). Decision aids also allowed patients to make a decision in line with their values (low quality evidence). Additionally, when compared to usual care decision aid users were more active in the decision-making process and had lower decisional conflict and feelings of unclear values. Among the studies assessing communication between patients and health care providers, a positive effect was found. Decision aid users also had equal or more satisfaction with the decision-making process and their decision compared to those who had usual care. Secondary outcomes found that the median time added to a consultation when using a decision aid was 2.6 minutes (ranging from shorter by 0.4 minutes and longer by 23 minutes). Additionally, those who used decision aids were more likely to choose conservative surgery options, similar to findings from Whelan et al. Overall, the updated review concluded that providing decision aids is advantageous as compared to usual care.

The U.S. Agency for Healthcare Research and Quality (AHRQ) also conducted a review and meta-analysis of cancer specific decision aids for screening and treatment. Among the 68 included studies involving 25,337 participants the review found an advancement in decision aid development as more recent decision aids were able to be delivered in a more practical manner (e.g., as an online version) and included explicit values clarification methods. Similar to the Cochrane review, the meta-analysis found higher knowledge and lower decisional conflict among decision aid users. However, limited information was available on the effect of decision aids in relation to a variety of factors including the impact on patient-provider communication, consultation length, and cost. Through qualitative synthesis the review found patients who used decision aids were more likely to make informed decisions that are in line with their values.
While decision aids can be effective, the impact of these tools on decisions may be influenced by inaccurate and biased information. The quality of decision aids varies - some lack references and others contain presentation biases in the information. A review of information in decision aids (n=98) by Feldman-Stewart et al., found most developers relied more heavily on guidance from health care providers for information versus patient input, included information that was not balanced between the options, did not include all the information that might be a key factor for informed decision-making, and rarely provided the sources of evidence. The effectiveness of decision aids depends on how they are integrated into the decision-making process and the quality and completeness of included information.

2.3.4 Decision aid use in clinical settings

Even though decision aids have been demonstrated to be effective, in general the uptake of these tools is low. Among general surgeons, radiation oncologists, and medical oncologists (n=477) in Ontario, only 24% use decision aids in their practice to enhance SDM. Notably most oncology health care providers (71%) who were not using decision aids have expressed interest in future use. A systematic review by Légaré et al., found the main barriers to SDM and decision aid use by health care providers included lack of time, lack of tool applicability to the patient characteristics, and variations in the clinical situation from those more generally described in the decision aid.

While lack of time was the most commonly cited barrier, there is variable evidence that engaging in SDM requires additional time. Additionally, in a qualitative study of cancer surgeons (n=22) by O’Brien et al. only one surgeon reported time as a barrier to decision aid use in practice; the main reason for surgeons not using a decision aid was high confidence in their verbal communication skills. In contrast, patient surveys show patients consistently desire better communication with health care providers. However, even when a decision aid is used it may not result in a decision that reflects patients’ personal values. Scherr et al., found that among prostate cancer patients (n=257) who used a decision aid, patients generally decided on the option recommended by the health care provider instead of the option that aligned with their personal preference, representing a potential lack of SDM. Other barriers to decision aid use are poor design fit with clinical settings and workflow, limited health care provider knowledge on the content, and lack of trustworthiness of information in the decision aid.

Decision aids can be completed by a patient in clinic with a health care provider, alone before or after a clinical appointment, or in conjunction with their partner or other members of their support
Some decision aids are designed to be used during a clinical visit – these are generally shorter in length and not as comprehensive as traditional decision aids. Most traditional decision aids have been designed for independent patient use before or after a clinical appointment. While this alleviates the barrier to lack of time, there is no guarantee that use of a decision aid outside of clinic will facilitate SDM. If patients use decision aids outside of clinic then follow up at the next clinical appointment is required to ensure SDM occurs. Légaré et al. has suggested that to ensure SDM occurs interventions can also be targeted at patients to facilitate their active involvement instead of relying on health care providers to determine if a patient would like an active role. There is no consensus on the best framework or implementation process to deliver decision aids in clinical practice. However, frameworks including the Knowledge to Action Framework and Ottawa model for research have been used to measure implementation of decision aids. Elwyn et al., also completed a systematic review on the implementation of decision aids using five levels of implementation (orientation, insight, acceptance, change, and maintenance). The authors found that 10 of the 17 studies reached the level of “insight” defined as “understanding and insight into implications for routines,” and four achieved the level of “change” defined as “actual adoption, try out change in practice, exploratory use, confirmation of value of change.” Facilitators to decision aid use among health care providers include motivation as well as perceived improvements in patient outcomes and process of care. Additional facilitators to decision aid implementation include identifying clinical champions and providing training to increase the skills of health care providers.

2.4 Decision aid development best practices

The best practices for decision aid development are summarized in Appendix A and further described in the sections below.

2.4.1 Criteria and frameworks for decision aid development

Decision aid developers should follow recognized methods for development to avoid bias and ensure a high-quality decision aid. However, not all decision aids are developed with the use of a theoretical framework. An evaluation of decision aids (n=50) by Durand et al. found that only 17 (34%) were based on a theoretical framework.

There are six main recognized criteria and frameworks that have been developed by organizations to assist decision aid developers including the: (1) International Patient Decision Aids Standards; (2) Ottawa Decision Support Framework; (3) Dutch Institute for Healthcare Improvement; (4) Cardiff
University; (5) Informed Decision Making Foundation; and (6) Mayo Clinic. Each framework has a specific development process for decision aids as outlined in Table 2.4.

Table 2.4 Decision aid framework development steps

<table>
<thead>
<tr>
<th>Framework</th>
<th>Decision Aid Development Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>International Patient Decision Aids</td>
<td>1. Define scope</td>
</tr>
<tr>
<td>Standards</td>
<td>2. Assemble steering or working group</td>
</tr>
<tr>
<td></td>
<td>3. Needs assessment of patients and providers, determine distribution plan, review, and</td>
</tr>
<tr>
<td></td>
<td>synthesize evidence</td>
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<tr>
<td></td>
<td>4. Draft decision aid</td>
</tr>
<tr>
<td></td>
<td>5. Alpha testing with patients and providers to test acceptability,</td>
</tr>
<tr>
<td></td>
<td>comprehensibility, and usability</td>
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<tr>
<td></td>
<td>6. Review decision aid with steering group and revise as needed</td>
</tr>
<tr>
<td></td>
<td>7. Beta testing (field testing) with patients and providers to assess feasibility</td>
</tr>
<tr>
<td></td>
<td>8. Revisions and final decision aid created</td>
</tr>
<tr>
<td>Ottawa Decision Support Framework</td>
<td>1. Determine factors of a decision</td>
</tr>
<tr>
<td></td>
<td>2. Delivery of decision support intervention</td>
</tr>
<tr>
<td></td>
<td>3. Evaluation of decision support intervention success</td>
</tr>
<tr>
<td>Dutch Institute for Healthcare</td>
<td>1. Establish criteria</td>
</tr>
<tr>
<td>Improvement</td>
<td>2. Needs assessment using literature and focus groups</td>
</tr>
<tr>
<td></td>
<td>3. Draft decision aid</td>
</tr>
<tr>
<td></td>
<td>4. Determine responsibility of the decision aid</td>
</tr>
<tr>
<td>Cardiff University</td>
<td>1. Specify content</td>
</tr>
<tr>
<td></td>
<td>2. Design decision aid using storyboard, sandpit, and usability testing</td>
</tr>
<tr>
<td></td>
<td>3. Field testing with patients and clinicians</td>
</tr>
<tr>
<td>Informed Decision Making Foundation</td>
<td>1. Involvement of providers</td>
</tr>
<tr>
<td></td>
<td>2. Involvement of patients</td>
</tr>
<tr>
<td></td>
<td>3. Review and evaluation with providers and patients</td>
</tr>
<tr>
<td>Mayo Clinic</td>
<td>No specific development process but discuss needs assessment, developing prototypes, and review</td>
</tr>
<tr>
<td></td>
<td>by end users of the decision aid</td>
</tr>
</tbody>
</table>

The information in the table is a summary of the development steps as outlined in a systematic review completed by Coulter et al., (International Patient Decision Aids Standards) on the systematic development process of decision aids.

International Patient Decision Aid Standards

The International Patient Decision Aid Standards (IPDAS) (www.ipdas.ohri.ca) was established in 2003, bringing together a group of over 100 stakeholders including practitioners, researchers, patients, and policy makers from 14 countries. The IPDAS aims to enhance the quality and effectiveness of decision aids. Through a web-based Delphi consensus and synthesis of evidence, the group developed an evidence-based framework that contains 74 criteria to guide the development, implementation, and evaluation of decision aids. The criteria are broken down into 12 quality dimensions. The quality dimensions focus on using a systematic process to develop a decision aid, formatting and types of information to include in a decision aid, health literacy, and the delivery of a decision aid.
In 2005, the IPDAS published 13 systematic reviews to help guide decision aid development. The reviews were updated in 2013, with theoretical underpinnings for a variety of topics. The reviews include information on disclosing conflicts of interest, providing information in decision aids, basing information on scientific evidence, having a balanced presentation of information, presenting probabilities, clarifying values, using personal stories, health literacy, guiding and coaching to ensure SDM, systematic development establishing effectiveness, delivering decision aids on the Internet, and implementing decision aids in clinical practice. The review pertaining to the systematic development process of decision aids by Coulter et al., includes eight steps to development as outlined in Table 2.4.

**Ottawa Decision Support Framework**

The Ottawa Decision Support Framework (ODSF) was developed by the Patient Decision Aids Research Group, which is part of the Ottawa Hospital Research Institute (OHRI) and University of Ottawa (decisionaid.ohri.ca). The group was established in 1995 and developed one of the first frameworks to assist in the development of decision aids. The ODSF draws on multiple theories and concepts from various disciplines including social psychology, decision analysis and conflict, social support, and economic principals of values and expectations. The ODSF includes three elements (decisional needs, decision outcomes, and decision support). Decisional needs describe the gaps between what should be presented and what is actually presented. Decisional needs can encompass patients’ knowledge and expectations, values, resources and support, decisional conflict, and characteristics. Unresolved needs can have a negative impact on the outcome of a decision. Decision outcomes can be measured through the quality of decisions made (e.g., value-based or informed), actions (e.g., delays in care), and impact (e.g., decisional regret, appropriate use of services, and cost of services). The use of decision support to clarify needs and values, provide information, and enhance support from others can help to improve decision outcomes. Decision support can be achieved through clinical counselling, decision coaching through open discussions, and/or the use of decision tools. The ODSF steps to developing decision aids are outlined in Table 2.4 and include determining the factors needed to make a decision, delivering an intervention to provide decisional support, and evaluating the impact of the intervention on outcomes.

The framework is routinely updated to meet the internationally approved quality criteria by the IPDAS. The framework includes a development workbook and implementation toolkit. While the ODSF is commonly used, there are limitations to the framework. Specifically, the framework...
does not state how to achieve consensus on information to include, address conflicts of interest, or ensure maintenance of a decision aid.95

Dutch Institute for Healthcare Improvement95,100
The Dutch Institute for Healthcare Improvement develops decision aids drawing on information contained in existing clinical guidelines. The guidelines should be of a high quality as evaluated by an established instrument. The development process draws on the ODSF and the IPDAS through four steps as outlined in Table 2.4. The steps for designing a values clarification method are not included in the development process. The developers’ advocate for the release of decision aids with the associated clinical practice guidelines to enhance implementation and use of the decision aids. More research is required to determine the impact of these decision aids on patient outcomes.

Cardiff University95
The framework developed by Elwyn et al. at Cardiff University includes the process of creating a web-based decision aid. The ‘process map’ includes three main steps to development as outlined in Table 2.4. The process map emphasized involvement of patients to seek out and incorporate their perspectives, in addition to the review and synthesis of scientific evidence. Stakeholders including clinicians and policymakers are also involved in each step of the process. The framework emphasizes the documentation of a protocol, evidence synthesis, and documents used to guide the development. The developers cite that the process includes challenges such as limited best practice evidence on navigating web-based decision aids and the level of interactivity that should be incorporated. The process is lengthy, increasing the cost of producing decision aids. The authors highlight that early insights could provide a more streamlined and less costly process for the development of future decision aids. Similar to the ODSF, there is limited guidance on how to reach consensus on information to be included, how to manage conflicts of interest, and how to maintain the decision aid.

Informed Medical Decisions Foundation95
The Informed Medical Decisions Foundation is an organization that specializes in SDM and develops decision aids for the purposes of research and for public distribution (www.informedmedicaldecisions.org). The three steps used to develop the decision aids are listed in Table 2.4, and surrounds the continual involvement of patients and health care providers. The method outlines the process used to review and synthesize evidence, disclose sources of funding and conflicts of interest, and the maintenance, review and update of the decision aids.
Mayo Clinic\textsuperscript{95,101} 
The Mayo Clinic is a not-for-profit organization that aims to provide the best care for patients through education, research, and integrated clinical practice (www.mayoclinic.org). Montori et al. described insights into the development of a decision aid, as shown in Table 2.4, but do not list definitive steps to development.\textsuperscript{101} The development process involves observations of the clinical encounter to create an early prototype of the decision aid that will inform the development of the final decision aid. The observations are used to help ensure the tool will work as intended in clinical situations and have a meaningful impact on the SDM process. The authors highlight that design flexibility is key in the early stages and advocate for involvement from patients and clinicians throughout the process.

**Best practice:** Developers should use a transparent and systematic development process when creating decision aids.\textsuperscript{95} Most of the frameworks state that stakeholders should be involved at each stage of the development process but there is little guidance or empirical evidence for developers on the best practice or methods for engaging stakeholders.\textsuperscript{102} As such, Witteman et al. is currently completing a systematic review to formulate strategies for involving stakeholders in the development process drawing on the user-centred design framework.\textsuperscript{102}

### 2.4.2 Theory in decision aids

Theory is used in various ways when developing a decision aid.\textsuperscript{78} The theoretical grounding of decision aids varies from classical decision theory to intuitive choice models. Expected utility theory is one of the most common theories used in decision aids and includes weighing the values associated with each option to analytically determine the best option for patients.\textsuperscript{78} However, the theory predominately focuses on monetary values, does not include patient values, is not descriptive of values clarification, and lacks guidance on how to present information in the decision aid.\textsuperscript{103,104} The theory also indicated a “best” decision is possible and measures of this theory surround validating the best decision provided instead of measuring if it was a “good” decision for the patient.\textsuperscript{104} Elwyn et al., also discuss a variety of additional decision-making theories that could be used by developers to inform the design and evaluation of decision aids including: (1) the conflict model of decision making (a theory that reviews cognitive dissonance and attitude change in decision-making and suggests five stages of a decision); (2) fuzzy-trace theory (a theory of memory and reasoning in decision-making); (3) prospect theory (a theory of heuristics role in decision-making); (4) ecological rationality (a theory based on bounded rationality and the use of fast and
frugal heuristics in decision-making); (5) differentiation and consolidation theory (a theory on differentiating and consolidating opposing options until one option is superior); (6) rational–emotional model of decision avoidance (a theory on the role of negative emotions in avoiding decision-making); (7) attend, react, explain, adapt model of affective forecasting (a theory on the role of predicted emotions in deciding on future events). Fagerlin et al., outline additional decision process theories including: (1) behavioural decision framework (a framework based on identifying consequences of options and making tradeoffs to help make a decision that rates the highest); (2) image theory (a descriptive theory that includes a pre-choice and the actual choice that is decided on because the consequences are most attractive); (3) parallel constraint satisfaction model (deliberative and automatic processes in decision-making); (4) search for dominance structure mode (a perspective to make an optional decision between the available options and the option that will be chosen through four stages). However, Elwyn et al., states overall that based on the current decision-making theories, there is no one theory that encompasses how decision aids can be developed to help patients make “good” decisions and as such there is a theory-practice gap. This has led to the IPDAS ensuring all criteria and recommendations are based on theory as they are standards developers use to design decision aids.

**Best practice:** Developers should base decision aids on theory and the theory used should be reported. However, there is limited guidance on the best theory to use and how theory should be applied to specific decision aid components.

### 2.4.3 Decision aid components and criteria

Each decision aid varies but Bekker et al. reports that a minimum of two components make a decision aid: (1) visual representation of the benefits and risks for all options presented; (2) an explicit discussion of the decision aid users unique attitude and values on the benefits and risks for each option. Irrespective of the included components, patients and health care providers expect that decision aids are evidence based tools that contain accurate information.

**Information and presentation of the healthcare options**

The ability to make informed decisions is dependent on a patient’s knowledge base regarding their health condition and the available healthcare options. Therefore, relevant information must be presented in decision aids including information about the condition/treatment, the steps required to complete each option, the benefits and risks/side effects, and any other informational needs identified by stakeholders. The informational needs of patients vary and can extend past the
information that is required to make an informed decision between the options. The needs of patients can also differ from what healthcare providers think is warranted. Thus developing a decision aid that meets the informational needs of all stakeholders is challenging. Decision aids can be created as complex or simple tools. A 2014 Cochrane review found that in comparison to simple decision aids, more detailed and complex decision aids resulted in a slight improvement in knowledge and lowered decisional conflict. A separate review by Feldman-Stewart et al. came to similar conclusions.

Decision aids should contain comprehensive information on all the health options (including the option to wait and see), and the benefits and risks of each option. The IPDAS recommends that information contained in decision aids be evidence-based, relevant, up-to-date, and subjected to critical appraisal. All information in decision aids should also be validated by experts in the field, patients, and other stakeholders through an iterative process. The uncertainty and degree of confidence in the information should be presented through phrases, symbols, or numbers to help users determine the strength of the evidence and degree of trustworthiness in the evidence. However, literature on the best way to present uncertainties is limited, for example there is mixed evidence that patients comprehend a range of values when shown with confidence intervals.

In addition, the included information should be presented in an unbiased format to avoid influencing patients’ decisions. When facing difficult decisions, people often rely on heuristic strategies, where subtle cues and the way the information is presented influence the decision versus the information itself. Therefore, the presentation of information should aim to be balanced, defined as a “complete and unbiased presentation of the relevant options and the information about those options -in content and in format- in a way that enables individuals to process this information without bias.” Balancing the presentation of information is perceived to be the best when a horizontal side by side format is used to display the health options. A linear sequence for listing the health options can impact how patients perceive the importance of the options (e.g., the perception that the first option is the better option). The presentation of information can also cause a framing effect; Trevena et al. describe how presenting gains or survival leads to preference for a sure outcome whereas presenting information as a loss or death leads to riskier choices. Ubel et al., found that when risk information was presented last in a decision aid on hormone therapy for women with breast cancer (n=632), participants expressed worry about the side effects more than being impressed by the benefit of preventing a breast cancer recurrence.
Visuals in decision aids should be carefully considered by developers. Graphics that do not relate to the text can distract readers and reduce their recall ability. An expert review consensus by Trevena et al. found that using visual depictions for the probabilities through icon arrays/pictographs or bar charts are perceived as easier to understand by patients. The depictions can also help to enhance understanding of the information by reducing biases such as the framing effect, denominator neglect, and narrative. However, graph literacy work by Garcia-Retamero and Galesic caution that the ability to read and comprehend visual displays of information varies. Individuals who lack graph literacy may prefer to read numbers, while visuals can benefit those with high graph literacy skills. In addition, visuals may result in patients focusing on patterns in the data versus the specific values. Therefore, developers need to be aware of the impact visuals can have on the understanding of information. Developers should also consider the population using the decision aid and their numeracy and graph literacy.

Trevena et al. also recommends that to ensure clear presentation of risk communications the denominator should be the same across options to help with comparisons and should be consistent throughout the decision aid (e.g., 1 out of 100 people experience ‘x’ side effect for Option 1 and 2 out of 100 people experience ‘x’ side effect for Option 2) versus different denominators (1 out of 100 people experience ‘x’ side effect for Option 1 and 1 out of 50 people experience ‘x’ side effect for Option 2). Developers should also use lower numbers for the denominator (e.g., 100) opposed to larger numbers (e.g., 10,000), and present probabilities as numbers instead of words such as ‘15% risk’ opposed to ‘a lower risk’. In addition, developers should not interpret percentages as high or low for patients as it may influence how they view the option (e.g., a low risk of 15%). Developers should also avoid using relative risk presentations (e.g., 30% higher risk) and instead should use absolute risk presentations (e.g., risk is higher by 5 percentage points) as they are easier to understand.

To reach a specific audience some decision aids tailor the messaging and information based on a patient’s characteristics. However, Trevena et al. discuss how the evidence of tailoring information in decision aids to the unique factors of the user is mixed and more research is required on personalizing risk messages to further understand the impact on health decisions and information. Trevena et al. also recommend developers include a version date in the decision aid and suggest an annual observation of evidence to ensure the decision aid includes current information.
**Best practices:** Developers should create decision aids with up-to-date evidence that is of high quality, and critically appraised with appropriate indication by various means (phrases, symbols, or numbers) of uncertainties in the data. There should also be a clear reference area in the decision aid where evidence is listed to allow for transparency on the sources of data and evidence.106 Developers should identify the specific informational needs from the target population of the decision aid to determine the level of detail and length of information on the general health condition and available options.107

No best practices exist for the presentation of risk and probabilities in decision aids. However, developers should refer to the known causes of biases and challenges that influence patients’ perceptions (e.g., framing and order effect, use of visuals and presentation of probabilities) when developing decision aids.110

No best practices exist for ensuring balanced information in decision aids. However, developers should consider the balance of information in their decision aid and aim to have an unbiased and neutral presentation (e.g., through horizontal side by side presentation of information such as benefits and risks) unless a strong argument can be made for promoting one option.106,108,113

**Values clarification methods**

Values clarification methods are defined as “strategies that are intended to help an individual patient evaluate the desirability of options or attributes of options within a specific decision context, in order to identify which option he/she prefers.”105 There are two types of methods:

1. **Explicit values clarifications:** These are interactive and requiring individuals to actively engage in and complete an exercise. The exercises can be completed alone, with support persons or a partner, or with a health care provider. Examples of explicit values clarification methods include utility assessment, pro and con chart, and rating scales.114,115 A review of decision aids by Fagerlin et al. found that pro and con lists were the most common format for values clarification methods.105

2. **Implicit values clarifications:** These are not interactive and do not require individuals to actively fill out a worksheet exercise. Examples of implicit values clarification methods include personal stories and descriptive scenarios.114,115
Fagerlin et al., found that various values clarification methods were used in decision aids but few reported the theory associated with the design. However, the authors noted that the development processes were well described. There are also mixed results in the literature on the effectiveness of the various explicit values clarification methods on the quality of a patient’s decision. Some studies have found that a decision aid with an explicit values clarification method can help increase preparedness for decision-making, agreement with the decision, and lower regret as compared to a decision aid with implicit values clarification or no decision aid. A 2014 Cochrane review found that patients using decision aids with explicit values clarification methods decided on options that were more in line with their values. Peate et al. found that the presentation of information in decision aids may be sufficient to clarify concepts but if the decision is more complex (e.g., multiple options) a patient may find value in completing an explicit values clarification method. However, other studies evaluating decisional conflict have shown no benefit of an explicit values clarification method. Because of the conflicting evidence it is challenging for decision aid developers to create a values clarification method that is evidence-based. On a positive note, no studies evaluated by Fagerlin et al. found that values clarification methods led to worse outcomes. Further research is also required to determine how values clarification methods fit with SDM. For example, are the methods helpful for others involved in the decision-making process (e.g., partners, family or surrogate decision-makers of the patient), what type of person benefits most from completing the method, and how should multiple options be presented?

Based on current research it is unclear if explicit values clarification methods have an impact on the quality of decisions, if a formal method for reviewing values is superior to intuitive approaches for identifying values, or the extent to which patients have preexisting preferences that they are consciously aware of when completing the exercise. Nelson et al. argue that values clarification exercises are not one-size-fits-all and they may not be appropriate for every patient. Yet there is acknowledgement among decision aid developers and consensus guidelines that decision aids should include values clarification methods because they help guide patients through the process of making a decision. A review by Witteman et al., on design features of explicit value clarification methods recommend decision aid developers use and be aware of theory and previous designs used in other decision aids. The authors also recommend transparency in publications on the design of the values clarification method and rational for the design choices.
**Best Practice:** An explicit values clarification method should be included in decision aids. However, there is no best practice identified for the development or format of a values clarification method in decision aids.\(^{103,105}\) As such, it is recommended that developers report on the rationale for the particular design by citing the theory and previous literature used, people involved in the development, and incorporation of input from stakeholders.\(^{103,105}\)

**Personal stories**

Personal stories are illustrative examples of the experiences of others who have made the same health decision that are used to communicate health information.\(^{119}\) Personal stories can be presented by patients or actors in the form of a testimonial, scripted narratives (experience of patients or of health care providers experiences of patients decision-making), documentaries, or interactions between patients and others such as health care team members, family or support persons.\(^{119}\) Personal stories can also be used to present probabilities and chances of events occurring.\(^{110}\) Cognitive learning theories suggest that viewing personal stories may have a processing advantage, allowing patients to store and retrieve information more effectively, in comparison to text or didactic information.\(^{120}\) The processing advantage has raised concerns that stories may influence decision-making more than statistical information, and as a result may bias or facilitate information and/or a patients values clarification process.\(^{119,120}\) Due to the ability of stories to bias or facilitate the decision under consideration, decision aid developers face a difficult decision on whether to include personal stories and the types of personal stories that should be included. There are three types of personal stories: (1) outcome based (describing the decision made); (2) experience based (describing the experience); and (3) process based (describing the process).\(^{120}\) Shaffer et al. found that women (n=300) who viewed process based stories were more likely to spend time searching for further information and those who viewed experience based stories were better able to imagine the treatment experience.\(^{121}\) Shaffer et al. suggest that outcome based personal stories should not be included in decision aids as they may influence or bias patients’ decisions.\(^{120}\) However, personal stories generally include a combination of all story types, and thus it is challenging to know how personal stories will influence patients’ decision-making.\(^{119,120}\)

Many patients value the inclusion of personal stories, and use them to help understand the health condition, cope, learn and adjust to their treatment, navigate through the healthcare system, and better comprehend factual information.\(^{119}\) In addition, patients with lower literacy levels respond more positively to the inclusion of personal stories in decision aids as compared to those with higher
literacy. If personal stories are included they should make explicit the importance of exploring all options to ensure there is no biasing of information and present both successful and unsuccessful stories for each option.\textsuperscript{119,120} However, while stories are perceived as valuable sources of knowledge, Bekker \textit{et al.} found that there is insufficient evidence that including them in decision aids enhances the tools effectiveness in supporting people to make informed decisions.\textsuperscript{119} The authors state that each individual's unique characteristics and experiences will affect the type of information they focus on and use when making a decision.\textsuperscript{119}

**Best practice:** No best practice has been identified for the inclusion or format of personal stories in decision aids. Developers should exercise caution regarding the types of stories they are including (if any) and evaluate them to determine how they influence patient decision-making.\textsuperscript{119}

Other considerations

Health literacy, conflicts of interest, and the delivery method are other aspects of decision aids that developers need to consider.

**Health literacy:** Health literacy is commonly defined as “the ability to obtain, process, and understand health information to make informed decisions about health care.”\textsuperscript{122} Other definitions also include the role of communication in health literacy.\textsuperscript{123} Health literacy was measured in Canada by the 2003 International Adult Literacy and Life Skills Survey. On a scale of five literacy levels, in which level three is the minimum to fully and fairly participate in society, 42\% of Canadians were below a level three.\textsuperscript{124} Additionally, it has been reported that 60\% of Canadians have low literacy and difficulty with health materials and tasks needed to understand the condition, manage health, and evaluate the available options.\textsuperscript{125}

In a review of decision aids (n=97), only three decision aids were developed specifically for the low literate population and 90\% did not report on the literacy or readability level of the decision aid.\textsuperscript{126} The lack of reporting is problematic; patients’ literacy level and ability to comprehend the information has an impact on SDM and the effective use of decision aids. In a 2004 review by DeWalt \textit{et al.}, a clear association between lower health literacy and lower patient knowledge in 14 of 16 included studies was found.\textsuperscript{127} A review by McCaffery \textit{et al.} also found that lower health literacy resulted in higher decisional regret and uncertainty, less desire for involvement in decision-making, less questions asked during consultations, and less patient-centred communication.\textsuperscript{126} The authors also noted that the effect of low health literacy on the quality and satisfaction of communication varied.\textsuperscript{126}
McCaffery et al. outline decision aid use in relation to health literacy using Nutbeam’s model for health literacy by the IPDAS (Table 2.5). The benefits derived from decision aid use depend on users’ level of health literacy. Individuals with basic literacy levels can acquire information from the decision aid and use it to make a more informed decision on the available options. Individuals with higher literacy levels can use the information to critically analyze the best option for them based on their values and communicate the information and feelings to health care providers and engage in SDM.

Table 2.5 Nutbeam’s health literacy model and relation to decision aid use

<table>
<thead>
<tr>
<th>Nutbeam’s Model Levels</th>
<th>Description</th>
<th>Relation to Decision Aid Use</th>
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</thead>
<tbody>
<tr>
<td>1. Functional health literacy</td>
<td>Writing and reading comprehension skills needed to understand health information, knowledge of health systems, services and conditions</td>
<td>Ability to understand the health information and available options</td>
</tr>
<tr>
<td>2. Communicative or interactive health literacy</td>
<td>Communication and social skills to discuss information that has been extracted from materials with other individuals</td>
<td>Ability to read the information and have an active discussion with health care providers and engage in shared decision-making</td>
</tr>
<tr>
<td>3. Critical health literacy skills</td>
<td>Advanced skills in literacy, social and cognition to analyze information in materials and make informed decisions in line with values</td>
<td>Ability to read the information and complete the values clarification method to identify and clarify personal values</td>
</tr>
</tbody>
</table>

The information in the table is a summary of the relationship between Nutbeam’s health literacy model and decision aid use from a systematic review by the International Patient Decision Aid Standards.

It is not always an easy task for health care providers to tell who has low health literacy and therefore it is recommended that developers are universally precautious and develop plain language health materials for patients across the spectrum of health literacy. Writing in plain language allows for a clear and concise presentation of information. Plain language considers the use of everyday language and writing strategies, the structure and sequence of information, and the layout and design of information as listed in Table 2.6. Additionally, developers should state how the decision aid addressed low health literacy, ensure low literate individuals evaluate the tool, assess any outcomes that are known for low literate populations, and evaluate the information with a readability tool. While the readability level is important, readability tools have limitations. For instance, the tools do not take into consideration common everyday vocabulary, longer 3-4 syllable words that are commonly used words (e.g., “information”), medical terms that are defined in the document, or the design and organization of information in the document. Therefore, information in decision aids should be written at a maximum grade 6-8 reading level and take into consideration the unique target population.
Best practice: Developers should follow plain language techniques, evaluate the decision aid with low literate patients during development, use a readability tool to ensure it is written at no more than a grade 8 reading level, and report health literacy levels when publishing on the decision aid.126,128

Table 2.6 Plain language considerations126,128,129

<table>
<thead>
<tr>
<th>Overarching Considerations</th>
<th>Specific Plain Language Techniques</th>
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</thead>
</table>
| Write information in everyday language utilizing clear writing strategies | – Use short words (1 or 2 syllables), sentences (10 to 15 words), and paragraphs (3 to 5 sentences per paragraph)  
– Avoid using medical terminology and define the term if it is required  
– Use common language that is written in a positive tone using active language and directly to the reader in conversational style  
– Write out any instructions in the order they should be carried out  
– Separate and list important points instead of grouping with text  
– Use consistent terminology throughout  
– Use verbs, do not change verbs to nouns |
| Write using well-structured, focused and logically sequenced information | – Limit the information to include only what a patient needs to know  
– Context should be presented first  
– Organizing the information in a way that is most useful for a patient  
– Group similar information together |
| Design the material using an effective layout and design | – Include meaningful visuals that relate to the text and that are inclusive of different races, cultures, and lifestyles  
– Use white space to break up text  
– Ensure text is at least a 13 pt font  
– Use no more than 2 fonts throughout the document (sans serif fonts work better for titles and serif fonts work better for text)  
– Use left justification for all information  
– Avoid italics, all caps, underlining, and difficult to read fonts  
– Use different ways to present the information (audio, video, animations) |

The plain language techniques in this table were retrieved from a workbook on Patient Education from the Patient Education Group at St. Michael's Hospital, a systematic review on health literacy from the International Patient Decision Aid Standards, and a book on teaching patients with low literacy skills by Doak et al.

Conflict of interest: A conflict of interest is commonly defined as “a set of conditions in which professional judgment concerning a primary interest (such as a patients’ welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain).”130 Conflicts of interest may be more challenging for patients to recognize and since decision aids can be published for public use without being subjected to a peer-reviewed process, patients may be at risk of reading and acting on biased information.131 The financial ties to industry can influence how patients and health care providers view the quality of studies and may result in less health care providers being willing to use the tools and change their practice.132,133 Most studies have found that patients believe financial support should be disclosed in the information presented.131

There is limited evidence on the effect of conflict of interest policies on reducing the negative impact that conflicts of interest may have on behavior. However, the IPDAS criteria and other health
organizations still advocate that conflicts be reported. The disclosure of financial gains, industry funding, and exclusion of individuals with conflicts of interest from development panels has also been advocated for clinical practice guidelines by the Institute of Medicine. Therefore, Barry et al. recommend creating a decision aid that states in plain language any sources of funding or financial support from organizations or health care providers, affiliations of decision aid developers, and the loss or gain achieved by developers when patients make a choice on the options. The authors also state that “disclosure is necessary but not sufficient” and that no funds should be used from for-profit or commercial entities that sell any of the treatments or tests included in the decision aid.

**Best practice:** Developers should disclose conflicts of interest and funding sources to ensure transparency in the decision aid. Developers should also avoid accepting funds from entities that may benefit from the choice a patient makes after using the decision aid.

**Delivery of decision aids:** Decision aids can be delivered to stakeholders through an online, paper, video, audio guided, and/or app format. The use of different decision aid formats may improve comprehension among patients when they are used to complement each other. A developer should consider the target population and setting when determining the type of format for a decision aid as well as the goals of the materials, quantity of information, and emotional needs of patients.

**Best practice:** Developers should select a format for the decision aid that best aligns with the target population and clinical setting for which it is developed.

### 2.5 BEFORE decision aid development justification

Young women diagnosed with breast cancer are experiencing higher survival rates due to the advancements in treatment. However, young breast cancer patients are expected to make challenging decisions on future childbearing quickly prior to treatment with limited and inconsistent information that is not directed towards younger women. Since there is no “best” choice about whether women should have fertility preservation prior to cancer treatment, it is a preference-sensitive decision that is unique to each woman’s situation and life circumstances. Yee *et al.*, has shown that among cancer survivors in Canada (n=188), approximately half had to initiate fertility discussions with oncologists and were less satisfied with the exchange compared to oncology-initiated discussions. Infertility can have a lasting negative impact on the quality of life of survivors and therefore current guidelines of the ASCO and Rethink Breast Cancer recommend early information provision and referrals to fertility specialist for women of reproductive age. Many young breast
cancer patients want to be active members of their care team and currently have fertility concerns that they feel are inadequately addressed.\textsuperscript{47} As such, the development and use of tools such as decision aids that enhance patients’ ability to engage in fertility discussions and prepare oncologists for these discussions have been advocated in the literature and seen as a useful strategy by patients.\textsuperscript{40,52,135-137}

A Canadian specific decision aid was deemed to be an optimal tool to assist young women with fertility decisions as they can identify the benefits and risks of each fertility option and make an informed decision that aligns with their personal values in partnership with health care providers.

### 2.6 BEFORE decision aid conceptual framework

Based on the review of best practices, the BEFORE decision aid was developed following the IPDAS criteria and drawing on the ODSF.\textsuperscript{69,98,138} These frameworks were chosen as they provide guidance on the development process and have been used in the development of multiple decision aids for preference-sensitive decisions, similar to fertility preservation decisions prior to cancer treatment.\textsuperscript{95} Following the ODSF, the unresolved decisional needs of young breast cancer patients such as inadequate fertility information and resources leading to low fertility knowledge, can result in negative decision outcomes such as low quality of life and psychosocial distress in survivorship.\textsuperscript{34-36} Therefore, the aim of using the BEFORE decision aid is to ensure patients will be able to engage with health care providers, clarify their personal values, enhance the support and resources they receive, gather information on the fertility options and benefits and risks of each option with probabilities, and make an informed fertility decision. The IPDAS criteria was used to ensure the international recognized standards for the development of the BEFORE decision aid were followed.

Based on these frameworks, stakeholders (breast cancer survivors, multi-disciplinary health care providers, cancer organizations, advocacy groups, and patient education experts) were continually engaged in the development process to ensure the decision aid was a relevant and user-friendly resource. To address the lack of established best practices for some components of decision aids and to determine the specific informational needs of stakeholders for the BEFORE decision aid, existing fertility decision support resources from varying jurisdictions were evaluated with breast cancer survivors and health care providers from across Canada.
Chapter 3
Evaluation of Existing Decision Support Resources

This chapter outlines how existing fertility decision support resources were evaluated to gain an understanding of the BEFORE decision aid end users’ informational needs. The evaluations were completed to determine the preferred content and design for the BEFORE decision aid using existing fertility decision support resources through interviews with health care providers and breast cancer survivors. The chapter describes the research design used for the evaluation of the resources, the sampling and recruitment methods, methodological rigor of the evaluation, and ethics. The results are presented using descriptive statistics and qualitative excerpts and highlight how aspects of existing resources could be adapted for use in the BEFORE decision aid. The chapter concludes by outlining how the results were utilized to develop the BEFORE decision aid and the strengths and limitations of the evaluation.

3.1 Methods

3.1.1 Research design
This evaluation utilized descriptive statistics and a descriptive qualitative research approach as described by Sandelowski. These approaches are appropriate, as the analysis aimed to provide a broad summary of the valuable aspects of existing fertility decision support resources that may be adapted for the BEFORE decision aid by staying close to the data instead of completing a more abstract interpretation of the data. Insights about what is useful in existing decision support resources were solicited to help further our understanding of what information should be available to breast cancer patients when facing fertility decisions. The evaluation is not attempting to create a theory on fertility decision-making or informational needs among breast cancer patients as many decision-making theories exist in the field.

3.1.2 Theoretical perspective
This evaluation was guided by an overarching critical realist perspective. This perspective is associated with Roy Bhaskar and social theorists in Britian. A key feature of critical realism is defined by Maxwell:
…an integration of a realist ontology (there is a real world that exists independently of our perceptions, theories, and constructions) with a constructivist epistemology (our understanding of this world is inevitably a construction from our own perspectives and standpoint).\textsuperscript{142}

This perspective recognizes the unique nature of each decision and how decisions can be shaped by personal experience and influenced by cultural and social mechanisms such as the patient-provider relationship.\textsuperscript{143} Additionally, critical realism does not exclude the use of any method, and Danermark \textit{et al.} states that the method chosen should be based on the knowledge to be gained and the learning to be achieved from the use of different methods.\textsuperscript{143} Specifically, multiple methods can be used since “\textit{realism provides a philosophical stance that is compatible with the essential methodological characteristics of both qualitative and quantitative research, and it can facilitate communication and cooperation between the two.}”\textsuperscript{142}

Applying this approach, the evaluation utilized descriptive quantitative data to rate the usefulness of fertility information, level of agreement on design and usability, and the delivery and completion of decision aids. Qualitative data were then used to explore the rationale for the ratings. The qualitative data identified the experiences and perspectives of participants and enriched our understanding of the relationships and constructs that influence fertility informational needs. The use of both quantitative and qualitative data was deemed to be the best way to systematically evaluate the existing decision support resources while also recognizing that participants’ experiences and perspectives may extend past the structured constructs available in the closed-ended responses. The combination of these methods also allowed for a clear picture on what detailed information and components from existing decision support resources could be incorporated into the BEFORE decision aid.

Realism is an ontological argument surrounding the nature of reality whereas critical realism integrates a constructivist epistemology (nature of knowledge) with a realist ontology in one paradigm stance allowing for the combination of multiple methods.\textsuperscript{142} While Bhaskar describes critical realism as identifying issues of power differences that are not shown in this evaluation, a critical realist perspective was still taken for the evaluation. The definition of critical realism provided by Maxwell and focusing on Bhaskar’s ontological and epistemological arguments surrounding the combination of qualitative and quantitative research methods was used to attain in-
depth knowledge and learning on the informational needs of BEFORE decision aid stakeholders to better inform its development.142

3.1.3 Sampling and recruitment
Participants (health care providers and breast cancer survivors) were purposively recruited through convenience and snowball sampling.144 This sampling approach allowed for the selection of specific individuals who have experience making a fertility decision prior to commencing cancer treatment in addition to those who have experience treating young women facing fertility decisions. We aimed to include participants from diverse geographic locations in Canada, treatment centres (e.g., academic or community hospital), medical disciplines (e.g., fertility experts, medical and surgical oncologists, and nurse practitioners), and age at diagnosis. Participants were recruited from March 2016 to June 2016 with interviews occurring concurrently. Following completion of the interview, each participant was provided a $20 gift card through email or in-person as an honorarium.

Breast cancer survivor participants
Survivor participants were included if they were diagnosed with breast cancer between the ages of 18 and 45, had completed active treatment (surgery, radiation, and chemotherapy but could still be taking hormone therapy), and had treatment with the potential to impact fertility within the past five years. Women who had undergone fertility preservation prior to their breast cancer diagnoses were excluded, as their fertility experiences would be different compared to those who were facing fertility decisions for the first time following their cancer diagnoses. Women were also not approached if they had a breast cancer recurrence or metastatic breast cancer. Eligible participants were recruited through three strategies including: (1) in-person at breast cancer clinics; (2) through mail; and (3) online.

In-person recruitment: occurred in two breast cancer clinics in the Greater Toronto Area (GTA), of Ontario. The oncology health care providers identified eligible participants in the clinics. The eligible participants were approached by a member of the health care team and asked if they were interested in hearing about the study. If interest was expressed, the team member would introduce the recruiter and leave the room. The recruiter provided a thorough overview of the study by going through an information letter (Appendix B). If women expressed verbal interest in the study, the recruiter provided a paper copy of the information letter and obtained their full name, phone number, and email address to ensure follow-up after clinic. Within one week of the clinic visit, the recruiter emailed the women, and if they replied with written interest in participating in the study, then
interviews were scheduled. If the women did not reply within one week, a reminder email was sent. If they did not respond to the reminder email, no further recruitment attempts were made.

**Mail recruitment:** occurred in two breast cancer clinics in the GTA. The surgeons and administrative assistant identified eligible participants online through electronic medical records. Eligible participant’s full names, phone numbers, and addresses were retrieved and a cover letter (Appendix C) and the information letter (Appendix B) were sent to their mailing address. Two weeks after mailing the information, the recruiter phoned the women using a standardized phone script (Appendix D) and asked if they were interested in participating in the study. If the women expressed verbal interest, then the study overview was provided and their email address was obtained to schedule an interview. Women who did not answer the phone call were left a voice message describing the study and opportunity for their involvement. If they did not respond to the message, no further recruitment attempts were made.

**Online recruitment:** occurred through posting the study recruitment poster (Appendix E) on websites for national breast cancer survivor support groups and non-for-profit breast cancer groups across Canada, including:

- Canadian Cancer Survivor Network ([www.survivornet.ca](http://www.survivornet.ca))
- Cancer Knowledge Network ([www.cancerkn.com](http://www.cancerkn.com))
- Rethink Breast Cancer ([www.rethinkbreastcancer.com](http://www.rethinkbreastcancer.com))
- Wellsprings (Calgary, Downtown Toronto) ([www.wellspring.ca](http://www.wellspring.ca))
- Willow Breast & Hereditary Cancer (now the Canadian Cancer Society) ([www.cancer.ca](http://www.cancer.ca))
- Young Adult Cancer Canada ([www.youngadultcancer.ca](http://www.youngadultcancer.ca))

Online recruitment was used to support recruitment of a more geographically diverse sample of participants from outside of the GTA. Interested participants emailed the recruiter and were in return sent the study information letter (Appendix B). When women replied with their written consent, then interviews were scheduled. If women did not reply, they were emailed a reminder one week following the last contact date. If they did not respond to the reminder, no further contact attempts were made.
Health care provider participants

Health care provider participants from a variety of disciplines (medical and surgical oncologists, fertility specialists, and nurse practitioners) were included who regularly provide care or assist in fertility discussions with young women (18 to 45 years of age) diagnosed with breast cancer.

All health care provider participants were identified through professional networks and recruited through email. Provider participants were asked to recommend additional providers who may be interested in participating in the study at the end of each interview. A standardized email invitation (Appendix F) was sent to each participant with the information letter (Appendix B). When responses from the participants indicating their written interest and consent to participate in the study were received, interviews were scheduled.

3.1.4 Data collection

Participants evaluated six existing fertility decision support resources. The resources consisted of two decision aids; one from Australia and the other from the Netherlands, as well as four decision support resources; three from the United States and one from Canada. The format, content, and fertility options described varied in each decision support resource (Table 3.1). The resources were identified in a systematic literature review of peer-reviewed and grey literature, as well as by experts in the field of decision-making (described in Chapter 1).

One week prior to the interviews, electronic copies of two decision support resources (one decision aid and one decision support resource) were sent to participants, allowing for time to familiarize themselves with the content. The participants were sent a decision aid and decision support resource so they could view the different formats in which fertility information could be provided. All six decision support resources were not evaluated with each participant because in general the review of two decision support resources took at minimum 30 minutes to complete. Since the Sunnybrook option grids were designed for use by surgical oncologists they were sent and evaluated by breast surgeons. The remaining participants received two randomly assigned decision support resources for evaluation. One day prior to the interview, the participants were sent a reminder email that contained the interview time, location, and resources.
Rather than surveys, interviews were used to collect evaluation data in order to encourage participants to fully express, elaborate, and explain their opinions, thoughts and feelings.\textsuperscript{144} Interviews ranged from 30 to 90 minutes. Participants evaluated one or both decision support resources that were sent depending on the participant’s availability. Participants in the GTA chose between an in-person or telephone interview. Participants located outside of the GTA completed telephone interviews. In-person interviews were conducted at St. Michael’s Hospital in a private room at 250 Yonge Street, Toronto, Ontario or in a location of the participants choosing.

Telephone interviews enabled participants located outside of the GTA to participate in the evaluation and Novick describes that telephone interviews may be advantageous by allowing participants to relax and disclose more sensitive information.\textsuperscript{145} Additionally, data gathered through telephone interviews have been shown to be rich, detailed, and of high quality.\textsuperscript{145} While there are disadvantages to telephone interviews such as the lack of nonverbal and visual cues captured during in-person interviews and shorter interview time,\textsuperscript{145,146} the advantage of having geographically diverse participants from across Canada was critical for the evaluations. Therefore, telephone interviews were completed in addition to in-person interviews.
<table>
<thead>
<tr>
<th>Fertility Decision Support Resources</th>
<th>Year Created</th>
<th>Format</th>
<th>Language</th>
<th>Included Fertility Options</th>
<th>Included Sections</th>
</tr>
</thead>
</table>
| 1. Australian Decision Aid<sup>64</sup> | 2011 last updated in 2016 | Paper decision aid and online PDF for young breast cancer patients | English | - Wait and see  
- In vitro fertilization (embryo freezing)  
- Egg freezing  
- Ovarian tissue freezing  
- Ovarian suppression (in 2016 version)  
- Adoption  
- Embryo and egg donation  
- Surrogacy | - Summary option grid  
- Background information (breast cancer rates, effect of treatment on fertility)  
- Fertility information (information on options, pros and cons of options, cost, legal issues, delay in treatment, link to fertility clinics in Australia)  
- Values clarification method (questions and a pros and cons list for all fertility options)  
- Patient story (example of a patient completing the values clarification method)  
- Graphics of women and couples  
- Graphs and icon arrays to display statistics |
| 2. Dutch Decision Aid<sup>65</sup> | 2013 | Online decision aid for young breast cancer patients | Dutch | - Wait and see  
- Embryo freezing  
- Egg freezing  
- Ovarian tissue banking  
- Egg donation  
- Adoption/fostering | - Background information (effect of treatment on fertility, fertility in women, pregnancy and breast cancer)  
- Fertility preservation options (information on options, pros and cons of options, location of procedures in the Netherlands, options after treatment)  
- Values clarification method (weighted scale) and summary page  
- List of questions for health care providers  
- Animated graphics depicting fertility procedures  
- Graphs and tables to display statistics |
<table>
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<tr>
<th>Fertility Decision Support Resources</th>
<th>Year Created</th>
<th>Format</th>
<th>Language</th>
<th>Included Fertility Options</th>
<th>Included Sections</th>
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<td>− Ovarian suppression</td>
<td>− Timing</td>
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<td></td>
<td></td>
<td>− Embryo banking</td>
<td>− Average delay to start of treatment</td>
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<td></td>
<td></td>
<td></td>
<td>− Egg banking</td>
<td>− Success rates</td>
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<td></td>
<td></td>
<td>Physician Version:</td>
<td>− Average cost and location of services</td>
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<td>− Ovarian suppression</td>
<td>− Special considerations</td>
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<td></td>
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<td>− Embryo banking</td>
<td>− The grid does not contain any graphics or colours</td>
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<td>− Egg banking</td>
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<td>− Ovarian tissue banking</td>
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<td>− In vitro maturation</td>
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<td>− Ovarian tissue cryopreservation</td>
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<td>− Adoption</td>
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<td>− Surrogacy</td>
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<td></td>
<td></td>
<td>− Egg or embryo donation</td>
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<tr>
<td>4. MyOncofertility Website</td>
<td>2011</td>
<td>Online educational website for male and female cancer patients, partners, and parents in the United States (<a href="http://www.myoncofertility.org">www.myoncofertility.org</a>)</td>
<td>English and Spanish</td>
<td>Options for Women:</td>
<td>Background information based on stage of cancer journey</td>
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<td></td>
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<td>− Embryo freezing</td>
<td>Fertility preservation options</td>
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<td></td>
<td>− Egg freezing</td>
<td>(information on each option, option grid summarizing options, medical status,</td>
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<td></td>
<td>− Ovarian shielding</td>
<td>definition, pubertal status, timing, success rates, cost, time requirements,</td>
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<td></td>
<td></td>
<td>− Ovarian suppression</td>
<td>other considerations) and questions to ask about each option. Information</td>
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<td></td>
<td>− Ovarian tissue cryopreservation</td>
<td>presented as text, animations, and videos.</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>− Adoption</td>
<td>− Survivor experiences (videos of patient stories), expert videos, speaker bios</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>− Surrogacy</td>
<td>− List of web information resources/ helpful organizations</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>− Egg or embryo donation</td>
<td>− List of printable resources and list of tools</td>
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</tbody>
</table>

(Continue on following page)
Table 3.1 Fertility decision support resources evaluated (Continued)

<table>
<thead>
<tr>
<th>Fertility Decision Support Resources</th>
<th>Year Created</th>
<th>Format</th>
<th>Language</th>
<th>Included Fertility Options</th>
<th>Included Sections</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. LIVESTRONG Family-Building Option Tool¹⁴⁹</td>
<td>Not listed</td>
<td>Personalized online tool for male and female cancer patients in the United States (<a href="https://www.teamlivestrong.org/we-can-help/fertility-services/options/">https://www.teamlivestrong.org/we-can-help/fertility-services/options/</a>)</td>
<td>English</td>
<td>Options for Women:  - Embryo freezing  - Egg freezing  - Ovarian tissue freezing  - Ovarian transposition  - Ovarian suppression  - Adoption  - Surrogacy  - Egg or embryo donation  - Using frozen eggs/embryos after treatment</td>
<td>Fertility preservation options for men and women (age, cost, timing, success rates, medical status, other considerations)  - Support telephone number  - Navigation to LIVESTRONG Cancer Navigation Services</td>
</tr>
<tr>
<td>6. LIVESTRONG Brochure¹⁴⁹</td>
<td>2013</td>
<td>Paper booklet and online PDF created for male and female cancer patients in the United States (<a href="http://images.livestrong.org/pdfs/livestrong-fertility/LIVESTRONG-Fertility-Brochure.pdf">http://images.livestrong.org/pdfs/livestrong-fertility/LIVESTRONG-Fertility-Brochure.pdf</a>)</td>
<td>English</td>
<td>Options for Women:  - Embryo freezing  - Egg freezing  - Ovarian shielding  - Ovarian transposition  - Fertility-sparing surgery  - Ovarian tissue freezing  - Ovarian suppression  - Adoption  - Surrogacy  - Donor eggs or embryos</td>
<td>Brief background information for men and women  - Fertility preservation options for men and women (information on each option, parenthood options after cancer, information tips)  - Information on financial assistance from LIVESTRONG  - List of LIVESTRONG resources  - List of questions for health care providers</td>
</tr>
</tbody>
</table>
Based on the findings from previous needs assessment interviews (described in Chapter 1), six interview guides were developed, which identified factors that impact fertility decisions. The guides were designed to gather more specific information pertaining to participants’ fertility informational needs. Each of the six interview guides were slightly modified to account for the differences in each decision support resource being evaluated. For example, the Australian and Dutch decision aids were the only resources to include a value clarification method. Therefore, questions were included in these guides to inquire about the usefulness of the values clarification methods (Appendix G, interview guide for the Australian decision aid). The guides contained a mix of open-ended questions and structured closed-ended questions (Likert scale and multiple choice). The closed-ended questions were used to determine on a 5-point Likert scale the usefulness of each section in the decision support resources, as well as the level of agreement on the design and usability of the resources. Questions also asked about the best format for delivery (e.g., online, paper or video) and completion of decision aids (e.g., patients complete them with a medical oncologist, social worker, or alone) (Appendix G). Qualitative questions were used to help participants expand on and explain their responses to the closed-ended questions. At the beginning of each interview the participants were asked to draw from their personal experiences and think aloud/expand on the responses they selected to the Likert scale and multiple choice questions. Data were collected until four participants (two health care providers and two breast cancer survivors) had evaluated each of the six decision support resources. There were a total of 16 participants, as some participants evaluated more than one decision support resource in the evaluation. This sample size was judged to be sufficient to gain insight on common fertility informational needs, recognizing that irrespective of sample size the amount of information needed to make an informed decision will vary slightly for each person.107,150

The interview guides were piloted with four participants (two breast cancer survivors and two health care providers). The participants were asked five questions at the end of the interview on the format of the interview, their understanding of the interview questions, and the need to add or delete questions for subsequent interviews (Appendix G). As the interviews progressed, meetings with a qualitative expert, Dr. Marcia Facey, were completed to discuss the interviews and clarify any questions based on participant responses. The interview guide was reviewed and revised iteratively throughout the evaluations to clarify questions and allow for participants to expand and provide more detailed responses to the questions.
3.1.5 Data analysis

Interviews were audio-recorded and transcribed verbatim. The first two interviews were transcribed by the interviewer to become familiar with the data. The interviews were then transcribed by a professional transcriptionist. The transcribed interviews were audited to ensure all the transcripts accurately reflected what participants said in the interviews.

All Likert scale and multiple choice questions were coded numerically and inputted into Microsoft Excel software. Descriptive statistics in the form of frequencies for the closed-ended questions were calculated in Microsoft Excel to examine the evaluation results for each of the decision support resources. Qualitative data that expanded on the descriptive statistics were coded deductively. A coding guide that reflected the questions and sections in each decision support resource was developed through an iterative process with a qualitative expert (Dr. Marcia Facey). Transcripts were independently coded and analyzed by two individuals (Brittany Speller and Amanda Sissons) who regularly discussed the findings in-person and through email. Interviews were then inputted and organized using NVivo 11.2.2. For the qualitative analysis, repetition in the data corresponding to the sections and information in the existing decision support resources was used to identify themes. The analyzed syntheses of the evaluations were presented to some of the interviewees and additional individuals with similar experiences as those interviewed to validate the findings and ensure there were no major disagreements (described in Chapter 4).

3.1.6 Methodology rigour

Decision-making theory

The Fuzzy-Trace Theory (FTT) was used to enhance the interpretation of the data. The FTT is a dual-process theory and discusses the use of memory as gist or verbatim processes. Gist and verbatim processes are defined by Reyna:

\[
\text{\ldots much as they are in everyday parlance, except that verbatim applies to more than verbal information but also to graphs, numbers, pictures, and any other form of information. Thus, a gist representation is vague and qualitative; it captures the bottom-line meaning of information, and it is a subjective interpretation of information based on emotion, education, culture, experience, worldview, and level of development. A verbatim representation, in contrast, is precise and quantitative, and it captures the exact surface form of information (i.e., it is literal).}
\]
In healthcare, the theory claims that many patients rely on gist processing to make informed decisions. The FTT sets out that framing of information is important and information should be presented in a meaningful way that facilitates the gist processing among patients. The FTT has been used to develop educational materials, which have enhanced patient knowledge and their ability to make informed treatment decisions. The FTT was therefore selected to help understand the presentation of information in the existing decision support resources evaluated, and to determine how participants discussed their preferred presentation of fertility information for informed decision-making.

**Reflexivity**

Since this evaluation utilized qualitative findings to inform development of the BEFORE decision aid, it is critical to engage in researcher self-reflection. For qualitative description, the process of reflecting on existing professional roles and predetermined expectations are important to ensure methodological rigor is maintained throughout the research process. I have no previous clinical experience, involvement in the care, or previous relationship with any participant interviewed. My interest in patient education and informed decision-making stems from my experiences as a caregiver for family members interacting with the healthcare system and from previous research experience focusing on breast cancer. Breast cancer and the decision-making process for patients are widely explored fields in research but fertility among young cancer patients in Canada and their decision-making still contains research-practice gaps, as information and referrals to fertility specialists are not consistently provided. The opportunity to create a decision aid that patients can use to assist with fertility decision-making with the aim to increase their quality of life in survivorship was a chance to fill that gap.

Detailed notes and memos were taken during the interviews, directly following the interviews, and throughout the data analysis process. I aimed to ensure the results were representative of the interview data and not a reflection of my personal biases towards the type of information that I believed should be chosen for inclusion in the BEFORE decision aid. To achieve this, the data on information deemed valuable to include in the BEFORE decision aid was discussed with the second interview coder, my supervisor and committee, and research team. An audit trail was also kept ensuring the information and decisions made throughout the evaluations were documented. The audit trail consisted of memos as well as the rationale for decisions on the methods, coding process and revisions to the coding guide, analysis, and use of evaluation findings.
Ethical considerations

Ethics approval to recruit participants and to carry out the evaluation was obtained from St. Michael’s Hospital (REB 15-220), Sunnybrook Health Sciences Centre (REB 226-2015), and the University of Toronto (Protocol # 32801) (Appendix H).

At the beginning of each interview, the interviewer would describe the study, the interviewers’ role, and the consent and privacy information in the information letter (Appendix B) before obtaining verbal consent to proceed and record the interview. Basic demographic information from survivor participants including age, year at diagnosis, and time since treatment; and age, years in practice, and specialty type for health care provider participants was kept in a Master Linking Log with participant research numbers and no personal identifying information. Interview audio files were kept on a secure server at St. Michael's Hospital for one year before deleting. Transcribed interviews were password protected with all identifying information removed.

3.2 Results

Eight health care provider participants were invited and all consented to participate in the study (100%). The health care provider participants ranged in profession, location, hospital setting, and time working in their position. Most participants worked at an academic institution (Table 3.2).

Table 3.2 Health care provider participant characteristics

<table>
<thead>
<tr>
<th>Health Care Provider Participants</th>
<th>Number (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Health Care Provider</strong></td>
<td></td>
</tr>
<tr>
<td>Reproductive Endocrinology and Fertility Specialist</td>
<td>2 (25.0%)</td>
</tr>
<tr>
<td>General Surgeon (Specializing in Breast Cancer)</td>
<td>2 (25.0%)</td>
</tr>
<tr>
<td>Medical Oncologist</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td>Registered Nurse</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td>Social Worker</td>
<td>2 (25.0%)</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td></td>
</tr>
<tr>
<td>Greater Toronto Area, Ontario</td>
<td>5 (62.5%)</td>
</tr>
<tr>
<td>Vancouver, British Columbia</td>
<td>2 (25.0%)</td>
</tr>
<tr>
<td>Winnipeg, Manitoba</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td><strong>Hospital Setting</strong></td>
<td></td>
</tr>
<tr>
<td>Community</td>
<td>2 (25.0%)</td>
</tr>
<tr>
<td>Academic</td>
<td>6 (75.0%)</td>
</tr>
<tr>
<td><strong>Time Working in Field</strong></td>
<td></td>
</tr>
<tr>
<td>Range of Years</td>
<td>4 to 30</td>
</tr>
</tbody>
</table>

Among the 17 survivor participants invited to participate in the evaluation, interviews occurred with nine participants (52.9%) (five recruited from breast clinics, three recruited online, and one recruited through mail). Of the eight who refused the study, only one provided a rationale, indicating that she did not want to participate because she felt unwell and was not fluent in English. The recruitment of young women to participate in interviews is challenging due to the many simultaneous demands they
are facing. One participant was deemed to be ineligible to participate during the interview as she had previously completed fertility preservation to have her current child. While the interview was completed, her results were not analyzed in combination with the remaining eight participants as her experience and knowledge of fertility preservation varied compared to the other participants. Most of the survivor participants were married or in a long-term relationship at diagnosis, did not have children, and all completed post-secondary education. The survivor participants ranged in self-identified ethnicity and race as well as location and age (Table 3.3).

### Table 3.3 Breast cancer survivor participant characteristics

<table>
<thead>
<tr>
<th>Breast Cancer Survivor Participants</th>
<th>Number (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Children Prior to Diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3 (37.5%)</td>
</tr>
<tr>
<td>No</td>
<td>5 (62.5%)</td>
</tr>
<tr>
<td><strong>Relationship Status at Diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>Married/Common Law</td>
<td>5 (62.5%)</td>
</tr>
<tr>
<td>Long-Term Relationships</td>
<td>2 (25.0%)</td>
</tr>
<tr>
<td>Single</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td><strong>Self-Identified Ethnicity/ Race</strong></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>4 (50.0%)</td>
</tr>
<tr>
<td>African American</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td>Filipino</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td>Chinese and Portuguese</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td>East Indian</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>Post-Secondary</td>
<td>4 (50.0%)</td>
</tr>
<tr>
<td>Completed/Enrolled in Graduate Studies</td>
<td>4 (50.0%)</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td></td>
</tr>
<tr>
<td>Greater Toronto Area, Ontario</td>
<td>6 (75.0%)</td>
</tr>
<tr>
<td>Windsor, Ontario</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td>Gatineau, Québec</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td><strong>Age at Diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>Age Range</td>
<td>21 to 35</td>
</tr>
<tr>
<td><strong>Time Since Diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>Year Range</td>
<td>1 to 4</td>
</tr>
</tbody>
</table>

Most participants evaluated two decision support resources (one decision aid and one decision support resource) and each decision support resource was fully evaluated (all questions answered) or received a general overview (some questions answered and additional feedback outside of the set questions) by at least two health care provider participants and two survivor participants (Table 3.4).

### Table 3.4 Participants evaluating each decision support resource

<table>
<thead>
<tr>
<th>Decision Support Resources</th>
<th>Health Care Provider Participants (n)</th>
<th>Survivor Participants (n)</th>
<th>Total (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Australian Decision Aid</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>2. Dutch Decision Aid</td>
<td>3</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>3. MyOncofertility</td>
<td>1 full and 1 general</td>
<td>2</td>
<td>3 full and 1 general</td>
</tr>
<tr>
<td>4. LIVESTRONG Option Tool</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>5. LIVESTRONG Brochure</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>6. Sunnybrook Option Grid</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>
3.2.1 Descriptive statistics review of fertility decision support resources

Table 3.5 displays results of the closed-ended questions that assessed the usefulness of the sections within each of the six fertility decision support resources. Overall, most participants rated the Australian decision aid, Dutch decision aid, MyOncofertility, and LIVESTRONG brochure as useful. Additionally, most participants felt it was useful to include information on the fertility options before and after treatment, financial assistance and cost of the fertility options, question list for health care providers, links to additional resources, and a glossary. There were also sections participants had varying opinions on including the usefulness of the background information, personal stories in the Australian decision aid, values clarification method in the Australian and Dutch decision aids, presentation of ongoing research in MyOncofertility, and the use of animations/graphics/videos in the Dutch decision aid, MyOncofertility, and LIVESTRONG brochure. Finally, all participants felt the option grid included in MyOncofertility was not useful.

Table 3.6 displays results of the closed-ended questions that assessed the level of agreement on the information, design, and usability of the six fertility decision support resources. Most participants rated the Australian and Dutch decision aids as too long, the LIVESTRONG family-building option tool as too short, and the remaining decision support resources as just the right length. Most participants felt the information in all the decision support resources, with the exception of the Dutch decision aid, was easy to read and that the resources would be easy to use. Additionally, most participants rated that the information in the six decision support resources flowed in a logical order. Participants had mixed opinions on the balance of fertility information in the Dutch decision aid and LIVESTRONG family-building option tool but rated the information as balanced in the remaining four decision support resources. Participants had varying opinions on the need for patient and health care provider training prior to use of the decision support resources. Most participants disagreed that training would be needed for patients but had mixed opinions on whether training would be needed for health care providers. Participants also had varying opinions on whether the decision support resources contained enough information to make an informed fertility decision. Finally, most participants agreed that the decision support resources, with the exception of the LIVESTRONG family-building option tool, would have been useful if it were used when making a fertility decision or when supporting a patient making a fertility decision.

The results for both survivor participants and health care provider participants are reported together in Table 3.5 and 3.6.
Table 3.5 Descriptive statistics on the usefulness of each fertility decision support resource

<table>
<thead>
<tr>
<th>Decision Support Resource Sections</th>
<th>Australian Decision Aid (n=5)</th>
<th>Dutch Decision Aid (n=7)</th>
<th>MyOncofertility (n=3)</th>
<th>LIVESTRONG Family-Building Option Tool (n=4)</th>
<th>LIVESTRONG Brochure (n=4)</th>
<th>Sunnybrook Option Grid (n=4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Usefulness</td>
<td>5/5 rated useful</td>
<td>5/6 rated useful*</td>
<td>3/3 rated useful</td>
<td>1/3 rated useful*</td>
<td>4/4 rated useful</td>
<td>3/4 rated useful</td>
</tr>
<tr>
<td>Summary of Fertility Options in a Grid</td>
<td>5/5 rated useful</td>
<td>–</td>
<td>3/3 rated not useful</td>
<td>2/4 rated useful</td>
<td>–</td>
<td>3/3 rated useful*</td>
</tr>
<tr>
<td>Background Information–Fertility/Cancer</td>
<td>4/5 rated useful</td>
<td>5/7 rated useful</td>
<td>3/3 rated useful</td>
<td>–</td>
<td>3/4 rated useful</td>
<td>–</td>
</tr>
<tr>
<td>Fertility Options (before treatment)</td>
<td>5/5 rated useful</td>
<td>7/7 rated useful</td>
<td>3/3 rated useful</td>
<td>2/4 rated useful</td>
<td>4/4 rated useful</td>
<td>3/3 rated useful*</td>
</tr>
<tr>
<td>Fertility Options (after treatment)</td>
<td>5/5 rated useful</td>
<td>6/7 rated useful</td>
<td>3/3 rated useful</td>
<td>–</td>
<td>4/4 rated useful</td>
<td>–</td>
</tr>
<tr>
<td>Financial Assistance (costs)</td>
<td>5/5 rated useful</td>
<td>–</td>
<td>–</td>
<td>4/4 rated useful</td>
<td>4/4 rated useful</td>
<td>4/4 rated useful</td>
</tr>
<tr>
<td>Personal Stories</td>
<td>3/5 rated useful</td>
<td>–</td>
<td>3/3 rated useful</td>
<td>–</td>
<td>4/4 rated useful</td>
<td>–</td>
</tr>
<tr>
<td>Values Clarification Methods</td>
<td>2/5 rated useful</td>
<td>5/6 rated useful*</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Health Care Provider–Directed List of Questions</td>
<td>5/5 rated useful</td>
<td>7/7 rated useful</td>
<td>3/3 rated useful</td>
<td>–</td>
<td>4/4 rated useful</td>
<td>–</td>
</tr>
<tr>
<td>Links to Resources</td>
<td>5/5 rated useful</td>
<td>–</td>
<td>3/3 rated useful</td>
<td>–</td>
<td>4/4 rated useful</td>
<td>–</td>
</tr>
<tr>
<td>Glossary</td>
<td>5/5 rated useful</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Ongoing Fertility Research</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>1/2 rated useful*</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Animations/Videos/Graphics</td>
<td>4/5 rated useful*</td>
<td>5/7 rated useful</td>
<td>1/2 rated useful*</td>
<td>–</td>
<td>2/4 rated useful</td>
<td>–</td>
</tr>
</tbody>
</table>

*One participant was not sure how useful this section of the decision support resource would be for fertility decision-making or chose not to answer the question

Legend

- All participants thought this section was useful
- Mixed opinions between participants on whether this section was useful
- All participants thought this section was not useful
- Section was not included in this decision support resource
Table 3.6 Descriptive statistics on the design and level of agreement on the information and usability of each fertility decision support resource

<table>
<thead>
<tr>
<th>Design and Usability</th>
<th>Australian Decision Aid (n=5)</th>
<th>Dutch Decision Aid (n=7)</th>
<th>MyOncofertility (n=3)</th>
<th>LIVESTRONG Family-Building Option Tool (n=4)</th>
<th>LIVESTRONG Brochure (n=4)</th>
<th>Sunnybrook Option Grid (n=4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length</td>
<td>4/5 rated long</td>
<td>6/7 rated long</td>
<td>2/3 rated just right</td>
<td>4/4 rated short</td>
<td>3/4 rated just right</td>
<td>3/4 rated just right</td>
</tr>
<tr>
<td>The information easy to read</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4/5 agree</td>
<td>5/7 agree</td>
<td>2/3 agree</td>
<td>4/4 agree</td>
<td>4/4 agree</td>
<td>4/4 agree</td>
</tr>
<tr>
<td>The information flows in a logical order</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5/5 agree</td>
<td>6/7 agree</td>
<td>3/3 agree</td>
<td>3/4 agree*</td>
<td>4/4 agree</td>
<td>4/4 agree</td>
</tr>
<tr>
<td>The presentation of the fertility options is balanced</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4/5 agree*</td>
<td>5/7 agree*</td>
<td>3/3 agree</td>
<td>2/4 disagree</td>
<td>3/4 agree</td>
<td>4/4 agree</td>
</tr>
<tr>
<td>There is enough information to decide on a fertility option</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3/5 agree*</td>
<td>4/7 agree*</td>
<td>2/3 agree</td>
<td>3/4 disagree*</td>
<td>3/4 disagree</td>
<td>2/4 disagree*</td>
</tr>
<tr>
<td>The resource is easy to use</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4/5 agree</td>
<td>5/7 agree</td>
<td>3/3 agree</td>
<td>4/4 agree</td>
<td>4/4 agree</td>
<td>4/4 agree</td>
</tr>
<tr>
<td>Training is needed for patients before using this resource</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training is needed for health care providers before using this resource</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3/4 agree</td>
<td>4/7 disagree</td>
<td>3/3 disagree</td>
<td>2/4 disagree*</td>
<td>2/4 disagree</td>
<td>2/3 disagree*</td>
</tr>
<tr>
<td>This resource would have been useful if it was used</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4/5 agree</td>
<td>6/7 agree</td>
<td>2/3 agree</td>
<td>2/4 disagree</td>
<td>4/4 agree</td>
<td>4/4 agree</td>
</tr>
</tbody>
</table>

*One additional participant was not sure how useful this section of the decision support resource would be for fertility decision-making, did not answer the question, or rated it as “neither agree nor disagree” in the Likert scale

Legend

Most participants agreed with this statement
Mixed opinions between participants on whether they agreed with this statement
Most participants disagreed with this statement
Timing and delivery the BEFORE decision aid in clinical practice

Most participants (9 of 16, 56.3%) felt that the decision aid should be provided to patients when they are discussing their treatment plan and before treatment began, 6 of 16 participants (37.5%) thought a decision aid should be provided as soon as patients learn about their diagnosis, and one participant (6.25%) was not sure of the best time to provide patients with a decision aid. There were diverse opinions between participants on how patients should receive the decision aid; 3 of 16 (18.75%) thought patients should receive it at an appointment with the surgeon, 4 of 16 people (25.0%) thought they should receive it at an appointment with the oncologist, 5 of 16 people (31.25%) thought they should receive it from another provider (e.g., nurse or social worker), 2 of 16 people (12.5%) thought multiple health care providers could deliver the decision aid, and 2 of 16 people (12.5%) were not sure how patients should receive the decision aid. Most participants (8 of 16, 50.0%) thought patients should read and complete the decision aid by themselves, 4 of 16 (25.0%) thought patients should read and complete the decision aid with another provider (e.g., nurse or social worker), 2 of 16 (12.5%) thought patients could read and complete the decision aid with a fertility specialist, one participant (6.25%) thought patients could read and complete the decision aid with an oncologist, and one participant (6.25%) was not sure of the best way for patients to read and complete the decision aid. Finally, most participants felt that the decision aid should be created in a paper and/or online format (14 of 16, 87.5%), and two participants (12.5%) were not sure of the best format for the decision aid.

3.2.2 Qualitative review of fertility decision support resources

The qualitative analysis aimed to expand on the descriptive statistics and explore more general perspectives of decision aids and informed decision-making. Four themes were discerned from the data collected from participants, guided by the pre-determined sections in the interview guide: (1) delivery and use of fertility information in clinical practice; (2) fertility information needed for informed decision-making; (3) factors influencing fertility preservation decisions; and (4) use and delivery of decision aids in clinical practice. The perspectives from survivor participants and health care provider participants are presented together and compared.

(1) Delivery and use of fertility information in clinical practice

Most health care provider participants relied solely on verbal discussions in clinic and referrals to fertility specialists as ways to inform patients about fertility. The rationale behind not providing fertility resources was the feeling among provider participants that it was not their role and that
current resources contained misleading information and were unable to convey important information to patients such as the emotional aspects of care. One provider participant also described how patients may not be ‘making their own decisions’ on the fertility options but opting in or out of the options that are presented to them based on their clinical situations (e.g., ovarian reserve).

“\textit{I don’t think we have a strict policy on [providing fertility resources], I think some people have their own resources and sometimes we have a printed thing, sometimes we send them the LIVESTRONG link but for me personally probably not.” (HCP, 03)

“\dots I do find it a little bit misleading some of the information that can be provided on resources... potentially having a baby in the future versus being alive is often a dilemma that our patients face... I don’t think that you can convey that kind of information very well in an online tool... there’s something about conveying that information in kind of a verbal way that I think is needed.” (HCP, 06)

“We do fertility options but options really are individualized in fertility, you can’t as a patient walk in and choose yourself between 5 things... your options are presented to you based on your clinic situation. I mean you can opt in or out but yeah, they are not necessarily making their own decisions.” (HCP, 02)

Health care provider participants who provided fertility resources referred patients to online resources such as the Power of Hope Program through Fertile Future (www.fertilefuture.ca) because it is a program that provides financial support for fertility preservation, Health Canada brochures, Cancer Knowledge Network (cancerkn.com) because it provides general information for all cancer patients and specific fertility clinics in Canada that accept oncology referrals, and the LIVESTRONG Foundation (www.livestrong.org) that has fertility information and resources (two of which were evaluated as described in Table 3.1). One participant was part of a hospital with a dedicated program for young breast cancer patients and had a program-specific fertility information package for patients at their centre.

Most breast cancer survivor participants did not use any fertility decision support resources to assist them when making their fertility decisions. The main form of information provided to participants was through verbal discussions in clinic and referrals to fertility specialists. However, some survivor participants felt that not enough information was provided and one participant even noted how her fertility decision may have changed if she had been provided more information. The discussions and support by the oncology care team was a key factor that helped or hindered fertility preservation discussions and decision-making.
“I would say more of a counselling session. I only now understand I guess the nitty gritty of it even when I saw her I guess, I feel that they don’t want to give you as much information as maybe you would like, I know that they had suggested to me that they thought it would be overwhelming to give too much information and I feel for my personality it was the opposite. I didn’t have enough information. I might not have made the same decision actually....” (Survivor, 02)

“I must admit that my medical oncologist and the nurse that worked with her were very supportive and spent a long time with me answering all of my questions about [fertility]. So, that coupled with some of the text kind of did help.” (Survivor, 01)

Among survivor participants who received information, perspectives varied on the value of the information. Information was described as ‘piece meal’ or ‘dumped on my lap’. While some participants thought that young women would be too overwhelmed with the information, in general, survivor participants noted that if fertility was important to them they would make a point of reading any information provided. Additionally, all survivor participants discussed searching for further information online and in some instances having to use that information and act as their own advocates to bring up and start fertility discussions with their oncology health care providers. There were varying perspectives on the quality of online information as some felt it was too vague and hard to put together and others found it valuable.

“[The information] was very piece meal and it was a lot, and it was kind of just dumped on my lap…and it was a lot of text....” (Survivor, 01)

“No fertility resources were provided] because I was diagnosed so quickly and they wanted to start chemo within 4 days um, you didn’t really have a chance to process everything, you are more or less processing the diagnosis and not thinking about the other stuff so you really just have, it’s just a little bit too overwhelming to consider when you have been diagnosed.” (Survivor, 07)

“So basically it’s some information I found on the internet that I learned about the chemotherapy and the fertility issues so I had to bring it up myself to the oncologist.” (Survivor, 03)

(2) Fertility information needed for informed decision-making

All participants felt that the fertility information included in decision support resources should avoid heavy text and be written in lay language as well as be inclusive of all family types and gender identities. Background information in the decision support resources varied in content and depth of detail. The Australian and Dutch decision aids also included general information about breast cancer. Most participants felt the inclusion of information on breast cancer in the population resulted in too much information that was text heavy and overwhelming. Additionally, it was noted that most of the
information on general breast cancer was already provided to patients during other parts of their care resulting in repetitive information.

“... the best way is to include only the essential information in [a] booklet so any more information put in references... simple, as simple as possible.” (HCP, 08)

“...I just found that it was a little bit too lengthy, like right now I am finished treatment so I would sit down, I actually read everything but if I got this when I was newly diagnosed it would just be too overwhelming, it’s just too much information.” (Survivor, 04)

Straightforward information on the impact of cancer treatment on fertility, age-related and treatment-related declines in fertility, menopause, pregnancy rates after treatment, and health of children born to cancer survivors and to those born after using fertility preservation were viewed as useful to include as a way to ensure patients have realistic expectations. However, there were varying opinions between health care provider participants and survivor participants on some fertility information required for decision-making. Survivor participants valued additional information on menstrual cycles, genetic testing, breastfeeding, and contraception. In contrast, health care provider participants felt that this information was not essential for fertility decision-making before treatment and that it did not address the main issue of fertility. Additionally, health care provider participants thought that information on hereditary breast cancer may not be practically relevant because genetic testing cannot be done in the short period a patient has from diagnosis to treatment. However, one survivor participant who had genetic testing completed thought hereditary testing information was very relevant and valuable to include in a decision aid. Similarly, opinions about the incorporation of information on pregnancy prior to a breast cancer diagnosis were mixed – one health care provider participant felt it was not relevant but a survivor participant who was pregnant at the time of diagnosis felt this information was valuable to include.

“... It’s very clear, there’s you know, no misunderstanding what’s being said here. Maybe if it’s more basic it’s more of I think like an older school presentation like not as much as the glitz and the glam but very straight forward the information...” (Survivor, 02)

“I found it really useful, I like the part where they said not all treatments could affect your ability to have kids and also if your period returns it doesn’t necessarily mean that your ovaries are as effective, because I think that sometimes is a misconception. So, I think it’s pretty good.” (Survivor, 06)

“My feeling is that patients should have as little information as they absolutely need, they are completely overwhelmed with information so, I don’t actually think they need to know how chemotherapy destroys the ovaries, I think they believe us if we say it does, so I think it’s a bit more information than they need...” (HCP, 03)
Mixed opinions were also seen among participants on the inclusion of generalized or personalized information. Most participants found the information on cancer treatment and associated fertility risks useful due to the simple and clear lay out in the resources. The LIVESTRONG family-building option tool contained a tailored first page where patients could select their gender, if they had reached puberty, what phase of their treatment they were in, and general treatment they would be receiving. While survivor participants valued the straightforward layout of the tailored information, health care provider participants expressed concerns that it lacked the ability to tailor the information based on the stage/severity of a cancer diagnosis and type of chemotherapy. Therefore, health care provider participants felt the tailored page may result in misleading fertility options being presented to patients.

“I think that there’s, I don’t think there’s enough information here, I think this is very generic. I think that…if you are really personalizing it looking at you know what type of cancer do you have and what is the stage of your cancer. I think the other misleading thing here is that it doesn’t talk about whether or not this person has a curable cancer or an incurable cancer…so I think it’s a bit too generic.” (HCP 06)

“I like it because it’s not like overwhelming, and then if you want more information like you can just click on the dashboard and then drop-down menus come out which is good, as opposed to having it all there. I like that.” (Survivor, 01)

The fertility options presented in each of the fertility decision support resources varied as some include all established options (e.g., embryo and egg freezing), experimental options (e.g., ovarian suppression, in vitro maturation, ovarian tissue banking), and after treatment options (e.g., adoption, surrogacy, donor eggs and embryos) and others only include established options or excluded after treatment options. Mixed opinions were expressed by participants on whether experimental options should be listed. Some health care provider participants felt these options may not be available to all patients across Canada and thus should not be presented. Survivor participants however preferred to know all their fertility options. The order of the listed fertility options was also discussed and it was felt that experimental fertility options should not be listed before established fertility options. There was agreement among participants that fewer fertility options may be a better starting point with an additional website or pamphlet for patients to access more fertility options if they desired.

“...I didn’t have access to this kind of information so, I wish I did. I don’t think I really understood what [the options] meant before I just thought I want to have another baby this will allow me to do that and I didn’t know any of this other information. I would like...to know what all my options are and then make an educated decision, my only option in my mind was to you know, freeze embryos not even just eggs and that was it...” (Survivor, 02)
“I think it’s important for them to know the options, but I would not talk to a patient who is about to undergo chemotherapy for breast cancer on how we go about egg donation right...”  
(HCP, 03)

Parenthood options after cancer treatment (e.g., adoption, surrogacy, donor eggs and embryos) were presented in all decision support resources expect for the Sunnybrook option grids. Most participants thought the information on parenthood options after treatment was useful. Survivor participants felt that information on all the parenthood options after cancer treatment should be provided so patients have realistic expectations and are aware upfront about the options available (even if some options, such as adoption, are perceived by some as less favourable to having genetically related children). However, some health care provider participants did not think presenting after treatment options were as useful because they felt that patients knew they could adopt or foster after treatment.

“It was great that it included like fostering and adoption too...adoption was always like something like oh, and you could adopt but it was never like discussed really and it’s certainly one of those things you don’t know anything about until you have done it...and I actually think that that’s very important to mention from the beginning because many women don’t have the option of [in vitro fertilization] because they were in a rush to do their chemotherapy or something...there wasn’t enough information for me I like to know all my options...”  
(Survivor, 02)

“...Even though [adoption] like, it’s really you don’t want to look at that option...but I think it’s good that it’s included because it just gives you like even if it’s something that you choose not to at least you kind of, you are aware of it...”  
(Survivor, 04)

“... I think people hopefully know that they can adopt or foster children, or just not have children so, it’s not necessarily bad to have it in there but I think it’s maybe less useful.  
(HCP, 07)

“... so, they still have options to build a family in the future using alternative methods such as adoption or egg donation, embryo donation but it’s confusing. Because when I look at adoption like why do I have to make an adoption decision right now? I mean I am looking at it from a cancer patient who really know[s] nothing about the whole area...they are so overwhelmed that I think the best way is to avoid information overload. So, anything that is not necessary for patients you know, at this moment is better to take it out.”  
(HCP, 08)

Based on previous experiences, survivor participants also highlighted the importance of including realistic cost ranges to ensure patients are not shocked and disappointed about the final cost of fertility preservation. All participants thought the information on resources (financial and supportive) was useful to incorporate in a decision aid. It was also recommended that cost information for each province be made available due to the variance across Canada.
“...it would have been nice to have like more specifics in terms of the cost because like again, if you are looking at service fee, if you are looking at adoption it’s like you need to know instead of just saying like on that summary page where it just says ‘costly’ I think you need a little bit more direction because that’s very subjective...” (Survivor, 04)

“...the estimate they gave us was like 2 to 4000 dollars just on the meds and my meds were like 7000 and coming from someone who didn’t have trouble getting pregnant I thought it would be cheap...and I was shocked with what the total was, and they didn’t actually go through this is what it costs...” (Survivor, 02)

“... I think it’s important to have this piece because there is a practical element around finances and making sure that finances aren’t a barrier for women and what their options are around that.” (HCP, 05)

Additionally, a focus on information pertaining to the success rates and risks of the fertility options using the same denominator, timing and availability of fertility preservation, and the impact of fertility preservation on cancer treatment, steps of fertility preservation procedures, and legal and ethical consideration were viewed as important for informed fertility decision-making.

While some mixed views were encountered on the information needed for informed fertility decision-making, there was consensus that the information included should be accurate. Health care provider participants noted how some decision support resources contained inaccurate information and lack of transparency on the sources of the evidence. As such, the health care provider participants stated that they were suspicious of the developers and would not promote these types of resources to their patients.

“...I am shocked and offended by the oocyte frequent success rate statistics of 36 to 61% clinical pregnancy rate. You know our gynaecologists and obstetricians quote a 1% pregnancy with oocyte freezing alone... so now I am suspicious of where they have gotten all this information from and there’s no references here... it makes me wonder if it’s coming from a clinic that might have funded the tool.” (HCP, 06)

The format of an option grid to present fertility information was used by in the Australian decision aid, MyOncofertility, Sunnybrook option grids, and LIVESTRONG family-building option tool. This method of presentation was seen as useful by participants as a concise summary of the information. However, some participants felt that the grids did not provide enough information as stand-alone documents. When the option grid included many options participants felt the abundance of information caused them to feel overwhelmed and they perceived the grid as too complicated to comprehend. There was recognition that certain information, such as support systems and emotional aspects of fertility decision-making cannot be included in a grid.
“... I think it’s just more summary for patients after they’ve had a consultation or read something [longer]...” (HCP, 01)

“... I definitely think [the Option Grids are] a good starting point though but, you know, there’s things that you are never going to build into a grid like...your partner or your support system, support, any kind of like emotional aspects that you are not really going to capture I don’t think, not that, nor should you but this is just sort of one piece of the puzzle.” (HCP, 07)

“... I think the grid at first is great as a starting point and then if you do want more information something like a larger grid maybe or a website or a pamphlet regarding any additional options that are available with more detailed information.” (Survivor, 08)

A values clarification method was included in the Australian and Dutch decision aids. The perceived usefulness of a values clarification method was mixed among participants. Health care provider participants felt that the prelisted values in the exercises were too long and may unintentionally cause patients to become overwhelmed. However, some health care provider participants did recognize that the exercise may provide a way to help patients formalize their thought processes to make fertility decisions.

“I don’t love this...I just think it’s kind of confusing...especially early on in treatment women with breast cancer get so much information that this might be a little overwhelming. Being a long list of pros and cons.” (HCP, 05)

“... I do think it’s help[ing] them I guess in a more calm way kind of formalize their thought process right, when their life is sort of a little bit coming undone...” (HCP, 01)

Survivor participants thought the exercises were beneficial to use as a starting point and additional information could stem from them. Some survivor participants felt it would be good to get information down on paper and others highlighted that the use of the exercise was dependent on the decision-making process for each patient. Another survivor participant thought the values clarification method was a systematic way to break down and help solidify decisions. However, one survivor participant felt that the decision was too emotional and this format may be overwhelming.

“...It’s probably good to get things down on paper...it can kind of shape the discussion so, even like if other things stem from it at least it’s like a big, a starting point.” (Survivor, 01)

“I just didn’t find that this whole breakdown was necessary, but I guess it just depends on the user and how they normally breakdown how to make a decision.” (Survivor, 04)

“Very useful, yeah...because it kind of breaks it down and allows me to go through it you know, systematically. Which I think when you are going through something like this, there is like no system in your brain, so it kind of breaks it down that like you can actually go through it one step at a time...” (Survivor, 02)
“... I think there are good questions to ask yourself but sometimes those scales can be hard to answer... Because it depends on like where you are at that day...I am not sure that I would have completed it because it doesn’t seem kind of long, just because the emotional things it’s not just like yes, or no to whatever it’s like a really emotional deep thing and...looking at it all together can seem really overwhelming but...it’s still again good questions to have, ask yourself and like good information.” (Survivor, 05)

Personal stories were embedded in the Australia decision aid (as an example of a patient filling out the values clarification exercise), LIVESTRONG brochure (as a link to an online video), and MyOncofertility (as videos). Most participants valued the inclusion of personal stories because patients can relate to the stories and be assured that others have been through the same experience, which can lead to them feeling less isolated.

“I think it’s what we all want is to know that someone else has done it before us, someone’s had success doing it you know, I don’t want to be their guinea pig...so, I love hearing survivor experiences in general....” (Survivor, 02)

“...I found [personal stories] really useful, because like even for me in talking to other individuals who experienced cancer, especially at a younger age it’s very isolating and sometimes you want to hear like other people’s like success stories, even if let’s say they were, there fertility was affected but knowing that these fertility options can be successful, because I know like on paper and in theory it says it’s successful but actually hearing stories that it was, was really nice.” (Survivor, 06)

However, some participants were concerned that the stories would influence patient decisions and others expressed concerns that the story format did not portray a real patient. Additionally, there were mixed opinions among participants on the best format for personal stories in a decision aid. All participants thought the personal stories presented in a video format with successful and unsuccessful stories on fertility preservation were useful. For the paper decision aids, most participants did not find the Australian decision aid’s example of a patient filling in the values clarification method useful. One health care provider participant discussed how a link to a personal story (similar to the format of the LIVESTRONG brochure) would result in less information in the resource but questioned whether patients would go back to manually input the link to access the video, ultimately calling it a ‘double edged sword’.

“I am a little bit concerned...like if you have a 29-year-old single woman reading this would she feel that she should be feeling like [the person in the story] or not...” (HCP, 01)

“... I didn’t find it useful because again it just also felt like an exemplar which again I am used to using with students so that they understand how to fill something out or how to do a particular task. But for me...it kind of made me feel like oh, so if I am in that exact situation should I go that way so I thought it was a little bit leading.” (Survivor, 04)
“I think it’s important to know that people have gone onto do it and that they are satisfied with their decision and they have no regrets, but I think also it’s important for people to know that it doesn’t always work out for everybody, and to be prepared because I wasn’t prepared for that.” (Survivor, 02)

“I think patient stories are very useful, there’s a link in [the brochure] I don’t know how that would really work, like I think that patients get so much information that to then have to like go back and find more information may not be the most helpful. At the same time having too much text in these booklets I think is a barrier to actually getting through it. So it’s a double edged sword in a way…” (HCP, 05)

All participants felt the links to resources for additional information included the Australian decision aid, MyOncofertility, and LIVESTRONG brochure were useful. The incorporation of credible resources specific to young breast cancer patients was described as a way for patients to avoid random Google searches.

“I think this is a very good idea because it will help direct people... to the resources that you want them to go to as opposed to random Google searches.” (Survivor, 01)

“I think if there’s resources available for your guide I think that is valuable to people. I think they like information.” (HCP, 02)

“...very useful. I think it is important to include other sources outside of this particular booklet.” (HCP, 05)

The Australian and Dutch decision aids, MyOncofertility, and LIVESTRONG brochure all contained question lists for health care providers. All participants felt the example question lists for health care providers were useful due to short appointment times and the need for patients to be prepared in advance with questions. While the question list was perceived as useful, a survivor participant stated that in her experience health care providers only answered three to four questions during each clinical appointment. Therefore, it was suggested by some participants to identify the specific health care provider the questions should be directed towards. Identifying health care providers to ask could also avoid embarrassing members of the healthcare team with questions they are unable to answer, ensure correct and consistent information is provided to patients, and contribute to efficient use of appointment time for both patients and health care providers.

“...I thought that the questions, I think there were maybe a little bit too many but I also thought that I did think [they were] good questions to ask your doctors because of course you just really if you are in the situation and the first person in your family or in your circle to experience something like this, you have no clue what to ask, so, I thought it was a good you know, starting point...” (Survivor, 04)
“…The doctor’s appointment it goes so fast you need to prepare your questions in writing because [health care providers] are always super busy and they don’t have much time so, you need to be prepared and have the questions.” (Survivor, 03)

“I think this is of value because I think [patients] don’t know what to ask so a guide for what to ask is helpful.” (HCP, 02)

“…very helpful…I didn’t know who to ask that question to [question on use of contraception while on ovarian suppression] and I got conflicting information and I trust the fertility doctor… and you would ask, you know, your oncologist just wants to keep you alive they don’t care about those side effects it’s like ah, suck it up but we have lives, and I want to live my life and I am married you know, and I want to have a marriage and all that stuff…and no one knows who to ask.” (Survivor, 02)

Some participants felt the videos and animations in the resources that explained the background information and fertility options were useful. Survivor participants found that videos provided an interactive way to review information compared to reading. Videos as opposed to a booklet full of medical language and text were also seen to benefit patients who are visual learners.

“I like the base information and also the animation is good…lot of people are visual learners.” (HCP, 08)

“…some of them had like some animation which was good…because sometimes I find when, if you are just reading with no notice of the message you are just constantly like just reading, like which I don’t mind reading in general but you can totally get lost in the information sometimes.” (Survivor, 07)

(3) Factors influencing fertility preservation decisions

Many factors were perceived to influence fertility decision-making, including:

- Stage and severity of the cancer diagnosis and the chance of recurrence
- Cost of fertility preservation procedures
- Wanting to have genetically related children in the future
- Timing to complete fertility preservation prior to treatment
- Relationship status at the time of diagnosis
- Prior fertility preservation completed
- What the fertility preservation procedure involves (e.g., does it involve an invasive component?)
- Health of a child conceived through fertility preservation and success rates of fertility preservation
- Current children or being pregnant when diagnosed
Health care provider participants drew on their past discussions with patients and felt some factors were very dependent on the individual patient. Survivor participants also highlighted the individuality of fertility decisions as they drew on their own experiences to identify the factors that influenced them. However, there were some factors all participants said commonly impacted fertility decisions. These included the cost of fertility preservation, stage and severity of patients’ diagnosis, and timing to complete fertility preservation prior to treatment. The accurate total cost prior to the fertility preservation treatment beginning was important and decision-making was seen as more complicated when fertility preservation was not funded.

“...it was out of pocket but it was just more of like this is what we are going to do sign here, let’s do it and they gave me rough estimates of what things would cost and my actual costs was way over the rough estimate...when any one goes through treatment that’s a huge financial setback for anybody that’s going through it at a young age I think you know, especially with small children I think we’re more price sensitive to this kind of stuff because obviously other women are not planning on having babies in their 50s, 60s and 70s, I think that should be something that should be discussed and maybe there should be some I don’t funding or something to help, because you feel stuck...” (Survivor, 02)

“...[Cost is] a thing you need to know from the start, because if it’s not covered, it might change everything in your, in your decision...because honestly I don’t think I would have gone through the fertility preservation if it was not covered...since it was so easy because it was covered it was, it was like a no brainer like let’s have this plan B just in case.” (Survivor, 03)

Although many participants thought timing to complete fertility preservation was an important factor, one survivor participant was adamant that timing would not influence her fertility decision because if she wanted more children than the time to have fertility preservation would not matter.

“Yeah, [timing] would be important based on when you are starting your treatment for sure.” (Survivor, 07)

“If I was very adamant about wanting to have kids the time it took to be able to get pregnant again wouldn’t matter.” (Survivor, 08)

Survivor participants expressed how the experience of having to make a quick fertility decision in the face of a new cancer diagnosis was an emotional time. Patients’ experiences would vary based
on those emotions and factors that were relevant to their unique situation. Emotional support was brought up by participants as being important in the fertility decision-making process.

“I think the emotional support... I don’t think they realize how emotionally taxing it is and also how taxing it is on your body and then you say you’re going into treatment... we definitely need some more emotional support.” (Survivor, 02)

“... with medical counselling [patients] will be presented [their] options based on [their] personal situation but then the choice from that point quite often is emotional.” (HCP, 02)

(4) Use and delivery of decision aids in clinical practice

Most participants felt that the delivery of a decision aid should be at the beginning of the cancer journey or when discussing the treatment plan. However, one health care provider participant cautioned against early referrals to fertility specialists. The caution was due to her experience of seeing patients going through the steps to complete fertility preservation when they did not require cancer treatment that impacts fertility. Additionally, some survivor participants felt that information too early in the care journey may be overwhelming but recognized the importance of receiving the information early enough to become informed and receive fertility preservation if desired.

“...by the time it was [presented] than everything was just crunched and everything seemed like a rush because...it was presented like when they had a treatment plan right. So that’s why I think it’s really important to get [the decision aid] like basically at diagnosis right or you know when they sit you down so that you can start thinking about it. And you have the time frames in front of you, so you know how it will affect your treatment plan.” (Survivor, 04)

“... I think it would be great, if they would get that on day 1 essentially and really read it before they come to their fertility consult.” (HCP, 01)

“I would say when discussing their treatment plan, I think at diagnosis is too early. I often see women who have gone to fertility specialists and are getting pumped full of hormones which is causing their cancer to grow and they didn’t need it in the first place because they were never going to get chemo, so, yeah I would say when discussing [the] treatment plan.” (HCP, 06)

“...my husband and I we didn’t want to have kids so for me it was like a no brainer at that point to be like okay, let’s go ahead with the treatment. But let’s say someone who was waiting to have children or let’s say hasn’t met the right person like I feel like they need this information right away, even though you are going through a tough period...because some people might be upset that they didn’t have this option available to them regardless of the shortage of time, I feel like it still should be presented to them at this level if they are willing to look through it.” (Survivor, 07)
There were mixed opinions among participants on which health care provider should be responsible for presenting the decision aid. Some health care provider participants felt surgeons should initiate the fertility discussion and provide the referral to the fertility specialist to avoid overwhelming the patient with the decision right before beginning chemotherapy. Most survivor participants generally preferred to receive a decision aid from the health care provider they had the most rapport with throughout their treatment, while others expressed the need to have it delivered by someone who would not bias their decision.

“We usually get women referred after they’ve already seen their oncologist who wants to start the chemotherapy and oh by the way this might affect your fertility and then there’s really very little time for them to digest it all...and yet there is a period of time after their biopsy or their lumpectomy where they are healing and waiting for their oncology appointment that’s the time they should be referred [to a fertility specialist].” (HCP, 01)

“I think it would probably be best if it was delivered by maybe like the social worker, so someone who’s, who understands, who is not going to necessarily have that particular bias of like oh you need to focus on yourself first and then think about children because that’s what I was told, but I think if it was someone who was not maybe a medical professional they might just present the information to you.” (Survivor, 03)

Some participants thought patients should complete the decision aid and values clarification method by themselves due to: the lack of personnel available to assist them, the emotional process of decision-making, and the possible skewing of their decision based on a medical opinion. However, there were also some participants who thought the decision aid and values clarification method should be completed with health care providers of varying types (e.g., surgeons so patients can receive information early in their care journey; medical oncologist because they can provide information on the fertility risks of treatment; and social workers to ensure patients have psychological counselling) or were unsure on the best approach for completion.

“My advice would be that we don’t have enough people in the field that it better be self-administered or we would run into a lot of problems in really getting it done.” (HCP, 03)

“I’d rather go through it and then ask them questions I think if you go through it with them, sometimes it’s sort of like...a business for [fertility specialists] but for someone like me it’s not about the business and I wouldn’t want my decision to be skewed based on a medical opinion, because it’s not just a medical opinion that helps you make your decision, it’s what’s in your heart, what do you want for your future, your fears, they don’t really address that stuff, not as simple as that. So, I would never want a medical professional to go through this with me.” (Survivor, 02)
“I honestly don’t know if this would be of value to people to do individually…it just seems like a lot for them to have to work through on their own because presumably they’re at home looking at this or something…I think it could be useful in the context of counselling… I am talking more about psychological counselling versus medical counselling.” (HCP, 02)

Most participants thought a decision aid would be best designed in a paper and/or online format.

“My generation online/website…I find that people lose pamphlets, I mean I have got tons when I started treatment on chemo or whatever, I have no idea where they are, don’t think I ever really read them.” (Survivor, 02)

“I think paper for this would be totally fine… I think that’s going to be a good supplement [referring to online tools] but you want the basic thing to make sure that all of the patients actually get it, so paper still works the best.” (HCP, 07)

“I think a combination of you know, written material and online as well…” (HCP, 01)

**3.3 Summary of descriptive statistics and qualitative data**

Participants identified sections of existing fertility decision support resources that were useful to consider adapting to the Canadian context for the BEFORE decision aid. While participants rated the decision support resources using closed-ended Likert scale questions, they expanded on their responses and provided rationale for their ratings based on their experiences during in-depth interviews.

All participants rated that it would be useful to include the cost of fertility preservation and the available funding, health care provider directed question lists, and a glossary in a decision aid. Participants expanded that the cost and funding was important to many survivors, especially those who lived in provinces where fertility preservation was not funded. Additionally, direct questions could help them start conversations with health care providers, and links to resources would provide them with reliable sources of information thereby allowing them to avoid unreliable online information searches.

While most participants rated the fertility options before treatment as useful, the qualitative data showed that some health care provider participants felt only established fertility options should be listed and others felt all available fertility options should be listed. Additionally, most participants rated the inclusion of after treatment parenthood options as useful but the qualitative data showed that some health care provider participants also felt that it may be overwhelming for patients and that they may not need to know the parenthood options after treatment at that point in their care journey. In contrast, survivor participants preferred to know the after treatment options upfront to help set realistic expectations. Some options grids were rated as useful to include, except those that contained
too much information causing the grid to be large and overwhelming. The qualitative data showed that participants felt the grids were a good starting point and a way to present the fertility options in a balanced format. However, it was noted that grids do not encompass the emotional aspects of care.

Mixed opinions were seen among participants in the closed-ended questions on incorporating ongoing research in the field of oncofertility and including graphics and photos with no relation to the text. The closed-ended questions and qualitative data showed that participants thought personal stories and a values clarification method may be useful for some women and not as useful for others. While personal stories were rated as useful in some decision support resources, there was concern expressed that women may decide on the same fertility option as the storyteller if similarities existed in their experiences. Finally, while most participants thought background information was useful to include through the closed-ended questions, there were varying opinions on some information that should be included (e.g., breastfeeding, contraception, and genetic testing).

Based on findings, Table 3.7 summarizes the aspects of the six decision support resources that should be applied to the BEFORE decision aid, aspects that should not be applied, and aspects that participants had mixed opinions on that requires further evaluation. These aspects were derived from the review of the descriptive statistics and qualitative data. The quantitative data were first examined to determine the components of the decision support resources that most participants felt were useful and not useful for informed fertility decision-making. The qualitative data were then examined to gain a better understanding on the specific types of information that participants felt were useful and not useful, and to determine why the participants felt certain information would be important to include in the BEFORE decision aid.
Table 3.7 Aspects of evaluated decision support resources for the BEFORE decision aid

<table>
<thead>
<tr>
<th>Results</th>
<th>Content and design features</th>
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| **Consider including** in the BEFORE decision aid | - Simple option grid summarizing fertility options  
- Limited background information highlighting essential information  
  - Essential information includes: cancer treatment impacting fertility, age-related declines in fertility, menopause, pregnancy rates after treatment, health of children born to cancer survivors and by using fertility preservation  
- Essential information on the fertility options with links to more information/resources  
  - Essential information includes: fertility options success rates (using the same denominator), timing of fertility preservation, impact of fertility preservation on cancer, possible fertility outcomes after treatment, cost of fertility options and sources of funding, and any legal and/or ethical considerations of fertility preservation in Canada  
- Using inclusive language and writing in lay language  
- Adding a glossary for all medical terminology used  
- Question list, with sample questions, for health care providers  
- Visuals that display important information that is relevant to text in the decision aid  
  - Citing the information and listing references to ensure transparency in the evidence used |
| **Do not include** in the BEFORE decision aid | - Writing using heavy text and high level language  
- Information patients will already be receiving (e.g., general breast cancer information)  
- Photos that have no purpose or have no meaning to the text in the decision aid  
- Including a complicated and text heavy fertility option grid |
| **Mixed opinions on whether to include in the BEFORE decision aid – Requires further input** | - Including background information on menstrual cycles, breastfeeding, contraception, and genetic testing  
- Including information on fertility options after treatment (e.g., adoption)  
- Inclusion of experimental fertility options  
- Inclusion and formatting of a values clarification method and personal stories  
- Information on current research being completed in the field of oncofertility |

3.4 Discussion

The evaluation of six fertility decision support resources increased our understanding of the fertility informational needs of breast cancer patients and health care providers and assisted in identifying critical content to include in the BEFORE decision aid. There were similarities among participants with respect to the usefulness of a simple option grid to summarize information, background information on fertility and breast cancer, using inclusive and lay language, including a glossary, list of resources, reference page, and question list for health care providers, as well as using visuals that related to the text. Participants agreed that heavy text and high level language should be avoided, as well as repetitive information, photos with no purpose, and complicated option grids. Differences in opinions were seen as well on the depth of background information to include, inclusion of after treatment parenthood options and experimental options, formatting and inclusion of a values clarification method and personal stories, and current research in the field of oncofertility. Health
care provider participants based their opinions on their experiences or knowledge on fertility decision-making with young women. Survivor participants based their opinions on their personal experiences and reflected on the types of information they believed would have benefited them when making their fertility decisions.

While all health care provider participants recognized the benefits of increasing patients’ knowledge surrounding fertility, verbal communication was the main form of providing fertility information and there were few instances where material information was provided as a supplement. Even though health care provider participants expressed their best intentions for patients, some survivor participants felt they needed more information than what was presented to them. The quantity and form of information provided to survivor participants was not always in line with the amount of information they preferred to receive or felt they needed to make an informed decision. Across survivor participants there was a common feeling of needing targeted and comprehensive fertility information. While the experience of being overwhelmed by the amount of information provided after a breast cancer diagnosis was seen throughout the interviews by all participants, there was still a need expressed by survivor participants for written fertility information in addition to verbal communication prior to making a fertility decision. This finding is consistent with literature surrounding the unmet fertility needs of young breast cancer patients.47,156 Thewes et al. found unmet fertility informational needs among young women with breast cancer and concluded that there is a need among patients to have both verbal and written information.52 The authors stated that decision tools could help to fulfill the unmet fertility informational needs among young cancer patients prior to treatment.52 In situations where written or verbal fertility information was not provided by the health care providers, survivor participants sought out the information themselves. In a few instances, survivor participants acted as their own advocates and brought information and questions to their healthcare team to ensure their fertility needs were heard and acted on prior to cancer treatment. While young women may prefer an active or collaborative role in fertility decision-making, health care providers also need to be knowledgeable on the fertility preservation options available so that they can act as advocates to ensure patients have adequate time to address any fertility concerns after fertility discussions.27,157

There were discrepancies between health care provider participants and survivor participants regarding the optimal amount of information to include in the BEFORE decision aid. Most health care provider participants opted for providing simple and condensed information to patients. In
contrast, survivor participants preferred more detailed information with summaries to allow patients the ability to choose the information to read based on their specific situation. The amount of information to incorporate in decision aids is a challenge; tools should provide all the information a patient needs to make an informed decision but too much information can result in confusion and may overwhelm patients and risk them missing key information.\textsuperscript{158} Feldman-Stewart \textit{et al.} also noted how priority information differs between health care providers and patients and varies from person to person.\textsuperscript{107}

This evaluation identified some specific information needed for decision-making such as the cost of fertility preservation and sources of funding in Canada, age-related declines in fertility, impact of cancer treatment on fertility, pregnancy rates post-treatment, fertility options success rates, fertility outcomes after treatment, health of children born to cancer survivors and through fertility preservation. However, for other areas the optimal amount of information that should be included in the BEFORE decision aid was unclear and required further input such as information on breastfeeding, contraception, hereditary breast cancer, genetic testing prior to treatment, after treatment parenthood options, and experimental fertility options.

The findings of a qualitative study of 24 young women with breast cancer in Australia by Thewes \textit{et al.}, were similar to results from this evaluation.\textsuperscript{66} The study, which provided data to guide the development of patient education materials, also reported a lack of information provision by the health care team, and found patients preferred to be given fertility information before or during treatment decision-making. The authors found that patients had many fertility-related, menopause-related, treatment specific, and sexuality questions when they were first diagnosed with breast cancer. There were 22 unique questions patients had regarding fertility (e.g., questions on the ability to conceive after treatment, chances of pregnancy after treatment, fertility options available, success rates of fertility preservation, risk of cancer recurrence from a pregnancy, and use of contraception).\textsuperscript{66} However, in this evaluation, survivor participants also noted questions surrounding the impact of genetics on the retrieval of eggs for fertility preservation, the cost of the fertility options, and the fertility options after treatment if treatment-related infertility occurred.

\subsection*{3.4.1 Application of Fuzzy Trace Theory}
Fuzzy Trace Theory was used to examine how gist (general meaning of information) and verbatim (precise understanding of the exact information),\textsuperscript{153} was used in the decision support resources evaluated and how survivor participants described their preferred presentation of information in
written information on fertility. In line with the FTT, survivor participants relied on the underlying meaning of the information when making their decision and when relaying back the information that was useful when making their decision. They felt that having a general understanding of all the fertility options was important to help make informed decisions. There was limited description of specific or verbatim information that helped survivors make their decisions. However, survivor participants were keen on incorporating specific costs for each fertility option. The Australian decision aid presented their fertility cost information qualitatively (e.g., ‘costly’ and ‘less costly’). Participants thought that this presentation was subjective and may not allow for a good understanding of the information as people could have different interpretations of the descriptions (e.g., what is costly to one person may not be costly to another). This supports the FTT, and the idea that each person will have a different meaning of the verbatim information and interpret it as a gist understanding based on emotions, culture, experience, and education. For example, a patient’s social status, external influences on decision-making (e.g., health care providers, support persons) and desire of having future children may play an important role in the interpretation of the verbatim information presented. These are important factors to consider when creating a decision aid that aims to be utilized by young women from different social classes and in different stages of family planning.

Emotions in particular, were discussed by participants as having a key impact on fertility decision-making and on the use of written and verbal fertility information. Emotions have been shown by Zikmund-Fisher et al., to have a more influential role in decision-making compared to factual knowledge. Additionally, emotions can influence how information is processed and those with cancer concerns may be more likely to pay attention to verbatim details. The topic of fertility and fertility decision-making can evoke positive or burdensome emotions among young women. Yet, fertility is still a common concern among young cancer patients. Therefore, the presentation of information is important to ensure patients are making informed decisions that reflect their values.

3.4.2 Use of evaluation results to inform the BEFORE decision aid
There were components of each decision support resource that participants rated as useful for informed fertility decision-making. Therefore, we utilized the evaluation results to inform the sections for inclusion in the prototype BEFORE decision aid, specific content to include in the sections, and level of detail that participants felt was needed for informed fertility decision-making. The BEFORE decision aid prototype will also differ from the decision support resources evaluated
by including Canadian specific fertility information, detailed cost information by province and territory in Canada, and success rates for pregnancy and menses resumption after treatment for the fertility options using icon arrays personalized by age. The BEFORE decision aid prototype was also written in lay language ensuring inclusivity. We aimed to present the gist of information using graphs but also presented the verbatim fertility option costs and success rates for patients to interpret based on the meaning they attribute to the information (e.g., we presented that embryo freezing costs between $0 and $20,000 instead of describing it as ‘costly’). The BEFORE decision aid was also created as a paper and online format as most participants (87.5%) viewed these formats as the most useful for the decision aid. Additionally, the evaluation results highlighted that stakeholders have varying opinions on the usefulness of some components of existing decision support resources. The need was seen to bring together stakeholders of the BEFORE decision aid to discuss the components participants had mixed opinions on to determine if they should be adapted and incorporated into the BEFORE decision aid design.

3.4.3 Strengths and limitations
Breast cancer survivor participants were chosen to reflect on their experiences to help other women who may be going through similar situations in the future. Women who were recently diagnosed with breast cancer within the past five years were included to help reduce recall bias and allow for better reflection on their experiences and informational needs. However, some survivor participants were still unable to recall the information that helped them make their decisions. Survivor participants who completed active treatment were selected because approaching young breast cancer patients with a new breast cancer diagnosis may have resulted in the patients feeling more overwhelmed and conflicted with the varying fertility information in the decision support resources from different jurisdictions. All participants were identified using convenience and snowball sampling to determine the specific opinions of individuals who would potentially be end users of the BEFORE decision aid and other fertility decision support resources. These recruiting strategies have been criticized for being non-randomized sampling methods and therefore may not represent the entire population of interest. They were still deemed to be the most appropriate form of sampling participants to ensure a range of perspectives from individuals who have experienced fertility decision-making or cared for those who are making fertility decisions. Survivor participants were successfully recruited with diverse characteristics in terms of age, ethnicity/race, treatment completion, and timing from cancer diagnosis. However, the sample of survivor participants interviewed completed at minimum post-secondary education and therefore it was a higher educated
sample that provided their informational needs and they may not be representative of all young women who are diagnosed with breast cancer in Canada. The IPDAS criteria advises evaluation of a decision aid and its development by individuals who have low literacy,¹²⁶ and this is planned in the alpha and pilot testing of the BEFORE decision aid. To account for the limited input from low literacy survivors we were in constant contact and communication with a plain language expert at St. Michael’s Hospital to ensure the BEFORE decision aid was readable by individuals across the literacy spectrum. Additionally, almost half of the young women we approached were not interested in participating and most did not provide a rationale for choosing not to participate in the evaluation. The transferability of the findings from this evaluation may be limited as the informational needs vary between each person based on their unique experiences and situation.¹⁰⁷ While we aimed, and succeeded in gaining a comprehensive understanding of the informational needs of survivor participants in this study, it may not be representative of the needs of every young breast cancer patient faced with a fertility decision. However, the BEFORE decision aid can act as a starting point for further fertility discussions between patients and health care providers to fulfill patients unmet informational needs. Finally, different opinions were seen between health care provider participants and survivor participants on some sections that would be valuable to include in the BEFORE decision aid (e.g., personal stories and values clarification method). For the purposes of this analysis, these varying opinions were noted as areas for further exploration with stakeholders of the BEFORE decision aid to determine consensus on the appropriate format and content to include in the decision aid (described in Chapter 4).

3.5 Conclusion
The information from the fertility decision support resource evaluations assisted in the development of the paper prototype BEFORE decision aid. While the evaluations provided valuable insights into the sections to include and design features to incorporate into the BEFORE decision aid, there were mixed opinions expressed by participants on the inclusion and formatting of some sections. Further insights from stakeholders of the BEFORE decision aid is required to finalize all the included sections and formatting of the decision aid.
Chapter 4
BEFORE Decision Aid Development

The aim of this chapter is to provide a comprehensive and transparent understanding of the systematic process that was taken to develop the paper and online BEFORE decision aid. This chapter describes the development framework, the development of the prototype, the stakeholder meeting to finalize the design, content, and presentation of information, and the post-meeting review of the BEFORE decision aid.

4.1 Methods
4.1.1 Development framework
The development of the BEFORE decision aid followed an adaptation of the systematic development process outlined by the IPDAS. While, as emphasized by Coulter et al., there is no evidence supporting the relationship between a systematic development process and better use of decision aids in actual practice, a systematic process is still recommended to ensure transparency on the development steps. A transparent development process allows the end users to adequately check and confirm the reliability and validity of the process. The ability to confirm the validity and reliability of the tool is especially important as poor quality decision aids could cause harm to patients and interfere with SDM. Additionally, transparency enables end users to identify the stakeholders involved in the development and determine if any biases exist.

4.1.2 Prototype development overview
The BEFORE decision aid was designed based on the findings from a previously conducted needs assessment of young cancer patients and health care providers, literature reviews on decisional needs and best practice for decision aid development, evaluations of existing fertility decision support resources, as well as input from experts in the field of oncology and fertility, and breast cancer survivors. Consultation on the design of the decision aid was an iterative process between my supervisor (Dr. Nancy Baxter) and committee members (Dr. Erin Kennedy and Dr. Kelly Metcalf) who have experience in decision aid development.

The data included in the decision aid was identified through: (1) peer-reviewed published literature on the risk of infertility, success rate and risks of the fertility options, general information on pregnancy after breast cancer and fertility, birth outcomes of children born to cancer survivors, and psychosocial aspects of fertility after care (2) existing decision
aids;64,65,147-149 (3) credible organizations (Canadian Cancer Society,173 Fertile Future,174 American Society for Reproductive Medicine,175 Breastcancer.org176); and (4) the ASCO 2006 and 2013 fertility guidelines.24,30 When no other sources of data were available or the data were not up-to-date to current clinical practice, expert opinion was used as a substitute.

The initial prototype of the BEFORE decision aid (Version 1) was developed through an iterative process with content experts in medical oncology, surgical oncology, fertility, and patient education. Based on the feedback the BEFORE decision aid was revised (Version 2). The prototype decision aid was a paper version that contained information about the decision aid, background information on fertility and breast cancer, the most common fertility options (wait and see, embryo and egg freezing, and ovarian suppression), information pertaining to the fertility options in an option grid format, parenthood options after cancer, timeline of the fertility options, question list for health care providers, additional resources, glossary, acknowledgements, and references. The BEFORE decision aid (Version 2) was then reviewed by the research team (myself, committee members, supervisor, and research program manager) and further developed by stakeholders at a large engagement meeting. For content and design features of the decision aid that participants had varying opinions on (as described in Chapter 3), multiple versions of the content that displayed the varying options were developed for further input at the engagement meeting. Based on the feedback from the meeting, the prototype was revised (Version 3). The revised prototype was then evaluated post-meeting by meeting attendees and content experts to ensure the modifications reflected the discussion and recommendations from the meeting. The prototype was then revised again based on the feedback after the meeting (Version 4). Finally, the paper prototype was designed by a professional graphic designer (Version 5) and created into a mirrored online version by a web designer. Figure 4.1 depicts this development process with the involved team members.
BEFORE Decision Aid Sections: Findings from needs assessment interviews and evaluation of existing fertility decision support resources

BEFORE Decision Aid Content: Evidence from peer-reviewed papers, existing decision aids, credible and established organizations, fertility guidelines and expert opinion

Figure 4.1 BEFORE decision aid development process
4.1.3 Preliminary survey

Prior to the engagement meeting, attendees were asked to review the meeting materials including the BEFORE decision aid (Version 2), two examples of visually presenting the fertility options success rates (Table 4.1), and four examples of explicit values clarification methods (Table 4.2). In addition, meeting attendees were asked to answer an anonymous survey that included four questions to prepare them for the meeting and ensure they reviewed the meeting materials. The survey was created through an online survey software, FluidSurveys (www.fluidsurveys.com). Survey questions included the preferred format of the fertility options success rates and risks, inclusion of an explicit values clarification method and personal stories in the decision aid, and any additional comments or suggestions for the meeting (Appendix I).

Table 4.1 Example formats for the success rates and risks (embryo freezing example)

<table>
<thead>
<tr>
<th>Format 1 – Pictograph/Icon Arrays</th>
<th>Format 2 – Graphs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before the age of 39</strong></td>
<td><img src="https://example.com/graph1.png" alt="Graph Example" /></td>
</tr>
<tr>
<td>35 to 37 years of age</td>
<td><img src="https://example.com/graph2.png" alt="Graph Example" /></td>
</tr>
<tr>
<td>38 to 39 years of age</td>
<td><img src="https://example.com/graph3.png" alt="Graph Example" /></td>
</tr>
<tr>
<td>40 to 41 years of age</td>
<td><img src="https://example.com/graph4.png" alt="Graph Example" /></td>
</tr>
<tr>
<td>42 to 43 years of age</td>
<td><img src="https://example.com/graph5.png" alt="Graph Example" /></td>
</tr>
</tbody>
</table>

Each dot represents one person who completed a frozen embryo transfer. The green dots show the number of people who had a live birth after freezing embryos and having a frozen embryo transfer completed.
### Table 4.2 Example formats for the values clarification methods (wait and see example)

#### Example 1. Pro/Con Charts with Pre-listed Information – Adapted from the Australian Decision Aid

<table>
<thead>
<tr>
<th>Categories</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td>There is no cost</td>
<td>I may regret not spending the money to preserve my fertility if I become infertile after cancer treatment</td>
</tr>
<tr>
<td>Time</td>
<td>I will not have to wait to begin cancer treatment</td>
<td>I may be infertile after cancer treatment and unable to have a natural pregnancy</td>
</tr>
<tr>
<td>Future Children</td>
<td>If I become infertile I have the option to adopt/foster children or use donor eggs</td>
<td>If I become infertile after treatment I will not be able to have a biologically related child</td>
</tr>
</tbody>
</table>

Please circle on the scale what you are leaning towards for the Wait and See Option

| I am leaning towards waiting to see | I am still not sure | I am NOT leaning towards waiting to see |

#### Example 2. Blank Pro/Con Chart – Adapted from the MyKidney’s My Choice Decision Aid

<table>
<thead>
<tr>
<th>Fertility Option</th>
<th>Pros</th>
<th>Cons</th>
<th>Additional Thoughts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wait and See</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Example 3. Weighted Scale – Adapted from the Dutch Decision Aid

<table>
<thead>
<tr>
<th>Wait and See</th>
<th>This is a disadvantage</th>
<th>This is an advantage</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is no cost</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I will not have to wait to begin cancer treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If I become infertile I have the option to adopt/foster children or use donor eggs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I may be infertile after cancer treatment and unable to have a natural pregnancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Example 4. Rating Scale – Adapted from the BRCA 1/2 Mutation Breast Cancer Prevention Decision Aid and the Ottawa Decision Aids

<table>
<thead>
<tr>
<th>Fertility Options</th>
<th>Reasons to CHOOSE this fertility option</th>
<th>How important is it to you? 0= Not important 5=Very Important</th>
<th>Reasons to DECLINE this fertility option</th>
<th>How important is it to you? 0= Not important 5=Very Important</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wait and See</td>
<td>There is no cost</td>
<td>0 1 2 3 4 5</td>
<td>I may regret not spending the money to preserve my fertility if I become infertile after cancer treatment</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td></td>
<td>I will not have to wait to begin cancer treatment</td>
<td>0 1 2 3 4 5</td>
<td>I may be infertile after cancer treatment and unable to have a natural pregnancy</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td></td>
<td>If I become infertile I have the option to adopt/foster children or use donor eggs</td>
<td>0 1 2 3 4 5</td>
<td>If I become infertile after treatment, I will not be able to have a biologically related child</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td></td>
<td>Other Reasons:</td>
<td>0 1 2 3 4 5</td>
<td>Other Reasons:</td>
<td>0 1 2 3 4 5</td>
</tr>
</tbody>
</table>
4.1.4 Engagement meeting

The engagement meeting was held on November 11, 2016 in Toronto, Ontario at the Li Ka Shing Knowledge Institute. The goal of the meeting was to share results of the study, discuss the best way to present information in the decision aid, gather general feedback on the decision aid, and generate recommendations for strategic dissemination and implementation. To achieve these goals, the agenda included presentations on the completed research, three break-out groups, and a general discussion on the decision aid (Appendix J). The goals of the break-out groups and general discussion included:

**Break-out group 1** – (1) to gain input on the best way to present the fertility options success rates and risks in the face of uncertain data and determine how best to format the rates visually (as shown in Table 4.1).

**Break-out group 2** – (1) to determine if an explicit values clarification method should be included in the paper and online BEFORE decision aid; (2) to gain input on the best format for the values clarification method using the examples as a guide (as shown in table 4.2); and (3) to highlight any other important factors that should be included in the pre-written sections of the values clarification method.

**Break-out group 3** – (1) for survivor and advocacy group representative attendees – to determine if personal stories should be included in the BEFORE decision aid and determine the story format. Attendees were shown videos of personal stories from LIVESTRONG Foundation\textsuperscript{149} and MyOncofertility;\textsuperscript{148} (2) for health care provider and advocacy group representative attendees to determine implementation and dissemination strategies for the decision aid after development to ensure it is accessible and regularly updated.

**General discussion** – (1) to gain general feedback on the decision aid (e.g., comprehensibility, formatting, missing information, repetitive information, information to remove, what participants liked and did not like).

Instructions were provided to each break-out group to help guide discussions. Each group consisted of 5-7 participants and a group facilitator who took detailed notes. The overall meeting was facilitated by experienced facilitator, Dr. Erin Kennedy. The online BEFORE decision aid was not created at the time of the meeting but the attendees reflected and discussed the type of information that should be included in the online decision aid.
4.1.4.1 Meeting attendee recruitment

Recruitment of meeting attendees was completed using convenience and snowball sampling with the aim to engage a diverse group of stakeholders including breast cancer survivors, multi-disciplinary health care providers (medical oncologists, surgeons, nurses, social workers, etc.), advocacy group and cancer organization representatives, patient education specialists, and decision-making experts. Breast cancer survivors and health care providers previously involved in the study were recruited as well as new individuals identified through: (1) in person recruitment; (2) online recruitment; and (3) professional networks. The recruitment strategy was deemed to be an appropriate way to engage stakeholders knowledgeable on the study who were interested in providing further input; in addition to new stakeholders who had no previous involvement or knowledge on the study to incorporate additional perspectives. We also aimed to ensure representation from the diverse groups of individuals who are involved in the care of young cancer patients facing fertility decisions and from young breast cancer patients who have been through the experience of making a fertility decision. Since the BEFORE decision aid was developed for use across Canada, we ensured there was representation from stakeholders outside of Ontario. Travel and accommodations for individuals attending from outside of the GTA were reimbursed.

Breast cancer survivor attendees

Similar to the eligibility criteria described in Chapter 2, survivor attendees were invited to the meeting if they were diagnosed with breast cancer between the ages of 18 and 45, had completed active treatment (surgery, radiation, and chemotherapy but could still be taking hormone therapy), and had treatment with the potential to impact fertility within the past five years. Women who had undergone fertility preservation prior to their breast cancer diagnosis were excluded, as their fertility experiences would be different compared to those who were facing fertility decisions for the first time following their cancer diagnosis. Women were also not approached if they had a breast cancer recurrence or metastatic breast cancer. Breast cancer survivors in attendance received $150 as an honorarium for wages lost from taking a day off work to attend the meeting.

Breast cancer survivors who expressed an interest in continuing to help with the decision aid development were invited to attend the meeting through an email invitation. Breast cancer survivor attendees were also recruited through advertisements at breast cancer and advocacy groups as well as through postings in an oncology day clinic at a hospital in the GTA. If survivor attendees were interested they emailed the recruiter and in return the invitation letter (Appendix K) was provided to
them. Survivor attendees provided written consent and were then sent information on the meeting and the calendar invitation. If they did not reply to the email, they were contacted one week after the last point of contact. If women did not respond to the reminder email, no further attempts for recruitment were made.

**Health care provider, patient education specialist, and decision-making expert attendees**

Past health care providers who expressed an interest in continuing to help with the decision aid development were invited to attend the meeting through an email invitation. If the provider was not able to attend the meeting they were asked to recommend additional providers who may be interested in participating. The patient education specialist involved in the project and decision-making experts were also invited to participate. Additional multi-disciplinary health care providers from across Canada were identified through professional networks, and emailed information on the study and an invitation for the meeting (Appendix K). If attendees provided written consent they were sent further information on the meeting and the calendar invitation.

**Advocacy group and cancer organization attendees**

Representatives from advocacy groups with information and support targeted to young cancer patients were identified based on the groups that had previously recruited survivor participants for the study (e.g., ReThink Breast Cancer, Cancer Knowledge Network, and Young Adult Cancer Canada). Information on the meeting and the invitation letter (Appendix K) was emailed to the advocacy group representatives. Additionally, representatives from national and provincial cancer organizations (e.g., Canadian Partnership Against Cancer, Canadian Cancer Society, and Cancer Care Ontario) were identified, and emailed information on the study and the invitation letter (Appendix K). If attendees provided written consent they were sent further information on the meeting and the calendar invitation.

### 4.1.4.2 Data collection

The meeting materials were electronically sent to attendees one week prior to the meeting including the agenda (Appendix J), draft BEFORE decision aid, fertility options success rates and risks examples, and the explicit values clarification method examples. Information was sent out to allow attendees time to familiarize themselves with the documents for more in depth discussions at the meeting.

During the meeting, all discussions were documented by two designated note takers and break-out group facilitators. Additionally, for each break-out group session, the discussion summary was
captured on paper and presented to the larger group. The notes were also used to assess the feedback from the meeting and to ensure appropriate modifications to the BEFORE decision aid.

4.1.4.3 Data analysis
The discussion stemming from the engagement meeting was documented using designated note takers and following the meeting the notes were collated and summarized for the research team. Following an in-depth discussion, the team decided on how to proceed with the development of the BEFORE decision aid. While the aim of the engagement meeting was not to reach consensus on all the discussion items, there were some aspects of the discussion that participants were unanimous on and those aspects of the BEFORE decision aid were modified in accordance with the feedback. The diversity in opinions between attendees was also valued and noted in the discussion notes. Modifications were made to the BEFORE decision aid and sent out to expert content reviewers and meeting attendees to confirm that the changes accurately reflected the discussion, prior to finalizing the design with the graphic designer.

4.1.4.4 Ethical considerations
Ethics approval to recruit attendees and to hold the meeting was obtained from St. Michael’s Hospital (REB 15-220), Sunnybrook Health Sciences Centre (REB 226-2015), and the University of Toronto (Protocol # 32801) (Appendix H).

At the beginning of the meeting, the facilitator and research team members described the study to all attendees and outlined their role in the meeting as described in the invitation letter previously sent (Appendix K). No demographic or personal identifying information was collected from meeting attendees. The meeting was not audio-recorded and extensive notes were taken as a substitute by two designated note takers. The notes were collated, summarized, and kept on a secure server at St. Michael’s Hospital. The notes were password protected with all identifying information removed.

4.1.5 Post-meeting evaluations
Meeting evaluation
Meeting attendees were asked to fill out an evaluation during the last 10 minutes of the meeting (Appendix L). The evaluation contained 10 questions that were rated using a 7-point Likert scale from 1 (disagree) to 7 (agree), and three open-ended questions on what they liked most at the meeting, what they liked least at the meeting, and additional suggestions for the BEFORE decision aid.
BEFORE decision aid post-meeting review
Following the meeting, attendees were asked to complete a review of the revised BEFORE decision aid. Each attendee was emailed three questions:

1. Do you think the changes in the decision aid reflect the discussions from the meeting on November 11, 2016?
   a. Is there any information that you feel is still missing from the decision aid or information that you feel should be removed?

2. Do you think the information is written clearly? In particular, are you able to clearly understand the chances of pregnancy on pages 9-11 with the different fertility options?

3. As previously mentioned, we will be working with a graphic designer to format the decision aid but based on the revisions are there any general formatting comments?

Health literacy assessment
The Suitability Assessment of Materials (SAM) for evaluation of health-related information for adults was used in combination with the Flesch-Kincaid Grade Level to assess the health literacy of the BEFORE decision aid. The SAM is a tool used to review text readability as well as organization, format, and design of information. The SAM assessment measures how well the health materials fit with the intended audience and determines the readability and comprehension of the information. The SAM assessment rates 22 specific criteria over six areas including content, graphics, literacy, layout and type, cultural appropriateness, and learning and motivation. Each of the 22 criteria is scored as superior (+2), adequate (+1), or not suitable (0). The literacy assessment was completed independently by two assessors (Brittany Speller and Amanda Sissons) and any discrepancies were resolved by a separate assessor (Tari Little). The Flesch-Kincaid Grade Level of the BEFORE decision aid was assessed multiple times throughout the development using an online calculator (www.Readable.io). The readability assessments were done alongside iterative plain language reviews from a patient education specialist at St. Michael’s Hospital.

IPDAS criteria assessment
A final assessment was completed on the BEFORE decision aid against the IPDAS quality criteria. The evaluation was completed independently by two assessors (Brittany Speller and Amanda Sissons) and any discrepancies were resolved by a separate assessor (Tari Little). The assessment was completed as an internal check to ensure adherence to the criteria that guided the development of the BEFORE decision aid. An additional assessment against the IPDAS criteria can be completed
by independent assessors following the pilot testing of the decision aid. For example, the OHRI allows developers to submit decision aids to their decision aid library inventory to be publically posted on the website. Each decision aid undergoes an administrative review and approval of the criteria prior to posting.\textsuperscript{180}

4.2 Results

4.2.1 Preliminary survey

The preliminary survey was electronically sent to all meeting attendees (n=28) one week prior to the meeting, of which 23 (82.1\%) completed the survey. Of the options presented to the attendees, 14 of 23 (60.9\%) respondents preferred the pictograph/icon array format for the success rates, 7 of 23 (30.4\%) preferred the graphs, and 2 of 23 (8.7\%) did not like either option – one of whom felt the optimal presentation of information would depend on the types of information or preference of an individual.

For the values clarification method, 21 of 23 (91.3\%) respondents thought that it would be valuable to include an explicit values clarification method. Those who felt the method was not a valuable addition to the BEFORE decision aid stated that it may be too much information that could add to confusion and may not realistically reflect the way people make treatment decisions. However, most individuals recognized that those who do not find the method valuable are not required to complete it and that it should be included for those who would find it useful.

Finally, 16 of 23 (69.6\%) respondents thought that it would be valuable to include personal stories in the BEFORE decision aid. Those who did not think personal stories should be included felt that they may result in the decision aid becoming too long, bias patients’ decision-making, appear fictitious if the identities of patients are not revealed, and create false hope of a pregnancy after treatment. Those who thought they should be included felt personal stories could be optional online and that the use of successful and unsuccessful fertility stories may help to normalize the experience for young women.

Additional comments were that some of the information in the decision aid was repetitive and there was an opportunity to streamline the information and reduce the amount of text.
4.2.2 Engagement meeting results

Meeting attendee demographics

The meeting included 28 attendees from across Canada and nine support staff (Table 4.3). Participants attended from the GTA, Ontario; Ottawa, Ontario; St. John’s, Newfoundland; Vancouver British Columbia; Calgary, Alberta; and Gatineau, Québec.

Table 4.3 Engagement meeting attendees

<table>
<thead>
<tr>
<th>Meeting Attendees</th>
<th>Number (n=28)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Health Care Providers</strong></td>
<td>12 (42.9%)</td>
</tr>
<tr>
<td>Reproductive Endocrinology and Fertility Specialists</td>
<td>4</td>
</tr>
<tr>
<td>General Surgeons (Specializing in Breast Cancer)</td>
<td>2</td>
</tr>
<tr>
<td>Medical Oncologists</td>
<td>3</td>
</tr>
<tr>
<td>Registered Nurses</td>
<td>2</td>
</tr>
<tr>
<td>Social Worker</td>
<td>1</td>
</tr>
<tr>
<td><strong>Decision Aid Experts</strong></td>
<td>2 (7.1%)</td>
</tr>
<tr>
<td><strong>Patient Education Specialist</strong></td>
<td>1 (3.6%)</td>
</tr>
<tr>
<td><strong>Breast Cancer Survivors</strong></td>
<td>8 (28.6%)</td>
</tr>
<tr>
<td><strong>Cancer Organizations and Advocate Representatives</strong></td>
<td>5 (17.9%)</td>
</tr>
<tr>
<td>Rethink Breast Cancer</td>
<td>1</td>
</tr>
<tr>
<td>Young Adult Cancer Canada</td>
<td>1</td>
</tr>
<tr>
<td>Canadian Cancer Society</td>
<td>1</td>
</tr>
<tr>
<td>Cancer Care Ontario</td>
<td>1</td>
</tr>
<tr>
<td>Cancer Knowledge Network</td>
<td>1</td>
</tr>
</tbody>
</table>

Break-out group 1 – Presentation of the fertility options success rates and risks

Similar to the preliminary survey results, most attendees preferred the pictograph/icon array format to present the success rates. However, modifications were recommended such as changing the circle images to shapes of women that are inclusive and reducing the denominator from 100 to 10. Attendees also agreed that the information should be rearranged to list the common age groups (under 35 years of age, 35 to 39 years of age, and over 40 years of age) and the success rates for each fertility option to allow for easier comparisons across options (Table 4.4).
### Table 4.4 Success rates format selected and modified

<table>
<thead>
<tr>
<th>Selected success rates table – Version 2</th>
<th>Modified success rates table – Version 5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age Range</strong></td>
<td><strong>Fertility options before cancer treatment</strong></td>
</tr>
<tr>
<td>Under the age of 35</td>
<td><strong>What are my chances of natural pregnancy by age range?</strong></td>
</tr>
<tr>
<td>35 to 37 years of age</td>
<td><strong>Before 40 years of age</strong></td>
</tr>
</tbody>
</table>
| 38 to 42 years of age                   | Under 35 years of age – What is the risk of chemotherapy affecting fertility?
| 43 to 47 years of age                   | While a limited number of patients will become pregnant after fertility-sparing treatments, your chances depend on your individual situation. Talk with your healthcare team to understand your specific chances.
| 48 years of age                         | Figure 4.2: Fading colour scheme to represent a range (wait and see example)

Additionally, the use of a fading colour scheme to represent a range in the rates was not clear to most attendees as shown in Figure 4.2. While the inclusion of a range to show success rates was seen by most attendees as suitable, some attendees cautioned on the use of ranges; they felt patients were only interested in their specific situation and may find it challenging to understand where they fit in the range. Attendees also thought including the average or best estimates was suitable because presenting any known information, even if it is uncertain, was better than not including the information. Therefore, averages and best estimates were used instead of ranges.
The success rates and risks for each fertility option differed between each patient. As such, there was discussion surrounding the presentation of uncertain data in the BEFORE decision aid. It was suggested to highlight disclaimers and important information surrounding the uncertainty by stating:

- The information is based on current knowledge and uncertainty exists
- The information presented will vary on an individual basis
- The success rates are based more on the age when the patient is attempting to get pregnant (for wait and see) and the age when they removed their eggs (for embryo and egg freezing)
- The importance of having a discussion with health care providers after reviewing the decision aid since it is an adjunct to consult

There was also consensus that the success rates and risk information presented alongside the icon arrays was too dense for a lay reader. For example, Table 4.5 shows the original text preceding the embryo freezing icon arrays. Therefore, modifications were made to condense the information for each fertility option (Table 4.5). Survivor attendees concluded the discussion on formatting of success rates and risks by noting that information in this section should be accurate but also include hope in the messaging and be inclusive of all young women who may be going through the experience of making a fertility decision.

Table 4.5 Example text for fertility success rates and risks

<table>
<thead>
<tr>
<th>Dense text on embryo freezing (similar page of text for all fertility options) – Version 2</th>
<th>Modified text for all fertility options before pictographs – Version 5</th>
</tr>
</thead>
</table>
| **Embryo Freezing**

   **What are your success rates if you choose Embryo Freezing?**

   The success rates for embryo freezing are the average live birth rates from 34 fertility clinics across Canada in 2014. These averages include all women who froze embryos in Canada after trouble having a natural pregnancy. The chances of having a live birth after freezing embryos are based on:

   - your age when your eggs were collected
   - quality of your eggs when they are collected
   - number of your eggs that were ovulated and fertilized with sperm to make embryos
   - type of freezing method used. Your embryos can be frozen using a slow freezing method or vitrification (fast freezing method).

   **How many embryos will survive the thawing process?**

   Research looking at embryo freezing shows:

   - approximately 7 out of 10 (70%) of your embryos will survive using slow freezing
   - over 9 out of 10 (90%) of your embryos will survive using fast freezing

   If you have 30 eggs collected and successfully fertilized to create embryos, approximately 7 to 9 are expected to survive the thawing. These embryos will then be transferred into your womb.

   **How many embryos will be transferred per cycle?**

   The number of embryos that are transferred will be based on:

   - number of embryos successfully transferred
   - your age
   - under the age of 35 you will generally have 1 to 2 embryos transferred per cycle
   - over the age of 42 you may have up to 5 embryos transferred per cycle

   The chances of having a live birth from one frozen embryo transfer by age are shown in the chart below.

   **Please note:** More than one transfer is possible if you have multiple frozen embryos.

   **Fertility options before cancer treatment**

   **What is my chance of having a child with the fertility options?**

   Your current age and your age when you decide to have a child will have a significant impact on your fertility. Consider the information below and go to your oncologist or gynaecologist for more information. The success rates are based on the average success rates from all fertility clinics across Canada in 2014.

   1. **Live Birth**
      - Successful pregnancy and birth of a child
      - Surrogate someone who carries your child for you
      - Fertility Preservation
      - Embryo Transfer
      - Freezing the frozen embryos and transferring them back into your womb or a surrogate

   **Egg freezing**

   - Egg freezing is a way to keep your eggs safe until you are ready to use them. How many eggs will survive the freezing process?
   - The chances of having a live birth after an embryo transfer are based on the age when your eggs were frozen and the age when they were used for IVF.

   **How many eggs will survive the freezing process?**

   - The number of eggs that survive freezing increases with age.

   **How many embryos will survive after freezing?**

   - The number of embryos that survive freezing increases with age.

   **How many eggs will survive the freezing process?**

   - The number of eggs that survive freezing increases with age.
Break-out group 2 – Explicit values clarification method

There was consensus among the attendees to include an explicit values clarification method in the BEFORE decision aid. Most attendees preferred the weighted scale values clarification method example that was based on the method used in the Dutch decision aid. Modifications to the selected values clarification method included changing the scale headers from ‘this is a disadvantage’ and ‘this is an advantage’ to ‘more important to me’ and ‘less important to me’, including more blank spaces for patients to add in their own values that are not listed, changing the colour scheme to be more balanced (e.g., darker colours were perceived as worse than the lighter colours) and removing the colour red. There were also suggestions to include a simple statement before the method recommending that patients go through the exercise with a partner or support persons as it may be emotionally challenging. Additionally, the terminology was seen as too high level and rewriting the values in lay language was recommended. Concern was expressed that the pre-listed values included mainly pragmatic values and not as many personal values or psychological considerations. Therefore, the group brainstormed other values that would be important when making a fertility decision, including:

- Moral/religious concerns (e.g., belief that an embryo is human life)
- Testing embryos for genetic mutations
- Distance needed to travel to fertility clinics
- Stress of completing fertility preservation
- Family before cancer (whether children are part of the picture now)
- Success rates of the fertility options
- Embryo use requires both egg and sperm donor’s approval (unless donor sperm was used)

Based on the suggestions a revised values clarification method was created (Table 4.6)
Table 4.6 Values clarification method example selected and modified (wait and see example)

**Selected values clarification method – weighted scale – Version 2**

<table>
<thead>
<tr>
<th>Wait and See</th>
<th>This is a disadvantage</th>
<th>This is an advantage</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is no cost</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I will not have to wait to begin cancer treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If I become infertile I have the option to adopt/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>foster children or donate eggs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I may be infertile after cancer treatment and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>unable to have a natural pregnancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Modified values clarification method based on meeting feedback – Version 5**

Additionally, attendees noted that the final question in the values clarification section, asking patients to select the fertility option they are leaning towards, made the options seem mutually exclusive, which is not accurate. The values clarification method was noted to be a resource to help patients clarify how they are feeling towards the options not to definitively decide on an option, as discussions with health care providers are still warranted. Therefore, it was recommended that the final statement be modified to show the options patients want more information on instead of asking them to definitively deciding on their selected fertility option (Table 4.7).

Table 4.7 Modified final question for the values clarification method

**Final component of the values clarification method – Version 2**

*Which option am I leaning towards? Thinking about your pros and cons list circle which fertility option you are leaning towards overall.*

<table>
<thead>
<tr>
<th></th>
<th>Wait and See</th>
<th>Embryo Freezing</th>
<th>Egg Freezing</th>
<th>Ovarian Suppression</th>
<th>Still Not Sure</th>
</tr>
</thead>
</table>

**Modified final component of the values clarification method – Version 5**

*Which options am I leaning towards? Check all of the below options that you would like more information on.*

- Wait and see
- Embryo freezing
- Egg freezing
- Ovarian suppression
- I am not sure yet
Break-out group 3 – Personal stories, dissemination, and updating of the BEFORE decision aid

Personal stories: The survivor and advocacy representative attendees who discussed personal stories in the BEFORE decision aid believed that they were important to include as a way of providing hope and to help normalize the experience for patients. Personal stories could be included in the BEFORE decision aid in a variety of formats including videos (for the online version only), hyperlinks to videos, quotes, or as an example of completing the values clarification method. While personal stories were seen as valuable, it was strongly suggested that the team seek out platforms that are already available to avoid extra work and time to complete the decision aid. The attendees expressed the importance of having diverse patients and successful and unsuccessful fertility stories to ensure inclusivity and realistic expectations to the possible outcomes. Additionally, an example of a hypothetical patient completing the method (similar to the Australian decision aid example) was not thought to be helpful and added unnecessary length to the decision aid.

In addition to personal stories, some attendees felt a video on what to expect when attending a fertility appointment and the steps involved with the fertility preservation options would be valuable. However, there was caution expressed that these videos would have to be updated regularly based on the changing evidence. Finally, the attendees discussed creating a “my advice” list on the top 10 pieces of wisdom from breast cancer survivors to young women newly diagnosed with breast cancer or quotes of wisdom to provide support to these young women. Following the meeting survivor attendees were asked to provide quotes on the advice they would give to young cancer patients and these were incorporated throughout the online decision aid.

Implementation and Dissemination: The decision aid was seen as a starting point but not an end point since a discussion with health care providers is still required. There was agreement that a layered approach should be used for dissemination of the BEFORE decision aid following pilot testing in clinical practice. Multiple areas for dissemination were discussed including:

- Curriculum for medical students as well as continuing medical education for health care providers already in practice
- Physician checklists
- General surgery updates or other meetings that would allow for the discussion of the tool
- Directed patient advertising (e.g., on the walls of physician office)
- Flag use of the decision aid in electronic medical records
- Advertise in medical journals
• National dissemination (e.g., providing links to the decision aid through groups such as the Cancer Knowledge Network, Rethink Breast Cancer, Canadian Cancer Society)
• Search engine optimization
• Survivor and health care provider champions
• Determining a host location to reach as many young breast cancer patients as possible (e.g., Canadian Cancer Society, Cancer Knowledge Network, Rethink Breast Cancer, Cancer Care Ontario, Wellsprings)

The online dissemination methods were discussed in detail among attendees. Survivor attendees noted that they received information on fertility online from the Canadian Cancer Society and other platforms, friends, and through their health care providers. An advocacy representative attendee noted that up to half of new connections to their group are from patients finding them online using their mobile phones. There was discussion surrounding the development of a multi-functional app in addition to the paper and online version of the BEFORE decision aid. However, survivor attendees felt that the project should not be delayed to develop the mobile app and that it should be completed as an additional project. Most attendees cautioned against the development of the BEFORE decision aid as solely an online tool as paper can be a useful format to show and discuss fertility with partners or support persons (e.g., older parents). There was agreement among survivor attendees that the format of the decision aid is not as important as the provision of information and that the focus should be on providing fertility information to patients in a timely manner.

Attendees stated that most organizations would require evidence of the BEFORE decision aids efficacy before dissemination, addition into clinical pathways, or hosting. There were challenges noted with hosting a decision aid including continual maintenance and annual costs to an online decision aid. Discussion of the decision aid through meetings, small educational sessions, and at young adult cancer groups was recommended to help educate a wide range of people. Additionally, suggestions were made to market the decision aid to organizations or groups where fertility or patient-centred care for cancer patients is an established part of their mandate.

General discussion
There was discussion surrounding the general appearance and components of the decision aid that were not previously discussed in the break-out groups. There was a recommendation that the decision aid consider fertility concerns after treatment for young women as well as before treatment. The group agreed that while the presentation of information through multiple formats (e.g., charts,
frequently asked questions, and bullets) was best, attendees felt the decision aid should be more user-friendly. Recommendations included having a larger table of contents, using colour coded headers, and including more white space throughout the decision aid. Additionally, attendees felt that too much of the colour pink was used in the decision aid.

The BEFORE decision aid’s background section contained breast cancer and fertility information. Most attendees found the section too long and felt that the chart outlining the impact of each cancer treatment on fertility should be modified with alternate photos and colours. The initial table was organized by standard care path but it was recommended to group treatments with no risk, possible risk, and unknown risk together to clearly illustrate the treatments that may risk fertility (Table 4.8).

<table>
<thead>
<tr>
<th>Table 4.8 Modified background information chart in the BEFORE decision aid</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment and fertility chart – Version 2</strong></td>
</tr>
<tr>
<td><strong>Background</strong></td>
</tr>
<tr>
<td>How will my cancer treatment affect my fertility?</td>
</tr>
<tr>
<td>Breast cancer and your fertility</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Additional information that was seen as important to highlight included: cancer treatment delaying childbearing, the importance of a patient’s age when deciding on the fertility options, and the long duration of some cancer treatments and natural declines in fertility during that time.

The fertility option grid outlining the most common fertility options in Canada was seen to be too dense and recommendations were made to include graphics in the grid. The option grid was therefore reviewed and adjusted to reduce the amount of information and graphics were added where space was available to help with the visual presentation. There were recommendations about the presentation of cost information; since some provinces fund fertility treatment for cancer patients the cost range was modified to $0–$20,000 for embryo freezing, $0–$15,000 for egg freezing, and $0–$500 for ovarian suppression. The parenthood options after cancer treatment were seen as valuable.
to include but survivor attendees highlighted the need for more specific and sensitive information on adoption – adoption can be challenging particularly for someone with a cancer diagnosis and it may not be cost appropriate for everyone. Therefore, the adoption information was modified based on the challenges cancer survivors face when attempting to adopt a child after treatment.

There was consensus among attendees that health care providers should be discussing fertility with patients. The group felt that fertility discussions should occur early in the care journey at patients’ initial consult with their health care provider, and should then be touched on by the multiple health care providers they see during their journey.

**Logo**

Two logo examples were presented at the meeting to allow attendees the opportunity to vote and provide comments (Table 4.9). Both logos showed fertility in an abstract way through the use of plants opposed to common fertility images (e.g., pregnant women or a baby) to avoid biasing any patients’ decisions on the fertility options. However, the general consensus among attendees was that the connotation of plants as it relates to fertility was not apparent in the logos. The logos reminded attendees of the environment and were too green in colour. Additionally, another font style for the text was recommended as the current text reminded attendees of a pharmaceutical advertisement. However, some attendees did like that the logos were not the typical breast cancer pink ribbon but felt they needed to feel more young, fresh, and engaging. Modifications were made based on the feedback and recommendations to create a new logo (Table 4.9).

**Table 4.9 Modified BEFORE decision aid logos**

<table>
<thead>
<tr>
<th>Logo 1</th>
<th>Logo 2</th>
<th>Final Logo</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Logo 1" /></td>
<td><img src="image2" alt="Logo 2" /></td>
<td><img src="image3" alt="Final Logo" /></td>
</tr>
</tbody>
</table>

**4.2.3 Post-meeting evaluations**

**Meeting evaluation**

19 of the 28 attendees (67.9%) completed the evaluation. On a Likert scale of 1 to 7, the mean of all Likert scale responses was greater than six showing that in general participants were satisfied with the meeting (Table 4.10).
Table 4.10 Evaluation results from the engagement meeting

<table>
<thead>
<tr>
<th>Statement</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The goals and objectives of the meeting were clear</td>
<td>6.24</td>
</tr>
<tr>
<td>2. The meeting was well organized</td>
<td>6.82</td>
</tr>
<tr>
<td>3. Length of meeting was appropriate</td>
<td>6.59</td>
</tr>
<tr>
<td>4. Presentations contributed to my understanding</td>
<td>6.53</td>
</tr>
<tr>
<td>5. Break-out activities were well prepared and encouraged collaboration</td>
<td>6.53</td>
</tr>
<tr>
<td>6. Full group discussion generated useful ideas</td>
<td>6.59</td>
</tr>
<tr>
<td>7. I had adequate opportunity to express my thoughts relative to the topics discussed</td>
<td>6.12</td>
</tr>
<tr>
<td>8. I felt heard and able to contribute</td>
<td>6.18</td>
</tr>
<tr>
<td>9. The meeting stimulated participation and interaction among health care providers, advocacy groups, and survivors</td>
<td>6.76</td>
</tr>
<tr>
<td>10. Overall satisfaction</td>
<td>6.47</td>
</tr>
</tbody>
</table>

Some attendees made recommendations for future meetings including separating health care provider and survivor attendees into different groups as they felt both brought distinctive perspectives that may be competing. Additionally, attendees felt that inclusivity should have been addressed at the beginning of the meeting. However, most participants valued the inclusion of an array of stakeholders and thought it was useful to work together to hear ideas and opinions from various groups (e.g., survivors and health care providers). The aspects of the meeting that attendees liked the most included hearing survivors, the engaging discussion, networking and meeting various attendees, and the opportunity to come together as a large group to give important feedback on an issue impacting many young women.

BEFORE decision aid post-meeting review

The revised decision aid was sent to expert reviewers and meeting attendees to determine if the modifications reflected the discussion from the meeting. All attendees felt the modifications reflected the day’s discussion. There were minor modifications to the content and wording of some components of the decision aid. Additionally, fertility specialists approved the content pertaining to the fertility options success rates and risks and other fertility-related information. Minor changes were made to the document based on feedback from this review. All changes were approved and accepted by the expert reviewers and meeting attendees. The BEFORE decision aid was then designed by a graphic designer and web developer from Off to Market Inc. (www.offtomarket.ca) in Toronto, Ontario. The design concept was discussed with the graphic and web designers to ensure they were in line with plain language and the Accessibility for Ontarians with Disabilities Act (AODA) requirements, the IPDAS criteria, and feedback from stakeholders gathered throughout the development process.
Health literacy assessment

Using the Flesch-Kincaid Grade Level the BEFORE decision aid was assessed multiple times during development between a sixth to eighth grade level. The grade level is in line with the IPDAS criteria that require decision aids be below an eighth grade reading level. Using the SAM assessment the BEFORE decision aid scored 35 points out of a possible 42 points (Table 4.11).

Table 4.11 SAM assessment score of the BEFORE decision aid

<table>
<thead>
<tr>
<th>SAM Dimension</th>
<th>Superior (+2)</th>
<th>Adequate (+1)</th>
<th>Not Suitable (0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Content topics</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary and review</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Reading grade level</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Writing style</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sentence construction</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Vocabulary</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Road signs</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Graphic</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Type of illustration</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Relevance of illustration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graphic: charts</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graphics: caption</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Layout and typography</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Layout</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subheading and chunking</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Learning simulation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Desired behaviour</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Motivation</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Culturally appropriateness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cultural images</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>30</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

NA – not applicable, SAM – Suitability Assessment of Materials

IPDAS criteria assessment

The BEFORE decision aid was assessed against the criteria by the IPDAS (Table 4.12). In general, most of the IPDAS criteria were met.

Table 4.12 BEFORE decision aid evaluated against IPDAS criteria

<table>
<thead>
<tr>
<th>IPDAS Criteria Checklist</th>
<th>Yes</th>
<th>No</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide information about options in sufficient detail for decision making?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA describe the health condition?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA list the options?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA list the options of doing nothing?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA describe the natural course without options?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA describe procedures?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA describe positive features [benefits]?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA describe negative features of options [harms/side effects/disadvantages]?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA include the chances of positive/negative outcomes?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDS describe what test is designed to measure?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Continue on following page)
Table 4.12 BEFORE decision aid evaluated against IPDAS criteria (Continued)

<table>
<thead>
<tr>
<th>IPDAS Criteria Checklist</th>
<th>Yes</th>
<th>No</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Provide information about options in sufficient detail for decision making?</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA include chances of true positive, true negative, false positive, false negative test results?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA describe possible next steps based on test result?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA include chances the disease is found with/without screening?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA describe detection/treatment that would never have caused problems if one was not screened?</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td><strong>Present probabilities of outcomes in an unbiased and understandable way?</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA use event rates specifying the population and time period?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA compare outcome probabilities using the same denominator?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA compare outcome probabilities using the time period?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA compare outcome probabilities using the scale?</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Does the PDA describe uncertainty around probabilities [words, numbers, diagrams]?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA allow the patient to select a way of viewing probabilities based on their own situation [i.e. age]?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA place probabilities in context of other events?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA use both positive and negative frames [i.e. showing both survival and death rates]?</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td><strong>Include methods for clarifying and expressing patients’ values?</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA describe the procedures and outcomes to help patients imagine what it is like to experience their physical, emotional and social effects?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA ask patients to consider which positive and negative features matter most?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA suggest ways for patients to share what matters most with others?</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td><strong>Include structured guidance in deliberation and communication?</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA provide steps to make a decision?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA include tools [worksheet, question list] to discuss options with others?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Part 2 - Development Process</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Present information in a balanced manner?</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the PDA able to compare positive/negative features of options?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA show negative/positive features with equal details [fonts, order, display if statistics]?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Have a systematic development process?</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA include developers’ credentials/qualifications?</td>
<td>✓ online</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA find out what patients, practitioners need to discuss options?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA have a peer review by patient/professional experts not in the development and field testing?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has the PDA been field tested with users patients facing the decision?</td>
<td>TBD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has the PDA been field tested with practitioners presenting options?</td>
<td>TBD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The field tests with patients, practitioners show the PDA is acceptable?</td>
<td>TBD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The field tests with patients, practitioners show the PDA is balanced for undecided patients?</td>
<td>TBD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The field tests with patients, practitioners show the PDA is understood by those with limited reading skills?</td>
<td>TBD</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Continue on following page)
Table 4.12 BEFORE decision aid evaluated against IPDAS criteria (Continued)

<table>
<thead>
<tr>
<th>IPDAS Criteria Checklist</th>
<th>Yes</th>
<th>No</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use up to date scientific evidence that is cited in a reference section or technical document?</strong></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA provide references to evidence used?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA report steps to find, appraise, summarize evidence?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA report date of last update?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA report how often PDA is updated?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA describe quality of scientific evidence [including lack of evidence]?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA use evidence from studies of patients similar to those of target audience?</td>
<td>✓ where possible</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Disclose conflicts of interest?**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the PDA report source of funding to develop and distribute the PDA?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA report whether authors or their affiliations stand to gain or lose by choices patients make after using the PDA?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Use plain language?**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the PDA written at a level that can be understood by the majority of patients in the target group?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the PDA written at a grade 8 or equivalent level or less according to readability score [SMOG or FRY]?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA provide ways to help patients understand information other than reading [audio, video, in-person discussion]?</td>
<td>✓ in person discussion</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Meet additional criteria if the PDA is internet based?**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the PDA provide a step-by-step way to move through the web pages?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA allow patients to search for key words?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA provide feedback on personal health information that is entered into the PDA?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA provide security for personal health information entered into the PDA?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA make it easy for patients to return to the decision aid after linking to other web pages?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA permit printing as a single document?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Meet additional criteria if stories are used in the PDA?**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the PDA use stories that represent a range of positive and negative experiences?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA report if there was a financial or other reason why patients decided to share their story?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PDA state in an accessible document that the patient gave informed consent to use their stories?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Part 3 - Effectiveness**

**Decision process leading to decision quality...**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>The PDA helps patients to recognize a decision needs to be made?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The PDA helps patients to know options and their features?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The PDA helps patients to understand that values affect decision?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The PDA helps patients to be clear about option features that matter most?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The PDA helps patients to discuss values with their practitioner?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The PDA helps patients to become involved in preferred ways?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PDA – patient decision aid, TBD – to be determined, IPDAS – International Patient Decision Aid Standards
4.3 Strengths and limitations

The development process of the BEFORE decision aid had some strengths and limitations. We aimed to present the chances of pregnancy after treatment separated by age for the most common fertility options presented in the decision aid. This inclusion sets the BEFORE decision aid apart from existing decision aids in Australia and the Netherlands, that have not presented personalized chances of pregnancy or live births after treatment by age.\textsuperscript{64,65} Since patients age at the time of diagnosis and age when completed treatment is a key factor that impacts the ability to have a child post-treatment, it was identified by stakeholders as a necessary personalized component of the BEFORE decision aid. However, there is limited research available on the pregnancy rates of cancer patients after treatment broken down by age. The ability to become pregnant after treatment also varies for each patient based on their ovarian reserve prior to treatment, ovarian reserve after treatment, and the type and total dose of chemotherapy received. Therefore, the chance of pregnancy following wait and see was calculated using fertility rates over the course of one year in the population taking into consideration the risk of permanent amenorrhea by age for common chemotherapy agents as outlined by the ASCO guidelines.\textsuperscript{24} The chances of pregnancy for embryo freezing were presented per embryo transfer using averaged pregnancy rates presented by the Canadian Fertility & Andrology Society and expert opinion.\textsuperscript{163} This averaged data is not specific to breast cancer patients who are seeking fertility preservation due to treatment-related infertility concerns; it is based on the women who are undergoing fertility preservation due to existing infertility problems. However, this data was the most comprehensive available and experts confirmed it should be used along with expert opinion to confirm and modify the chance of pregnancy per embryo transfer for each age range (e.g., pregnancy rates for women under the age of 30 were modified to 50\% per embryo transfer based on consensus expert opinion). Finally, limited research exists on pregnancy rates following the administration of ovarian suppression in young cancer patients. Therefore, chances of period resumption following chemotherapy was used as a substitute based on a meta-analysis by Lambertini \textit{et al.}\textsuperscript{166} Additionally, limited data is available in the Canadian population for pregnancy rates using egg freezing as it is a newer technique. Expert opinion was used to determine that egg freezing is slightly less successful than embryo freezing due to fewer eggs successfully surviving the freezing and fertilization process. Egg freezing is not presented as icon arrays in the decision aid due to the limited Canadian data. As a substitute, patients are provided with a link to a calculator based on an individual patient meta-analysis by Cil \textit{et al.},\textsuperscript{164} that estimates the chances of a live birth following egg freezing taking into consideration the
patient’s age, number of eggs collected, and number of embryos created. Due to the variability in the messaging and scales (e.g., chances of pregnancy for wait and see and embryo freezing and period resumption for ovarian suppression) each fertility option was presented in a separate table with highlighted disclaimers on the uncertainty in the information and available evidence. Comprehensibility testing was completed with patients during alpha testing and will be continued during pilot testing to ensure the messaging and presentation of outcomes for each fertility option are clear.

The meeting was strengthened by the representation from a multitude of stakeholders and the use of break-out groups to compliment the larger group discussion. However, multiple attendees provided their regrets the morning of the meeting and as such there was no representation from general practitioners and limited representation from national cancer organizations. These individuals were therefore sought out to provide insights at other stages of the development and through alpha testing (described in Chapter 5).

Additionally, three of the IPDAS criteria were not met from the decision aid development. In particular for the online decision aid a search bar was not added due to budgetary constraints and recognition that if the decision aid is hosted on an organizational webpage following development they may have their own process for searching. Additionally, no feedback on personalized health information is provided in the online BEFORE decision aid. When patients complete the values clarification method their responses are summarized on a summary page for them to print and bring to their consultations but no personalized health information is requested from patients. Finally, the scale for each of the presented fertility options is not the same as previously mentioned.

4.4 Summary
The vast amount of feedback from the engagement meeting and post-meeting reviews shaped the design and content included in the BEFORE decision aid. The design aimed to contain inclusive images of women, a range of colours, and ample white space. Due to the layout and addition of white space, the paper BEFORE decision aid (Version 5) was 31 pages in length. Consultations with the patient education specialist and design team were completed to discuss the downfalls of a longer decision aid. All team members reached agreement that it was more important to have a document with material laid out in a user-friendly format that is longer compared to having a smaller, condensed document that appears text heavy with little white space. Therefore, the longer page length was considered the optimal format for the BEFORE decision aid. The length of the decision
aid will be further evaluated in the alpha and pilot testing. The online version was mirrored to the content in the paper version and was developed using a linear design to allow for accessibility on computers and mobile devices. The online version also contains supplementary information including the cost of fertility preservation and funding by province/territory; list of resources and support groups available by province/territory; quiz questions for users to test their knowledge; and full team list. Table 4.13 outlines the paper and online BEFORE decision aid sections, provides descriptions of the sections, rationale for inclusion, and the decision support resources that were adapted to fit the Canadian context.

Table 4.13 BEFORE decision aid components

<table>
<thead>
<tr>
<th>Sections</th>
<th>Description</th>
<th>Reason for inclusion</th>
<th>Decision support resource adapted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background information – breast cancer and fertility</td>
<td>A concise description of breast cancer treatments and how they may impact fertility. Information on how age impacts fertility. Fertility outcomes following treatment including normal fertility, early or premature menopause, or permanent menopause. Also includes frequently asked questions patients have on fertility before cancer treatment.</td>
<td>– Input from end users&lt;br&gt;– DA best practices</td>
<td>– Fertility outcomes from LIVESTRONG brochure&lt;br&gt;– Age decline graph from MyOncofertility and Australian decision aid&lt;br&gt;– FAQ format from MyOncofertility</td>
</tr>
<tr>
<td>Fertility options before treatment</td>
<td>Information on the most common fertility options including wait and see, embryo freezing, egg freezing, and ovarian suppression. Frequently asked questions patients have on fertility options prior to treatment. Option grid of information on the fertility options including what the fertility option involves, availability, cost, funding, time required, success and risks, and other factors to consider. Also includes fertility option success rates presented as icon arrays by age group.</td>
<td>– Input from end users&lt;br&gt;– DA best practices</td>
<td>– Option grid format from Sunnybrook option grids and Australian decision aid&lt;br&gt;– FAQ format from MyOncofertility</td>
</tr>
<tr>
<td>Parenthood options after cancer treatment</td>
<td>Information on the parenthood options after cancer treatment including natural pregnancy, using frozen embryos and eggs, in vitro fertilization, egg donor, surrogacy, and adoption. Also includes frequently asked questions after treatment.</td>
<td>– Input from end users</td>
<td>– LIVESTRONG brochure&lt;br&gt;– Dutch decision aid&lt;br&gt;– Australian decision aid</td>
</tr>
<tr>
<td>Timeline of fertility options</td>
<td>A timeline of the available fertility options at each point of the care journey.</td>
<td>– Input from end users</td>
<td>– NA</td>
</tr>
<tr>
<td>Summary</td>
<td>A summary of the key points identified in the background, fertility options before treatment, parenthood options after treatment, and timeline of fertility options sections.</td>
<td>– Input from end users</td>
<td>– NA</td>
</tr>
</tbody>
</table>

(Continue on following page)
<table>
<thead>
<tr>
<th>Sections</th>
<th>Description</th>
<th>Reason for inclusion</th>
<th>Decision support resource adapted</th>
</tr>
</thead>
</table>
| Fertility options exercise    | Values clarification method for the most common fertility options using a weighted scale and pre-listed values with blank space to include additional values for each option. At the end the patient can select the option they are leaning towards *(if applicable)* and the option that they would like more information on from their health care providers.  

The exercise was designed to help systematically structure and highlight the values that are important or not important to each woman. The purpose was to help women think about the importance of their values and communicate them to others when making a fertility decision to arrive at a decision that is in line with their values.  

181                                                                                                                                               | – Input from end users  

– DA best practices                                                            | – Dutch decision aid |
| Questions                      | A detailed outline of the common health care providers who provide care to young cancer patients. Includes an explanation of each provider’s role in relation to the patients cancer care to help patients determine who the most suitable provider is to contact for each question.  

A list of 10 common questions for patients to ask health care providers on their fertility to initiate fertility discussions with space for patients to include more questions.                                                                 | – Input from end users                                                            | – Dutch decision aid  

– Australian decision aid  

– MyOncofertility  

– LIVESTRONG brochure |
| Resources by province in Canada | List of national resources for patients to access for more information, peer-to-peer support, and financial support. The resources are sources patients can access but they are not endorsed by the team who created the decision aid. | – Input from end users  

– DA best practices (tailored by province/territory)                                      | – Resources outside of Canada from MyOncofertility |
| Life after breast cancer        | A description of how life can change after breast cancer and resources to access more information and support on fertility in survivorship.                                                                 | – Input from end users                                                            | – Australian decision aid |
| List of terms                  | A glossary with definitions of the medical terms used throughout the decision aid.                                                                                                                                 | – Input from end users  

– Plain language best practices                                                                                                                   | – Australian decision aid |
| Sources and recognition        | Description of the team that developed the decision aid, funding information, conflicts of interest, and date of last update. In addition to sources of evidence that were used for the content in the decision aid. | – DA best practices                                                            | – Dutch decision aid |

(Continue on following page)
<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
<th>Reason for inclusion</th>
<th>Decision support resource adapted</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDF download of paper decision aid</td>
<td>On each page of the decision aid, individuals can download the full paper version of the BEFORE decision aid.</td>
<td>– DA best practices</td>
<td>– NA</td>
</tr>
<tr>
<td>Less common and experimental fertility options before treatment</td>
<td>Information presented in a grid format for the less common and experimental fertility options before treatment (in vitro maturation and ovarian tissue banking)</td>
<td>– Input from end users</td>
<td>– Ovarian tissue banking from LIVESTRONG brochure and Australian decision aid</td>
</tr>
<tr>
<td>Cost of fertility options by province/territory</td>
<td>A drop-down chart listing the cost of fertility preservation by province/territory in Canada using information publically available on fertility clinic webpages.</td>
<td>– Input from end users, DA best practices (tailored by province/territory)</td>
<td>– NA</td>
</tr>
<tr>
<td>Resources by province/territory in Canada</td>
<td>A drop-down chart listing the organizations in each Canadian province/territory that provide information, support, and funding to cancer patients. Resources include peer-to-peer support groups, information support and financial support. Patients can access the resources for more information but no resource is endorsed by the developers.</td>
<td>– Input from end users, DA best practices (tailored by province/territory)</td>
<td>– Resources outside of Canada from MyOncofertility</td>
</tr>
<tr>
<td>Test myself questions</td>
<td>Questions that test an individual’s knowledge on the information in the decision aid and knowledge on the next steps after reviewing the decision aid.</td>
<td>– DA best practices, Expert opinion</td>
<td>– NA</td>
</tr>
<tr>
<td>Interactive fertility options exercise and summary page</td>
<td>The information from the values clarification method, summary page, and question list for health care providers is available for individuals to personalize, download, and print. The summary page aims to help facilitate fertility discussions with health care providers and allow for earlier referrals to fertility specialists.</td>
<td>– DA best practices</td>
<td>– Dutch decision aid (modified to a bubble format from the sliding scale used in the Dutch decision aid)</td>
</tr>
<tr>
<td>Quotes integrated throughout the pages</td>
<td>Quotes from breast cancer survivors involved in the study that are pieces of advice or knowledge for young women newly diagnosed with breast cancer.</td>
<td>– Input from end users</td>
<td>– NA</td>
</tr>
<tr>
<td>Full team member list</td>
<td>Formal list and acknowledgements of team members who assisted in the development of the decision aid.</td>
<td>– DA best practices</td>
<td>– Australian decision aid</td>
</tr>
<tr>
<td>Contact page</td>
<td>A page where individuals can provide feedback and ask questions to the developers.</td>
<td>– Input from end users</td>
<td>– Dutch decision aid, MyOncofertility</td>
</tr>
</tbody>
</table>

DA – decision aid, NA – not applicable
Chapter 5
Alpha Testing

This chapter describes the process taken to complete alpha (usability, comprehensibility, and acceptability) testing of the BEFORE decision aid. The goal of the alpha testing was to provide an opportunity for a broader breast cancer survivor and health care provider community to review and evaluate the BEFORE decision aid prior to pilot testing with young women newly diagnosed with breast cancer. The chapter describes the sampling and recruitment process, data collection, modifications to the BEFORE decision aid, and concludes with a discussion on the results, strengths and limitations.

5.1 Methods

5.1.1 Research design
Alpha testing is a component of the development steps outlined by the IPDAS as a way to test the usability, comprehensibility, and acceptability of a decision aid through an iterative process with end users of the tool.\textsuperscript{95} Alpha testing was conducted using a descriptive qualitative approach as described by Sandelowski.\textsuperscript{139,140} This approach was deemed the most appropriate to allow participants to identify and expand on usability, comprehensibility, and acceptability issues and strengths in the paper and online BEFORE decision aid. A focus group and interviews were used as the data collection methods to evaluate the BEFORE decision aid opposed to surveys to allow participants the ability to fully express, elaborate, and explain their opinions, thoughts and feelings.\textsuperscript{144}

5.1.2 Sampling and recruitment
Participants were purposively recruited through convenience sampling.\textsuperscript{150,182} These sampling approaches allowed for the insights of stakeholders who had been previously involved in the study and insights from new stakeholders. Vizri has shown that five participants are able to uncover approximately 80% of the usability problems and with more users the identified problems are reduced and less significant to the usability of the tool.\textsuperscript{183} However, additional research by Faulkner has found the benefit of having more than five participants conduct usability testing; with 10 participants the minimum problems revealed was 80% and with 20 participants this increased to 95%.\textsuperscript{184} Therefore, we aimed to have between 10 and 20 participants complete alpha testing on the BEFORE decision aid. Recruitment occurred from April 2017 to May 2017 with alpha testing occurring concurrently. Following completion of the alpha testing, each participant was provided a $20 gift card through email as an honorarium.
Breast cancer survivor participants
Survivor participants were recruited using three strategies: (1) contacting past participants; (2) online; and (3) at a breast cancer clinic in the GTA. Similar to the eligibility criteria described in Chapter 2, survivor participants were invited to complete alpha testing if they were diagnosed with breast cancer between the ages of 18 and 45, had completed active treatment (surgery, radiation, and chemotherapy but could still be taking hormone therapy), and had treatment with the potential to impact fertility within the past five years. Women who had undergone fertility preservation prior to their breast cancer diagnoses were excluded, as their fertility experiences would be different compared to those who were facing fertility decisions for the first time following their cancer diagnoses. Women were also not approached if they had a breast cancer recurrence or metastatic breast cancer.

Past participants: breast cancer survivors who participated in the decision support resource evaluations (described in Chapter 3) and those who were invited to the November 11, 2016 engagement meeting (described in Chapter 4) and expressed an interest in participating in the study further were contacted to evaluate the BEFORE decision aid. Past survivor participants were contacted through email with the information letter (Appendix M) describing the alpha testing. If they replied with written interest in the study then the alpha testing was arranged. If past survivor participants did not reply a reminder email was sent two weeks after the initial email. If they did not respond after the reminder email, no further attempts for recruitment were made.

Online recruitment: occurred by updating a prior study poster (Appendix E) and posting it at breast cancer survivor support groups and non-for-profit breast cancer groups across Canada, including:

- Canadian Cancer Survivor Network (www.survivornet.ca)
- Cancer Knowledge Network (www.cancerkn.com)
- Gilda’s Club (www.gildasclubtoronto.org)
- Hearth Place Cancer Support Centre (www.hearthplace.org)
- Inspire Health (www.inspirehealth.ca)
- Rethink Breast Cancer (www.rethinkbreastcancer.com)
- Saskatchewan Breast Cancer Connect (www.saskbreastcancerconnect.org)
- Wellsprings (Calgary, Oakville, Brampton, Downtown Toronto) (www.wellspring.ca)
- Young Adult Cancer Canada (www.youngadultcancer.ca)
Online recruitment was used to identify new survivor participants who had not previously participated in the study or provided their insights on the BEFORE decision aid. Interested survivor participants emailed or called the recruiter and were in return sent the information letter (Appendix M) informing them of the study. When they replied with their written consent, the alpha testing was scheduled. If they did not reply, survivor participants were emailed a reminder one week following the last contact date. If they did not respond to the reminder, no further attempts to contact them were made.

**Breast cancer clinic recruitment:** the modified study poster (Appendix E) was posted in a breast cancer clinic at a hospital in the GTA. Breast surgeons identified eligible survivor participants and provided them with a brief description of the study as well as the recruiters contact information. Interested participants contacted the recruiter and the recruiter provided a thorough overview of the study by sending the information letter (Appendix M) and discussing it over the telephone. If they expressed verbal or written interest in the study then the alpha testing was scheduled. If survivor participants did not reply, they were emailed a reminder one week following the last contact date. If they did not respond to the reminder, no further attempts to contact them were made.

**Health care provider participants**

Health care provider participants were recruited through professional networks via email. Health care providers who were interested but unable to attend the November 11, 2016 engagement meeting (described in Chapter 4) were emailed by the recruiter informing them of the alpha testing and providing the information letter (Appendix M). Additional health care providers who were not previously involved with the study were also contacted to complete alpha testing on the BEFORE decision aid. If health care provider participants were interested and provided their written consent then the alpha testing was scheduled. If they did not reply a reminder email was sent two weeks after the initial email. If provider participants did not respond to the reminder, no further attempts to contact them were made.

### 5.1.3 Data collection

Each participant was electronically sent a graphically designed version of the paper decision aid and access information to the online prototype prior to their scheduled interview or focus group. One day prior to the focus group or interview the participants were sent a reminder email that contained the alpha testing time, location, and decision aid. Each participant was asked to provide feedback on the paper and online BEFORE decision aid by answering open-ended questions on the ease of use,
visuals, and presentation of information (Appendix N). Interview guides were developed based on acceptability questions from the OHRI and following usability testing guides in the literature developed to evaluate existing decision aids.\textsuperscript{185,186} Interviews were continued until repetitive information was heard on the usability, comprehensibility, and acceptability issues in the decision aid. New survivor participants also completed an exit survey on their overall satisfaction with the BEFORE decision aid (Appendix O).

**Focus group:** The focus group was held on April 6, 2017 at 250 Yonge Street in a private room after working hours and lasted 70 minutes. An experienced focus group facilitator led the group and a research team member (Tari Little) took extensive notes. The focus group followed an agenda that began with an icebreaker and time to review the decision aids (Appendix P). The survivor participants were then asked open-ended questions on the paper and online BEFORE decision aid prototypes (Appendix N). Survivor participants went through each section of the paper BEFORE decision aid and provided their insights and then moved to the online version and were asked to seek out specific sections and think aloud while navigating to encourage discussion and feedback.

**Telephone interviews:** Telephone interviews were conducted with survivor participants who were not able to make the focus group due to other commitments and health care provider participants in April 2017 and May 2017. Interviews lasted 17 to 40 minutes. Participants did not provide insights on each individual section of the paper and online decision aid due to time constraints, but provided their insights on the sections that they made notes on prior to the interview and answered open-ended questions (Appendix N). Telephone interviews were conducted opposed to in-person interviews to allow for insights from stakeholders outside of the GTA and to accommodate the schedules and preferences of participants. While disadvantages exist when using telephone interviews such as the lack of nonverbal and visual cues captured during in person interviews and shorter interview time,\textsuperscript{145,146} the advantage of having a geographically diverse sample from across Canada was essential for the alpha testing.

**Email exchange:** email exchanges were completed with participants who had attended the engagement meeting (described in Chapter 4). These participants were well informed of the study and provided iterative feedback throughout the BEFORE decision aid prototype development. Participants were sent the paper and online BEFORE decision aid and the open-ended questions to help guide the review and their responses (Appendix N).
5.1.4 Data analysis
Interviews were audio-taped and transcribed to gather quotes that were organized and analyzed using Microsoft Excel software. Audio taping was not completed in the focus group due to technical difficulties with the recorder but extensive notes were taken by the facilitator and note taker as a substitute. Therefore, quotes are only presented from the interviews and email exchanges with participants. Data analysis was an iterative process occurring concurrently with the alpha testing. Based on the data collected, revisions were made to the paper and online BEFORE decision aid. The research team decided on the final changes based on the recurrence of similar recommendations and areas requiring modifications. Each recommendation was carefully considered with the research team to ensure it did not contradict any previous design or content feedback from stakeholders. If any recommendations were contradictory, then the research team engaged with multiple experts to determine the best resolution.

5.1.5 Ethical considerations
Ethics approval to recruit participants and to carry out the alpha testing was obtained from St. Michael’s Hospital (REB 15-220), Sunnybrook Health Sciences Centre (REB 226-2015), and the University of Toronto (Protocol # 32801) (Appendix H).

Basic demographic information from breast cancer survivor participants such as age, year at diagnosis, and time since treatment; and age, location, hospital setting, and specialty type for health care provider participants was kept in a Master Linking Log with participant research numbers and no personal identifying information. The audio files for the interviews were kept on a secure server at St. Michael's Hospital for one year before deleting. Focus group participants were informed that the study team would not share information that revealed their identities but could not guarantee other focus group attendees would not share information. This was agreed on and all participants provided verbal consent to proceed with the focus group.

5.2 Results
Of the 17 health care providers invited to participate in the alpha testing, feedback was provided by seven (41.2%) (six through interviews and one previously involved with the study through email). The health care provider participants ranged in profession and location in Canada and were evenly split between community and academic settings (Table 5.1).
Table 5.1 Health care provider participant characteristics

<table>
<thead>
<tr>
<th>Health Care Providers</th>
<th>Number (n=7)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Health Care Provider</strong></td>
<td></td>
</tr>
<tr>
<td>Medical Oncologists</td>
<td>3 (42.9%)</td>
</tr>
<tr>
<td>Fertility Specialist</td>
<td>1 (14.3%)</td>
</tr>
<tr>
<td>General Practitioners</td>
<td>2 (28.6%)</td>
</tr>
<tr>
<td>Survivorship Expert</td>
<td>1 (14.3%)</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td></td>
</tr>
<tr>
<td>Greater Toronto Area, Ontario</td>
<td>4 (57.1%)</td>
</tr>
<tr>
<td>Ottawa, Ontario</td>
<td>1 (14.3%)</td>
</tr>
<tr>
<td>Victoria, British Columbia</td>
<td>1 (14.3%)</td>
</tr>
<tr>
<td>Montréal, Québec</td>
<td>1 (14.3%)</td>
</tr>
<tr>
<td><strong>Hospital/Work Setting</strong></td>
<td></td>
</tr>
<tr>
<td>Community</td>
<td>3 (42.9%)</td>
</tr>
<tr>
<td>Academic</td>
<td>4 (57.1%)</td>
</tr>
</tbody>
</table>

Among the 18 survivors invited to participate in the alpha testing, 10 provided feedback (55.6%) (three in the focus group; three through interviews; and four previously involved in the study through email). Most of the survivor participants did not have children prior to their diagnosis and were married or in long-term relationships. The survivor participants varied in self-identified ethnicity and race and most were treated for their cancer in the GTA.

Table 5.2 Breast cancer survivor participant characteristics

<table>
<thead>
<tr>
<th>Breast Cancer Survivors</th>
<th>Number (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Children Prior to Diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3 (30.0%)</td>
</tr>
<tr>
<td>No</td>
<td>6 (60.0%)</td>
</tr>
<tr>
<td>Unknown (did not provide answer)</td>
<td>1 (10.0%)</td>
</tr>
<tr>
<td><strong>Relationship Status at Diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>4 (40.0%)</td>
</tr>
<tr>
<td>Long-Term Relationship</td>
<td>3 (30.0%)</td>
</tr>
<tr>
<td>Single</td>
<td>2 (20.0%)</td>
</tr>
<tr>
<td>Unknown (did not provide answer)</td>
<td>1 (10.0%)</td>
</tr>
<tr>
<td><strong>Self-Identified Ethnicity/ Race</strong></td>
<td></td>
</tr>
<tr>
<td>Filipino</td>
<td>1 (10.0%)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1 (10.0%)</td>
</tr>
<tr>
<td>East Indian</td>
<td>1 (10.0%)</td>
</tr>
<tr>
<td>Caucasian</td>
<td>2 (20.0%)</td>
</tr>
<tr>
<td>Persian/Iranian</td>
<td>1 (10.0%)</td>
</tr>
<tr>
<td>African Canadian</td>
<td>1 (10.0%)</td>
</tr>
<tr>
<td>Chinese/Portuguese</td>
<td>1 (10.0%)</td>
</tr>
<tr>
<td>Unknown (did not provide answer)</td>
<td>2 (20.0%)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>Some College or Post High School Training</td>
<td>2 (20.0%)</td>
</tr>
<tr>
<td>Post-Secondary</td>
<td>1 (10.0%)</td>
</tr>
<tr>
<td>Graduate Studies/Professional Degree</td>
<td>5 (50.0%)</td>
</tr>
<tr>
<td>Unknown (did not provide answer)</td>
<td>2 (20.0%)</td>
</tr>
<tr>
<td><strong>Treatment Location</strong></td>
<td></td>
</tr>
<tr>
<td>Greater Toronto Area, Ontario</td>
<td>8 (80.0%)</td>
</tr>
<tr>
<td>Vancouver, British Columbia</td>
<td>2 (20.0%)</td>
</tr>
<tr>
<td><strong>Age at Diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>Age Range</td>
<td>21 to 43</td>
</tr>
<tr>
<td><strong>Time Since Diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>Year Range</td>
<td>1 to 4</td>
</tr>
</tbody>
</table>
5.2.1 Identified alpha testing issues and modifications

The areas identified by participants that should be modified were categorized into four areas of focus: (1) layout and graphics; (2) comprehensibility and acceptability of information; (3) usability; and (4) use and delivery in clinical practice. The perspectives from breast cancer survivor participants and health care provider participants are presented together.

(1) Layout and graphics

Modifiable areas

Table 5.3 outlines the main modifiable layout and graphics issues in the BEFORE decision aid identified by participants.

Table 5.3 Modifiable issues identified on the layout and graphics in the paper and online BEFORE decision aid

<table>
<thead>
<tr>
<th>Aspect of the decision aid</th>
<th>Example of participants’ comments prompting change</th>
<th>Modifications made</th>
<th>Example screenshot of modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper decision aid</td>
<td>The survivors were provided with two graphically different versions of the decision aid. Version 1 (V1) separated out each topic in the decision aid with images and Version 2 (V2) grouped the topics into different sections.</td>
<td>Selected V2, kept the original V2 table of contents, and modified each section break within the decision aid to include the information that is presented in each section.</td>
<td>BEFORE V1</td>
</tr>
<tr>
<td></td>
<td>Preferred V1 due to the labelling of the topics clearly throughout the decision aid but felt V2 would be the better choice if it was labelled (FG, Survivors 01, 02, 03)</td>
<td></td>
<td>BEFORE V2</td>
</tr>
<tr>
<td></td>
<td>[on V2] “The colours are calmer and are separate – in the first one [V1] there are so many colours it just makes you dizzy, especially at that point when everything is spinning in your head you don’t want to look at that many visual things…” (Interview, Survivor 05)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Continue on following page)
Table 5.3 Modifiable issues identified on the layout and graphics in the paper and online BEFORE decision aid  (Continued)

<table>
<thead>
<tr>
<th>Aspect of the decision aid</th>
<th>Example of participants’ comments prompting change</th>
<th>Modifications made</th>
<th>Example screenshot of modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Paper decision aid</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Photos used to break up the sections</td>
<td>In regards to family types, I don’t believe I saw couples. If couple are included, perhaps consider including both oppose sex relationships and same-sex relationships. (Email, Survivor 07)</td>
<td>Changed two photos that were identified as possibly triggering photos of people smiling or laughing to a same-sex and oppose sex couple.</td>
<td><img src="before1.png" alt="BEFORE" /> <img src="after1.png" alt="AFTER" /></td>
</tr>
<tr>
<td>“I thought they were great, the patients look very healthy…they are looking very very happy…” (Interview, HCP 01)</td>
<td><img src="before2.png" alt="BEFORE" /> <img src="after2.png" alt="AFTER" /></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“…they all look very happy to me but it is multi-cultural. I just felt that this is often not a topic that women smile about, they are terrified about this…” (Interview, HCP 03)</td>
<td><img src="before3.png" alt="BEFORE" /> <img src="after3.png" alt="AFTER" /></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Graph on fertility decline with chemotherapy in the background information</strong></td>
<td>For the paper version there were suggestions to increase the size of the graph showing the decline in fertility (FG, Survivors 01, 02, 03) As for the graph, it looks like the chance for fertility by age 37 is absolutely zero and that is definitely not true so I don’t think it’s acceptable in its current format. I’ve had several patients get pregnant after chemo in their late 30’s or even very early 40’s. (Email, HCP 06)</td>
<td>Modified the graph to a larger size and changed the location based on modifications to the content recommended by participants. Removed the decline in fertility after chemotherapy line so the graph only visually presents the natural declines in fertility as a person ages.</td>
<td><img src="before4.png" alt="BEFORE" /> <img src="after4.png" alt="AFTER" /></td>
</tr>
</tbody>
</table>

(Continue on following page)
Table 5.3 Modifiable issues identified on the layout and graphics in the paper and online BEFORE decision aid (Continued)

<table>
<thead>
<tr>
<th>Aspect of the decision aid</th>
<th>Example of participants’ comments prompting change</th>
<th>Modifications made</th>
<th>Example screenshot of modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Online decision aid</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Myself Questions</td>
<td>…feedback sentences on quiz page should be a different colour than the answers (Email, Survivor 07)</td>
<td>Highlighted the correct answer for the questions</td>
<td><img src="BEFORE_AFTER.png" alt="Bildvorlage" /></td>
</tr>
<tr>
<td>Resources</td>
<td>Emphasize the National drop-down menu in the drop-down table of resources. People go straight to their province and do not realize that there are additional resources in the National section (FG, Survivors 01, 02, 03)</td>
<td>Darkened the colour of the national drop-down table row and separated it from the list to emphasize the row.</td>
<td><img src="BEFORE_AFTER.png" alt="Bildvorlage" /></td>
</tr>
</tbody>
</table>

FG– focus group, HCP– health care provider
Non-modifiable layout and graphic areas

While most of the layout and graphic concerns were modified as outlined in Table 5.3, there were areas that could not be modified due to design constraints and previous stakeholder consensus. For example, there was a recommendation by the focus group participants to follow the same colour scheme for the online and paper version. However, the online version is designed to organize the sections (e.g., “BEFORE decision aid,” “Fertility after Cancer,” and “Sources”) by colour. It was advised by the web designer that organization would be compromised if each page in the “BEFORE decision aid” section had a different colour. Therefore, the colour scheme for the online version was not altered. A health care provider participant also recommended the removal of the graph showing the natural decline in fertility as a person ages perceiving it as too challenging for patients to process. However, this graph was approved for inclusion by stakeholders at the engagement meeting (described in Chapter 4) for those who are visual learners and can facilitate gist processing.

Therefore, it was agreed by the research team to keep the graph in the decision aid. The focus group participants also recommended the paper version be reformatted into a booklet but due to the amount of information and budgetary constraints to complete a redesign, this modification was not possible but noted for future revisions. Additionally, while the drop-down box feature in the online version was seen as useful to avoid an overwhelming amount of information, participants preferred how the paper version used boxes to break up the frequently asked questions (FAQs) (Table 5.4). However, the design concept for the online version was a linear format to be compatible with mobile phones and compliant with the AODA. As such, the formatting of the paper FAQs could not be mirrored in the online version.

<table>
<thead>
<tr>
<th>Table 5.4 Comparison of frequently asked question section in the paper and online decision aid</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Paper decision aid</strong></td>
</tr>
<tr>
<td><strong>Background</strong></td>
</tr>
<tr>
<td>How will I know if we are still able to get pregnant when I finish chemotherapy and hormone therapy?</td>
</tr>
</tbody>
</table>
Similarly, the timeline of fertility options in the paper version used colour and a visual to show the fertility options at each point in the care journey. However, due to the established online design and AODA compliance it was not feasible to mirror formatting in the paper and online versions for the timeline (Table 5.5).

Table 5.5 Comparison of timeline section in the paper and online decision aid

<table>
<thead>
<tr>
<th>Paper decision aid</th>
<th>Online decision aid</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Length and photo selection</strong></td>
<td><strong>Timeline of your fertility options</strong></td>
</tr>
<tr>
<td>In general, participants found the length of the decision aid appropriate and even those who expressed it may be too long recognized all the information included was important and the preferred amount of information will vary for each person.</td>
<td>The fertility options available to you depend on when you choose to see your fertility provider.</td>
</tr>
<tr>
<td>“No I don’t think it is too long...I think it is quite good.” (Interview, HCP 03)</td>
<td><strong>1. Before treatment options</strong></td>
</tr>
</tbody>
</table>
| “You would think it’s long but when a person wants answers and you want to read certain things a couple of times to make sense to you... I was like reading it actually and I am not a reader...” (Interview, Survivor 05) | – Fertility options
   - Eggs freezing
   - Egg donation
   - Frozen embryos

“...while I think shorter would be better you guys have a lot of great information here and I would hate to see it cut out completely because people might peruse it or want more information and it would be right there...it will depend on the patient right some will want to be really involved and other will be like overwhelmed right...so it just depends.” (Interview, Survivor 04) |
| Additionally, there was diversity in opinions between participants on the photos. Most participants acknowledged that the photos were diverse and inclusive. Modifications were made to the photos of women laughing to be sensitive to the emotional challenges associated with fertility decision-making. However, it was also noted by survivors that while the photos did not resemble people |  |
going through cancer treatment, they felt that this was acceptable as images of women during cancer treatment may be emotionally triggering and cause patients to discontinue reading the decision aid. Therefore, no images of women going through treatment were included.

“I thought it was good that it was very inclusive, it showed different types of women and I thought that was really important and it really just gave a lot of examples…” (Interview, Survivor 06)

You don’t want to see sad things you don’t want to see everyone is going through misery…it was kinda just like women of different ethnicity just doing regular life…so it could be anybody so it was peaceful in a way it didn’t make me emotional like staring at a photo being like oh wow what is this photo.” (Interview, Survivor 05)

Overall, participants approved the layout and graphics in the decision aid and felt that the information was organized.

“…very informative, very organized so whatever your concern is you can go to that section and read about it and it answered questions I didn’t know I had to ask like it covered almost everything…” (Interview, Survivor 05)

“You have lots of graphics and charts where you can which is great…I think it is laid out really nicely.” (Interview, HCP 02)

(2) Comprehensibility and acceptability of information

Modifiable areas

While the information in the BEFORE decision aid was confirmed by multiple stakeholders throughout development, new participants provided insights that resulted in valuable modifications to wording and content in the decision aid (Table 5.6).

Table 5.6 Modifiable issues identified by participants on the information in the BEFORE decision aid

<table>
<thead>
<tr>
<th>Aspect of the decision aid</th>
<th>Example of participants’ comments prompting change</th>
<th>Modifications made</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper and online decision aid</td>
<td>Resources</td>
<td>Remove some funding resources (e.g., Canadian Breast Cancer Support Fund) since they only provide funding for prosthetic bras and not fertility preservation (Email, Cancer Organization Representatives)</td>
</tr>
<tr>
<td></td>
<td>“The Canadian Breast Cancer Society is now part of the Canadian Cancer Society … somewhere just capturing the nature of peer to peer support…If you don’t mention the peer to peer support you are missing the flavor of what the Canadian Cancer Society does.” (Interview, HCP 04)</td>
<td>Modified the listed resources to account for the merger of the Canadian Breast Cancer Foundation and Canadian Cancer Society and included peer to peer support as a key resource provided by the Canadian Cancer Society.</td>
</tr>
</tbody>
</table>

(Continue on following page)
Table 5.6 Modifiable issues identified by participants on the information in the BEFORE decision aid (Continued)

<table>
<thead>
<tr>
<th>Aspect of the decision aid</th>
<th>Example of participants’ comments prompting change</th>
<th>Modifications made with example screenshots</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health literacy level</td>
<td>“I think it is very comprehensive, it is a very much needed resource so I commend your group on doing this. I think it is really really valuable. I find it is maybe a little bit too complex. I think it could be simplified a little bit...I think the language is written at too high a level.” (Interview, HCP 02)</td>
<td>The decision aid was reviewed by the research team and patient education specialist again to modify any words or phrases that were not in lay language (e.g., “per embryo transfer” was modified to “each time embryos are put into the womb”).</td>
</tr>
<tr>
<td>Success rates tables icon array</td>
<td>“…found that tables a little bit overwhelming but also felt it was overwhelming information that needs to be discussed upfront because there are all kinds of different probabilities.” (Survivor, 06)</td>
<td>The tables were adjusted to breakout each fertility option in a separate table by age opposed to presenting the fertility options with each other. Fertility experts also confirmed all statistics again. Additionally, the age groups were broken down further and important disclaimers on the sources of data were highlighted.</td>
</tr>
<tr>
<td></td>
<td>“…I find I am a bit confused. And if I am confused I would think someone else is confused... it looks like in fact if you freeze your embryos you have more chance of getting pregnant by waiting and seeing than embryo freezing because that is what it looks like when you have them juxtaposed...” (Interview, HCP 04)</td>
<td></td>
</tr>
</tbody>
</table>
Table 5.6 Modifiable issues identified by participants on the information in the BEFORE decision aid (Continued)

<table>
<thead>
<tr>
<th>Aspect of the decision aid</th>
<th>Example of participants’ comments prompting change</th>
<th>Modifications made with example screenshots</th>
</tr>
</thead>
<tbody>
<tr>
<td>Online decision aid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Myself Questions</td>
<td>...I might add a couple more [questions] and ask some specific questions to make sure that the women understand. The correct/incorrect answers will give the health care team and indication of what they need to explain further/if this woman is ready to make a decision. (Email, Expert Content Reviewer)</td>
<td>The test myself questions were modified and confirmed by the expert reviewer. The questions were directed to ask about the challenging information contained in the decision aid such as age related fertility decline and chances of pregnancy for the fertility options.</td>
</tr>
</tbody>
</table>

HCP – health care provider

Amount of sourced information

In general, participants thought there was the right amount of information in the BEFORE decision aid. However, some participants noted that information was repetitive on some topics such as fertility decline with age but recognized it was important information to consider for each fertility option. Participants also valued the reference list so they could determine the sources of information. The amount of information presented was also beneficial as some participants learned new information and were better able to understand their health care provider’s recommendations given to them at a time when there was an abundance of information.

“I think there was probably just the right amount...I thought that it was a little bit repetitive just in terms of like I think I remember reading several times that your eggs naturally decrease as you get older and you have less and I think that comes up through several of the fertility options but that applies to each of them.” (Interview, Survivor 04)

“Some of the wording at the beginning was maybe a little bit repetitive but that’s ok, it is ok to repeat some of the information.” (Interview, HCP 01)

“...realized now why my fertility specialist was recommending an embryo so much. At the time it didn’t make sense but after reading the decision aid it just clicked...” (Interview, Survivor 05)

Health literacy level

While the content in the decision aid was viewed by one health care provider participant as too high level, most participants felt that it would be easy for patients to read and use.

“I thought it was really easy to read for the lay person. I actually liked the layout, I thought it was easy to read, I thought there wasn’t too much information on a page. It looked quite good to me to be honest overall.” (Interview, HCP 03)
“I like that it was very informative, very simple, like for someone like me you know just understanding, it was sectioned, it was explained over and over again to let it sink into you somehow and again you guys didn’t point out one thing or favour one thing you kinda gave everything its own respect…” (Interview, Survivor 05)

After the modifications, the decision aid was reviewed to ensure it was written in lay language. Participants also provided minor content and wording modifications to most sections of the BEFORE decision aid that were incorporated into the final version to help with the clarity and comprehensibility of the information. For example, it was recommended by a survivor to include a specific bullet on ‘age when you try to get pregnant’ as an important factor that may contribute to infertility after treatment since it was discussed in the decision aid.

Balance of information
While most participants thought that the information was balanced between the fertility options, one survivor participant noted that it seemed slanted to embryo freezing because it is the more successful option. However, since her opinion was based on the success of the option itself and not the presentation of information it was not modified in the decision aid. Additionally, one health care provider participant who had gone through the process of adopting a child felt the wording on adoption was negative; leading her to think it would result in favouring of the other fertility preservation options. The wording for adoption was modified to reflect these insights.

“I didn’t find it slanted towards any options…in my opinion it was a good way to present all of the options...” (Interview, Survivor 06)

“…I thought it was pretty balanced. I think you did a good job with that.” (Interview, HCP 02)

“It seemed a little bit slanted towards embryo freezing I think because it is more successful that the others...” (Interview, Survivor 04)

“... I am just going to flag the adoption thing...I have an adopted daughter so maybe this is me being a little sensitive...to me while that is true [information on adoption]...it seems a little biased toward expensive infertility options over adoption. You could say, frankly if you are doing a public adoption it is not expensive, private adoptions are expensive.” (Interview, HCP 04)

Non-modifiable information
Information was identified by participants that could not be modified due to previous consensus feedback from stakeholders and best practices for decision aid development. First, two health care provider participants did not believe the explicit values clarification method would help women
make fertility decisions. However, following best practices for decision aid development and consensus agreement from stakeholders at the engagement meeting (described in Chapter 4), the team decided to keep the explicit values clarification method in the BEFORE decision aid. Second, there was a suggestion to include the specific fertility tests that fertility specialists complete to help patients measure ovarian reserve (e.g. anti-mullerian hormone (AMH) testing, follicle-stimulating hormone (FSH) testing, antral follicle count (AFC) testing). Due to the complexity of the tests and multiple test options, these test names were not included in the BEFORE decision aid. The section does still encourage patients to speak with their fertility specialists about the available tests to measure the amount of eggs in their ovaries. Finally, it was suggested to modify the table that outlines the treatment that can impact fertility in the background section of the decision aid. A health care provider participant thought hormone therapy should not be grouped with chemotherapy since hormone therapy itself does not impact fertility but because women are on it for a long duration their natural fertility declines. However, this concern was not raised by any other participant in iterative reviews or through the alpha testing, and stakeholders at the engagement meeting recommended the grouping. Due to these factors, the table was not modified.

(3) Usability

Usability concerns were identified and surrounded the functionality and navigation of the online decision aid. Similar areas to modify were addressed by participants as outlined in Table 5.7.

**Computer vs. mobile phone usability**

Most participants accessed the online decision aid using their computer. Only two survivor participants access the decision aid using their phone. Those that used their phones to access the BEFORE decision aid were able to easily navigate through using the section menu. However, those who accessed the BEFORE decision aid using their computers had navigation challenges as they did not notice the section menu or blue navigation buttons at the top of the page. Most participants navigated through the decision aid using the “Next” button at the bottom of each page.

[referring to the section menu when accessed using a phone] “...right away and you see it in the right corner and you click on, then it was scrolling down and you could read everything nicely and click on the questions. It wasn’t taking a lot of space you could open every individual thing you wanted to see which was great.” (Interview, Survivor 05)

[accessed through a computer] “...yeah I think it was pretty easy to navigate...they blended into each other because I just kept hitting next at the bottom.” (Interview, Survivor 04)
Table 5.7 Modifiable usability issues identified by participants for the online BEFORE decision aid

<table>
<thead>
<tr>
<th>Aspect of the decision aid</th>
<th>Example of participants’ comments prompting change</th>
<th>Modifications made</th>
<th>Example screenshot of modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Online decision aid</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Navigation buttons</td>
<td>The blue buttons at the top of the decision aid where patients could download the paper decision aid and access the values clarification method were not noticed until specifically directed to the buttons. (FG, Survivors 01, 02, 03)</td>
<td>Modified the navigation buttons to be more apparent for users.</td>
<td><img src="BEFORE.png" alt="Before" /> <img src="AFTER.png" alt="After" /> Navigation Buttons</td>
</tr>
<tr>
<td></td>
<td>“I don’t know if care kit is the right term for it …maybe a decision checklist or something. It is not a kit to help me actually move forward with my treatment.” (Interview, Survivor 04)</td>
<td>Changed the title of “Care Kit” to “Fertility Options Exercise” throughout the decision aid to be more reflective of the content.</td>
<td><img src="BEFORE.png" alt="Before" /> <img src="AFTER.png" alt="After" /></td>
</tr>
<tr>
<td>Section Menu</td>
<td>Section menu was not apparent for users accessing the decision aid through a computer without specific direction to the location. (FG, Survivors 01, 02, 03) [referring to the section menu] “…no I didn’t actually…I am just noticing that now.” (Survivor, 04)</td>
<td>Moved the section menu to the left of the screen so it is visually apparent to the user before they start to read and made the colour darker to contrast against the background.</td>
<td><img src="BEFORE.png" alt="Before" /> <img src="AFTER.png" alt="After" /> Section Menu</td>
</tr>
</tbody>
</table>

(Continue on following page)
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Online decision aid</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Next button</td>
<td>The “Next” button at the bottom of the page was hard to see due to the similarities in colour against the background (FG, Survivor 01, 02, 03)</td>
<td>Changed the “Next” button colour so that it contrasts against the background of the decision aid.</td>
<td><img src="before.png" alt="Before" /> <img src="after.png" alt="After" /></td>
</tr>
<tr>
<td>Hyperlinks to additional information</td>
<td>Emphasize the hyperlinks to access more information (e.g., “less common and experimental fertility options” and “Cost of fertility preservation page.”) (FG, Survivor 01, 02, 03)</td>
<td>Emphasized the hyperlinks that lead to more information in the body of text so users know more information is available.</td>
<td><img src="before.png" alt="Before" /> <img src="after.png" alt="After" /></td>
</tr>
</tbody>
</table>

“...on the first page it talks about the customized care kit, I clicked it and then you get to go through the exercise before you read the material, which is ok, but then I went back and read the material and was like oh I already kinda saw this…” (Interview, Survivor 04)

Removed the hyperlink to access the care kit from the home page so users do not accidentally access it prior to reviewing the decision aid.

FG– focus group
Use and delivery in clinical practice

The feasibility of using the BEFORE decision aid in clinic was addressed by participants. Survivor participants noted how fertility is not uniformly discussed with all premenopausal cancer patients. Some survivor participants were adamant that discussions should occur early in the care journey and should be mentioned by each health care provider along the journey. One survivor participant felt that the discussion on fertility should occur at all levels as it can impact treatment choices and provide awareness on life after breast cancer.

“...important to put conversation out there so that people are aware that there is life after cancer there are these options, really talk about it at all levels of government, pharmacist, just talk about it...that might have an impact on the type of treatment someone takes if you have those conversations.” (Interview, Survivor 05)

Most health care provider participants noted that they would use the BEFORE decision aid in their clinic or link to it on their organizations website. Multiple health care provider participants recommended developing a strategic and systematic implementation plan to ensure the BEFORE decision aid is the tool that people think about and access when they provide care for young women with breast cancer. A health care provider participant noted how the issue of fertility is very dependent on the comfort level of health care providers and partnerships they have with fertility specialists. Therefore, implementation strategies need to include education for health care providers on the use and content in the decision aid in addition to clear referral paths to fertility specialists. Health care provider participants thought that both a paper and online decision aid would be beneficial for consultations as some patients prefer to have a paper version of information to review following consultation. A health care provider participant also discussed the value of developing an app that people can quickly access in the clinic prior to their appointments. It was also noted that having the decision aid translated to French and Cantonese after pilot testing would allow for dissemination to a wider audience.

5.2.2 Strengths of the BEFORE decision aid

While multiple comprehensibility, acceptability, and usability issues were identified and modified based on the alpha testing, participants noted many strengths of the decision aid and felt that it would be a valuable tool for young breast cancer patients.
“It is really good and it’s brilliant...you are helping these women have children and that is huge, the power to change women’s lives is phenomenal so this is a very powerful document, I commend you for it.” (Interview, HCP 04)

[referring to using the decision aid] “…I could get a conversation started with my family and friends and get this out there as one of my concerns. So it might be uncomfortable but at least it would show individuals what I am concerned about, what I am thinking about, what my stresses are and I think some mental issues that one might go through when making certain decisions. So yes I am extremely satisfied with the information and I would use it to make a decision with my family.” (Survivor, 06)

The paper and online guides do a great job at hand holding and supporting women through this journey by presenting a lot of information in a format that is usable and easy to read, understand and digest. I really like the design and content of the material in both the website and the guide. (Email, Survivor 07)

I had a look at the online prototype and I absolutely LOVE IT! I am so impressed by how it turned out. So much information without being overwhelming. It's wonderful! I think the overall length was perfect, very balanced, easy to read and navigate…It maintained a high level of information without being overbearing and pushy one way or the other. Very fluid and diverse. (Email, Survivor 09)

Additionally, the exit surveys completed by new survivor participants (n=6) found that all were very satisfied with the decision aid and thought it would be easy or very easy to use at home. All new survivor participants also agreed or strongly agreed that the decision aid will help people think about what is most important in making a fertility decision before treatment; that the decision aid will help people in making a fertility decision that is right for them; and that the decision aid would have been useful when making a fertility decision before their cancer treatment.

5.3 Discussion
The alpha testing aimed to gather information from breast cancer survivors and multi-disciplinary health care providers on the usability, comprehensibility, and acceptability of the paper and online BEFORE decision aid. Feedback was also obtained informally from decision aid experts, advocacy groups, cancer organizations, and the research team. Alpha testing was completed in adherence to the IPDAS systematic development process for decision aids and used adapted acceptability questions from the OHRI and previous literature on usability testing. Our results show that overall the BEFORE decision aid was well received by participants and modifications were suggested from small wording changes to larger changes in the presentation of the fertility option success rates tables. No major design changes were suggested for the online decision aid but navigation challenges were noted and modified. All modifiable changes were made to the paper and
online decision aid to reflect the results following discussion with the research team and the graphic and web designers. However, due to pre-established design plans based on best practices all suggested modifications could not be made, but each suggested modification was given careful consideration prior to determining the inability to incorporate it in the BEFORE decision aid.

The findings from the alpha testing are similar to other findings following testing of decision aids. For example, Toupin et al., found participants had differing opinions on the correct amount of information to present for the options in the decision aid. Similarly, during alpha testing of the BEFORE decision aid some participants noted there was repetitive and an abundance of information but others thought that it was just the right length with the right amount of information for their preference. This further highlights the variances in informational needs among stakeholders to make an informed decision. In another study that evaluated a decision aid for patients with advanced heart failure, iterative changes on the tone and balance of information, flexibility in use, sensitivity towards the emotional aspects of the decisions being made, and modification of complex data into meaningful information for users were modified, similar to the BEFORE decision aid. During alpha testing of the Dutch fertility decision aid, Garvelink et al., found similar results to the BEFORE decision aid alpha testing. For example, both studies found that overall participants were appreciative that the decision aid had been created. The Dutch decision aid was also viewed by some participants as written too high level similar to the views of one health care provider that evaluated the BEFORE decision aid. The Dutch decision aid also had pre-determined design formats that could not be extensively modified similar to the BEFORE decision aid design. These findings show that more engagement may be required with stakeholders when discussing all design concepts of decision aids with web and graphic designers to allow for a better suited design concept at the onset. Differences were also seen between the evaluation of the BEFORE decision aid and Dutch decision aid. Participants evaluating the Dutch decision aid were unclear on the purpose and navigation of the values clarification method and felt that some values were not comprehensible (e.g., written as double negatives). In contrast, most participants evaluating the BEFORE decision aid knew the purpose of the values clarification method (even if they did not think it would be of value to them or women in their clinics) and suggested minor modifications to the pre-listed values. Interestingly, the values clarification method in the Dutch decision aid was used to inform the BEFORE decision aid values clarification method. The difference in evaluation findings may be reflective of our engagement with a large group of stakeholders at the engagement meeting.
(described in Chapter 4) and through iterative reviews to develop and modify the values clarification method to be reflective of Canadian patients’ needs.

The described studies and this current study highlight the importance of completing alpha testing prior to decision aid use in clinical practice. Multiple changes were made based on the feedback that will help to enhance the user experience during pilot testing. By gathering feedback on the comprehensibility, usability, and acceptability, we have aimed to create a tool that will be valuable to stakeholders. This in turn may also help to increase usage of the tool by end users and result in easier implementation in clinical practice.

5.3.1 Strengths and limitations

Participants were identified using convenience sampling to gather the opinions of individuals who would potentially be end users of the BEFORE decision aid. This recruiting strategy has been criticized for being a non-randomized sampling method and therefore may not represent the entire population of interest. It was still deemed to be the most appropriate form of sampling participants to gather insights from those involved in the development process and insights from individuals who were not involved in the development of the decision aid or were not represented during the development process (e.g., general practitioners).

Additionally, the initial intention was to complete alpha testing with survivors using multiple focus groups to allow for the exploration of interactions and group discussion. Even though multiple focus group dates/times were proposed, only three survivor participants could attend the focus group on the same day due to varying schedules and prior family and work commitments. Women also expressed interest in participating after the focus group date. The ability to test the decision aid with a variety of stakeholders in a timely period was determined as the main objective and as such only one focus group was conducted. Therefore, there were a mixed of data collection methods including the focus group, telephone interviews, and email exchanges.

In the focus group conducted with survivor participants, there were technical difficulties with the audio recorder and the focus group was not recorded. This provided challenges presenting direct quotes from participants but all recommended changes were noted in detail by the facilitator and note taker. Survivor participants were also mainly treated in the GTA. However, survivor participants who had not completed post-secondary education were successfully recruited, which was a limitation of the evaluations of existing fertility decision support resources (described in Chapter 3). Additional literacy evaluations could occur with a healthy low literate population who
are asked to imagine they have breast cancer similar to work completed to ensure readability of the Dutch decision aid by Garvelink et al. 65

During the alpha testing, few health care provider participants accessed the online decision aid prior to the interviews and provided feedback mainly on the acceptability of the content in the paper decision aid. Regardless, the main comprehensibility, acceptability, and usability issues in the BEFORE decision aid were identified by multiple participants throughout the alpha testing. To ensure usability of the online BEFORE decision aid, Dr. Nancy Baxter’s research team that included eight people, in addition to one medical oncologist and one survivor went through the online version after the modifications were completed. Any areas of concern were noted and modified to create the online BEFORE decision aid that will be pilot tested in clinical settings.

We were also not able to address all the alpha testing concerns identified by participants due to prior design decisions made to comply with the AODA for the online decision aid (e.g., unable to transfer all graphics and colours from the paper version to the online version). Also, large redesign changes to the paper decision aid were not able to be made due to budgetary constraints (e.g., unable to completely reformat the paper version to a booklet format but it was noted for potential future changes). Finally, changes suggested that went against decision aid development best practices were not able to be made (e.g., unable to remove the values clarification method from the decision aid but provided further clarification on the purpose of the method).

Despite the limitations identified, the alpha testing results from a variety of stakeholders were instrumental in allowing for the refinement of the paper and online BEFORE decision aid. The alpha testing also allowed for external reviews from content experts prior to use in clinical settings.

5.4 Conclusion
The alpha testing was a vital step in finalizing the BEFORE decision aid that will be pilot tested in clinical practice across Canada with young women newly diagnosed with breast cancer and their health care providers. Through the alpha testing concerns surrounding usability and comprehensibility of the decision aid were raised and modified. Additionally, acceptability and content concerns raised by participants were addressed to ensure the core content was accurate. Further modifications are expected through the pilot testing phase as the development process involves iterative changes to the decision aid to meet the needs of end users.
Chapter 6
Study Conclusion

6.1 Reflection on thesis research objectives

The overall aim of this study was to develop a decision aid for young Canadian women diagnosed with breast cancer who are at risk of infertility following cancer treatment. This aim was achieved through the development of a paper and online BEFORE decision aid for young breast cancer patients in Canada. The BEFORE decision aid www.before.offtomarket.ca (indirect link), has been co-developed through a systematic process with a multitude of stakeholders (breast cancer survivors, multi-disciplinary health care providers, survivorship experts, patient education specialists, advocacy representatives, and cancer organizations).

6.1.1 Research objectives

Objective 1: Identify the aspects of existing fertility decision resources that breast cancer survivors and health care providers find valuable to include in the BEFORE decision aid.

As described in Chapter 3, the evaluation of six existing fertility decision support resources from varying jurisdictions was successfully completed with eight breast cancer survivor participants and eight multi-disciplinary health care provider participants from across Canada. Participants determined the specific information needed to make an informed fertility decision prior to treatment, which shaped the initial prototype of the BEFORE decision aid.

Objective 2: To co-develop the BEFORE decision aid based on current best practices for decision aid development with breast cancer survivors, health care providers who treat young breast cancer patients and infertility in cancer patients, cancer organizations, advocacy groups, patient education specialists, and decision-making experts.

As described in Chapter 4, the initial prototype of the BEFORE decision aid was created based on the needs assessment interviews, evaluations of existing fertility decision support resources, and adhered to the best practices of decision aid development. The prototype content was based on peer-reviewed literature and was confirmed by experts in the field. However, the decision aid required further insights from stakeholders to finalize the content and format of the decision aid. Engagement with end users was achieved through a one-day meeting with breast cancer survivors, multi-disciplinary health care providers, decision-making experts, patient education experts, advocacy group representatives, and cancer organization representatives. Based on the meeting discussion, the content and format of the BEFORE decision aid was finalized and a complete paper prototype was
created. The paper prototype was then designed by a graphic designer and mirrored into an online decision aid.

**Objective 3: Conduct usability, comprehensibility, and acceptability (alpha) testing of the BEFORE decision aid (paper and online prototypes) with breast cancer survivors and health care providers.**

As described in Chapter 5, the paper and online BEFORE decision aid required another round of evaluation to ensure it was acceptable and usable before pilot testing with newly diagnosed breast cancer patients making a fertility decision. The alpha testing of the BEFORE decision aid was crucial in identifying modifiable navigation, content, and layout issues. These issues were determined through a focus group, interviews, and email exchanges with six health care provider participants and 10 breast cancer survivor participants. Alpha testing modifications were made to create a final version of the paper and online BEFORE decision aid [www.before.offtomarket.ca](https://www.before.offtomarket.ca) (indirect link), that is ready to pilot test in Canada.

### 6.2 BEFORE decision aid adherence to decision aid development best practices

The BEFORE decision aid was designed to adhere to the best practices of decision aid development identified in the literature (described in Chapter 2). Table 6.1 outlines the best practices for decision aid development and describes how the BEFORE decision aid met the criteria.

**Table 6.1 BEFORE decision aid adherence to decision aid development best practices**

<table>
<thead>
<tr>
<th>Criteria and frameworks for decision aid development</th>
<th>BEFORE Decision Aid Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stakeholders should be involved at each stage of the development process.(^ {102})</td>
<td>Engagement of stakeholders was completed iteratively throughout the development of the BEFORE decision aid. Survivors, advocates, breast surgeons, medical oncologists, fertility specialists, among other stakeholders provided reviews of the decision aid at multiple points during development: (1) interviews; (2) engagement meeting to finalize the content in the decision aid; (3) post-meeting iterative reviews; and (4) alpha testing. All participants who engaged in the development of the decision aid were identified in the acknowledgements, except for survivor participants who preferred not to be named to maintain their privacy.</td>
</tr>
</tbody>
</table>

(Continue on following page)
Table 6.1 BEFORE decision aid adherence to decision aid development best practices (Continued)

<table>
<thead>
<tr>
<th>Decision Aid Development – Best Practices</th>
<th>BEFORE Decision Aid Development</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Criteria and frameworks for decision aid development</strong></td>
<td></td>
</tr>
<tr>
<td>Developers should use a transparent and systematic development process when creating decision aids.95</td>
<td>The BEFORE decision aid was created using an adapted systematic development process outlined by the IPDAS. The reporting of the development through this thesis and future peer-reviewed publications aims to ensure transparency on the development process for the BEFORE decision aid.</td>
</tr>
</tbody>
</table>

*Theory in decision aids*

| Developers should base decision aids on theory and the theory used should be reported.96,97 | Theory was used throughout the development process of the BEFORE decision aid. Fuzzy Trace Theory was used to interpret the findings from the evaluations of existing fertility decision support resources. The values clarification method was developed based on patient-centred care values.153,181 The decision aid also followed the Ottawa Decision Support Framework and IPDAS development process, a theoretically based systematic approach to decision aid development.97,99 |

*Decision aid components and criteria - Information and presentation of the health options*

| Developers should create decision aids with up-to-date evidence that is of high quality, and critically appraised with appropriate indication by various means (phrases, symbols, or numbers) of uncertainties in the data.106 | The BEFORE decision aid contains the most up-to-date evidence available that was confirmed by experts in the field of fertility and oncology. Phrases have been used throughout the BEFORE decision aid to indicate uncertainties in the data and direct patients to seek personalized advice from their health care providers. For example, a note before the success rate tables states “Please note: this information is based on the success rates for people with and without cancer. We have limited information about fertility success rates for breast cancer survivors. Your chance of success depends on your individual situation. Talk with your healthcare team to understand your specific chances.” |

| Include clear reference area in the decision aid where evidence is listed to allow for transparency on the sources of data and evidence.106 | A reference section that lists the sources of evidence for the decision aid content is included in the paper and online version of the BEFORE decision aid. Many stakeholders provided iterative feedback throughout the development of the BEFORE decision aid. The specific informational needs of breast cancer patients and health care providers were identified and they determined the specific sections and content included in the prototype decision aid. Sections that had mixed opinions were evaluated further and discussed collaboratively by stakeholders to identify the final information needed by young breast cancer patients when making a fertility decision. |

Developers should identify the specific informational needs from the target population of the decision aid to determine the level of detail and length of information on the general health condition and available options.107 | |

(Continue on following page)
Table 6.1 BEFORE decision aid adherence to decision aid development best practices (Continued)

<table>
<thead>
<tr>
<th>Decision Aid Development – Best Practices</th>
<th>BEFORE Decision Aid Development</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Decision aid components and criteria - Information and presentation of the health options</strong></td>
<td>Icon arrays were used to present the chance of pregnancy after treatment for wait and see and embryo freezing, and rate of period resumption after treatment for ovarian suppression. The presentation of probabilities as icon arrays is easier for patients to understand and can reduce framing bias, denominator neglect bias, and narrative bias.110</td>
</tr>
<tr>
<td>Developers should refer to the known causes of biases and challenges that influence patients’ perceptions (e.g., framing and order effect, use of visuals and presentation of probabilities) when developing decision aids.110</td>
<td>Developers should consider the balance of information in their decision aid and aim to have an unbiased and neutral presentation (e.g., through horizontal side by side presentation of information such as benefits and risks) unless a strong argument can be made for promoting one option.106,108,113</td>
</tr>
<tr>
<td><strong>Decision aid components and criteria - Values clarification methods</strong></td>
<td>The most common and experimental fertility options were all presented in an option grid allowing for horizontal side by side comparison of the options. This format helps to ensure the information is balanced and has a neutral presentation. However, information on the chances of pregnancy and on parenthood options after treatment were presented in a vertical format due to spacing challenges and the inability to incorporate the icon arrays into an option grid. To ensure minimal framing and order effects, the options were not numbered (e.g., 1, 2, 3, 4) or ordered from most advantageous to least advantageous. Information on the fertility options aimed to avoid any bias towards one fertility option. 14 of 16 participants (87.5%) in the alpha testing felt that the presentation of the options and information was balanced.</td>
</tr>
<tr>
<td>An explicit values clarification method should be included in decision aids. Developers report on the rationale for the particular design by citing the theory and previous literature used, people involved in the development, and incorporation of input from stakeholders.105</td>
<td>An explicit values clarification method was included in the decision aid. The values clarification method was developed using patient-centred care values and insights from end users’ evaluation of existing values clarification methods. The format (weighted scale) was agreed on by end users of the tool at the engagement meeting and the pre-listed values included were based on the factors breast cancer survivors and health care providers felt were the most commonly considered when young women make fertility decisions. Blank space was provided under each fertility option so that patients could add in additional values that are personalized to their unique situation.</td>
</tr>
<tr>
<td><strong>Decision aid components and criteria - Personal stories</strong></td>
<td>Based on the insights from the engagement meeting, survivors’ quotes were included in the online decision aid. The paper and online BEFORE decision aid also contains links to other organizations (e.g., Rethink Breast Cancer and MyOncofertility) that house diverse personal stories through videos and blog posts.</td>
</tr>
<tr>
<td>Developers should exercise caution regarding the types of stories they are including (if any) and evaluate them to determine how they influence patient decision-making.119</td>
<td></td>
</tr>
</tbody>
</table>
Table 6.1 BEFORE decision aid adherence to decision aid development best practices (Continued)

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<tr>
<th>Decision Aid Development – Best Practices</th>
<th>BEFORE Decision Aid Development</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Other considerations - Health literacy</strong></td>
<td>A patient education expert provided multiple reviews of the BEFORE decision aid to ensure it was written in lay language. The BEFORE decision aid was assessed between a sixth and eighth grade reading level using the Flesch–Kincaid Grade Level. Additionally, using the SAM Checklist a high score was achieved showing the suitability of materials in the decision aid was good. A glossary was also included in both the paper and online decision aid to ensure patients could look up medical or challenging terms used in the decision aid (e.g., ‘fertility’ and ‘infertility’).</td>
</tr>
<tr>
<td>Developers should follow plain language techniques, evaluate the decision aid with low literate patients during development, use a readability tool to ensure it is written at no more than a grade 8 reading level, and report health literacy levels when publishing on the decision aid.¹²⁶,¹²⁸</td>
<td></td>
</tr>
<tr>
<td><strong>Other considerations – Conflict of interest</strong></td>
<td>Conflicts of interest (none declared) and funding source (Canadian Cancer Society Quality of Life Grant) was reported in both the paper and online decision aid in lay language alongside the references.</td>
</tr>
<tr>
<td>Developers should disclose conflicts of interest and funding sources to ensure transparency in the decision aid. Developers should also avoid accepting funds from entities that may benefit from the choice a patient makes after using the decision aid.¹³¹</td>
<td></td>
</tr>
<tr>
<td><strong>Other considerations – Format of decision aids</strong></td>
<td>The decision aid was created as a paper version and online version that is easily accessible through a computer or mobile phone. A paper and online format was viewed as important for the BEFORE decision aid to ensure information is accessible in the format best suited to the patient preferences. Stakeholders also identified a mobile app as a useful tool to disseminate the BEFORE decision aid to a wider audience. An app is a potential future direction for the BEFORE decision aid.</td>
</tr>
<tr>
<td>Developers should select a format for the decision aid that best aligns with the target population and clinical setting for which it is developed.¹²⁸</td>
<td></td>
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</tbody>
</table>

IPDAS– International Patient Decision Aid Standards, SAM– Suitability Assessment of Materials

6.3 Study strengths and limitations

The overall development process of the BEFORE decision aid has strengths and some limitations. The development was strengthened by the multitude of stakeholders that assisted in the co-development of the BEFORE decision aid. However, the development process did not include insights from patients’ partners or support persons. During the study partners and support persons were noted as having a significant role in fertility decision-making and future work to expand this area would benefit from the insights of these individuals in addition to patients. The thesis also does not include the pilot testing or implementation and dissemination plan for the BEFORE decision aid due to the time required for these study steps. This presents a limitation as the current design of the decision aid will undoubtedly be modified once it is used in clinical settings with patients making fertility decisions. The feedback from the pilot testing stage will help to shape the final BEFORE
decision aid that is disseminated in Canada. Additionally, integrated knowledge translation was used throughout the study by engaging stakeholders in the development process. A formal dissemination plan following pilot testing is essential to ensure the BEFORE decision aid is used by health care providers and young women diagnosed with breast cancer facing a fertility decision.

6.4 Lessons learned
Many lessons were learned in the development of the BEFORE decision aid in the areas of stakeholder engagement and decision aid development. These lessons can help to inform a more seamless development process for future decision aids and identified areas for further research.

6.4.1 Stakeholder engagement
Throughout the development process many participants provided insights during the needs assessment interviews, evaluation of existing fertility decision support resources, engagement meeting, alpha testing, and rounds of revisions. Breast cancer survivor participants in the needs assessment interviews and evaluations of existing fertility decision support resources were invited to participate further in the engagement meeting and iterative reviews of the decision aid. While most survivor participants were eager to provide insights, some did not respond or stopped responding to requests for reviews of the BEFORE decision aid. Similarly, a diverse group of health care providers were engaged as fertility discussions can occur throughout the care journey with various providers. Early in the development process, content experts specializing in medical oncology, surgical oncology, fertility, and patient education were engaged. However, engagement also occurred with a larger group of health care provider participants throughout the development process to provide iterative reviews and confirm content. Some health care provider participants stopped responding, did not respond, or provided feedback late in the process resulting in expanded timelines to finalize changes. Regardless of the engagement challenges, the insight provided by stakeholders was a vital requirement that contributed to the successful development of the BEFORE decision aid. Future work could benefit from adopting a formal engagement strategy and setting firm deadlines for reviews and feedback.191 The engagement strategy could focus on the features that matter most to stakeholders including building trust, clear communication on the roles and responsibilities, time commitment, and expectations of each team member.192 The systematic review by Witteman et al.102 will also help to identify optimal engagement strategies and should help decision aid developers establish an evidence-based stakeholder engagement plan.
6.4.2 Decision aid development

Reaching consensus and management of feedback

The development of the BEFORE decision aid was benefited by the large amount of feedback from stakeholders. Feedback provided at each stage of the development process was summarized and presented to the research team (committee members, supervisor and research program manager). When consensus on feedback was achieved among stakeholders, the changes were made to the BEFORE decision aid. However, some feedback varied and was contradictory; there are differences in opinion regarding the essential content that should be included to enhance informed fertility decision-making. Additionally there is considerable uncertainty surrounding pregnancy rates after treatment for the various fertility options generally, and for the population of survivors of breast cancer specifically. Multiple health care providers’ views and insights were solicited in instances where content concerns were raised and consensus with more than one expert was sought before making a final decision regarding inclusion, exclusion, or modification of content. However, this process lengthened the development timeline. Future decision aid development could benefit from the inclusion of a core steering committee that includes survivors, multi-disciplinary health care providers, decision-making experts, patient education specialists, and other relevant stakeholders. The committee could oversee the formatting and development of the decision aid and collaboratively decide on the final information for inclusion. However, a broad group of stakeholders’ perspectives would still be required so that the content in the decision aid is not based solely on the perspectives of the committee.

Detailed versus simple decision aids

Decision aids can be designed and developed in a variety of formats and range from simple to detailed tools. The BEFORE decision aid was developed as a detailed decision aid that includes components such as background information on breast cancer and fertility, benefits and risks of the fertility options, an explicit values clarification exercise, and resources for more support and information. More detailed decision aids result in improvements in knowledge, lower decisional conflict, and variable impact on the final choice. The advantages of detailed tools in part informed the development of the BEFORE decision aid as well as input from stakeholders on the amount and type of information they felt was needed when making fertility decisions before treatment based on the review of simple and detailed decision support resources (as described in Chapter 3). The benefit of a detailed decision aid, especially for fertility decision-making, is that it can be reviewed and
completed by young breast cancer patients at home with their partner or support person(s) or it can be completed with a trusted health care provider if a process is in place within an organization that enables these discussions to occur. The development of the detailed BEFORE decision aid also allows for the tool to be publically available and hosted on an organization or advocacy group’s webpage for patients to seek out themselves. This approach was taken as further information seeking online following clinical appointments was noted in all breast cancer survivor participants interviewed for this study. In contrast, simple decision aids can enhance shared decision-making in clinical encounters. However, this design approach requires that a set health care provider(s) uses the tool in clinic, which may not be a realistic expectation due to the many barriers identified for decision aid use in clinic. Particularly this approach would be challenging for fertility discussions because there is not a set provider who universally brings up fertility and participants in this study had a range of opinions on what provider should start fertility discussions. Therefore, it was apparent that the creation of a tool requiring use in clinic between a provider and patient may cause implementation challenges in determining the responsible provider. A more detailed tool can be provided to patients at any point in the care journey by any provider. By making the BEFORE decision aid publically available online the tool can reach a wide audience of young breast cancer patients in Canada and allows patients to take an active role in their health care to broach the topic of fertility if it is not brought up by their care team. Arguments can be made for the development of both detailed and simple decision aids but overall the decision aid design should be informed by the stakeholders’ needs and the context of the clinical situation of focus for the decision aid.

Development of components with no identified best practice

The IPDAS quality criteria and literature surrounding decision aid development allowed for direction on the design of the BEFORE decision aid; however, some areas of development do not have any identified best practices such as the design of values clarification methods, inclusion of personal stories, and presentation of risks and probabilities. As such, we engaged with stakeholders to determine the ideal format of these components in the BEFORE decision aid and adopted designs used in existing decision aids. Subsequent studies would benefit from the identification of values clarification method formats that are optimal for use with specific patient populations and their partners or support person(s), additional strategies to present a large amount of detailed information in a balanced format to minimize cognitive biases, as well as understanding if and why patients follow through with their decision after use of a decision aid.
6.5 Next steps for the decision aid

This thesis project outlined the development and alpha testing of a fertility decision aid for young Canadians diagnosed with breast cancer who are at risk of treatment-related infertility. The work completed as part of this thesis will contribute to planned future work, including pilot testing in clinical practice and wide dissemination to health care providers and breast cancer patients across Canada.

Pilot testing

Pilot testing is planned to occur in clinical settings across Canada with health care providers and breast cancer patients. Pilot testing will aim to utilize a mixed methods approach with a sequential explanatory design including questionnaires and subsequent telephone interviews with a subset of the patient participants and health care providers. The quantitative data collection will occur with approximately 128 young breast cancer patients to assess the primary outcome of informed fertility decision-making in line with patients’ values through the decisional conflict and preparedness for decision-making scales and secondary outcomes will assess knowledge, decisional regret, and decision satisfaction. The qualitative component will occur with 15 to 20 breast cancer patients who completed the closed-ended questions and 10 health care providers. Health care providers will be diverse in geographic location in Canada and hospital setting (e.g., academic and community hospitals) and patients will include women newly diagnosed with invasive breast cancer between the ages of 18 and 40 who will be receiving treatment that may impact their fertility. Each health care provider and site lead will participate in a webinar training session on the decision aid and pilot testing plan.

The quantitative data will use T-test, ANOVA and Chi-squared tests to analyze the effect of the BEFORE decision aid from a univariate perspective for continuous and categorical variables and correlation (all components of the questionnaire). Stratification will also be completed by hospital site will be used to control for local variations in fertility decision-making. A qualitative descriptive approach will then be used for the qualitative component as described by Sandelowski. The qualitative data will be used to control for local variations in fertility decision-making. A qualitative descriptive approach will then be used for the qualitative component as described by Sandelowski. The qualitative component will be used to control for local variations in fertility decision-making. A qualitative descriptive approach will then be used for the qualitative component as described by Sandelowski. Through 30 to 40 minute semi-structured telephone interviews patients will discuss their decisional needs, decision quality, and decision support provided from using the BEFORE decision aid. They will also be asked questions on the comprehensibility of the information. Health care providers will be asked to elaborate on the barriers and facilitators to using the BEFORE decision aid in practice with a focus on suitability, ease of use, and flexibility. All interviews will be recorded, transcribed
verbatim, and coded by two independent assessors to identify themes and aspects of the BEFORE decision aid that require modification. All modifiable recommendations will be made to the BEFORE decision aid and the final version will be ready for wide dissemination across Canada.

Implementation and dissemination
Decision aids are regularly used in some Canadian provinces such as Saskatchewan for prostate cancer.\textsuperscript{193} However, in general decision aid use in Canada is variable and there is generally low uptake of decision aids by health care providers.\textsuperscript{75} Therefore, the BEFORE decision aid was designed to be used as an adjunct to health care provider consultation. This design consideration was made by the research team as many implementation challenges are perceived when decision aids are used in consultations to enhance SDM such as time constraints.\textsuperscript{86} Additional implementation challenges include health care providers’ negative attitudes towards decision aids, lack of trust and perceived acceptability of the decision aid, lack of funding and cost to maintain and continually update decision aids, and organizational structure and process of care that does not support decision aid use.\textsuperscript{86,92,193} Despite the challenges surrounding implementation and dissemination of decision aids, we have strategized with stakeholders to identify multiple implementation and dissemination methods.

Engagement with end users of the BEFORE decision aid occurred throughout the development process to ensure the decision aid contained accurate and acceptable information. Additionally, most health care provider participants who reviewed the BEFORE decision aid were eager to promote the tool through their organizations or link to it on their organizations webpage. These health care providers can act as opinion leaders or local champions to promote use of the BEFORE decision aid. A Cochrane systematic review of 18 studies surrounding opinion leaders found an overall 12% absolute increase in compliance when using an opinion leader.\textsuperscript{94} The authors concluded that while the effectiveness of opinion leaders varied among studies, they may be successful in promoting evidence-based practice.\textsuperscript{94}

Additional implementation strategies include identifying who is responsible for providing patients with the decision aid and providing continuing education and support for health care providers.\textsuperscript{99} Fertility can be discussed with a multitude of health care providers and the ASCO guidelines do not state a specific provider responsible for the discussions.\textsuperscript{30} Vadaparampil \textit{et al.}, have also shown the benefit of training nurses to provide more personalized fertility counselling to patients following consultations.\textsuperscript{63} Based on the results of the engagement with stakeholders, there is a general
consensus that the decision aid should be presented early in the care journey. Breast surgeons could be responsible for providing the decision aid to allow for earlier referrals to fertility specialists and informed follow-up and discussions with nurses or the medical oncologist who can provide more personalized information on fertility risks from treatment. Additionally, while developing the BEFORE decision aid, there was a clear need to include more health care provider focused information to prepare them for fertility discussions stemming from patients’ use of the decision aid. Therefore, we aim to provide recent peer-reviewed publications and guidelines on fertility through the online BEFORE decision aid. The aim of this additional information is to help improve health care providers’ fertility knowledge and increase their comfort in providing the BEFORE decision aid to young breast cancer patients in their clinics.

Additional dissemination methods will involve publications in peer-reviewed journals as well as presentation of the decision aid at scientific conferences, clinical rounds or seminars, and at advocacy groups or support groups events that are targeted to young breast cancer patients. In addition, targeted messages to the health care community can be achieved through established partnerships with cancer advocacy groups, provincial cancer organizations (e.g., Cancer Care Ontario), and national cancer organizations (e.g., Canadian Cancer Society). We also aim to host the BEFORE decision aid through an organization or advocacy group that has the funds to complete regular maintenance and updating of the decision aid. The host location will also be strategically chosen to ensure the decision aid is easily accessible by health care providers and patients. Finally, we plan to create a BEFORE decision aid app to allow for wider dissemination and use by a younger cancer patient population. The BEFORE decision aid will therefore be a flexible tool that is available through multiple formats to suit the personalized preferences of patients and health care providers.

6.6 Impact and relevance of this research

Future fertility is a major concern of young women when facing a breast cancer diagnosis. While effective fertility preservation options exist in Canada, women do not receive regular referrals to these services and have insufficient information to make an informed fertility decision before commencing cancer treatment. Through the development of an evidence-based fertility decision aid, informed by young women with the lived experience of facing fertility decisions, and health care providers who have cared for young women making fertility decisions, we aimed to fill the fertility information gap. This decision aid will enable patients to weigh the risks and benefits of the fertility options to make an informed decision that aligns with their values prior to cancer treatment.
The lessons learned from the development of the BEFORE decision aid and extensive engagement of stakeholders throughout the process adds to the literature that highlights the importance of stakeholder engagement in developing tools and value of providing dedicated resources to young cancer patients facing preference-sensitive and challenging healthcare decisions. The BEFORE decision aid is an innovative new tool that will change iteratively throughout pilot testing and as new evidence become available on breast cancer and fertility. Additional efforts to ensure effective fertility discussions and referrals for young cancer patients are required such as promotion of other Canadian specific resources (e.g., Cancer Knowledge Network fertility referral network) and dedicated education and training on fertility for health care providers.
References


40. Yee S. Factors associated with the receipt of fertility preservation services along the decision-making pathway in young Canadian female cancer patients. *Journal of assisted reproduction and genetics.* 2016;33(2):265-280.


97. Volk RJ, Llewellyn-Thomas H, Stacey D, Elwyn G. Ten years of the International Patient Decision Aid Standards Collaboration: evolution of the core dimensions for assessing the


Appendix A

Chapter 2: Literature Review

Best practices for decision aid development

<table>
<thead>
<tr>
<th>Decision Aid Development – Best Practices</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Criteria and frameworks for decision aid development</strong></td>
</tr>
<tr>
<td>- Developers should use a transparent and systematic development process when creating decision aids. Most of the frameworks state that stakeholders should be involved at each stage of the development process but there is little guidance or empirical evidence for developers on the best practice or methods for engaging stakeholders. As such, Witteman et al. is currently completing a systematic review to formulate strategies for involving stakeholders in the development process drawing on the user-centred design framework.</td>
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<table>
<thead>
<tr>
<th>Theory in Decision Aids</th>
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<tbody>
<tr>
<td>- Developers should base decision aids on theory and the theory used should be reported. However, there is limited guidance on the best theory to use and how theory should be applied to specific decision aid components.</td>
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<table>
<thead>
<tr>
<th>Decision aid components and criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Information and presentation of the health options</strong></td>
</tr>
<tr>
<td>- Developers should create decision aids with up-to-date evidence that is of high quality, and critically appraised with appropriate indication by various means (phrases, symbols, or numbers) of uncertainties in the data. There should also be a clear reference area in the decision aid where evidence is listed to allow for transparency on the sources of data and evidence.</td>
</tr>
<tr>
<td>- Developers should identify the specific informational needs from the target population of the decision aid to determine the level of detail and length of information on the general health condition and available options.</td>
</tr>
<tr>
<td>- No best practices exist for the presentation of risk and probabilities in decision aids. However, developers should refer to the known causes of biases and challenges that influence patients’ perceptions (e.g., framing and order effect, use of visuals and presentation of probabilities) when developing decision aids.</td>
</tr>
<tr>
<td>- No best practices exist for ensuring balanced information in decision aids. However, developers should consider the balance of information in their decision aid and aim to have an unbiased and neutral presentation (e.g., through horizontal side by side presentation of information such as benefits and risks) unless a strong argument can be made for promoting one option.</td>
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</table>
## Decision Aid Development – Best Practices

### Values clarification methods
- An explicit values clarification method should be included in decision aids. However, there is no best practice identified for the development or format of a values clarification method in decision aids. As such, it is recommended that developers report on the rationale for the particular design by citing the theory and previous literature used, people involved in the development, and incorporation of input from stakeholders.

### Personal stories
- No best practice has been identified for the inclusion or format of personal stories in decision aids. Developers should exercise caution regarding the types of stories they are including (if any) and evaluate them to determine how they influence patient decision-making.

### Other considerations

#### Health literacy
- Developers should follow plain language techniques, evaluate the decision aid with low literate patients during development, use a readability tool to ensure it is written at no more than a grade 8 reading level, and report health literacy levels when publishing on the decision aid.

#### Conflict of interest
- Developers should disclose conflicts of interest and funding sources to ensure transparency in the decision aid. Developers should also avoid accepting funds from entities that may benefit from the choice a patient makes after using the decision aid.

#### Delivery of decision aids
- Developers should select a format for the decision aid that best aligns with the target population and clinical setting for which it is developed.
Appendix B

Chapter 3: Evaluation of Existing Decision Support Resources

Information letter for breast cancer survivor and health care provider participants

St. Michael's
Inspired Care. Inspiring Science.

Invitation to Participate in a Research Study

This is an invitation to participate in a research study entitled “Development of a Canadian Decision Aid for Women at Risk for Infertility Following Cancer Treatment” taking place at St. Michael’s Hospital under the direction of Principal Investigator, Dr. Nancy Baxter.

You are being asked to consider taking part in this research study because you [insert if healthcare provider - provide care to women with breast cancer and may inform/counsel patients about how cancer treatment may affect natural fertility] or [insert if breast cancer survivor - are a female who was diagnosed with breast cancer at a young age].

Study Overview
Decision-making around fertility preservation around the time of cancer diagnosis for young women is challenging and not all women are provided with help to make their decisions. Our team is seeking input from oncology providers to review and evaluate existing decision resources aimed to help young women with decision-making, but were previously developed in other countries. Our goal is to modify these resources to suit young Canadian women with breast cancer based on recommendations from patients and providers. We aim to involve approximately [insert if health care provider - 5-10 providers this study] or [insert if breast cancer survivor - 10 young women in this study].

Description of Your Involvement
If you agree to participate in this study, you will be asked to take part in a single one-on-one in-person (or telephone) interview lasting approximately 30 minutes. You will be asked to review a decision resource and provide feedback on what tools and exercises you found the most and least useful. We will provide you with the decision resource prior to the discussion. At the end of the discussion, we kindly ask you to answer a few open-ended questions about the content and any recommended changes.

If you indicate interest in participating, our graduate student, Ms. Brittany Speller, will follow-up with you to review the goals and methods for the conduct of this study. She will be happy to address any questions or concerns you may have. If you agree to participate, she will arrange a convenient date and time for the interview. To ensure that your input is accurately captured, your permission is sought to audio record and transcribe the interview. After completion of the study, a $20 gift card will be sent to you.

Potential Harms and Benefits of Participating in the Study
There are no anticipated direct risks or benefits to you from participating in this study.

Participation and Withdrawal
Participation in this study is completely voluntary. If you participate in an interview, you may choose to decline answering any of the questions you do not wish to answer and you may stop the interview at any time without any [if health care provider - effect on your position or duties] or [if breast cancer survivor - care you or your family receive at St. Michael’s Hospital, now or in the future]. Furthermore, you may decide to withdraw from the study at any time, without any negative consequences, simply by letting us know your decision. If you choose to withdraw from the study we will destroy any data associated with your participation.
Confidentiality and Privacy
The Research Team is committed to respecting your privacy. They will make every effort to keep your study information private and confidential in accordance with all applicable privacy legislation. No information that reveals your identity will be published without consent unless required by law.

All participants will be identified in study documentation only by a unique study number. Your interview will be transcribed by an external transcription service. Any identifying information in your transcript, such as names of persons, places or institutions will be removed by the researcher. All study data (i.e. audio recordings, transcripts) will be kept confidential and will be securely retained by the study team. Access to the study data will be limited to the study investigators and research team, and the St. Michael's Hospital Research Ethics Board for the purposes of monitoring the study.

Publication of Results
The results of the study will be reported only as aggregated findings. Any quoted material will be attributed only by study number. Any responses, records or personal information that could be directly linked to you will not be reported or shared with anyone outside of the study team.

Research Ethics Board Contact
If you have any questions as a research participant you may contact Dr. David Mazer, Chair of the St. Michael’s Research Ethics Board at 416-864-6060, extension 2557.

Study Contact
This study has been reviewed by the St. Michael’s Hospital Research Ethics Board. The decision to participate in the study is yours. If you have any comments or concerns resulting from you participation in this study, please contact our graduate student, Brittany Speller, at (416) 864-6060 ext. 7039, or by email at speller@smh.ca.

Your consent to participate in this study is demonstrated by your verbal agreement to take part in the interview. Note: your consent will be audio-recorded at the time of the telephone contact.

Please keep a copy of this document for your records.

Sincerely,

Dr. Nancy Baxter
Principal Investigator
Head, Division of General Surgery
St. Michael’s Hospital
Phone: (416) 864-6060 ext. 77021
Appendix C

Chapter 3: Evaluation of Existing Decision Support Resources

Cover letter for breast cancer survivor participants

St. Michael’s
Inspired Care. Inspiring Science.

[insert address if being mailed]
[insert date]

Dear Ms. [insert first name last name],

[Introduction paragraph if Cover Letter is being mailed: We would like you to kindly consider participating in a research study that aims to develop a decision aid designed to help young women diagnosed with breast cancer make informed decisions about fertility preservation.]

[Introduction paragraph if Cover Letter is being emailed in response from an advocacy group posting: Thank you for contacting us about participating in a research study that aims to develop a decision aid designed to help young women diagnosed with breast cancer make informed decisions about fertility preservation.]

Our plan is to ask approximately 10 women who were diagnosed with breast cancer at a young age to review existing decision resources and provide feedback on what tools and exercises might be helpful in assisting women make choices around fertility preservation after a cancer diagnosis.

Enclosed you will find a formal Information Letter that describes the details of your involvement if you choose to participate.

In one week from receipt of this letter, you will receive a phone call from our graduate student, Brittany Speller, to review the goals for this study, answer any questions you may have and confirm if you are interested in participating. If you are not interested in participating after reading this letter, or would like to opt out of a follow-up phone call, please contact the study coordinator at phone (416) 864-6060 ext. 7839 or email: spellerb@smh.ca.

Thank you in advance for your consideration of this important study.

Yours sincerely,

Dr. Nancy Baxter
Principal Investigator
Head, Division of General Surgery
St. Michael’s Hospital
Phone: (416) 864-6060 ext. 77021

Dr. Adena Scheer
Surgical Oncologist
Division of General Surgery, St. Michael’s Hospital
Phone: (416) 864-6060 ext. 7145

Dr. Jory Simpson
Assistant Medical Director, CIBC Breast Centre
Division of General Surgery, St. Michael’s Hospital
Phone: (416) 864-5804

Dr. Ralph George
Medical Director, CIBC Breast Centre
Division of General Surgery, St. Michael’s Hospital
Phone: (416) 864-6060 ext. 7145
Appendix D
Chapter 3: Evaluation of Existing Decision Support Resources

Phone script for breast cancer survivor participants

St. Michael's
Inspired Care. Inspiring Science.

Patient Follow-up Telephone Script

Hello, my name is Brittany. I am a graduate student from St. Michael's Hospital calling to follow up about information we sent you to participate in a research study.

Did you receive a letter in the mail regarding this study?
1. If potential participant replies "yes":
   Do you have any questions about the materials you received in the mail?
   Would you be interested in taking part in this research study?
   If "yes", then review information from the information/consent letter. Ask for dates and times when participant is available for an interview.
   If "no", then "thank you very much for your time, have a great day".

2. If potential participant replies "no":
   Would you be interested in hearing more about the study?
   With your permission, we can forward you another copy of the letter.

Thank you for your time.
Appendix E

Chapter 3: Evaluation of Existing Decision Support Resources

Study recruitment poster

Fertility Decision-Making
After a Breast Cancer Diagnosis

Young Female Breast Cancer Survivors Needed!
Researchers would like to know what resources would be useful to young women when making fertility preservation-related decisions during a cancer diagnosis. You would be asked to review a decision resource and answer some questions in a 30 minute interview.

Study Eligibility
Women diagnosed with breast cancer at 45 years of age or younger
Completed surgery/chemotherapy/radiation treatment in the last 5 years

Participation in this study is completely voluntary.
If you are interested in participating in an interview please contact Brittany Speller, our graduate student

Phone: (416) 864-6060 ext.7839 or
Email: spellerb@smh.ca
Department of Surgery, St. Michael’s Hospital
Appendix F

Chapter 3: Evaluation of Existing Decision Support Resources

Email invitation for health care provider participants

St. Michael's
Inspired Care. Inspiring Science.

Subject Line: IMPT: Your expertise in oncofertility is needed. Please see INVITATION to participate in research study.

Dear Dr. ____,

Our research team is planning to design a decision-aid for young women whose cancer treatment may affect their natural fertility as part of our study “Development of a Canadian Decision Aid for Women at Risk of Infertility Following Cancer Treatment”. As a practitioner who provides care to young women, we are seeking your expertise and input as we review and modify existing decision-aids from other jurisdictions to create a decision-aid for Canadian women facing fertility preservation decisions.

What would be involved?
We are asking you to take part in an informal discussion lasting about 30 minutes by telephone. During the discussion, you will be asked to review a decision-aid or resource and provide your opinions of what you believe is useful and comment on what changes could be made to improve the resource in the Canadian context. Please see attached invitation for further details. Everything you say will be strictly confidential.

If you wish to participate, you can simply reply all, or contact our graduate student, Ms. Brittny Speller, by email at spellerb@smh.ca or by phone at (416) 864-6060 x7839.

Thank you for your consideration.

Sincerely,

Dr. Nancy Baxter
Principal Investigator
Department of Surgery
St. Michael’s Hospital
Appendix G

Chapter 3: Evaluation of Existing Decision Support Resources

Decision support resource interview guide for breast cancer survivor and health care provider participants

Review of existing oncofertility decision aids and resources:

Interview guide

[Turn recorder on] Thank you for participating in this study. This interview will last between 30 to 45 minutes. The goal of our study is to design a Canadian decision aid on fertility preservation for young breast cancer patients. A decision aid is a tool that helps people become involved in decision making by describing the decision that needs to be made and providing information about the options and outcomes of the decision to clarify personal values. It is meant to be used in partnership with provider counseling. The aim of today’s interview is to evaluate existing fertility resources.

Before we begin I want to give a bit of background on my role in the study. I am a graduate student completing my MSc at the University of Toronto and the principal investigator on the study. Dr. Nancy Baxter, is my supervisor. I will be using this work for a component of my thesis project.

As a breast cancer survivor we are hoping you will be able to provide input on your experiences and the types of information that would have benefited you when you were considering fertility preservation after your diagnosis.

[Consent to participate] The interview will be audio recorded so that sections can be transcribed verbatim for analysis. Anonymized quotes from this interview may be included in research reports, presentations, publications and educational materials. Participation in any research study is voluntary. If you choose not to participate, this information will not be disclosed and you can change your mind at any time without giving reason. You may decline to answer any questions or halt the interview at any time. As a token of appreciation for participating in the study we will be sending you a $20 gift card after completion of the interview. Is all of this agreeable to you? Are there any questions before we begin?

Section 1: Background Questions

Background - Survivors
1) Did you receive surgery, chemotherapy, radiation or hormone therapy following your cancer diagnosis?
2) Did you seek fertility preservation treatment prior to your cancer diagnosis?
3) What was your relationship status when you were diagnosed?
4) Did you have any children when you were first diagnosed?
5) What is your current age?
6) What was your age at diagnosis?
7) Have you finished active treatment in the last 5 years?
8) How would you describe your race/ethnicity?
9) What is the highest grade or year of school you have completed?

Background - Health care providers
1) How long have you been in your role and what you do?
2) Fertility Specialists: And how many patients do you typically see in a day for consultations? How many of them are cancer patients and more specifically breast cancer patients?
   Medical Oncologists/Surgical Oncologists/Nurses/ Social Workers: How many breast cancer patients between the ages of 18-45 do you typically see in a year for consultation?
Section 2: Information used/provided when making a fertility decision

Decision Resources – Survivors
1) Did you use any decision resources on fertility preservation before you began treatment?
   i) If no ask – were you given any information on fertility preservation before you began treatment?
   ii) If yes ask – what specific aspects of the resource or information did you find useful?

Decision Resources – Health care providers
1) Do you routinely use resources to help cancer patients with decision making on fertility options?
   Probe: If yes, what aspects of the decision resource did you find useful or like in particular?

Section 3: Usefulness, comprehensibility, and usability of each decision support resource

<table>
<thead>
<tr>
<th>1) Review of Sections in Decision Aid – <strong>Australian Decision Aid</strong></th>
<th>Not at all useful</th>
<th>Not very useful</th>
<th>Useful</th>
<th>Very useful</th>
<th>Not sure (do not say in interview)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How useful do you think the following sections would have been in making a fertility decision?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of fertility options – pg. 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some background information – pg. 5-16</td>
<td></td>
<td></td>
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<tr>
<td>Fertility-related information – pg. 17-32</td>
<td></td>
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<tr>
<td>Clarify the decision – pg. 33</td>
<td></td>
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<tr>
<td>Compare the options – pg. 35-42</td>
<td></td>
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<tr>
<td>Compare how I feel about different options (values clarification) – pg. 43</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Determine your decision – pg. 44</td>
<td></td>
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<tr>
<td>Plan the next steps – pg. 44</td>
<td></td>
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<td></td>
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<tr>
<td>Jenny's story example – pg. 45-50</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some words used in this booklet – pg. 51-52</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where to go from here – pg. 53</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questions to ask your doctors – pg. 55</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Overall, how useful do you think this decision resource would have been in helping you make a fertility decision?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2) What do you think about the length of the decision resource?
   - Probe: If too long ask what sections they believed were too long and why they feel they are not important.
   - If too short ask what sections did they feel were missing from the aid and what other information would be required to make an informed decision.

<table>
<thead>
<tr>
<th></th>
<th>Too short, would prefer it to be much longer</th>
<th>Short, would prefer it to be a bit longer</th>
<th>Just right</th>
<th>Long, would prefer it to be a little shorter</th>
<th>Too long, would prefer it to be much shorter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Too few, would prefer a lot more</td>
<td>Few, would prefer a few more</td>
<td>Just right</td>
<td>A lot, would prefer a few less</td>
<td>Too many, would prefer a lot less</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>----------------------------------</td>
<td>------------------------------</td>
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<td>-------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>3) What do you think about the use of graphics in this decision resource?</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>• Proper risk graphic on pp. 5 and photos of people throughout the resource</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>• Are there any sections where figures or illustrations would be more useful to convey the information?</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statements</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>4) The information in the decision resource was easy to read</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>5) The information flows in a logical order</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>6) I am able to understand the information presented about fertility options</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>7) The options for fertility preservation were presented equally with no bias</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>• If (strongly) disagree then ask what sections or information did you think were biased</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>8) There is enough information provided to decide which fertility preservation option is right for me</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statements</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>9) The decision resource was easy to use</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>10) Training on how to use the decision resource is needed for patients</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>11) Training on how to use the decision resource is needed for health care providers</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>12) I think using this decision resource would do more good for women than harm</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>• If (strongly) disagree then ask why do you think it would be harmful for patients to receive this resource.</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>13) This decision resource would have been helpful to me in making a decision about fertility preservation had I been able to use it</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>
14) Would you recommend this decision aid to a friend in a similar situation?

15) Why do you think this method of decision making would have worked/wouldn’t have worked for you?

Section 4: Factors influencing fertility decisions

Next we are hoping you would be able to identify the importance of factors when making fertility preservation decisions. This is not a complete list but specific factors that have been identified from previous work and we will ask you after if there are any other factors that you consider important when making fertility preservation decisions.

<table>
<thead>
<tr>
<th>How important were the following factors when you were considering fertility preservation?</th>
<th>Not at all important</th>
<th>Not very important</th>
<th>Important</th>
<th>Very Important</th>
<th>Not sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>16) The stage/severity of diagnosis</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>17) How much fertility preservation procedures cost</td>
<td>☑</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>18) That future children are biologically related</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>19) How much time is required for fertility preservation procedures</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

20) Are there any other factors that you think are important when considering fertility preservation?

21) Which of the above factors would you rank as the top 2 most important factors when you were making fertility preservation decisions?

Section 5: Delivery and completion of decision support resources

1) At what time point would you have liked to receive a decision aid regarding fertility?

   a) As soon as you learned about your diagnosis

   b) When discussing your treatment plan and before treatment (what treatment plan?)

   c) During treatment

   d) After treatment has been completed

   e) Other – If selected, ask when they would have liked to receive it
2) How would you have liked to receive a decision aid regarding fertility?
   a) In the mail
   b) At an appointment with your surgeon
   c) At an appointment with your oncologist
   d) At an appointment with a fertility specialist
   e) Other – e.g., social workers or nurses

3) How would you have liked to read/completion a decision aid regarding fertility?
   a) With your surgeon
   b) With your oncologist
   c) With a fertility specialist
   d) By yourself
   e) Other – e.g., social workers or nurses

   Probe: why they would like to complete the decision aid with whichever one they selected

Section 6: General questions on decision support resources

1) What format do you believe would be the most useful for a decision resource?
   a) Paper booklet
   b) Online booklet
   c) Interactive online resource
   d) Audio-guide booklet/video
   e) Other format – if selected ask what format they believe the decision aid should be in

   Probe: why do you think the decision aid would be more useful in the format selected?

We are now completed all the questions on the Australian Decision Aid. thank you very much for going through it with me. Is there anything else you would like to add or aspects of the aid that you think would have been particularly useful for you when diagnosed with cancer and making a fertility decision?

Section 7: Pilot testing questions

First two interviews with survivors and health care providers

1. Were you able to understand how to answer the questions?

2. Were the questions asked in a logical order?

3. Are there any additional questions that you feel would be important to ask patients or providers in the next interviews?

4. Were there any questions asked that you feel are not important to continue asking in the next interviews?

5. Do you have any suggestions regarding the clarification of instructions or certain questions, or improvements in format?

Do you have any other feedback?
Appendix H
Ethics approval (St. Michael’s Hospital)

December 21, 2015

Dr. Nancy Baxter,
Department of Surgery, Division of General Surgery,
St Michael’s Hospital

Dear Dr. Baxter,

Re: REB# 15-220 - Development of a Canadian Decision Aid for Women at Risk for Infertility following Cancer Treatment

Original Approval Date
December 21, 2015

Annual/Interval Review Date

Thank you for your application submitted on 03 July, 2015. The above noted study has been reviewed through a delegated process (not by Full Board review). The views of the St. Michael’s Hospital (SMH) Research Ethics Board (REB) have been documented and resolved. Please note that no member of the St. Michael’s Hospital Research Ethics Board associated with this study was involved in its review or approval.

The REB approves the study as it is found to comply with relevant research ethics guidelines, as well as the Ontario Personal Health Information Protection Act (PHIPA), 2004. The REB hereby issues approval for the above named study for a period of 12 months from the date of this letter. Continuation beyond that date will require further review of REB approval. In addition, the following documents have been reviewed and are hereby approved:

1. Protocol ver: 1 25-Nov-15
2. Appendix 1: Introductory Email ver: 24-Sep-15
3. Appendix 2: HCP Information Letter ver: 1 25-Nov-15
4. Appendix 3: Poster ver: 24-Sep-15
5. Appendix 4: Patient Cover Letter (received 24-Sep-15) ver: 19-Jun-15
7. Appendix 6: HCP Follow-up Email ver: 19-Jun-15
8. Appendix 7: Follow-up Call Script ver: 19-Jun-15
9. Consent Script ver: 24-Sep-15
10. Email to accompany decision aid (received 25-Nov15)

Furthermore, the following documents have been received and are acknowledged:

1. Appendix 8-10: Compilation of Decision Aids (received 03-Jul-15)

During the course of this investigation, any significant deviations from the approved protocol and/or unanticipated developments or significant adverse events should immediately be brought to the attention of the REB.

Please note that if a Clinical Trial Agreement is required, it must be submitted to the Office of Research Administration for review and approval. Any additional institutional approvals must be
coordinated and approved through the Office of Research Administration prior to initiation of this research. All drug dispensing must be coordinated through the Research Pharmacy at 416-864-5413.

The St. Michael’s Hospital (SMH) Research Ethics Board (REB) operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans, the Ontario Personal Health Information Protection Act, 2004, and ICH Good Clinical Practice Consolidated Guideline E6. Health Canada Part C Division 5 of the Food and Drug Regulations, Part 4 of the Natural Health Product Regulations, and the Medical Devices regulations. Furthermore, all investigational drug trials at SMH are conducted by Qualified Investigators (as defined in the latter document).

With best wishes

Dr. David Mazer  
Chair, Research Ethics Board

Dr. Philip Berger  
Vice-Chair, Research Ethics Board

Dr. Brenda McDowall  
Vice-Chair, Research Ethics Board

Dr. Nancy Baxter (REB# 15-220)
Ethics approval (Sunnybrook Health Sciences Centre)

To: Dr. Ellen Warner
Medical Oncology
Room T2 053

From: Dr. Brian J. Murray

Date: July 9, 2015

Subject: Development of a Canadian Decision Aid for Women at Risk for Infertility Following Cancer Treatment

Project Identification Number: 226-2015
Approval Date: July 9, 2015
Expiry Date: July 9, 2016

The Research Ethics Board of Sunnybrook Health Sciences Centre has conducted a Delegated Board review of the research study referenced above and approved the involvement of human participants. Quorum for approval did not involve a member associated with this study.

The approval of this study includes the following documents:

- Protocol Version 1 dated June 3, 2015
- Advertisement Version 1 dated June 3, 2015 (Submit to Communication and Stakeholder Relations for review prior to posting)
- Patient Cover Letter Version 1 dated June 3, 2015
- Follow-Up Script Version 1 dated June 3, 2015
- Information Letter for Participants at Sunnybrook Version 1 dated July 7, 2015
- Consent Script Version 1 dated June 3, 2015
- Australian Decision Aid (received June 8, 2015)
- Dutch Decision Aid (received June 8, 2015)
- Livestrong Fertility Resource (received June 8, 2015)

Note that patients recruited from Sunnybrook that choose to participate in this study with the interview conducted off-site will be St. Michael’s Hospital participants.

As Principal Investigator you are responsible for the ethical conduct of this study which may be subject to review by the Quality Assurance and Education Program. The study must comply with current legislation outlined in the Ontario Personal Health Information Protection Act (PHIPA) and all acts, regulations, guidelines and policies that govern this research. The REB requires immediate notification of intern serious adverse events and significant deviations, submission of a renewal form prior to the approval expiry date, and notification of study closure.

The Research Ethics Board of Sunnybrook Health Sciences Centre operates in compliance with the Tri-Council Policy Statement 2nd edition, ICH GCP Guidelines, Part C Division 3 of the Food and Drug Regulations, Part 4 of the Natural Health Products Regulations, and Part 3 of the Medical Devices Regulations. All Health Canada regulated trials at Sunnybrook are conducted by a Qualified Investigator.

Fully affiliated with the University of Toronto
Ethics approval (University of Toronto)

PROTOCOL REFERENCE # 32801

March 7, 2016

Dr. Nancy Baxter  Ms. Brittany Speller
DEPT OF SURGERY  DEPT OF SURGERY
FACULTY OF MEDICINE  FACULTY OF MEDICINE

Dear Dr. Baxter and Ms. Brittany Speller,

Re: Administrative Approval of your research protocol entitled, "Development of a Canadian decision aid for women at risk for infertility following cancer treatment"

We are writing to advise you that the Office of Research Ethics (ORE) has granted administrative approval to the above-named research protocol. The level of approval is based on the following role(s) of the University of Toronto (University), as you have identified with your submission and administered under the terms and conditions of the affiliation agreement between the University and the associated TAHSN hospital:

- Graduate Student research - hospital-based only
- Storage or analysis of De-identified Personal Information (data)

This approval does not substitute for ethics approval, which has been obtained from your hospital Research Ethics Board (REB). Please note that you do not need to submit Annual Renewals, Study Completion Reports or Amendments to the ORE unless the involvement of the University changes so that ethics review is required. Please contact the ORE to determine whether a particular change to the University's involvement requires ethics review.

Best wishes for the successful completion of your research.

Yours sincerely,

[Signature]

Daniel Gyewu
REB Manager
Appendix I

Chapter 4: BEFORE Decision Aid Development

Pre-meeting survey

Oncofertility Engagement Meeting 2016

Pre-Meeting Survey
Thank you for joining us on November 11th, 2016 in Toronto for the Engagement Meeting to finalize the Canadian Fertility Decision Aid for young breast cancer patients. We would greatly appreciate your feedback before the meeting on the pre-meeting materials that were distributed. Please read through the Decision Aid Mock-up (Attachment 2), Success Rates and Risks - Options (Attachment 3), and Values Clarification Method - Examples (Attachment 4) before the meeting and provide your responses to the following four questions. The survey will remain open up to the meeting. We will not be tracking any identifying information. Your responses are completely anonymous.

This question asks about the Success Rates and Risks for the fertility options. Please read through Attachment 3, Fertility Options Success Rates and Risks - Options in the pre-meeting materials email and answer the below question. 1. What format for the fertility options success rates and risk do you prefer?
   ○ Pictograph format
   ○ Graph format
   ○ Neither format

If neither format, what other format would you suggest?

This question asks about Values Clarification Methods. Please read through Attachment 4, Explicit Values Clarification Method - Examples in the pre-meeting materials email and answer the below question. 2. Do you think an explicit values clarification method should be included in the decision aid?
   ○ Yes
   ○ No

If no, why do you think explicit values clarification method should not be included?
This question asks about Personal Stories in decision aids. Personal stories can be useful for some people but are optional to include. If included they can be in various formats such as videos online or as a written narrative followed by an example of a filled out values clarification exercise in paper decision aids. 3. Do you think personal stories should be included in the decision aid?

- Yes
- No

If no, why do you think personal stories should not be included?

4. Do you have any other comments or suggestions for the meeting?

Thank you for taking the time to fill out this pre-meeting survey.
Please send any questions to: Brittany Speller, brittany.speller@mail.utoronto.ca

We look forward to seeing you on November 11th, 2016!
Appendix J

Chapter 4: BEFORE Decision Aid Development

Engagement meeting agenda

Development of a Canadian Decision Aid for Women at Risk for Infertility Following Breast Cancer Treatment

Oncofertility Engagement Meeting
Friday, November 11, 2016
8:30 am to 3:30 pm
Li Ka Shing Knowledge Institute, St. Michael’s Hospital
Room 240/241, 209 Victoria Street, Toronto, ON

Goals: To share results to date of a multi-prong oncofertility study, discuss the best way to present information in the decision aid, gain general feedback on the decision aid, and generate recommendations for strategic dissemination and continual updating.

<table>
<thead>
<tr>
<th>Timing</th>
<th>Activity</th>
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<tbody>
<tr>
<td>AM 8:30</td>
<td><strong>Light Breakfast</strong> Registration, pick up meeting package</td>
</tr>
<tr>
<td>9:00</td>
<td>Welcome (Nancy Baxter, Erin Kennedy)</td>
</tr>
<tr>
<td>9:10</td>
<td>Presentations on Research to Date</td>
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<tr>
<td></td>
<td>• Background and goals of the meeting</td>
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<tr>
<td></td>
<td>• Findings from survivor interviews</td>
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<tr>
<td></td>
<td>• Findings from health care provider interviews</td>
</tr>
<tr>
<td></td>
<td>• Findings from decision support resource evaluation interviews</td>
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<tr>
<td></td>
<td>Questions/discussion</td>
</tr>
<tr>
<td>9:35</td>
<td>Break-out Groups - Presentation of success rates and risks of the fertility options (check name badge for assigned group)</td>
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<tr>
<td>10:10</td>
<td>Smaller groups report back to larger group</td>
</tr>
<tr>
<td></td>
<td>Full group discussion and questions</td>
</tr>
<tr>
<td>11:05</td>
<td><strong>Break</strong></td>
</tr>
<tr>
<td>11:20</td>
<td>Break-out Groups – Presentation and inclusion of an explicit values clarification method (check name badge for assigned group)</td>
</tr>
<tr>
<td>11:55</td>
<td>Smaller groups report back to larger group</td>
</tr>
<tr>
<td></td>
<td>Full group discussion and questions</td>
</tr>
<tr>
<td>PM 12:40</td>
<td><strong>Lunch</strong></td>
</tr>
<tr>
<td>1:10</td>
<td>Working Lunch - Review decision aid mockup and provide general feedback on format, readability, suggestions for improvements or missing information</td>
</tr>
<tr>
<td>1:40</td>
<td>Break-out Groups – 1. Presentation and inclusion of personal stories 2. Dissemination and updating of the decision aid after pilot testing (check name badge for assigned group)</td>
</tr>
<tr>
<td>2:10</td>
<td>Smaller groups report back to larger group</td>
</tr>
<tr>
<td></td>
<td>Full group discussion and questions</td>
</tr>
<tr>
<td>3:10</td>
<td>Presentation on Next Steps for the decision aid</td>
</tr>
<tr>
<td></td>
<td>• Final review of the decision aid, pilot testing plan, and timeline</td>
</tr>
<tr>
<td>3:20</td>
<td>Adjournement</td>
</tr>
</tbody>
</table>

This initiative was funded by a Canadian Cancer Society Research Institute Quality of Life Grant.
Appendix K

Chapter 4: BEFORE Decision Aid Development

Engagement meeting invitation letter

St. Michael's
Inspired Care. Inspiring Science.

Invitation to Participate in a Research Study

This is an invitation to participate in a research study entitled "Development of a Canadian Decision Aid for Women at Risk for Infertility Following Cancer Treatment" taking place at St. Michael's Hospital under the direction of Principal Investigator, Dr. Nancy Easter.

You are being asked to consider taking part in this research study because you are [insert: a female who was diagnosed with breast cancer at a young age/oncology health care provider].

Study Overview

Decision-making around fertility preservation around the time of cancer diagnosis for young women is challenging, and not all women are provided with help to make their decisions. Our team is seeking providers and young women previously diagnosed with breast cancer to help in the development of a Canadian fertility decision aid for individuals with breast cancer. Our goal is to review this decision aid and modify it to suit young Canadian women with breast cancer based on recommendations from women and health care providers who have experienced fertility decision-making. The meeting will have approximately 30 attendees including young women diagnosed with breast cancer and advocacy groups (10-15 attendees), health care providers (10-12 attendees), and representatives from provincial and national agencies (3-5 attendees).

Description of Your Involvement

If you agree to participate in this study, you will be asked to take part in a one-day meeting in Toronto, ON at the Li Ka Shing Knowledge Institute from 8:30am-3:30pm. You will be provided with an electronic copy of the decision aid to review prior to the meeting.

If you indicate interest in participating, a Graduate Student Ms. Brittany Speller, will follow-up with you to review the goals and methods for the conduct of this meeting. She will be happy to address any questions or concerns you may have. To ensure that your input is accurately captured, your permission is sought to audio record the meeting. If you are located outside of Toronto, ON, your travel, meals and accommodation expenses will be reimbursed following your participation in the meeting. [Insert if a breast cancer survivor: We will reimburse you $150 for wages lost for taking a day away from work to attend the meeting.]

Potential Harms and Benefits of Participating in the Study

There are no anticipated direct risks or benefits to you from participating in this study.

Participation and Withdrawal

Participation in this meeting is completely voluntary [insert if a St. Michael’s Hospital patient: and the care that you or your family receives at St. Michael’s Hospital will not be impacted by your decision to participate]. If you participate in the meeting, you may choose to decline answering any of the questions you do not wish to answer and you may leave the meeting at any time without any effect on your position or duties. If you chose not to participate, this information will remain confidential. Furthermore, you may decide to withdraw from the study at any time, without any negative consequences, simply by letting us know your decision.
St. Michael’s
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Confidentiality and Privacy
The Research Team is committed to respecting your privacy. They will make every effort to keep your study information private and confidential in accordance with all applicable privacy legislation. No information that reveals your identity will be published without consent unless required by law.

All participants will be identified in meeting documentation only by a unique study number. Any identifying information in our notes, such as names of persons, places or institutions will be removed by the researcher. The meeting will be audio recorded. All study data (i.e. audio recordings, notes) will be kept confidential and will be securely retained by the study team. Access to the study data will be limited to the study investigators and research team, and the St. Michael’s Hospital Research Ethics Board for the purposes of monitoring the study. Audio recordings will be kept for 1 year until study completion and then will be deleted from our files.

Publication of Results
The results of the meeting will be reported only as aggregated findings. Any quoted material will be attributed only by study number. Any responses, records or personal information that could be directly linked to you will not be reported or shared with anyone outside of the study team.

Research Ethics Board Contact
If you have any questions as a research participant you may contact Dr. David Mazer, Chair of the St. Michael’s Research Ethics Board at 416-864-6060, extension 2557.

Study Contact
This study has been reviewed by the St. Michael’s Hospital Research Ethics Board. The decision to participate in the study is yours. If you have any comments or concerns resulting from your participation in this study, please contact the Graduate Student, Ms. Brittany Speller, by email at brittany.speller@mail.utoronto.ca.

Your consent to participate in this study is demonstrated by your verbal agreement to take part in the meeting.

Please keep a copy of this document for your records.

Sincerely,

[Signature]

Dr. Nancy Baxter
Principal Investigator
Head, Division of General Surgery
St. Michael’s Hospital
Phone: (416) 864-6060 ext. 77021
Appendix L
Chapter 4: BEFORE Decision Aid Development
Evaluation survey

Development of a Canadian Decision Aid for Women at Risk for Infertility Following Breast Cancer Treatment
Meeting Evaluation, November 11, 2016

We would like to get your feedback on the Oncofertility Engagement Meeting. Thank you in advance for your participation. **Instructions:** Please circle the number that BEST represents your agreement or disagreement with the following statements.

1~Strongly Disagree, 2~Disagree, 3~Somewhat Disagree, 4~Neutral, 5~Somewhat Agree, 6~Agree, 7~Strongly Agree
(please circle the most appropriate response)

<table>
<thead>
<tr>
<th>Statement</th>
<th>Disagree</th>
<th>Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The goals and objectives of the meeting were clear</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2. The meeting was well organized</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3. Length of meeting was appropriate</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>4. Presentations contributed to my understanding</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>5. Breakout activities were well prepared and encouraged collaboration</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>6. Full group discussion generated useful ideas</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>7. I had adequate opportunity to express my thoughts relative to the topics discussed</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>8. I felt heard and able to contribute</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>9. The meeting stimulated participation and interaction among health care providers, advocacy groups, and survivors</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>10. Overall satisfaction</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

**Constructive comments/suggestions** related to any of the above statements:

Name/describe one thing you **liked most** about the meeting, and why

Name/describe one thing you **liked least** about the meeting, and how it could be improved

Do you have any **further suggestions** for the BEFORE decision aid?

THANK YOU!
Appendix M

Chapter 5: Alpha Testing

Alpha testing information letter

St. Michael's
Inspired Care. Inspiring Science.

Invitation to Participate in a Research Study

This is an invitation to participate in a research study entitled “Development of a Canadian Decision Aid for Women at Risk for Infertility Following Cancer Treatment” taking place at St. Michael's Hospital under the direction of Principal Investigator, Dr. Nancy Baxter.

You are being asked to consider taking part in this research study because you are [insert: a female who was diagnosed with breast cancer at a young age/oncology health care provider].

Study Overview

Decision-making around fertility preservation around the time of cancer diagnosis for young women is challenging and not all women are provided with help to make their decisions. Our team is seeking providers and young women previously diagnosed with breast cancer to review a Canadian Fertility decision aid aimed to help women like themselves. Our goal is to review this decision aid and modify it to suit young Canadian women with breast cancer based on recommendations from women who have experienced fertility decision-making and providers. We will be asking [insert: 10 individuals diagnosed with breast cancer for their input on the decision aid/ 3 to 4 experts in the fields of oncology and fertility for their input on the decision aid].

Description of Your Involvement

If you agree to participate in this study, you will be asked to take part in a [insert: brief one-on-one telephone interview or email exchange lasting approximately 10-15 minutes/ focus group with other breast cancer survivors lasting approximately 90 minutes]. You will be provided with an electronic copy of the decision aid to review and provide feedback on whether the decision aid was easy to use and readable.

If you indicate interest in participating, a Graduate Student Ms. Brittany Speller, will follow-up with you to review the goals and methods for the conduct of this study. She will be happy to address any questions or concerns you may have. If you agree to participate, she will arrange a convenient date and time for the [insert: interview or send the questions through an email exchange/ focus group]. To ensure that your input is accurately captured, your permission is sought to audio record and transcribe the [insert: interview/focus group]. After completion of the study, a $20 gift card will be sent to you.

Potential Harms and Benefits of Participating in the Study

There are no anticipated direct risks or benefits to you from participating in this study.

Participation and Withdrawal

Participation in this study is completely voluntary [insert: if a St. Michael’s Hospital patient and the care that you or your family receives at St. Michael’s Hospital will not be impacted by your decision to participate]. If you participate in an [insert: interview/focus group], you may choose to decline answering any of the questions you do not wish to answer and you may stop the [insert: interview/focus group] at any time without any effect on your position or duties. If you chose not to participate, this information will remain confidential. Furthermore, you may decide to withdraw from the study at any time, without any negative consequences, simply by letting us know your decision.
Confidentiality and Privacy
The Research Team is committed to respecting your privacy. They will make every effort to keep your study information private and confidential in accordance with all applicable privacy legislation. No information that reveals your identity will be published without consent unless required by law. All focus group participants will be reminded to keep the discussion confidential; but the investigators cannot guarantee that your information or responses will not be shared by other participants.

All participants will be identified in study documentation only by a unique study number. Any identifying information in our notes, such as names of persons, places or institutions will be removed by the researcher. [Insert: Phone interviews/Focus groups] will be audio recorded. All study data (i.e. audio recordings, notes) will be kept confidential and will be securely retained by the study team. Access to the study data will be limited to the study investigators and research team, and the St. Michael’s Hospital Research Ethics Board for the purposes of monitoring the study. Audio recordings will be kept for 1 year until study completion and then will be deleted from our files.

Publication of Results
The results of the study will be reported only as aggregated findings. Any quoted material will be attributed only by study number. Any responses, records or personal information that could be directly linked to you will not be reported or shared with anyone outside of the study team.

Research Ethics Board Contact
If you have any questions as a research participant you may contact Dr. David Mazer, Chair of the St. Michael’s Research Ethics Board at 416-864-6060, extension 2557.

Study Contact
This study has been reviewed by the St. Michael’s Hospital Research Ethics Board. The decision to participate in the study is yours. If you have any comments or concerns resulting from you participation in this study, please contact the Graduate Student, Ms. Brittany Speller, by email at brittany.speller@mail.utoronto.ca.

Your consent to participate in this study is demonstrated by your verbal agreement to take part in the interview.

Please keep a copy of this document for your records.

Sincerely,

[Signature]

Dr. Nancy Baxter
Principal Investigator
Head, Division of General Surgery
St. Michael’s Hospital
Phone: (416) 864-6060 ext. 77021
Appendix N

Chapter 5: Alpha Testing

Alpha testing focus group and interview questions

**Alpha Testing Interview and Focus Group Questions**

*Turn recorder on* Thank you for participating in this study. This interview will last between 15 to 20 minutes (or focus group will last 70 minutes). The goal of our study is to design a Canadian decision aid on fertility preservation for young breast cancer patients. A decision aid is a tool that helps people become involved in decision making by describing the decision that needs to be made and providing information about the options and outcomes of the decision to clarify personal values. It is meant to be used in partnership with provider counseling. The aim of today’s interview is to evaluate the prototype BEFORE paper and online decision aid.

*Consent to participate* The evaluation you provide will be audio recorded so that sections can be transcribed verbatim for analysis. Anonymized quotes from this interview may be included in research reports, presentations, publications and educational materials. Participation in any research study is voluntary. If you choose not to participate, this information will not be disclosed and you can change your mind at any time without giving reason. You may decline to answer any questions or halt the interview at any time. As a token of appreciation for participating in the study we will be sending you a $20 gift card after completion of the interview.

Is all of this agreeable to you? Are there any questions before we begin?

<table>
<thead>
<tr>
<th>Presentation of the decision aid</th>
<th>Probe Questions: Paper and Online - Do you like the layout? Paper and Online - Do you like the design? Added or removed? Paper and Online - Did you find the decision aid culturally appropriate, gender neutral, and inclusive to all family types (e.g. opposite sex relationships and same-sex relationships)? Online - Did you find it easy to navigate throughout the pages (online decision aid)? How could it be made better? Online - Did you need help navigating through the pages (online decision aid)? Online - Did you like the quotes used (online decision aid)? Why or why not?</th>
</tr>
</thead>
</table>
| 1. How did you feel about the presentation of the decision aid (online and paper)? | **Content in the decision aid**
| 2. What were your thoughts on the content in the decision aid? Where there any areas of concern when you were reading the decision aid? | Probe Questions: Paper and Online - Did you think the decision aid was too long, too short or just right? If too long, what sections do you think could be condensed? Paper and Online - Did you think there was too much information, too little information or just the right amount of information in the decision aid? Paper and Online - Did you find the presentation of information slanted to any fertility option? If so, which one and why? Paper and Online - Is there any wording changes you think should be made to make the decision aid easier to read? |
| Values Clarification Exercise | Probe Questions: Paper and Online - What is your impression of the summary of the values clarification questions? Paper and Online - Are there any values you think are currently missing from the exercise? Online - What are your thoughts on the format of the summary print document to take to the doctor’s appointment? Do you think any important information you may have wanted to have handy is missing? |
| 3. How did you find the values clarification exercise and summary page to print? | **Accessing the decision aid**
| 4. How did you initially access the decision aid when it was sent to you? | Probe Questions: Online - Phone, tablet, laptop or computer? Online - Did you find it easy to access on the device you used? Online - How could the access be improved if you had any difficulties? |
Appendix O

Chapter 5: Alpha Testing

BEFORE decision aid exit survey

Exit Survey

Thank you for taking the time to review the BEFORE decision aid. We look forward to using your insights to modify the tool before pilot testing across Canada.

1. Overall, how satisfied are you with the BEFORE decision aid (paper and online versions)?
   - □ Not at all satisfied
   - □ Slightly satisfied
   - □ Moderately satisfied
   - □ Very satisfied
   - □ Extremely satisfied

2. How difficult or easy will it be to use the BEFORE decision aid at home?
   - □ Very difficult
   - □ Difficult
   - □ Neutral
   - □ Easy
   - □ Very easy

Rate how much you agree or disagree with the following statements:

3. “This decision aid will help people think about what is most important in making a fertility decision before treatment.”
   - □ Strongly disagree
   - □ Disagree
   - □ Neither agree nor disagree
   - □ Agree
   - □ Strongly agree

4. “The tool will help people in making a fertility decision that is right for them.”
   - □ Strongly disagree
   - □ Disagree
   - □ Neither agree nor disagree
   - □ Agree
   - □ Strongly agree

5. “I would have found this decision aid useful when making my fertility decision before cancer treatment.”
   - □ Strongly disagree
   - □ Disagree
   - □ Neither agree nor disagree
   - □ Agree
   - □ Strongly agree

Thank you!
Appendix P
Chapter 5: Alpha Testing
Focus group agenda

Development of a Canadian Decision Aid for Women at Risk for Infertility Following Breast Cancer Treatment

Evaluation Focus Group
Thursday, April 6, 2017
5:30 pm to 7:00 pm
St. Michael’s Hospital, 250 Yonge Street, Toronto, ON

Goals: To share the paper and online prototypes of the BEFORE decision aid, discuss ease of use, acceptability, and recommendations to improve the decision aid.

<table>
<thead>
<tr>
<th>Timing</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>PM 5:30</td>
<td><em>Arrival and Dinner</em></td>
</tr>
<tr>
<td>5:30</td>
<td>Welcome (Brittany)</td>
</tr>
<tr>
<td>5:40</td>
<td>Review online and paper BEFORE decision aid (All)</td>
</tr>
<tr>
<td>5:55</td>
<td>Questions and discussion on the suggestions and recommendations for the BEFORE decision aid (All)</td>
</tr>
<tr>
<td></td>
<td>• Paper version (10 minutes) then online version (45 minutes)</td>
</tr>
<tr>
<td>6:50</td>
<td>Wrap up and summary of recommendations (All)</td>
</tr>
<tr>
<td>7:00</td>
<td>Concluding remarks and adjournment (Brittany)</td>
</tr>
</tbody>
</table>

This initiative was funded by a Canadian Cancer Society Research Institute Quality of Life Grant