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Risk reduction decision making in women with BRCA1/2 gene mutations

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Risk Reduction Decision Making in Women with *BRCA1/2* Gene Mutations

by

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ABSTRACT

With technological advances in testing for gene mutations, a new population of *BRCA1/2* women is becoming aware of their increased risk for developing breast and/or ovarian cancer. A salient issue these women face is which risk-reducing option to choose. Little is known about the decision making factors underlying the choice of prophylactic mastectomy for women with a *BRCA1/2* mutation. To address this issue, 137 unaffected, positive *BRCA1/2* gene mutation carriers (42 who opted for prophylactic mastectomy, 95 who did not) served as participants. All women completed an on-line battery that assessed the following theory-based decision making variables: advantages and disadvantages of prophylactic mastectomy (normative decision theory), physician recommendation (shared decision making theory), cancer worry (affect theory), and information-seeking coping style. With the exception of information-seeking style ($p = .8715$), the decision making variables of advantages and disadvantages of prophylactic mastectomy, physician input, and cancer worry did have a significant relationship with risk-reduction option chosen. Women who rated the advantages higher than the disadvantages of prophylactic mastectomy ($r = .31$, $p \leq .001$), whose physician had recommended prophylactic mastectomy exclusively ($X^2 = 11.85$; $p < .001$), and who reported higher cancer worry scores a month after receiving *BRCA1/2* positive results

($r = .28$, $p \leq .001$) were more likely to have chosen prophylactic mastectomy. The perceived impact (conflict, regret, cancer worry, and general well-being) of risk-reducing option selected was also explored. The direction of these relationships indicates that having chosen prophylactic mastectomy was associated with less decisional conflict ($r = -.38$, $p \leq .0001$), decisional regret ($r = -.58$, $p \leq .0001$), depressive symptomatology ($r = -.19$, $p \leq .05$), and cancer worry ($r = -.39$, $p \leq .0001$). The results suggest higher assessments of advantages over disadvantages of prophylactic mastectomy, doctor recommendation for prophylactic mastectomy exclusively, and higher cancer worry at time of testing is associated with choosing the risk-reducing option of prophylactic mastectomy. In addition, women who chose prophylactic mastectomy fared better psychologically than those who did not. Continued research addressing decision making variables and the impact of risk-reducing decisions may lead to improved understanding on how best to approach these difficult decisions.

Chapter One

Introduction

Due to technological advances in testing for gene mutations, a new population of women is becoming aware of their increased risk for developing breast and/or ovarian cancer. While this yet undiagnosed population is referred to as "unaffected" in the medical community, these women have a unique set of medical and psychological needs. The term "pre-vivors" was coined on the Facing Our Risk of Cancer Empowered, Inc. (FORCE; www.facingourrisk.org) message board to describe this population of individuals. FORCE is a non-profit organization created specifically to attend to the issues arising in carriers of the Breast Cancer 1 and Breast Cancer 2 (*BRCA1/2*) gene mutations which were discovered in 1994 (Miki et al.) and 1995 (Wooster et al.), respectively. Approximately, 1 out of every 345 and 1out of 1000 people in the general population in the United States are *BRAC1/2* gene mutation carriers (Whittemore, Gong, & Itnyre, 1997; Rubin, 2003). For certain populations this rate is even higher. For example, people with Ashkenazi Jewish heritage, 1 out of every 40 people is estimated to be *BRCA1/2* carrier (Robles-Diaz, Goldfrank, Kauff, Robson, & Offitt, 2004). The most salient issue for women who are carriers of the *BRCA1* and/or *BRCA2* gene mutations is the increased risk of developing breast and/or ovarian cancer in their lifetimes. Specifically, *BRCA1* carriers have a 65% chance (95% confidence interval 44%-78%) and *BRCA2* carriers have a 45% chance (95% confidence interval 31%-56%) of being

diagnosed with breast cancer by age 70. Ovarian cancer incidence rates are slightly lower with 39% (95% confidence interval 18%-54%) of *BRCA1* carriers and 11% (95% confidence interval 2.4%-19%) of *BRCA2* carriers (Antoniou et al., 2003). Since testing is considered appropriate for individuals with at least a 5% estimated chance of being a *BRCA1/2* gene mutation carrier (Armstrong, et al., 2000), a growing number of women are faced with a series of medical decisions. Should she undergo genetic counseling? Should she be tested and find out her *BRCA1/2* test results? With whom, if anyone, should she share the test results? Which type of risk-reducing strategy should she pursue—surveillance, prophylactic surgery/surgeries, and/or chemoprevention? Each decision comes with its own set of advantages and disadvantages. Because of the difficulty involved in making these decisions, it is imperative that researchers, medical providers, and patients understand the factors that go into the decision making process, as well as the subsequent impact of these decisions (Schwartz, Peshkin, Tercyak, Taylor, & Valdimarsdottir, 2005). This study will focus on the decision making factors underlying the choice of a risk-reducing strategy for women at increased risk for developing breast cancer due to the presence of a *BRCA1/2* mutation. Specifically, the primary aim of this study is to explore the relationship between four different theory-driven predictors (e.g., advantages and disadvantages of risk-reducing strategies, doctor recommendation, cancer worry, and information-seeking style) and the decision to undergo prophylactic mastectomy in unaffected carriers of a *BRCA1/2* gene mutation. The secondary aim is to explore how choice of risk-reducing strategy impacts these women through decisional conflict, decisional regret, current cancer worry, and depressive symptomatology.

First, a brief background on the motivation for undergoing, and the ambiguity surrounding, genetic testing will be provided. Then, an overview of risk-reducing strategies for breast cancer (surveillance, prophylactic mastectomy, and chemoprevention) currently available to *BRCA1/2* gene mutation carriers will be reviewed. These topics are followed by a discussion of four decision making theories that will provide a conceptual framework for studying risk-reducing decision making in this new population of women: a) normative decision theory, b) shared decision making theory, c) affect-based theory, and d) informational style theory. Finally, a review of literature on the impact of risk-reducing strategy choice, such as decisional regret and conflict, in this population will be provided.

Reasons for Pursuing Genetic Testing

Prior research suggests that people have four main reasons for obtaining genetic counseling and *BRCA1/2* testing (Pasacreta, 2003). The most popular reason has to do with wanting the information in order to determine their child's risk of inheriting the gene (Lerman, Daly, Masny, & Balshem, 1994; Struewing, Lerman, Kase, Giambaressi, & Tucker, 1995; Bluman et al., 1999; Lerman et al., 1997; Meijers-Heijboer et al., 2000). Another factor motivating testing is to seek an answer to uncertainty about future risk of developing cancer (Chaliki et al. 1995; Struewing et al., 1995; Bluman et al., 1999; Lerman et al., 1997; Jacobsen, Valdimarsdottir, Brown, & Offit, 1997). A third motivating factor for testing is to obtain information to inform decisions about which risk-reducing strategy to pursue. With a 45-65% increased risk of developing breast cancer (Antoniou et al., 2003) and an 11-39% increased risk of developing ovarian cancer in their lifetimes (Antoniou et al., 2003; Lerman et al., 1994; Chaliki et al., 1995;

Struewing et al., 1995; Bluman et al., 1999; Lerman et al., 1997; Jacobsen et al., 1997), many *BRCA1/2* carriers are motivated to find ways to limit mortality from breast and/or ovarian cancer. Finally, people have reported pursuing *BRCA1/2* testing in order to make informed decisions about marriage and/or childbearing (Lerman et al., 1994; Struewing et al., 1995; Bluman et al., 1999; Lerman et al., 1997; Jacobsen et al., 1997).

Ambiguity of Test Results

The results of testing for *BRCA1/2* gene mutations typically reflect ambiguity. Unlike genetic testing for Huntington's Disease, which almost always yields conclusive results, testing for *BRCA1* and *BRCA2* may be less informative since sensitivity and specificity of *BRCA1/2* mutation testing is high. The genetic test for *BRCA1/2* has the following three potential results: 1) true positive, 2) true negative, or 3) inconclusive negative. If a woman receives a positive result, she has a 45-65% chance of developing breast and/or 11-39% ovarian cancer in her lifetime (Antoniou et al., 2003). Therefore, not all people with a *BRCA1/2* gene mutation will go on to be diagnosed with cancer. Conversely, those without a gene mutation (a true negative result) may still develop sporadic breast or ovarian cancer in their lifetime. Finally, an inconclusive negative result may occur for several different reasons. A woman from a family in which no family member has been tested for the gene mutation may have an as yet unknown gene mutation that is not *BRCA1/2* (Baum, Friedman, & Zakowski, 1997; Prasacreta, 2003), or she may have a variant in *BRCA1/2* that cannot be detected by the sequencing method currently employed (Peshkin, DeMarco, Brogan, Lerman, & Isaacs, 2001). Therefore, all three test results have varying levels of ambiguity with regard to whether or not a woman will develop breast cancer. These varying levels may cause women with positive test

results to make decisions about future risk-reducing strategies differently from women with true negative or inconclusive negative results. Therefore, the scope of this study will be limited to a homogeneous sample of women who have received positive *BRCA1/2* genetic test results.

Risk-Reducing Strategies

The risk-reducing strategies available to *BRCA1/2* gene mutation carriers and other women at high risk for breast cancer include the following: surveillance, prophylactic mastectomy, and chemoprevention. The following section will summarize the medical findings of these three strategies. Specifically, the sensitivity and specificity of surveillance methods, the risk reduction rates for prophylactic mastectomy, and the known results from chemoprevention studies will be reviewed.

Surveillance for Breast Cancer

The American Cancer Society Guidelines for Breast Cancer Screening (Smith et al., 2003) suggest the following screening guidelines for women at average risk for breast cancer: clinical breast exams every three years starting in their twenties and thirties and annually for healthy women starting in their forties, the option to learn and conduct breast self-exams, and mammography starting at age 40. For women at increased risk of breast cancer, the American Cancer Society vaguely suggests modifications to the recommendations above including earlier initiation of all screenings, shorter intervals between screenings, and additional strategies like magnetic resonance imaging (MRI) and ultrasound. Without sufficient evidence, they suggest that women decide on a course of screening action via shared decision making with their doctors.

The U.S. Preventive Services Task Force (USPSTF; www.ahrq.gov/clinic/usptf/uspsbrgen.htm) only recommends mammography every one to two years for women over 40. They neither recommend for or against regular clinical breast exams or breast self-exams. For women who are carriers of the *BRCA1/2* mutation, USPSTF recommends a discussion between patient and doctor about the potential risks and benefits of chemoprevention. There is no conclusive research on how women at increased risk for breast cancer should screen for the disease.

Observational studies have been conducted to examine the sensitivity and specificity of surveillance for breast cancer in women with an increased risk for breast cancer. One study is a non-randomized observational study of a *BRCA1/2* mutation cohort. Brekelmans et al. (2001) followed 1,198 women with elevated risk for developing breast cancer. These women were divided into three groups based on their risk status. The first group consisted of *BRCA1/2* gene mutation carriers (n = 128). The second group was categorized as high-risk (n = 621) because they had three or more first or second-degree relatives with breast cancer diagnosed at an early age ($\leq$ 50 years of age). The third group of women was categorized as moderate-risk (n = 449) because they had more than two relatives with breast cancer. The research protocol involved instructions for monthly breast self-exams, clinical breast exams every 6 months, yearly mammography, and MRI starting in 1995 for either gene mutation carriers or women with dense breast tissue. After a mean follow-up of three years, the sensitivity of the screening for gene mutation carriers was substantially less (56%) than for the overall sensitivity of the screening program for high-risk women (74%). The small sample size of gene mutation carriers is a limitation, so conclusions must be made cautiously.

However, results suggest that current surveillance methods may be less effective for *BRCA1/2* gene mutation carriers than other women at high or moderate risk.

Kuhl et al. (2005) conducted a surveillance cohort study with a sample of 529 women (n = 43 *BRCA1/2* gene mutation carriers) with mixed levels of elevated risk for contracting breast cancer, as well as with mixed cancer histories. The aim of this study was to compare surveillance accuracies of the following methods: clinical breast exams, mammography, breast ultrasound, and MRI. Each participant received semiannual clinical breast exams and breast ultrasounds along with an annual mammography and MRI. During the course of the study, 43 cases of breast cancer were diagnosed. Of those, eight were diagnosed in mutation carriers. For women who were *BRCA1/2* gene mutation carriers, the sensitivity of MRI was 100% (versus 91% for the sample as a whole) and the sensitivity of mammography was 25% (versus 33% for the sample as a whole). The specificities were similar on all four imaging modalities for the gene mutation carriers and the group as a whole. This study suggests that MRI allows for earlier detection of breast cancer among women with *BRCA1/2* gene mutations.

Warner et al. (2004) conducted a similar study comparing the specificity and sensitivity of the four surveillance options (clinical breast exam, mammography, ultrasound, and MRI) among women with *BRCA1/2* mutations (n = 236) who did (39%) or did not (60%) have a history of breast cancer. Each participant received all four modalities each year, for one to three years. The following modalities are ranked in order from highest to lowest in sensitivity: MRI (77%), mammography (36%), ultrasound (33%), and clinical breast exam (9.1%). Specificity ranged from 95.4% (MRI) to 99.8% (mammography). It was suggested that, for MRI to become part of standard care for

carriers of the *BRCA1/2* gene mutations will require further research on mortality rates, the ideal timing of this surveillance method, continued studies on the specificity of this method, and the effectiveness of the MRI when conducted outside of a controlled research setting (Robson & Offit, 2004).

In addition to the limitations cited in the Warner et al. (2004) study, additional gaps in the literature on the surveillance options for unaffected *BRCA1/2* gene mutation carriers exist (Calderon-Margalit & Paltiel, 2004). These include heterogeneity of study samples that include gene mutation carriers with or without a previous cancer diagnosis as well as women at varying levels of high risk (Kuhl et al., 2005; Kuhl et al., 2000; Brekelmans et al., 2001) and the lack of important outcome measures, including mortality rates (Warner et al., 2004), grade and stage at diagnosis, and psychological well-being (Kuhl et al. 2005; Kuhl et al., 2000; Brekalmans et al., 2001).

The advantages and disadvantages of choosing surveillance are not clear-cut. The non-invasiveness of surveillance is a definite advantage. While surveillance is the least invasive risk- reducing strategy, there may be some temporary psychological distress as a result of inevitable false-positive test results (Lampic, Thurfjell, Bergh, & Sjödén, 2001; Steggles, Lightfoot, & Sellick, 1998; Fentiman, 1998; Gilbert et al., 1998; Lowe, Balanda, Del Mar, & Hawes, 1999). While there is promise that MRI may increase the potential for early detection (Kuhl et al., 2000; Warner et al., 2004; Stoutjesdijk et al., 2001; Tilanus-Linthorst, Obdeijn, Bartels, de Koning, & Oudkerk, 2000), it does nothing to reduce the incidence of breast cancer. No studies could be found that looked at surveillance in relation to breast cancer mortality, stage and grade, or quality of life (Calderon-Maergalit & Paltiel, 2004).

Prophylactic Mastectomy

Prophylactic mastectomy, or the removal of healthy breast tissue, can be done in various ways—subcutaneous mastectomy (removal of both breasts while keeping overlying skin and nipple), total simple mastectomy (removal of both breasts and overlying skin without axillary dissections), modified radical mastectomy (removal of both breasts with overlying skin and axillary contents), and radical mastectomy (removal of both breasts with overlying skin, pectoralis muscles, and axillary contents). Regardless of the type of mastectomy performed, no form of mastectomy can completely eliminate all of the breast tissue, and therefore no form can completely eliminate the risk of breast cancer (Lostumbo, Carbine, Wallece, & Ezzo, 2005).

Several studies yielded similar findings with regard to the reduction of breast cancer rates in women at high risk who opt for prophylactic surgery. Hartmann et al. (1999) conducted a retrospective study of 214 women categorized as high-risk who had opted for prophylactic mastectomy between 1960 and 1993. They were followed for a median time frame of 14 years. Their untreated sisters (n = 403) served as the control group. A 90% risk reduction was found for the high-risk group with only three women who had opted for prophylactic surgery being diagnosed with breast cancer compared to 156 of their untreated sisters.

Hartmann et al. (2001) conducted a follow-up study in which they obtained blood samples from their original sample of high-risk women. Twenty-six *BRCA1/2* gene mutation carriers were detected in the high-risk group. Of these women who had opted for prophylactic surgery, none had developed breast cancer after 13.4 years of follow-up.

Statistically, six to nine of these 26 women should have developed breast cancer suggesting a risk reduction of 89.5% as in the original study.

Rebbeck et al. (2004) reported a similar risk reduction rate. In this prospective study, 105 *BRCA1/2* gene mutation carriers who opted for prophylactic mastectomy alone, or in conjunction with prophylactic oophorectomy (i.e., the surgical removal of healthy ovaries in an attempt to prevent ovarian cancer), were matched on age, gene, and place of treatment with 378 *BRCA1/2* gene mutation carriers who did not opt for prophylactic surgery of any kind. The groups were followed for 5.5 years and 6.7 years, respectively. At the end of the follow-up period, two women from the surgery group and 184 women from the non-surgery group had been diagnosed with breast cancer. This represents a 95% reduction rate for women who had concurrent oophorectomy and a 90% reduction rate for women who did not have a concurrent oophorectomy relative to the non-surgery group.

While these studies suggest high rates of risk reduction for prophylactic mastectomy, there remain some limitations to consider (Eisen, 1999). The Hartmann et al. (1999, 2001) studies were made up of heterogeneous samples, with women of varying degrees of risk being compared to one another. Through blood samples drawn from the majority of the women at a later time (Hartmann et al., 2001), they found that approximately 15% (26/176) of the women in the high-risk group were *BRCA1/2* gene carriers. Therefore, approximately 85% of the sample was presumably not at the 45-65% increased risk for hereditary breast cancer. While some lives were saved by use of prophylactic mastectomy (Hartmann et al., 1999; Rebbeck et al., 2004), hundreds of women may have undergone surgery unnecessarily. Finally, self-selection bias may be a

problem with these studies, especially if baseline risk differs between surgical and nonsurgical groups (Klaren, van't Veer, van Leeuwen, & Rookus, 2003; Calderon-Margalit & Paltiel, 2004).

Chemoprevention and Breast Cancer

Chemoprevention, or the use of medication as a risk-reducing strategy for cancer, is currently being studied in *BRCA1/2* gene mutation carriers. Tamoxifen, one of the most studied medications, is already an established adjuvant treatment option for women diagnosed with cancer (Heuson, 1976; Margreiter & Wiegele, 1984). It is either prescribed alone or along with chemotherapy and has been shown to reduce the risk of a future, secondary cancer diagnosis in the unaffected breast (Rutqvist et al., 1991; Fisher & Redmond, 1991).

In the Breast Cancer Prevention Trial (BCPT; Fisher et al., 1998), 13,338 women at high risk for cancer were randomized into a tamoxifen group or a placebo group for five years. For the purposes of this study, high-risk was defined by one of the following three criteria: 1) age over 60 years, 2) age between 35 and 59 years with a greater than 1.66% risk of cancer as predicted by the Gail model, or 3) a history of lobular carcinoma in situ (i.e., benign change in the cells of the milk duct that suggest an increased risk for breast cancer in the future). Results of the study suggest that tamoxifen reduces the occurrences of both invasive and noninvasive breast cancer. Specifically, this medication reduced the risk of invasive cancer by 49% ($p < .01$) and noninvasive cancer by 50% ($p < .01$). At the time the study was conducted, blood samples were taken from each participant in order to be assessed for *BRCA1/2* gene mutations in the future. However, results from those blood samples suggest a low number of actual *BRCA1/2* gene mutation

carriers in this study. King et al. (2001) studied the 288 women who had been diagnosed with breast cancer while participating in the BCPT. Of this sample, 6.6% were *BRCA1/2* gene mutation carriers. Results suggest that tamoxifen reduced breast cancer incidence in women with *BRCA2*, but the results were not clear for *BRCA1*. The sample size was too small to make any generalizations. Further research is needed in the area of chemoprevention for breast cancer in *BRCA1/2* gene mutation carriers.

Decision Making Theories

What factors predict risk-reducing decisions for *BRCA1/2* carriers? In a review of decision making factors by Schwartz, Peshkin, et al. (2005), risk reduction rates alone did not predict risk-reducing strategy. If that were the case, the majority of women would pursue prophylactic mastectomy because of its 90% risk reduction rate compared to a 0% risk-reduction for surveillance (Rebbeck et al., 2004, Hartmann et al., 1999, 2001) and an unknown reduction rate for chemoprevention (Fisher et al., 1998; King et al., 2001). However, in three risk-reducing decision studies with *BRCA1/2* gene mutation carriers conducted in the U.S., only 3% of women had opted for mastectomies at one year (Lerman et al., 2000; Peshkin et al., 2002) and none of the women had opted for mastectomies at two years post-genetic testing (Botkin et al., 2003). Therefore, in looking beyond the numbers, it will be important to consider other factors that may go into the selection of risk-reducing strategies. This study will focus on the following theory-based predictors in the selection of mastectomy or no mastectomy in this population: 1) analysis of advantages and disadvantages, 2) doctor recommendation, 3) affect, and 4) information-seeking style.

Normative Decision Theory

Normative decision theory suggests that individual's decisions are made by a logical, unbiased, measured assessment of the advantages and disadvantages surrounding a choice. This theory is exemplified by the traditional model of genetic counseling. Cancer genetic counseling typically consists of an unbiased, nondirective relaying of information over three sessions. In the first session, pretest information is gathered, advantages and disadvantages of testing are presented, and the nature of the test and its results are explained. Patients are then asked to make a decision about testing. If they decide to test, there is a second meeting where a DNA sample is obtained. Finally, during the third session, test results are provided (Schwartz, Peshkin, et al., 2005). It is believed that if comprehensive and accurate information is provided during genetic counseling, the patient will utilize this information in combination with their personal preferences to arrive at a personally satisfactory decision about whether or not to engage in genetic mutation testing. The preferred outcome is then an informed decision that reflects a person's preferences. This theory can be extrapolated to involve decisions that people make about risk-reducing strategies following genetic testing.

The following two studies exemplify the normative decision making theory as applied to genetic counseling. Armstrong et al. (2000) retrospectively studied 211 women from the University of Pennsylvania Breast and Ovarian Risk Evaluation Program (BCREP). The BCREP is a university-based, multidisciplinary program in Philadelphia designed to provide women with individualized breast cancer risk assessment, as well as the option to pursue genetic counseling and testing. These women

were categorized into the following two groups based on gene mutation testing: those who had undergone *BRCA1/2* testing (n = 125) and those who decided against testing (n = 86). As predicted by the normative decision theory, women who ranked the beneficial factors for genetic testing significantly higher were more likely to undergo genetic testing. These beneficial factors included information for family members ($p <$ .01), learning about cancer risk (p = .01), as well as help in decision making about both prophylactic mastectomy (p = .01) and prophylactic oophorectomy ($p <$ .01). Conversely, women who rated negative effects of testing, such as insurance (p = .04) or job discrimination (p = .01) significantly higher were less likely to undergo genetic testing.

Lerman et al. (1996) conducted a prospective study that used principles from normative decision theory. This was accomplished by use of a base measure of decision making predictors for genetic testing. Information about 192 participants at high risk for the *BRCA1* mutation was collected via telephone interviews conducted one to two months prior to testing. As expected, participants who reported more benefits of genetic testing at baseline were significantly more likely to get tested.

The principles of the normative decision theory have also been applied to the study of choice of risk-reducing strategies. Because of a lack of studies looking specifically at the advantages and disadvantages of prophylactic mastectomy among *BRCA1/2* gene mutation carriers, a study looking at oophorectomy decision making is reviewed. In a cross-sectional, retrospective study, a group of high-risk women (n = 30) who had opted for prophylactic oophorectomy between 1-5 years previously were matched to high-risk women who had opted for surveillance (n = 28) during the same

time frame (Fry, Rush, Busby-Earle, & Cull, 2001). They were all assessed as to how they rated the advantages and disadvantages of oophorectomy. Women in the surgical group rated the following decision making factors significantly higher ($p < .05$) than women in the surveillance group: the desire to reduce cancer worry, desire to reduce the risk of ovarian cancer, and worries about the effectiveness of ovarian screening. This study exemplifies the normative decision theory, with differing ratings of advantages and disadvantages predicting surgical group membership.

Shared Model of Decision Making

The shared decision model is an outgrowth of the normative decision theory. It incorporates the view that patients are consumers of medical care and both desire and have a right to actively participate in decision making concerning treatment and risk-reducing strategies. Although the definition, timing, and purpose of the shared decision model is not universally agreed upon (McNutt, 2004), a broad definition typically involves comprehensive education on the risks and benefits that are part of the normative decision making theory. In addition, it includes an active attempt to engage patient values in the decision making process. This is often accomplished via decision aids such as brochures, videos, computer software, as well as physician input. Therefore, in this model, effective decision making is conceptualized as providing the patient with both objective medical information incorporated with his/her subjective values and opinions about the trade-offs that need to be made (Coulter, 2002).

Before reviewing if women at-risk for breast cancer incorporate their physician's opinion into their decisions to get genetic testing or pursue surgery as a risk-reducing strategy, the following studies review the opinions of health care providers regarding

these decisions. One hundred sixty-three genetic counselors from the National Society of Genetic Counselors Special Interest Group in Cancer were surveyed through the mail. They were asked if they would personally undergo genetic testing if they were found to be at 50% risk for carrying the *BRCA1/2* mutations (Matloff et al., 2000). They were further asked what risk-reducing strategy they would pursue if they were 35 years of age, had completed their families, and were found to be a carrier. Eighty-five percent of counselors stated they would pursue genetic testing with a 50% risk. They cited reasons for choosing testing that were consistent with those of actual women in this situation who opted for testing (Lerman et al., 1994; Chaliki et al., 1995; Struewing et al., 1995; Bluman et al., 1999; Lerman et al., 1997; Jacobsen et al., 1997; Meijers-Heijboer et al., 2000). Eight percent of the genetic counselors stated they would decline testing because of fear of discrimination and knowing this information would not alter plans for current medical management. With regard to risk-reducing strategies, a majority of the sample (68%) stated they would pursue oophorectomy while 25% stated they would pursue mastectomy. These results are higher than actual *BRCA1/2* carriers' reports of their intentions (17% for mastectomy and 33% for oophorectomy) reported by Lerman et al. (1996). However, they are consistent with other studies of doctors in this field (Geller et al., 1998; O'Malley, Klabunde, McKinley, & Newman, 1997). Stefanek (1995) surveyed female radiation and medical oncologists on the course of risk-reducing strategy they would choose if they had a known 35-40% chance of breast cancer risk. In this sample, 50% of the radiologists and 86% of the medical oncologists stated they would opt for prophylactic bilateral mastectomy.

While no studies could be found that directly looked at the relationship between physician opinion and prophylactic mastectomy in *BRCA1/2* gene mutation carriers, studies looking at physician opinion of genetic testing and treatment outcome in women for varying risk of breast cancer were identified. Based on the findings from these studies, one may extrapolate the way in which physician opinion may influence a *BRCA1/2* gene mutation carrier's decision to pursue prophylactic mastectomy.

Women with extensive family histories for breast cancer are potential candidates for the shared decision model at two different points. The first decision point involves whether or not a woman should pursue genetic testing. Armstrong et al. (2002) conducted a retrospective study with 335 women involved in the University of Pennsylvania Breast and Ovarian Risk Evaluation Program (BCREP). As discussed earlier, the BCREP is a multidisciplinary program designed to provide women with individualized breast cancer risk assessment, genetic counseling, and genetic testing. After making the decision whether or not to undergo genetic testing, each woman received a packet in the mail asking her to retrospectively state if she would have liked to have known the opinion of her primary care doctor and the opinion of her BCREP doctor (yes, no, or unsure). This approach is a challenge to the traditional, non-directive approach typically offered in genetic counseling because it brings in the opinions of the physician. In the sample as a whole, 33% pursued *BRCA1/2* testing while 67% did not. A majority of the women in this study (77%) wanted to know the opinions of the BCREP doctors. In addition, forty-nine percent wanted to know the opinions of their primary care doctors. Women who chose not to be tested were more likely to have wanted the opinions of their doctors. This study suggests that all the needs of women undergoing

gene mutation testing may not be met by the traditional approach to genetic counseling. The retrospective nature of this study is an obvious limitation, as well as the inability to generalize from the data because of the homogeneous sample of white, highly educated women that participated in this program.

Schwartz, Lerman, et al.'s prospective study (2005) of the utilization of *BRCA1/2* mutation testing in women newly diagnosed with breast cancer supports findings from Armstrong et al.'s (2002) study. Specifically, 211 women completed a structured phone interview assessing basic sociodemographic variables, psychological variables, medical variables, as well as whether or not their oncologist recommended *BRCA1/2* mutation testing. Then, they underwent a traditional, nondirective genetic counseling session, testing, and feedback sessions as desired. Results of a logistic regression model suggested that doctor recommendation was a contributing factor in determining whether or not women pursued genetic mutation testing. Patients who received a doctor's recommendation were three times more likely to pursue genetic testing. Though not part of the nondirective genetic counseling model, doctor recommendation emerged as a deciding factor. The findings from these two studies on preference to know doctor recommendation for genetic testing suggest the possibility that preference for doctor recommendation will also be true when choosing a risk-reducing strategy such as prophylactic mastectomy.

Van Roosmalen et al. (2004b) tested the shared decision model in an intervention study with 88 women who had undergone free *BRCA1/2* genetic testing. Half of the group was randomized to receive a shared decision model intervention, while the other half of the sample received usual care. The intervention consisted of three sessions with

a counselor over three weeks with decisional aides. Health states following treatment options were written on laminated cards. Patients rank-ordered these cards and then discussed the value of each of the health states using time as a unit of comparison. Outcome variables included treatment choice, decision related outcomes such as strength of treatment preference, decision uncertainty, perceived participation in decision making, weighing treatment choice, perceived preference of the specialists, and support and advice from specialists, as well as well-being. Although there was no effect on preventive treatment choices between the groups, women in the intervention group reported significantly stronger preferences ($p = .02$) and a stronger belief that they had weighed the advantages and disadvantages more effectively ($p = .01$). Women in the intervention group also felt that their specialists had a preference for one breast treatment over another ($p < .01$). While not significant ($p = .09$), women in the intervention group did report a desire for more support and advice about treatment choices for breast cancer from their specialists. The results suggest women who were given the chance to participate more fully in the decision making process felt that their specialists had an opinion about their treatment and were interested in their specialists' support and advice to a higher degree than those who did not partake in the decision making process as much. In addition to these treatment and decision outcomes, there were significant long-term effects on well-being. Women in the intervention group reported less intrusive thoughts ($p = .05$) and better general health ($p = .01$).

Van Roosmalen et al.'s (2004b) study on shared decision making adds to the current literature by broadening the scope of treatment outcomes addressed; specifically, patient well-being (as measured by intrusive thoughts and general health) and decision

related outcomes (such as strength of treatment preference, decision uncertainty, perceived participation in the decision making, and weighting of treatment choice). These issues were addressed in addition to preventive treatment choice alone. Limitations of this study included the time and labor intensiveness of the intervention evaluated. While the above review suggests the desire for physician input about genetic testing and treatment choices, there is a need in the literature to address how physician input specifically relates to choice of prophylactic mastectomy in women who are *BRCA1/2* carriers.

Affect-Based Decision Making

As shown above, women at varying risks for breast and ovarian cancers appear to be making decisions by weighing the advantages and disadvantages of risk-reducing options, as well as doctor recommendation. In addition, several studies have shown that cancer-specific distress may be an important factor in making decisions about genetic testing, as well as risk-reducing strategies. Specifically, cancer-related anxiety or fears appear to be a motivating factor for women to pursue testing or risk-reducing options more aggressively. The affect heuristic (Slovic, Finucane, Peter, & MacGregor, 2004; Ubel & Lowenstein, 1997, Schwartz, Peshkin, et al., 2005) may be a potential explanation for this phenomenon. This theory posits that people making decisions under duress will rely more on how they feel affectively than on other decisional factors.

While no studies that looked directly at the relationship of affect in *BRCA1/2* gene mutation carriers to pursuit of prophylactic mastectomy could be found, a review will be provided of studies using at-risk women with the following treatment outcomes: decision to undergo genetic testing and intentions to pursue mastectomy. Based the findings from

these studies, one may extrapolate the way in which affect may influence *BRCA1/2* gene mutation carriers' decisions to pursue prophylactic mastectomy.

The first study to be reviewed examined cancer-specific distress as a predictor for pursuit of *BRCA1* testing. The study involved 149 women and men with hereditary breast ovarian cancer (HBOC) syndrome, or multiple family members in multiple generations with early onset of breast and/or ovarian cancers (Lerman et al., 1997). Blood samples had been collected from most of the participants, years previously, in an effort to isolate the *BRCA1* gene (Feuntaun et al., 1993). These participants were contacted for the present study with notification that their test results were being made available. If they decided to participate, they would undergo a 40-minute phone interview, an education session, and if desired, receive their *BRCA1* results at a disclosure session. Baseline measures of general distress (Center for Epidemiologic Studies Depression Scale--CES-D; Radloff, 1977) and breast-cancer specific distress (Intrusion Subscale of the Impact of Events Scale—IES; Horowitz, Wilner, & Alvarez, 1979) were administered. Fifty-eight percent of the participants requested testing results, while 42% declined their results. In a hierarchical logistic regression analysis, cancer-specific distress was entered after sociodemographic variables and objective risk and was found to significantly improve prediction of receipt of *BRCA1* test results ($p < .05$). People with higher cancer-related distress scores were more likely to obtain their test results.

Van Dijk et al. (2003) looked at the relation of breast cancer worry to intentions to pursue prophylactic mastectomy in women at risk for familial breast cancer. As part of a larger study, a mixed sample of affected and unaffected women with varying rates of risk (n = 241) completed a questionnaire including two items from Lerman et al.'s (1991) Cancer

Worry Scale (CWS) both before and after a genetic counseling session in which their familial lifetime cancer risk was revealed. Higher levels of breast cancer worry at pre-counseling independently predicted intention to pursue prophylactic mastectomy (β = 0.32; $p < .01$), while objective risk information did not ($p = .78$).

In the following hypothetical, vignette study looking at decision factors, women with a first degree relative diagnosed with breast cancer ($n = 129$) were compared to women without a first degree relative with breast cancer ($n = 104$) (Stefanek, Enger, Benkendorf, Flamm Honig, & Lerman, 1999). Each participant read a vignette about a woman diagnosed with breast cancer and was asked to answer questions on whether she would choose prophylactic mastectomy or close screening given this fictitious woman's history. Women who reported higher levels of breast cancer worry (measured by one item) were more likely ($p < .05$) to voice an interest in prophylactic mastectomy.

Information Style Theory

Miller, Roussi, Caputo, and Kruss (1995) have identified two main information-seeking styles, monitoring and blunting, that relate to the way that individuals under stress apply information. For example, a medical patient who incorporates a monitoring style seeks out, focuses on, and amplifies threatening cues about her medical situation. She is attuned to the negative, dangerous, or painful portions of her illness. Conversely, a medical patient with a blunting style avoids, minimizes, and actively distracts herself from any threatening information, symptoms, or cues.

The following two studies focus on information-seeking style and genetic counseling decisions for women at high risk for breast and/or ovarian cancer. Before genetic testing for the *BRCA1/2* gene mutation was available, Lerman et al. (1994)

conducted a cross-sectional study with 121 first-degree relatives of ovarian cancer patients with no personal cancer history. The aims of this study were to assess factors that were related to intentions to test, along with expectations about the anticipated impact of such testing. The Miller Behavioral Style Scale (MBSS; Miller, 1987) was used to study information-seeking style. A majority of women (75%) expressed interest in testing. As expected, being a woman who employed a monitoring coping style was positively associated with an anticipated negative impact of testing. Specifically, monitors expected more of the negative consequences of testing including depression, anxiety, and decreased quality of life.

Schwartz, Lerman, Miller, Daly, and Masny (1995) studied 103 unaffected first-degree relatives of women with ovarian cancer assessed via a phone interview and self-report questionnaires, including the MBSS. As predicted in this study, being a woman with a monitoring coping style was positively related to higher perceived risk, intrusive thoughts, and psychological risk. In addition, high monitors overestimated their risk for ovarian cancer regardless of their actual risk.

No studies to date could be found looking at the role that this monitoring-blunting information-seeking style plays in actual choice of risk-reduction strategies by *BRCA1/2* carriers. However, given the findings of overestimation of risk (Schwartz et al., 1995) and psychological risk (Lerman et al., 1994; Schwartz et al., 1995) reported in genetic testing with this population, high monitoring women may be more likely to opt for prophylactic mastectomy.

Gaps in the Literature

The studies reviewed above have demonstrated that assessment of advantages and disadvantages, physician opinion, affect, and information-seeking appear to influence decisions made by women at increased risk for breast cancer. However, limitations exist in the current literature on predictors of decision making about prophylactic mastectomy for women who have tested positive for the *BRCA1/2* gene mutations. Specifically, the samples reviewed are heterogeneous. They have included women with varied risk levels (Van Dijk et al., 2003; Stefanek et al., 1999) and women with varied cancer histories (Van Dijk et al., 2003). In addition, the studies reviewed for the most part have not investigated risk-reducing strategy decisions in general, or prophylactic mastectomy decisions in particular. Finally, the studies reviewed have failed to look at the predictive value of the four variables of assessment of advantages and disadvantages, physician opinion, affect, and information styles simultaneously.

Perceived Impact of Risk-Reducing Choice

The second aim of this study focuses on the perceived impact of risk-reducing choice. Connolly and Reb (2005) identified some overarching, definitional features of the construct of regret. Specifically, regret involves both a cognitive and affective evaluation of two or more choices. Though an aversive feeling, it differs from disappointment or general negative affect. For the purpose of this study, the focus of the potential regret will be the type of risk-reducing alternative chosen (i.e., mastectomy or no mastectomy).

No studies could be found that compared decisional regret, decisional satisfaction, or decisional conflict among women with *BRCA1/2* gene mutations who chose prophylactic mastectomies versus women who opted for surveillance (Lostumbo et al.,

2005). However, a few studies have looked at decisional regret or satisfaction among women with unknown mutational status who have chosen prophylactic mastectomy. Borgen et al. (1998) looked at regret in a sample of 370 women who had undergone bilateral mastectomies between 1945 and 1996 and who signed up to be part of the National Prophylactic Mastectomy Registry. Five percent of the women (n = 21) reported regret with approximately half of these women (n = 10) stating they would not have chosen surgery again. The discussion initiator of surgery (physician versus patient) was the only statistically significant variable ($p < .05$) that distinguished women who had regrets from those who did not. Specifically, more women whose physicians initiated conversations about surgery (19/255) had regrets versus women who initiated conversations about surgery themselves (2/108). Overall, however, the majority of women (n = 349) did not express regret over undergoing prophylactic mastectomies.

One study (Stefanek, Helzlsouer, Wilcox, & Houn, 1995) assessed the satisfaction level of 14 women with a family history of breast cancer who opted for prophylactic mastectomy in the past 6-30 months (M = 9.4). Satisfaction in the following areas were assessed by a 5-point Likert scale: recovery time physically and emotionally, degree of discomfort and expectation of discomfort, support system as it pertained to their decision, overall satisfaction with decision, reconstruction, and proclivity to recommend to a friend. Satisfaction was high in all areas with the exception of reconstruction. This study will examine decisional regret and conflict in women who are *BRCA1/2* gene mutation carriers.

Aims

The current study has two aims. The first aim is to explore the relationship between a set of theory-driven decision making variables and the actual treatment decisions made by a group of healthy, unaffected women who have tested positive for a *BRCA1/2* gene mutation. Because the ideal treatment for carriers of the *BRCA1/2* gene mutation is yet unknown (Marchetti et al., 2004), women are forced to make their decisions on factors other than strict medical information. The four variables addressed are the advantages and disadvantages of prophylactic mastectomy (normative decision theory), doctor recommendation (shared decision making theory), cancer worry (affect theory), and information-seeking coping style. For purposes of analysis, the type of treatment chosen is classified as whether or not prophylactic mastectomy was performed.

The second aim is to explore the perceived impact (conflict, regret, cancer worry, and general well-being) of the treatment option selected. The study will look at the relationship of decisional conflict, decisional regret, cancer worry, and depressive symptomatology in relation to the treatment options women selected.

Decision Making Hypotheses

The first hypothesis posits that the way in which individuals assess the pros and cons of prophylactic mastectomy will be related to the type of treatment chosen.

1. Women who rate the pros of prophylactic surgery greater than the cons of prophylactic surgery will be more likely to have chosen surgery. Conversely, women who rate the cons of surgery greater than the pros of surgery will be more likely to have not chosen surgery.

The second hypothesis posits that the treatment chosen will be related to recommendation of that treatment by a physician.

2. If a physician had recommended prophylactic mastectomy, women will have been more likely to have chosen prophylactic mastectomy.

The third hypothesis posits that levels of cancer worry will be related to the type of treatment chosen.

3. Women with higher levels of reported cancer worry at the time of genetic testing will be more likely to have chosen prophylactic mastectomy than women with lower levels of reported cancer worry at the time of genetic testing.

The fourth hypothesis posits that information-seeking style will be related to treatment choice.

4. Women with greater tendencies to use a monitoring information-seeking style will be more likely to have chosen prophylactic surgery.

Depending on results of these hypotheses testing, exploratory analyses will be undertaken to examine which variable(s) accounts for the most variance in the treatment decision. Specifically, the analyses will seek to identify which variable(s) from the four decision making models provide(s) the best fit for predicting treatment choice in *BRCA1/2* positive, healthy, unaffected women.

Perceived Impact Hypotheses

The fifth set of hypotheses explores the perceived impact of treatment choice.

5A. Women who chose prophylactic surgery will experience less decisional conflict than women who have not chosen prophylactic surgery.

5B. Women who chose prophylactic surgery will experience less decisional regret than women who have not chosen prophylactic surgery.

5C. Women who chose prophylactic surgery will experience lower levels of depressive symptomatology than women who have not chosen prophylactic surgery.

5D. Women who chose prophylactic mastectomy will experience lower levels of cancer worry than women who have not chosen prophylactic mastectomy.

Chapter Two

Method

Participants

Women without a history of cancer who had tested positive for gene mutations in *BRCA1/2* were solicited via the website for Facing Our Risk of Cancer Empowered, Inc. (FORCE; www.facingourrisk.org). FORCE is a non-profit organization designed to educate, support, raise awareness, and promote research in the area of genetic susceptibility for breast and ovarian cancers. Demographic data made available about new FORCE website subscribers between June and August of 2006 (approximately 420 people) suggest that the majority of subscribers are women between the ages of 36 and 60 (97%), Caucasian (89%), with no personal history of cancer (57%). Of the women with no personal history of cancer, 25% reported having had genetic testing.

Between December 2006 and June 2007, a link to this study's on-line survey was advertised on the FORCE website message board, as well as via website pop-ups. In addition, five e-mail reminders about the study were distributed to individuals who subscribe to the FORCE newsletter.

In order to be considered eligible for the study, participants had to be women at least one year post genetic testing. By surveying women at least one year post-testing, we wanted to allow for a reasonable amount of time for these women to make and act on decisions regarding risk-reducing options. In addition to being tested and receiving their

positive genetic test results at least one year prior to completing the survey, these women also met the following eligibility criteria: 1) be at least 18 years of age, 2) be proficient in English, 3) have not undergone oophorectomy as a risk-reducing cancer strategy, 4) have not received chemoprevention as a risk-reducing strategy, and 5) have no personal history of cancer (with the exception of basal cell carcinoma).

Procedure

The survey was initially piloted on two women who met study criteria. The executive director of FORCE selected pilot participants. The purpose of piloting was to verify the estimated survey completion time and ensure that the questions were clearly worded and fully understood. Eligible pilot participants were contacted by phone. A scripted format (Appendix A) was followed on the telephone in order to describe the pilot study, ask questions to confirm pilot study eligibility, and obtain verbal informed consent. Upon receiving verbal consent, each participant was mailed the following materials: two copies of written informed consent (Appendix B), the survey web address, and a self-addressed stamped envelope. Each woman was asked to return one signed copy of the informed consent and provide three potential times that they would be available by phone after completing the survey. Upon receipt of the informed consent, the participants were contacted by phone and debriefed. Using the Question Appraisal System (QAS99; Center for Disease Control and Prevention, 1999), each item and set of instructions that was not part of standardized measures was reviewed. The QAS99 systematically assesses each item in all of the following areas: instructions, clarity, assumptions, knowledge/memory, sensitivity/bias, response categories, and miscellaneous problems. After collecting pilot data, minor changes including the

addition of one question and the clarification in the instructions for a section regarding attitudes about breast self-examination were made. One supplementary question was added about cosmetic surgery. In addition to inquiring if women underwent cosmetic surgery, a question was added about the specific kind of cosmetic surgery (e.g., reconstruction after prophylactic mastectomy, reduction, or augmentation). In addition, the instructions in front of five questions regarding attitudes about breast self-examination were modified

After the survey had been successfully piloted, interested parties were then able to click onto a secure link embedded into the FORCE website to complete the on-line survey. The first screen described the nature of the study and asked a series of questions evaluating eligibility criteria (Appendix C). If eligibility criteria were not met, individuals were directed to a screen thanking them for their interest but informing them that they were not eligible for the study. If eligibility criteria were met, a page with all the information relevant to provide informed consent was provided (Appendix D). Per IRB regulations for web-based studies, women provided their consent by clicking on an "I agree" button. If eligibility criteria were met and consent provided, individuals were then able to proceed through the battery of measures (Appendices E-M). All data was housed on a secure server.

It was anticipated that substantially more women who volunteered to participate would not have undergone prophylactic mastectomy. After extensive recruitment efforts, usable data were collected on 137 eligible women. As anticipated, more surveys were received from women who had not undergone prophylactic mastectomy (95 who did not opt for prophylactic and 42 who did opt for prophylactic mastectomy). Because these

two groups did not differ statistically by age (p = .53) or time since genetic testing (p = .77), this entire sample of eligible participants (N = 137) was used in the analyses rather than the proposed matching procedure that would have reduced the total sample size to 84 (42 in each group).

Measures

The on-line survey battery assessed demographic and clinical information, perceived advantages and disadvantages of prophylactic mastectomy, and physician recommendations regarding risk-reducing option. In addition, valid and reliable measures of cancer worry, information-seeking style, decisional conflict, decisional regret, and depressive symptomatology were included. The battery took approximately 25 minutes to complete.

Demographic and Clinical Information. A standardized self-report measure was used to obtain demographic and clinical information (Appendix E). The following demographic information was obtained from all participants: age, race, ethnicity, income, educational level, and marital status. The clinical information collected included menopausal status, height and weight, family history of breast and ovarian cancers, time since genetic testing, current perceived breast cancer risk, and intentions to undergo an oophorectomy. In addition, information was collected as to whether or not these women chose to share their positive genetic results with their primary care doctors. Time since surgery and perceived breast cancer risk prior to prophylactic mastectomy was also collected from women who had undergone prophylactic mastectomy. In addition to intentions to undergo prophylactic mastectomy in the future, information on surveillance behavior history and future surveillance behavior intentions was gathered from the group

who had not opted for prophylactic mastectomy. Specifically, we collected information on if and how often they performed breast self-exams and underwent clinical breast exams, mammography, and MRI for the detection of breast cancer.

Decisional Balance Scale for Prophylactic Mastectomy. The Decisional Balance Scale for Prophylactic Mastectomy (Appendix F) assessed the perceived advantages and disadvantages of undergoing prophylactic mastectomy. The scale was specifically designed for this study and consists of 8 items (4 worded as advantages or "pros", 4 worded as disadvantages or "cons"). Items for this measure were taken from the literature on the assessment of advantages and disadvantages of prophylactic mastectomy by women at increased risk for breast cancer (Claes et al., 2005). Women were asked to state the degree to which they had considered these items when deciding whether or not to undergo prophylactic mastectomy. Responses were provided on a 5-point Likert scale ranging from "strongly agree" to "strongly disagree." Coeffecient alphas calculated in the present study were .48 for the advantages scale and .44 for the disadvantages scale.

Physician Input. Participants answered questions as to whether or not one or more doctors made recommendations to them about which risk-reducing strategy they should pursue (Appendix G). They were also asked to state the recommendation(s) made.

Cancer Worry. The Cancer Worry Scale (CWS; Lerman et al., 1991; Lerman, Kash, & Stefanek, 1994) is a 4-item scale measuring the degree to which worrying about breast cancer hinders daily functioning (Appendix H-I). Participants rate each item on a 4-point Likert scale from "not at all or rarely" to "a lot." In several studies looking at womens' worries and concerns about breast cancer, the CWS is recognized as having

good internal consistency and test-retest reliability (Bowen et al., 2003; Rees, Fry, Cull, & Sutton, 2004). Women in this study were asked to complete this measure both retrospectively (Appendix I; one month after receipt of *BRCA1/2* results) as well as for the past month (Appendix H). Coefficient alphas were .84 for current reports and .87 for retrospective reports of cancer worry.

Decisional Conflict. The Decisional Conflict Scale (DCS; O'Connor, 1995) is a 16-item measure designed to assess uncertainty experienced by a person about an undertaking (Appendix J). Participants rate each item on a 5-point Likert scale ranging from "strongly agree" to "strongly disagree." Scores are summed and transformed to yield a total score ranging from 0 (no decisional conflict) to 100 (extremely high decisional conflict). The validity and reliability of the DCS has been demonstrated in prior research (O'Connor, 1995; Song & Sereika, 2006; University of Ottawa, 2006). Coefficient alpha for the total score in the present study was .94.

Decisional Regret. The Decision Regret Scale (O'Connor et al., 1998) is a 5-item measure designed to assess the degree of remorse or distress over a past decision (Appendix K). Participants rate each item on a 5-point Likert scale ranging from 1 "strongly agree" to 5 "strongly disagree." Scores are summed and transformed to yield a total score ranging from 0 to 100. The validity and reliability of the Decision Regret Scale has been demonstrated in prior research (Brehaut et al., 2003; University of Ottowa, 1996). Coefficient alpha in the current study was .91.

Depressive Symptomatology. The Center for Epidemiologic Studies, Depression Scale (CES-D; Radloff, 1977) is a 20-item self-report measure developed to assess current depressive symptomatology (Appendix L). Items are rated on a 4-point Likert

scale ranging from 0 (rarely or none of the time) to 3 (most or all of the time). Participants are asked to respond to each item based on the degree to which they have been experiencing each symptom in the past week. Total scores range from 0 to 60, with higher scores indicating more severe depressive symptomatology. The validity and reliability of the CES-D has been demonstrated in numerous studies (Devins, Orme, Costello, & Binik, 1988; Hann, Winter, & Jacobsen, 1999; Weissman, Prusoff, & Newberry, 1975). Coefficient alpha in the current study was .93.

Information-Seeking Style. The Miller Behavioral Style Scale (MBSS; Miller, 1987) measures differences in the way individuals either seek out (i.e., monitor) or avoid (i.e., blunt) information relevant to threatening situations (Appendix M). The scale is composed of four stressful situations (e.g., dentist appointment, hostage situation, airplane ride during a steep dive, and the possibility of being laid off at work) followed by eight statements that reflect different reactions in each situation. Each set of eight statements is evenly divided into monitoring and blunting reactions. Coefficient alphas for the monitoring scale range from .75 to.79 and .67 to .69 for the blunting scale (Miller, 1987). The coefficient alphas for the present study were .78 for the monitoring scale and .62 for the blunting scale. Because the monitoring scale has been proven to be a better predictor of health behaviors (Miller et al., 1988), only the monitoring scale was used in subsequent analyses.

Chapter Three

Results

Preliminary Analyses

Participants Who Opted for Prophylactic Mastectomy. Of the 192 women who completed the on-line survey, 56 women (29%) reported having undergone prophylactic mastectomies (see Figure 1). Of these women, 14 (25%) were found to be ineligible for the following reasons: genetic testing done within the past year (n = 8), duplicate survey entries (n = 3), report of both ovaries having been removed without a hysterectomy (n = 1), mastectomy prior to genetic testing (n = 1), and survey malfunction resulting in missing data (n = 1). The mean age of the remaining 42 women was 36 years (SD = 8.07, range = 19-55). The majority was Caucasian (93%), not of Ashkenazi Jewish heritage (57%), married (71%), had a college degree or higher education (81%), and had an annual household income greater than or equal to $40,000 (76%) (see Table 1). On average, these women underwent prophylactic mastectomy 14 months prior to participating in the study (M = 14.48; SD = 14.50) with time since prophylactic mastectomy ranging for 0 to 58 months. The time that elapsed between genetic testing and undergoing prophylactic mastectomy ranged from 1 month to 76 months (M = 18.69; SD = 21.24).

Figure 1. Flowchart of Recruitment

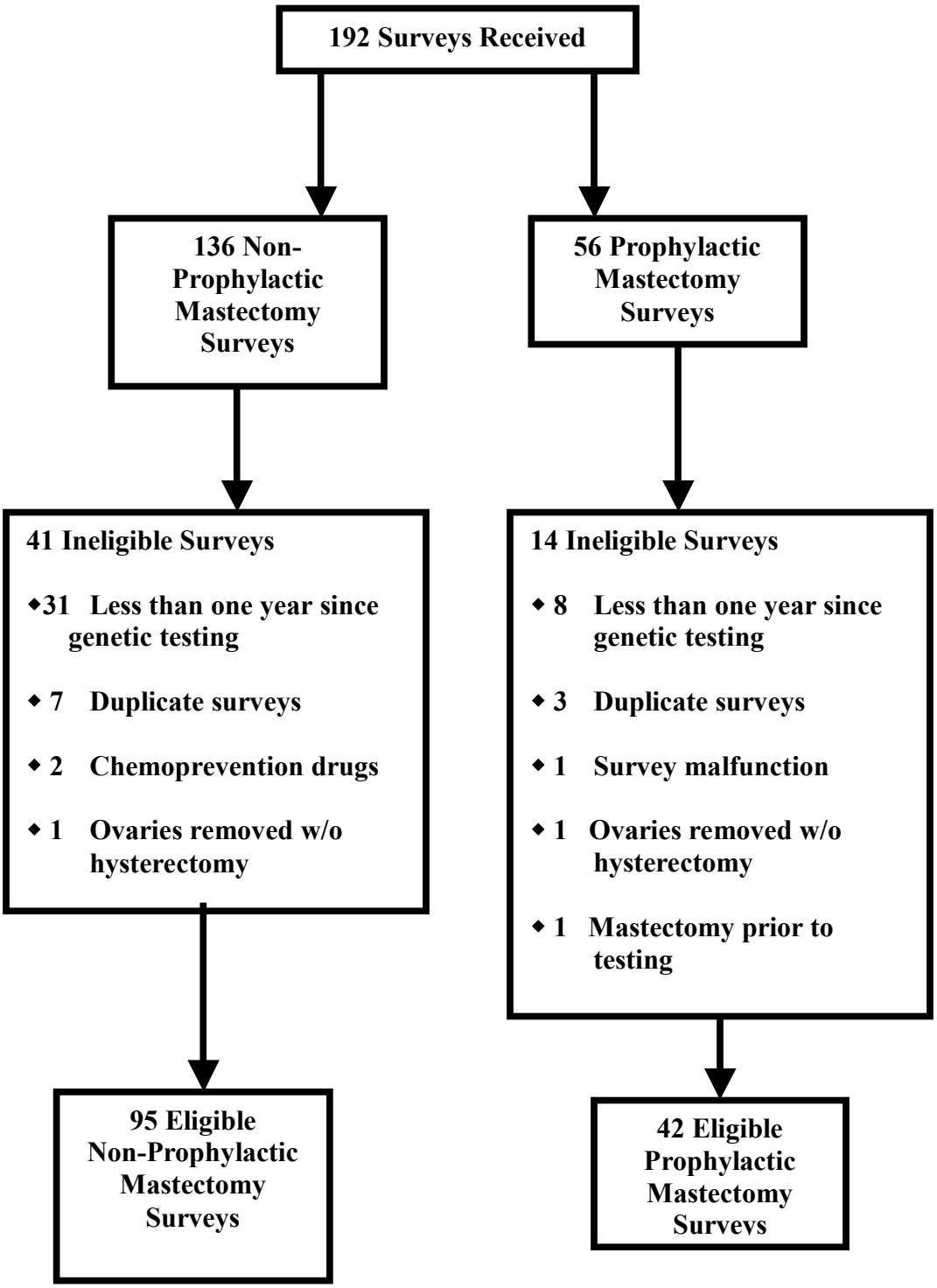

Table 1
Demographic Characteristics of Participants Who Had Opted for Prophylactic Mastectomy versus Participants Who Had Not Opted for Prophylactic Mastectomy

	Participants who Opted for Prophylactic Mastectomy		Participants who Did Not Opt for Prophylactic Mastectomy			
	N	(%)	N	(%)	χ^2	*p*
Ashkenazi Jewish					2.14	.14
Yes	18	(43%)	27	(28%)		
No	24	(57%)	68	(72%)		
Race					.91	.34
White	39	(93%)	93	(98%)		
Non-White	3	(7%)	2	(2%)		
Marital Status					1.72	.18
Married	30	(71%)	55	(58%)		
Not Married	12	(29%)	40	(42%)		
Education					.00	.97
≤ Partial College	8	(19%)	20	(21%)		
≥ College Grad	34	(81%)	75	(79%)		
Household Income					.02	.89
< $40, 000	5	(12%)	9	(9%)		
≥ $40, 000	32	(76%)	75	(79%)		
Did not answer	5	(12%)	11	(12%)		

Participants Who Did Not Opt for Prophylactic Mastectomy. Of the 192 women who completed on-line surveys, 136 women (71%) reported not having undergone prophylactic mastectomies (see Figure 1). Of these women, 41 were found to be ineligible for the following reasons: genetic testing done within the past year (n = 31), duplicate survey entries (n = 7), use of chemoprevention drugs (n = 2), and report of both ovaries having been removed without a hysterectomy (n = 1). The mean age of the remaining 95 women was 35 years (SD = 8.84, range = 21-65). The majority was Caucasian (98%), not of Ashkenazi Jewish heritage (72%), married (58%), had a college degree or higher education (79%), and had an annual household income greater than or equal to $40, 000 (79%) (see Table 1).

Women who did not opt for prophylactic mastectomy were asked about their breast cancer surveillance behaviors. The majority of these women reported the following breast cancer surveillance behaviors at least once in the past year: breast exam conducted by a medical professional (96%), mammogram (78%), and MRI (61%) (see Table 2). Regarding breast self-exams, 72% reported performing self-exams in the past month with 64% reporting regular self-exams in the past year ("about one per month" or "more than one per month") (see Table 3). Eighty percent reported intentions to perform regular self-exams in the upcoming year ("about one per month" or "more than one per month"). Even with these high rates, only 23% of women expressed feeling either "very confident" or "extremely confident" in personal performance of breast self-exams. Twenty percent of these women reported plans (either "likely" or "extremely likely") to have a prophylactic mastectomy in the next 6 months (see Table 3).

Table 2
Surveillance Behaviors of Participants Who Had Not Opted for Prophylactic Mastectomy

	N	(%)
Breast Exam Conducted by Medical Professional in Past Year		
Yes	91	(96%)
No	4	(4%)
Breast Exam Conducted by Medical Professional in Past Three Years		
0	1	(1%)
1	6	(6%)
2	7	(8%)
3	24	(25%)
4	57	(60%)
Mammograms in Past Year		
Yes	74	(78%)
No	21	(22%)
Mammograms in Past Three Years		
0	16	(17%)
1	14	(15%)
2	20	(21%)
3	33	(35%)
4	12	(12%)
MRI in Past Year		
Yes	58	(61%)
No	37	(39%)
MRI in Past Three Years		
0	35	(37%)
1	27	(28%)
2	14	(15%)
3	13	(14%)
4	6	(6%)

Table 3
Medical Characteristics of Participants Who Had Not Opted for Prophylactic Mastectomy

	N	(%)
Plan to have Prophylactic Mastectomy in the next 6 Months		
Extremely Unlikely	52	(55%)
Unlikely	13	(13%)
Not Sure	11	(12%)
Likely	8	(8%)
Extremely Likely	11	(12%)
Self Breast Exam in Past Month		
Yes	68	(72%)
No	27	(28%)
Self Breast Exam in Past Year		
Not al all	9	(10%)
Less than 1/month	25	(26%)
About 1/month	40	(42%)
More than 1/month	21	(22%)
Intentions to perform Self Breast Exam in Next Year		
Not al all	6	(6%)
Less than 1/month	13	(14%)
About 1/month	56	(59%)
More than 1/month	20	(21%)
Personal Confidence in Performing Self Breast Exam		
Not at all	17	(18%)
Little confident	21	(22%)
Fairly confident	35	(37%)
Very confident	17	(18%)
Extremely confident	5	(5%)

T-tests or chi-square analyses were conducted, as appropriate, to compare the participants who had opted for prophylactic mastectomy (n = 42) with the participants who had not opted for prophylactic mastectomy (n = 95) on demographic variables. The groups did not differ significantly on age (t = -.62, p = .53). On the demographic variables of race, Ashkenazi Jewish heritage, marital status, education, and household income, results revealed not even a marginally significant difference ($p < .1$) between the groups (see Table 1). Therefore, none of these variables were included is covariates in the subsequent analyses.

T-tests or chi-square analyses were also conducted to compare the groups on medical variables. The groups did not differ significantly on menopausal status (χ^2 = 1.82, p = .18), body mass index (t = .17, p = .86), time since genetic testing (t = -.03, p = .77), or whether or not they disclosed their positive genetic test results with their physicians (χ^2 = .29, p = .59). Regarding family history of first degree relatives with breast or ovarian cancers, the groups did not differ on whether or not they had first degree relatives with breast cancer (χ^2 = .59, p = .44), but did differ significantly on whether or not they had first degree relatives with ovarian cancer (χ^2 = 4.78, p = .03) (see Tables 4 and 5). Women in the prophylactic mastectomy group were less likely to have first degree relatives with ovarian cancer.

Table 4
Medical Characteristics of Participants Who Had Opted for Prophylactic Mastectomy versus Participants Who Had Not Opted for Prophylactic Mastectomy

	Participants who Opted for Prophylactic Mastectomy		Participants who Did Not Opt for Prophylactic Mastectomy			
	M	(SD)	M	(SD)	*t*	*p*
Body Mass Index					.17	.86
	24.42	(4.63)	24.57	(5.0)		
Time Since Genetic Testing (in months)					-.03	.77
	33.36	(21.70)	32.16	(21.81)		

Table 5
Medical Characteristics of Participants Who Had Opted for Prophylactic Mastectomy versus Participants Who Had Not Opted for Prophylactic Mastectomy

	Participants who Opted for Prophylactic Mastectomy		Participants who Did Not Opt for Prophylactic Mastectomy			
	N	(%)	N	(%)	χ^2	*p*
Tell Physician Test Results					.29	.59
Yes	35	(83%)	84	(88%)		
No	7	(17%)	11	(12%)		
First Degree Relatives with Breast Cancer					.59	.44
Yes	33	(79%)	67	(71%)		
No	9	(21%)	28	(29%)		
First Degree Relatives with Ovarian Cancer					4.78	.03*
Yes	4	(9%)	27	(28%)		
No	36	(86%)	65	(69%)		
Don't Know	2	(5%)	3	(3%)		
Menopausal Status					1.82	.18
Premenopausal	35	(83%)	88	(93%)		
Menopausal	7	(17%)	7	(7%)		

Relationship of Decision Making Variables to Choice of Risk-Reducing Option

The first hypothesis stated that the assessment of the pros and cons of prophylactic mastectomy would be associated with the type of risk-reducing option chosen. As predicted, more positive scores on the Decisional Balance Scale for Prophylactic Mastectomy (pros-cons) ($r = .31$, $p \leq .001$) and higher scores on the pros items alone ($r = .29$, $p \leq .001$) were significantly related to having undergone prophylactic mastectomy surgery. Also as predicted, higher scores on the cons items alone ($r = -.25$, $p \leq .05$) were significantly negative correlated with having undergone prophylactic mastectomy surgery (see Tables 6 and 7).

Table 6
Correlational Analyses of Decision Making and Perceived Impact Variables With Group Status

	Group Status
Decisional Balance Scale for Prophylactic Mastectomy	
Pros	.29**
Cons	- .25*
Total (Pros – Cons)	.31**
Cancer Worry Scale	
Past Month	- .39***
When Genetically Tested	.28**
Miller Behavioral Style Scale	
Monitors	.01
Blunter	- .06
Total Score (Monitors – Blunters)	.04
Center for Epidemiologic Studies-Depression Scale	- .19*
Decisional Conflict Scale	- .38***
Decisional Regret Scale	- .58***

* $p \leq .05$
** $p \leq .001$
*** $p \leq .0001$

Table 7
Comparisons between Participants Who Had Opted for Prophylactic Mastectomy versus Participants Who Had Not Opted for Prophylactic Mastectomy on Decision Making and Perceived Impact Variables

	Did Not Opt for PM		Opted for PM			
	M	(SD)	M	(SD)	*t*	*p*
Decisional Balance Scale for Prophylactic Mastectomy						
Pros	12.99	2.72	14.74	2.51	-3.55	.0005**
Cons	13.27	2.75	11.76	2.61	3.01	.0031*
Total (Pros – Cons)	-0.28	4.81	2.98	4.08	-3.83	.0002**
Cancer Worry Scale						
Past Month	7.61	2.78	5.19	2.45	4.87	<.0001***
When Genetically Tested	10.37	3.57	12.50	2.78	-3.43	.0008**
Miller Behavioral Style Scale						
Monitors	10.06	3.35	10.14	3.38	-.13	.8982
Blunters	4.98	2.63	4.64	2.71	.68	.4957
Total Score (M-B)	5.08	4.35	5.50	4.69	-.50	.6153
CES-D	12.02	10.15	8.10	7.51	2.52	.0133*
Decisional Conflict Scale	35.49	20.51	18.56	16.42	4.72	<.0001***
Decisional Regret Scale	29.63	17.17	6.07	10.96	9.65	<.0001***

* $p \leq .05$
** $p \leq .001$
*** $p \leq .0001$

The second hypothesis stated that the treatment chosen would be related to recommendation of that treatment by a physician. Specifically, if a physician had recommended prophylactic mastectomy, women would have been more likely to have chosen a prophylactic mastectomy. Of the 137 women surveyed, 91 reported receiving at least one physician's opinion about the risk-reducing option she should pursue. Regarding the content of physician opinions, each group received an assortment of physician opinions (see Table 8 and 9) ranging from one type of risk-reducing option only (surveillance, prophylactic mastectomy, or chemoprevention) to a mixture of opinions for all three options. Regarding recommendations for prophylactic mastectomy only, 71% of the prophylactic mastectomy group received doctor recommendations that included physician opinions only endorsing prophylactic mastectomy compared to 30% of the no prophylactic mastectomy group. Twenty-nine percent of the prophylactic mastectomy group and 70% of the no prophylactic group received opinions that included options other than prophylactic mastectomy alone. These rates reflect a significant relationship between physician opinions that only included prophylactic mastectomy and risk-reducing option (prophylactic mastectomy versus no prophylactic mastectomy) ($X^2 = 11.85$; $p < .001$) (see Table 10). For the group as a whole, there was no relationship between whether or not a woman received a physician opinion about the risk-reduction option she should obtain and risk-reducing option (prophylactic mastectomy versus no prophylactic mastectomy) ($X^2 = .00$, $p = 1.000$) (see Table 11). However, the risk-reducing groups did differ significantly on the number of doctor opinions received ($t = -2.59$, $p = .01$) (see Table 12) with women who underwent prophylactic mastectomy receiving more doctor opinions.

Table 8
Types of Doctor Recommendation for Women who Did Not Opt for Prophylactic Mastectomy

	N	(%)
Surveillance Only	23	(36%)
Prophylactic Mastectomy Only	19	(30%)
Chemoprevention Only	1	(2%)
Mixed Recommendations	20	(32%)

Table 9
Types of Doctor Recommendation for Women who Did Opt for Prophylactic Mastectomy

	N	(%)
Surveillance Only	0	(0%)
Prophylactic Mastectomy Only	20	(71%)
Chemoprevention Only	0	(0%)
Mixed Recommendations	8	(29%)

Table 10
Correlational Analyses of Doctor Recommendations with Group Status

	Participants who Opted for Prophylactic Mastectomy		Participants who Did Not Opt for Prophylactic Mastectomy			
	N	(%)	N	(%)	χ^2	*p*
Doctor Treatment Recommendations					11.85	.0006
PM Only	20	(71%)	19	(30%)		
Mixed	8	(29%)	44	(70%)		

Table 11
Correlational Analyses of Whether or Not MD Opinion was Obtained With Group Status

	Participants who Opted for Prophylactic Mastectomy		Participants who Did Not Opt for Prophylactic Mastectomy			
	N	(%)	N	(%)	χ^2	*p*
Ask MD Opinion					.001	.00
Yes	28	(67%)	63	(66%)		
No	14	(33%)	32	(34%)		

Table 12
Comparison Between Participants Who Had Opted for Prophylactic Mastectomy versus Participants Who Had Not Opted for Prophylactic Mastectomy on Number of MD Opinions

	Did Not Opt for PM		Opted for PM			
	M	(SD)	M	(SD)	*t*	*p*
Number of MD Opinions					-2.59	.0111*
Prophylactic Mastectomy			2.82	(.98)		
No Prophylactic Mastectomy			2.30	(.84)		

The third hypothesis stated that women with higher levels of cancer worry at time of genetic testing would be more likely to have chosen prophylactic surgery than women with lower levels of cancer worry. As predicted, women who retrospectively reported higher cancer worry scores a month after receiving their *BRCA1/2* positive results were more likely to have chosen prophylactic mastectomy ($r = .28$, $p \leq .001$) (see Tables 6 and 7).

The fourth hypothesis stated that information-seeking style would be related to treatment choice with women with greater tendencies to use a monitoring information-seeking style more likely to have chosen prophylactic surgery. Contrary to predictions, there was no significant relationship found between information monitoring ($r = .01$, $p = .8715$) and risk-reduction option chosen.

Exploratory analyses were undertaken to examine relationships among the variables found in the univariate analyses to be related to the risk-reducing option chosen. Specifically, the first analysis sought to identify which retrospective variables from the four decision making models provided the best fit for predicting risk-reducing choice in *BRCA1/2* positive, healthy, unaffected women. Because the dependent variable (risk-reducing option) is dichotomous, a logistic regression analysis was performed using the following significant ($p < .05$) retrospective variables for the entire sample: Decisional Balance Scale for Prophylactic Mastectomy and Cancer Worry Scale from time of genetic testing. Using the forward selection method, the Decisional Balance Scale for Prophylactic Mastectomy was entered in first followed by the Cancer Worry score from the time of genetic testing. The results (shown in Table 13) indicate that both measures were significant in the multivariate analyses. Consistent with previous correlational analyses, having a higher Decisional Balance Scale for Prophylactic Mastectomy total score and higher retrospective Cancer Worry Scale score were associated with membership in the prophylactic mastectomy group. Specifically, for every unit increase on the Decisional Balance Scale for Prophylactic Mastectomy total score the likelihood of being in the prophylactic mastectomy group increases by 21%. Similarly, for every

unit increase on the retrospective Cancer Worry Scale the likelihood of being in the prophylactic mastectomy group increases by 30%.

Table 13
Multivariate Logistic Regression Predicting Risk Reducing Option Group Membership on Entire Sample

Variable	OR	95% CI		*p*
Decisional Balance Total Score	1.211	1.10	1.33	<.0001
Cancer Worry Scale (at genetic testing)	1.298	1.13	1.49	.0002

Note: OR = odds ratio; CI = confidence interval

A second logistic regression analysis was conducted on only the 91 participants who reported receiving advice on risk-reducing option from at least one physician. Again in this case, the dichotomous dependent variable again was risk-reducing option. The significant ($p < .05$), independent variables included the Decisional Balance Scale for Prophylactic Mastectomy, the Cancer Worry Scale from time of genetic testing, and treatment recommendation of prophylactic mastectomy exclusively. Using the forward selection method, the treatment recommendation of prophylactic mastectomy only was entered in first followed by the Cancer Worry score from the time of genetic testing. The Decisional Balance Scale for Prophylactic Mastectomy was not included in this model, as it did not meet the .05 significance level. The results (shown in Table 14) indicate the two measures that were significant in multivariate analyses. Having a physician recommendation for prophylactic mastectomy exclusively and higher Cancer Worry Scale scores at time of genetic testing were associated with membership in the prophylactic mastectomy group. Specifically, having a doctor recommend prophylactic mastectomy exclusively increases the likelihood of being in the prophylactic mastectomy group by 625%. Likewise, for every unit increase on the retrospective Cancer Worry Scale score the likelihood of being in the prophylactic mastectomy group increases by 27%. A possible explanation for the exclusion of the Decisional Balance Scale for Prophylactic Mastectomy in this model is that it is significantly correlated with treatment recommendations of prophylactic mastectomy variable are significantly correlated ($r = -.38$, $p < .001$).

Table 14
Multivariate Logistic Regression Predicting Risk Reducing Option Group Membership the Subsample Who Reported Seeking Advice on Risk-Reducing Options from at Least One Physician

Variable	OR	95% CI		*p*
Treatment Recommendation of PM only	6.255	2.20	17.76	.0006
Cancer Worry Scale (at genetic testing)	1.266	1.06	1.51	.0081

Note: OR = odds ratio; CI = confidence interval

Relationship of Perceived Impact Variables to Choice of Risk-Reducing Option

A final set of analyses tested hypotheses that women who chose prophylactic mastectomy would experience less decisional conflict, less decisional regret, lower levels of depressive symptomatology, and lower levels of current cancer worry than women who did not choose prophylactic mastectomy. As predicted, scores on the Decisional Conflict Scale, Decisional Regret Scale, CES-D and Cancer Worry Scale were all negatively correlated with risk-reducing option. The direction of these relationships indicates that, as expected, having chosen prophylactic mastectomy was associated with less decisional conflict ($r = -.38$, $p \leq .0001$), decisional regret ($r = -.58$, $p \leq .0001$), depressive symptomatology ($r = -.19$, $p \leq .05$), and cancer worry ($r = -.39$, $p \leq .0001$) (see Tables 6 and 7).

Chapter Four

Discussion

The primary goal of the present study was to explore the relationship between a set of theory-driven decision making variables and the actual treatment decisions made by a group of healthy, unaffected women who had tested positive for a *BRCA1/2* gene mutation. In addition, the perceived impact (conflict, regret, depressive symptomatology, and current cancer worry) of the treatment option selected was explored. This discussion will review the findings, consider the limitations of the current study, and identify future research directions.

Consistent with predictions, the choice of risk-reducing option (prophylactic mastectomy versus no prophylactic mastectomy) was associated with the following decision making variables: assessment of advantages and disadvantages of risk reducing strategies, physician input, and past cancer worry. Like in the normative decision making theory (Schwartz, Peshkin, et al., 2005; Armstrong et al., 2000; Lerman et al., 1996), women who rated the advantages of prophylactic mastectomy higher were more likely to have obtained a prophylactic mastectomy while women who had rated the disadvantages of prophylactic mastectomy as higher were less likely to obtain a prophylactic mastectomy. As in the shared decision making theory (McNutt, 2004; Coulter, 2002), physician recommendations for prophylactic mastectomy only are significantly related to risk-reducing option (prophylactic mastectomy versus no prophylactic mastectomy) with

significantly more women from the prophylactic mastectomy group having received recommendations for prophylactic mastectomy only. As suggested in affect based theory (Slovic, Finucane, Peter, & MacGregor, 2004; Ubel & Lowenstein, 1997; Schwartz, Peshkin, et al., 2005), women who retrospectively reported higher levels of cancer worry at time of genetic testing were more likely to have undergone prophylactic mastectomy. Finally, contrary to predictions based in previous research on information-seeking style (Miller, Roussi, Caputo, & Kruss, 1995), no relationship existed between monitoring information-seeking style and risk-reduction option.

The predictive values of the significant, retrospective independent variables were looked at in two separate logistic regression models. When the Decisional Balance Scale for Prophylactic Mastectomy and Cancer Worry Scale from time of genetic testing were included in the model they both contributed significantly to the chances of a women choosing prophylactic mastectomy in the entire sample. In order to investigate the physician input variable, another logistic regression model was run only using the sample that had reported receiving an opinion on which risk-reducing option to undergo from at least one physician. In this model, only the physician recommendation and Cancer Worry Scale from the time of genetic testing were found to contribute significantly to a women choosing prophylactic mastectomy.

Finally, all the perceived impact variables (the Decisional Conflict Scale, Decisional Regret Scale, CES-D, and Cancer Worry Scale) were found to be negatively correlated with risk-reducing option. As expected, women who opted for prophylactic mastectomy reported less decisional conflict, regret, depressive symptomatology, and cancer worry.

These findings expand the current decision making information literature with *BRCA1/2* gene mutation carriers in three ways. The first way involves the sample studied. Past research has been conducted only on heterogeneous samples of women (e.g., affected and unaffected, *BRCA1/2* gene mutation carriers, and various definitions of women at high risk) (Van Dijk et al., 2003; Stefanek et al., 1999; Armstrong et al., 2000). This study focuses only on women without a personal history of cancer who have tested positive for the *BRCA1/2* gene mutation. Therefore, all these women have the elevated chances of being diagnosed with breast and/or ovarian cancers in their lifetimes. The second way this study extends the literature on decision making and *BRCA1/2* is to investigate variables related to the decision of whether or not to opt for prophylactic mastectomy. Although genetic testing decisions and prophylactic oophorectomy decisions have been studied previously, few studies have looked at decisions surrounding prophylactic mastectomy (Tercyak et al., 2007). Finally, this study examined variables from four different decision making theories. Previous research in this area has generally been more limited in scope.

As noted in previous research on normative decision making, women who ranked the advantages of either genetic testing (Armstrong et al., 2000; Lerman et al., 1996) or prophylactic oophorectomy (Fry, Rush, Busby-Earle, & Cull, 2001) higher than the disadvantages were more likely to pursue these options. Similar to this previous research, this study found that women who rated the advantages of prophylactic mastectomy higher than the disadvantages of prophylactic mastectomy were more likely to pursue prophylactic mastectomy. This study is novel in that it investigates the

normative decision making theory in relation to whether or not *BRCA1/2* gene mutations carriers without a history of cancer opt for prophylactic mastectomy.

The shared decision making, or physician input, literature on genetic testing and treatment outcome suggests that physician's opinions were both desired (Armstrong et al., 2002) and a contributing factor in whether or not women pursued genetic testing (Schartz, Lerman, et al., 2005). Likewise in this study, treatment recommendation for prophylactic mastectomy was significantly related to choice of prophylactic mastectomy in the women who sought out the opinion of one or more physicians.

Previous research with the affect-based decision making theory suggests that higher cancer-related distress and worry lead women to pursue genetic testing (Lerman et al., 1997) and report higher intentions for prophylactic surgery (Van Dijk et al., 2003; Stefanek et al, 1999). This research is similar to these studies. Women who reported higher cancer worry at the time of genetic testing were more likely to obtain prophylactic mastectomies.

Prior research on genetic counseling decisions and information-seeking style suggested that monitors are more likely to amplify the negative impact of testing (Lerman et al., 1994) and perceived risk (Sherman et al., 1995). Extrapolating from these findings, we hypothesized that high monitoring *BRCA1/2* genetic mutation carriers would amplify the negatives of their situation and amplify their risks thereby resulting in more prophylactic mastectomy decisions. Unlike the previous research on information-seeking style, greater use of a monitoring coping style was not related to risk-reducing option choice. This discrepancy may have something to do with the women sampled. Women who frequent the FORCE website are likely to be actively seeking out information on

their *BRCA1/2* status (i.e., monitoring). Therefore, women with blunting coping styles may have been less likely to have accessed the study through this information-based website.

Previous research has examined the relationship of *BRCA1/2* gene mutation status to quality of life and psychological distress. Tercyak et al. (2007) report on the quality of life and psychological distress of a sample of breast cancer patients with either positive results (15%) or uninformative results (85%). Whether or not women chose to undergo contralateral prophylactic mastectomy (versus unilateral mastectomy or lumpectomy) did not predict short-term quality of life or cancer-specific distress. In a study most similar to the present study, Madalinkska et al. (2005) compare high-risk women who opt for periodic gynecologic screening versus prophylactic bilateral salpingo-oophorectomy. While no significant differences were found in generic quality of life, the group opting for prophylactic oophorectomy did report significantly less worries specific to breast and ovarian cancers and lower cancer risk perceptions. These results are similar to findings from the present study which suggest that women who chose prophylactic mastectomy are actually doing better psychologically in terms of experiencing lower levels of current cancer worry and depressive symptomatology than women who did not opt for prophylactic mastectomy. Besides a measure of general quality of life (e.g., depressive symptomatology) and cancer specific worry, the present study includes variables of decisional conflict and decisional regret. This is similar to finding for decisional regret (Borgen et al., 1998) in which the majority of women (n = 349) who signed up for the National Prophylactic Mastectomy Registry between 1945 and 1996 did not express regret over their decision to undergo prophylactic mastectomy. Likewise, in a small

study ($N = 14$) on decisional satisfaction (Stefanek, Helzlsouer, Wilcox, & Houn, 1995) with women at high risk, satisfaction with prophylactic mastectomy was high for all participants. Therefore this study expands the psychological variables studied and focuses exclusively on a positive *BRCA1/2* sample.

Limitations

This study had several limitations. Without a valid and reliable measure of the perceived advantages and disadvantages of undergoing prophylactic mastectomy available in the literature, the Decisional Balance Scale for Prophylactic Mastectomy was specifically designed for this study. This measure was developed by taking items on the assessment of advantages and disadvantages of prophylactic mastectomy by women at increased risk for breast cancer from the literature (Claes, et al., 2005). Coefficient alphas calculated in the study were weak (.48 for the advantages scale and .44 for the disadvantages scale), suggesting the findings involving this measure be cautiously considered.

The physician input variables possessed a number of weaknesses. These variables included whether or not a physician gave his/her opinion regarding risk-reducing strategy, how many different physician opinions were obtained, and the specific nature of the recommendations. While 42 women in this sample underwent prophylactic mastectomies, only 28 women reported receiving a physician's opinion regarding risk-reducing strategies. However, all 42 women had to have worked with surgeons willing to perform their prophylactic mastectomies. Assuming they did not undergo prophylactic mastectomy against medical advice, all 42 women of these women had in a sense received opinions from at least one doctor regarding risk-reducing strategies.

Because of the cost of gene mutation testing (Peterson, Milliron, Lewis, Goold, & Merajver, 2002), the profile of FORCE members, and the need to have Internet access, it was no surprise that the sample for the current study was made up primarily of Caucasian, well-educated, higher income women. This feature limits the generalizability of these findings to populations more diverse with regard to race/ethnicity, education, and socioeconomic status.

In order to attain a sample of positive, unaffected women of this size, an anonymous web-based survey was necessary. This method of data collection has drawbacks in regards to limited access and limited tracking ability. As stated above, only women who had access to the Internet were able to participate. In addition, there was no way to track the response rate to determine if a systematic bias existed connected with whether or not a woman agreed to participate. Finally, based on same birthdates and similar demographic data, ten women were found to have completed the survey more than once.

Limitations of this study also exist because of the retrospective, self-report, cross-sectional nature of this study. Three of the measures (Decisional Balance Scale for Prophylactic Mastectomy, Cancer Worry Scale at time of genetic testing, and the Decisional Conflict Scale) asked respondents to provide retrospective information. Although care was taken in the instructions to provide context by cueing participants to both the season of the year and major events that coincided with their genetic testing, the accuracy of the recalled responses is impossible to verify. In addition, all data were collected via self-report without any means to verify that all eligibility criteria had been met or the accuracy of the medical information provided, including recommendations for

risk reduction. Ideally, corroborating medical data would also have been collected from medical care providers. Finally, the cross-sectional design limits the ability to make conclusions about the causal relationships between the decision making variables and the risk-reducing options chosen.

Future Directions

The research designs of future studies could be improved in several ways. More information about decision making variables for risk-reducing options could be obtained by designing prospective studies including pre-genetic testing baseline assessments. Therefore, differences between individuals prior to testing could be identified. In addition, a longitudinal research design would allow for a better understanding of the variables that go into risk-reducing decisions, as well as the impact of these risk-reducing decisions over time. Because women with the *BRCA1/2* gene mutation are at increased risk for both breast and ovarian cancers (Antoniou et al., 2003), future research should broaden the scope of risk-reducing options studied in these healthy, unaffected *BRCA1/2* gene mutation carriers. In contrast to the present study that focused only on the decision to undergo prophylactic mastectomy, future research should include decision making variables for prophylactic oophorectomy, as well as chemoprevention as the use of this option increases.

Data from this study suggest women who do not opt to undergo prophylactic mastectomy are experiencing higher levels of cancer worry, decisional conflict, decisional regret, and depressive symptomatology when compared to the women who do undergo prophylactic mastectomies. In order for healthy, unaffected, gene mutation carriers to make informed risk-reducing decisions, information on the psychological

distress of not opting for prophylactic mastectomy needs to be available. No studies of this kind could be found in the current literature. Future research should focus on the degree of distress experienced by this sample of healthy, unaffected, gene mutation carriers who do not opt for prophylactic mastectomy, along with the best ways to provide psychological services if and when necessary.

The current study includes only women who received a positive genetic test results. However, a woman may receive ambiguous (i.e., indeterminate) *BRCA1/2* test results. In these cases, the test may show a *BRCA1/2* mutation that has yet to be correlated with breast or ovarian cancers. Because women tested for the *BRCA1/2* gene mutation may receive ambiguous results, ultimately more future research should include large enough samples of women who have received indeterminate results in order to establish if and how their decision making differs from women who receive positive test results. Finally, all future studies should strive to recruit larger, more demographically diverse samples in order to generalize study findings.

Summary

This study addresses a salient issue that *BRCA1/2* gene mutation carriers face. Prior to this study, little was known about the decision making factors underlying the choice of prophylactic mastectomy for women with a *BRCA1/2* mutation. One hundred thirty-seven unaffected, positive gene mutation carriers were assessed via an on-line survey on the following theory-based decision making variables: advantages and disadvantages of prophylactic mastectomy (normative decision theory), physician recommendation (shared decision making theory), cancer worry (affect theory), and information-seeking coping style. The results suggest higher assessments of advantages

over disadvantages of prophylactic mastectomy, likelihood of doctor recommendation for prophylactic mastectomy exclusively, and higher cancer worry at time of testing are associated with choosing the risk-reducing option of prophylactic mastectomy. Additional findings suggested that women who chose prophylactic mastectomy fared better psychologically than those who did not in terms of experiencing less decisional conflict and regret as well as lower levels of cancer worry and depressive symptomatology. Continued research addressing decision making variables and the impact of risk-reducing decisions may lead to improved understanding and interventions on how best to approach these difficult decisions.

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Appendices

Appendix A: Pilot Participant Telephone Script

Hello, my name is Heidi King and I am calling from the Moffitt Cancer Center. Sue Friedman provided me with your name as someone who might be interested in completing a survey we are piloting for one of our new studies.

Have you spoken with Sue Friedman?

Is now a good time to tell you a bit more about the study?

We are interested in finding out how women who have tested positive for the *BRCA1/2* gene mutation go about making decisions to reduce their risk of breast cancer. The survey is posted on-line. Before we open the study up to the general population, we would like to verify the length of time it takes to complete the study, as well make sure all the questions are clearly stated.

Does this sound like something you might be interested in?

I have a few questions to ask you to ensure this pilot study is a good fit for you.

1. Have you tested positive for the *BRCA1/2* gene mutation? _____Must be +.

2. When was that? _____Must be at one year or more ago.

3. Have you ever been diagnosed with <u>any</u> type of cancer? _____
   Only exception is basal cell cancer.

4. Have you had a prophylactic oophorectomy (the removal of healthy ovaries in order to reduce your risk of cancer)? _____ Must be 'no'.

5. May I ask your age? _____Must be 18 or older.

6. Are you comfortable reading English?_____

7. Do you have access to the Internet?_____

Appendix B: Informed Consent for Pilot Study

Informed Consent Form

Social and Behavioral Sciences
University of South Florida

Researchers at the University of South Florida (USF) study many topics. We want to learn more about how women who are *BRCA1/2* gene mutation carriers go about making decisions about reducing their risk of breast cancer. To do this, we need the help of people who agree to take part in research studies.

Title of research study: Pilot Study for Risk Reduction Decision Making in Women with *BRCA1/2* Gene Mutations

Person in charge of study: Paul Jacobsen, PhD

Study staff who can act on behalf of the person in charge: Heidi M. King, MA

Where the study will be done: H. Lee Moffitt Cancer Center

General Information about the Research Study

The purpose of this pilot study is to verify the length of time it takes to complete the survey on how women who are *BRCA1/2* gene mutation carriers go about making decisions about whether or not to undergo prophylactic mastectomies (surgical removal of healthy breast tissue in order to reduce the risk of breast cancer) to reduce their risk of breast cancer. In addition, we need to ensure that the wording of all questions are clearly stated and fully understood by individuals completing the survey.

Plan of Study

If you agree to participate, you will be asked to complete a one-time, on-line questionnaire that does not ask for identifying information beyond your birthday and general demographic information. It should take you approximately 25 minutes to complete this on-line survey. Then a researcher will call you on the phone to go over the items to ensure that they were clearly stated.

Payment for Participation

There will be no financial compensation for participating in this study.

Benefits of Being a Part of this Research Study

You will not benefit directly by participating. However, the information you provide will help ensure that the survey is clearly worded prior to being disseminated.

Risks of Being a Part of this Research Study

We do not foresee any risk to you in participating in this study.

Confidentiality of Your Records

The information provided will be kept confidential to the extent feasible using the Internet. All electronic study data will be password protected with access restricted to approved personnel. However, certain people may need to see your study records. By law, anyone who looks at your records must keep them confidential. The only people who will be allowed to see these records are:

- Study staff.
- People who make sure that we are doing the study in the right way. They also make sure that we protect your rights and safety:
    - The USF Institutional Review Board (IRB)
    - The United States Department of Health and Human Services (DHHS)

▪ **Volunteering to be Part of this Research Study**

Your decision to participate in this research study is completely voluntary. You are free to participate in this research study or to withdraw at any time. If you to choose not to participate, or if you withdraw, there will be no penalty or loss.

▪ **Questions and Contacts**

- If you have any questions about this research study, contact Heidi King, MA at 1-800-456-3434 X4606 or Dr. Paul Jacobsen at 813-632-1810.
- If you have questions about your rights as a person who is taking part in a research study, you may contact a member of the Division of Research Compliance at the University of South Florida at 813-974-5638.

Consent to Take Part in this Research Study

It is up to you. You can decide if you want to take part in this study.

I freely give my consent to take part in this study. I understand that this is research. I have received a copy of this consent form.

_____

Signature Printed Name Date
of Person taking part in study of Person taking part in study

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect.

The person who is giving consent to take part in this study

- Understands the language that is used.
- Reads well enough to understand this form. Or is able to hear and understand when the form is read to him or her.
- Does not have any problems that could make it hard to understand what it means to take part in this study.
- Is not taking drugs that make it hard to understand what is being explained.

To the best of my knowledge, when this person signs this form, he or she understands:

- What the study is about.
- What needs to be done.
- What the potential benefits might be.
- What the known risks might be.
- That taking part in the study is voluntary.

_____	_____	_____
Signature of Investigator or authorized research investigator designated by the Principal Investigator	Printed Name of Investigator	Date

Appendix C: First Website Screen--Eligibility Criteria

Study of Risk Reduction Decision Making in Women with *BRCA1/2* Gene Mutations

The purpose of this study is to learn more about how women who are *BRCA1/2* gene mutation carriers go about making decisions about ways to reduce their risk of breast cancer. You will be asked to complete an on-line survey that takes approximately 25 minutes. Your participation in this study is anonymous to the extent possible using the Internet.

To participate in this study, you must meet all of the following conditions:

- You are a woman.
- You underwent genetic testing for the *BRCA1/2* gene mutation one year or more ago.
- You have tested positive for the *BRCA1/2* gene mutation.
- You have **never** been diagnosed with breast cancer.
- You have **never** been diagnosed with any other type of cancer (with the exception of basal cell skin cancer).
- You **have not** undergone a prophylactic oophorectomy (surgical removal of healthy ovaries in order to reduce the risk of breast and/or ovarian cancers).
- You are at least 18 years old.
- You are able to read and understand English.

CLICK HERE IF YOU MEET ALL OF THESE CONDITIONS	CLICK HERE IF YOU DO NOT MEET ALL OF THESE CONDITIONS

Ineligible Message:
Thank you for your interest. However, at this time, you do not meet eligibility criteria for this study. Have a great day**!**

Eligible Message:
You are eligible to participate in the study! Please read through the full description of the study provided below to become informed about any risks and benefits as a result of your participation. Please click on "Agree" or "Do Not Agree" at the bottom of the page once you have read through the entire informed consent.

Informed Consent Form

Social and Behavioral Sciences
University of South Florida

Researchers at the University of South Florida (USF) study many topics. We want to learn more about how women who are *BRCA1/2* gene mutation carriers go about making decisions about reducing their risk of breast cancer. To do this, we need the help of people who agree to take part in research studies. You are being asked to participate because you have met the following eligibility criteria:

1) You are a woman.
2) You have tested positive for the *BRCA1/2* gene mutation one year or more ago.
3) You have never been diagnosed with breast cancer, or any other type of cancer (with the exception of basal skin cancer).
4) You have not undergone a prophylactic oophorectomy (surgical removal of healthy ovaries in order to reduce the risk of breast and/or ovarian cancers).
5) You are at least 18 years old.
6) You are able to read and understand English.

Title of research study: Risk Reduction Decision Making in Women with *BRCA1/2* Gene Mutations

Person in charge of study: Paul Jacobsen, PhD

Study staff who can act on behalf of the person in charge: Heidi M. King, MA

Where the study will be done: H. Lee Moffitt Cancer Center

General Information about the Research Study

The purpose of this research study is to learn more about how women who are *BRCA1/2* gene mutation carriers go about making decisions about whether or not to undergo prophylactic mastectomies (surgical removal of healthy breast tissue in order to reduce the risk of breast cancer**)** to reduce their risk of breast cancer.

Plan of Study

If you agree to participate, you will be asked to complete a one-time, on-line questionnaire that does not ask for identifying information beyond your birthday and general demographic information. It should take you approximately 25 minutes to complete this on-line survey.

Payment for Participation

There will be no financial compensation for participating in this study.

Benefits of Being a Part of this Research Study

You will not benefit directly by participating. However, the information you provide will help researchers better understand decision making in *BRCA1/2* mutation carriers.

Risks of Being a Part of this Research Study

We do not foresee any risk to you in participating in this study.

Confidentiality of Your Records

You will be anonymously participating in this study to the extent feasible using the Internet. All electronic study data will be password protected with access restricted to approved personnel.

However, certain people may need to see your study records. By law, anyone who looks at your records must keep them confidential. The only people who will be allowed to see these records are:

- Study staff.
- People who make sure that we are doing the study in the right way. They also make sure that we protect your rights and safety:
    - The USF Institutional Review Board (IRB)
    - The United States Department of Health and Human Services (DHHS)

We may publish what we find out from this study. However, the data obtained from you will be combined with data from other people in the publication. We will not be collecting or disclosing any identifying information about you.

- **Volunteering to be Part of this Research Study**

Your decision to participate in this research study is completely voluntary. You are free to participate in this research study or to withdraw at any time. If you to choose not to participate, or if you withdraw, there will be no penalty or loss.

- **Questions and Contacts**
    - If you have any questions about this research study, contact Heidi King, MA at 1-800-456-3434 X4606 or Dr. Paul Jacobsen at 813-632-1810.
    - If you have questions about your rights as a person who is taking part in a research study, you may contact a member of the Division of Research Compliance at the University of South Florida at 813-974-5638.

By clicking the "agree" button below, you indicate that you have read and understood the information above including any possible risks and benefits of participation. You also indicate that you agree to participate in this study.

Appendix E: General Background Information

1. Today's date: ρρ/ρρ/ρρρρ (month/day/year)

2. Birth date: ρρ /ρρ/ ρρρρ (month/day/year)

3. Height: ρ (ft) ρρ (in)

4. Weight: ρ ρ ρ (pounds)

5. Are you:

ρ Hispanic or Latino
ρ Not Hispanic or Latino

6. Race:

ρ American Indian or Alaska Native
ρ Asian
ρ Black or African American
ρ Native Hawaiian/other Pacific Islander
ρ White
ρ More than one race

7. Are you of Ashkenazi Jewish heritage?

ρ Yes
ρ No

8. Marital status:

ρ Never married
ρ Currently married
ρ Separated
ρ Divorced
ρ Widowed

9. Number of children under 18: ρ ρ

Appendix E: General Background Information (Continued)

`10. Current living arrangement :

ρ Live alone ρ Live with roommate who is not partner
ρ Live with spouse/partner ρ Live with parents
ρ Live with children (no spouse/partner) ρ Other (specify)_____

11. How long in current living arrangement:

ρ Less than 1 month ρ Two to 5 years
ρ One to 6 months ρ More than 5 years
ρ Seven months to 2 years

12. Highest level of school completed:

ρ Less than 7th grade ρ Partial college/specialized training
ρ Partial high school (10th or 11th grade) ρ College or university graduate
ρ High School graduate ρ Graduate professional training (graduate degree)

13. Approximate annual gross income for your household:

ρ Less than $ 10,000 ρ $40,000 - $59,999
ρ $10,000 - $19,999 ρ $60,000 - $100,000
ρ $20,000 - $ 39,999 ρ Greater than $100,000
ρ Prefer not to answer

Genetic Testing Information

14. Who referred you for genetic testing?

No one, I referred myself

A family member

An oncologist

A surgeon

A primary care provider (family physician)

A gynecologist

A nurse

Other (describe _____)

15. When did you receive your genetic test results?

Month Year

16. Did you share these results with your primary care doctor?

No

Yes

Family History for Breast and/or Ovarian Cancer

17. Have any of your biological first degree relatives (i.e., your mother, your sister(s), or your daughter(s)) ever had breast cancer?

No (if checked, skip to item 18)

Don't know (if checked, skip to item 18)

Yes

17a. Who?

One First Degree Relative

Two First Degree Relatives

Three First Degree Relatives

More than Three First Degree Relatives

17b. Were any of them first told they had breast cancer at before age 50?

No

Yes

17c. How close is/was your relationship with this relative (if more than one relative had breast cancer, please rate for the relative you feel/felt closest to)?

Not at all close

Somewhat close

Very close

Extremely close

18. Have any of your biological first degree relatives (i.e., your mother, your sister(s), or your daughter(s)) ever had ovarian cancer?

No (if checked, skip to item 19)

Don't know (if checked, skip to item 19)

Yes

18a. Who?

One First Degree Relative

Two First Degree Relatives

Three First Degree Relatives

More than Three First Degree Relatives

18b. Were any of them first told they had breast cancer before age 50?

No

Yes

18c. How close is/was your relationship with this relative (if more than one relative had ovarian cancer, please rate for the relative you feel/felt closest to)?

Not at all close

Somewhat close

Very close

Extremely close

Appendix E: General Background Information (Continued)

Risk-Reducing Options Chosen

19. Have you undergone a prophylactic mastectomy (surgical removal of healthy breast tissue in order to reduce the risk of breast cancer)?

No (if checked, go to Item 20).

Yes (if checked, go to Item 19a)

19a. When did you undergo prophylactic mastectomy?

Month Year

Perceived Risk

19b. Prior to undergoing prophylactic mastectomy, how likely did you think you were to have breast cancer during your lifetime?

Extremely unlikely

Very unlikely

Somewhat unlikely

Somewhat likely

Very likely

Extremely likely

19c. Prior to undergoing prophylactic mastectomy, what did you think your chances were of having breast cancer in your lifetime compared to other women your age?

Much higher

Somewhat higher

About the same

Somewhat lower

Much lower

20. At this time, how likely do you think you are to have breast cancer during your lifetime?

Extremely unlikely
Very unlikely
Somewhat unlikely
Somewhat likely
Very likely
Extremely likely

21. At this time, what do you think your chances are of having breast cancer in your lifetime compared to other women your age?

Much higher
Somewhat higher
About the same
Somewhat lower
Much lower **PM Group now jumps to Item 34**

Intentions

22. In the next 6 months, how likely are you to undergo prophylactic mastectomy?

1	2	3	4	5
Extremely Unlikely	Unlikely	Not Sure	Likely	Extremely Likely

Surveillance Behaviors

23. A breast self-examination involves examining your own breasts to help identify any lumps or changes in your normal breast tissue. Have you performed a breast self-examination for the detection of breast cancer in the past month? (check one box)

    No

    Yes

24. How often have you performed breast self-examination for the detection of breast cancer in the past year?

    Not at all

    Less than once a month

    About once a month

    More than once a month

25. How often do you plan on doing a breast self-examination in the next year**?**

    Not at all

    Less than once a month

    About once a month

    More than once a month

26. How confident do you feel in your ability to perform breast self-examination? (check one box)

    Not at all confident

    A little confident

    Fairly confident

    Very confident

    Extremely confident

27. Please indicate the extent to which you agree or disagree with each of the following statements about a breast self-examination as they apply to women who are *BRCA1* or *BRCA2* positive:

	Strongly Disagree	Disagree	Neither Agree/ Disagree	Agree	Strongly Agree
a. A woman would be less anxious if she did a monthly breast self-examination……					
b. If a woman does a breast self-examination, she may find lumps before her regular check-up.					
c. A woman would gain a lot by doing breast self-examinations…...					
d. Breast self-examinations can prevent future problems……...					
e. Breast self-examinations will improve a woman's health……					

28. Have you had a breast exam conducted by a medical professional for the detection of breast cancer <u>in the past year</u>?

Yes

No - If no, why not?

No reason

My doctor(s) did not recommend it

I didn't think I needed it

I put it off or didn't get around to it

I couldn't afford it

I thought it would be too painful, unpleasant, or embarrassing

I never heard of it

I didn't have any problems or symptoms

I thought I was too young or too old to have it done

Other (please explain)

_____)

29. How many breast exams conducted by a medical professional for the detection of breast cancer have you had in the past 3 years?
(check one box)

0 1 2 3 4 or more

30. Have you had a mammogram for the detection of breast cancer in the past year?

Yes

No - If not, why not?

No reason

My doctor(s) did not recommend it

I didn't think I needed it

I put it off or didn't get around to it

I couldn't afford it

I thought it would be too painful, unpleasant, or embarrassing

I never heard of it

I didn't have any problems or symptoms

I thought I was too young or too old to have it done

Other (please explain
_____)

31. How many mammograms for the detection of breast cancer have you had in the past 3 years?

0 1 2 3 4 or more

32. Have you had magnetic resonance imaging (MRI) for the detection of breast cancer in the past year?

Yes

No - If no, why not?

No reason

My doctor(s) did not recommend it

I didn't think I needed it

I put it off or didn't get around to it

I couldn't afford it

I thought it would be too painful, unpleasant, or embarrassing

I never heard of it

I didn't have any problems or symptoms

I thought I was too young or too old to have it done

Other (please explain)

_____

33. How many MRI's for the detection of breast cancer have you had in the past 3 years?

0 1 2 3 4 or more

34. Have you ever had any cosmetic surgery on your breasts?

No (If checked, go to Item 35.)

Yes (If checked, go to 34a.)

34a. What surgery?

ρ Reconstruction following prophylactic mastectomy
ρ Breast augmentation
ρ Breast reduction
ρ Other

35. In the future, how likely are you to undergo a prophylactic oophorectomy (the surgical removal of healthy ovaries to reduce your risk of breast cancer)?

1	2	3	4	5
Extremely Unlikely	Unlikely	Not Sure	Likely	Extremely Likely

Menopausal Status Questionnaire

36.Have you ever had a hysterectomy (i.e., removal of the womb)?

ρ No
ρ Yes
ρ Don't know

37.Have you ever had one or both of your ovaries removed?

ρ No, neither of my ovaries have been removed
ρ Yes, one ovary removed
ρ Yes, both ovaries removed
ρ Do not know

38. Have you received any hormone replacement therapy within the past week (i.e., estrogen)?

ρNo
ρYes
ρDon't know

39. Have you ever received hormone replacement therapy (i.e., estrogen)?

ρ No
ρ Yes
ρ Don't know

40. Have you had a menstrual period within the past 3 months?

ρNo
ρYes
ρDon't know

41. Have you had a menstrual period within the past 12 months?
ρNo
ρYes
ρDon't know

42. Compared with 12 months ago, are your menstrual periods in the past 3 months, less regular, about the same, or more regular?
ρI have not had a menstrual period within the past 3 months
ρLess regular
ρAbout the same
ρMore regular
ρDon't know

43. Are you currently taking Tamoxifen / Nolvadex?

ρNo
ρYes

44. Are you currently taking Raloxifine / Evista?

ρNo
ρYes

45. Are you currently taking Anastrazole / Arimidex?

ρNo
ρYes

46.Are you currently taking Letrezole / Femara?

ρNo
ρYes

47.Are you currently taking Toremifine / Fareston?

ρNo
ρYes

48.Are you currently taking Exemstrane / Aromasin?

ρNo
ρYes

Appendix F: Decisional Balance Scale for Prophylactic Mastectomy

Below is a list of issues that a woman who is *BRCA1* or *BRCA2* positive might have considered when deciding whether or not to pursue prophylactic mastectomy. Think back to the time after you received your *BRCA1* or *BRCA2* results and were deciding about whether to undergo prophylactic mastectomy. Think about what season of the year it was. Think about the month it was. Think about the major holidays that occurred around this time. Most importantly, try to remember how were feeling, as well as what you were thinking around the time you considered whether or not to undergo a prophylactic mastectomy. Please read each item below and indicate the degree to which you believe you agreed or disagreed with each item when considering prophylactic mastectomy.

***At the time I was deciding about* prophylactic mastectomy….**	Strongly Agree	Agree	Neither Agree Or Disagree	Disagree	Strongly Disagree
49A. I believed prophylactic mastectomy would substantially reduce my risk of breast cancer.					
49B. I was concerned about how prophylactic mastectomy would affect my physical appearance.					
49C. I thought I would worry much less about getting breast cancer if I had prophylactic mastectomy.					
49D. I was not seriously concerned about the surgical risks involved with prophylactic mastectomy.					
49E. I believed having prophylactic mastectomy would not affect how I viewed my body.					
49F. I believed the recovery period following prophylactic mastectomy would be too physically draining for me.					
49G. I believed having a prophylactic mastectomy would negatively affect my sex life.					
49H. I believed, following prophylactic mastectomy, I would still be concerned with my risk for breast cancer.					

Appendix G: Physician Input

50. Did a doctor give his/her opinion to you about the risk-reducing strategy (for example, prophylactic mastectomy or mammography) you should choose?

ρ No (Go to .)
ρ Yes (Go to # 50a)

50A. Did more than one doctor give his/her opinion about the risk-reducing strategy you should choose?

ρ No (Go to #50C)
ρ Yes (Go to #50B)

50B. How many doctors made recommendations?

ρ ρ ρ
2 3 4

What did each doctor recommend?

50C. Doctor #1 most strongly recommended:

ρ Surveillance (e.g., breast self-exam, clinical breast exam, mammography)
ρ Prophylactic mastectomy
ρ Chemoprevention (i.e., use of medications to prevent breast cancer)

50D. Doctor #2 most strongly recommended:

ρ Surveillance (e.g., breast self-exam, clinical breast exam, mammography)
ρ Prophylactic mastectomy
ρ Chemoprevention (i.e., use of medications to prevent breast cancer)

50E. Doctor #3 most strongly recommended:

ρ Surveillance (e.g., breast self-exam, clinical breast exam, mammography)
ρ Prophylactic mastectomy
ρ Chemoprevention (i.e., use of medications to prevent breast cancer)

50F. Doctor #4 most strongly recommended:

ρ Surveillance (e.g., breast self-exam, clinical breast exam, mammography)
ρ Prophylactic mastectomy
ρ Chemoprevention (i.e., use of medications to prevent breast cancer)

Appendix H: Cancer Worry Scale

During the past month . . .

51. How often have you been concerned about getting breast cancer?

Not at all or Rarely	Sometimes	Often	A lot

52. How often have you thought about your own chances of having breast cancer?

Not at all or Rarely	Sometimes	Often	A lot

53. How often have thoughts about breast cancer affected your mood?

Not at all or Rarely	Sometimes	Often	A lot

54. How often have thoughts about breast cancer affected your ability to perform your daily activities?

Not at all or Rarely	Sometimes	Often	A lot

Appendix I: Retrospective Cancer Worry Scale

Think back to the time after you received your *BRCA1* or *BRCA2* results. Think about what season of the year it was. Think about the month it was. Think about the major holidays that occurred around this time. Most importantly, try to remember how you were feeling, as well as what you were thinking around the time you received your *BRCA1* or *BRCA2* results.

One month after receiving your *BRCA1/2* results. . .

55a. How often were you concerned about getting breast cancer?

Not at all or Rarely	Sometimes	Often	A lot

55b. How often did you think about your own chances of having breast cancer?

Not at all or Rarely	Sometimes	Often	A lot

55c. How often did thoughts about breast cancer affected your mood?

Not at all or Rarely	Sometimes	Often	A lot

55d. How often did thoughts about breast cancer affected your ability to perform your daily activities?

Not at all or Rarely	Sometimes	Often	A lot

Appendix J: Decision Conflict Scale

56. Think back to the time after you received your *BRCA1* or *BRCA2* results and were deciding about whether to undergo prophylactic mastectomy. Think about what season of the year it was. Think about the month it was. Think about the major holidays that occurred around this time. Most importantly, try to remember how you were feeling, as well as what you were thinking around the time you considered whether or not to undergo a prophylactic mastectomy. What did you think about the risk-reducing options for breast cancer (e.g., prophylactic mastectomy, mammography, MRI)?

	Strongly Agree	Agree	Neither Agree Or Disagree	Disagree	Strongly Disagree
56a. I knew which options were available to me.					
56b. I knew the benefits of each option.					
56c. I knew the risks and side effects of each option.					
56d. I was clear about which benefits mattered most to me.					
56e. I was clear about which risks and side effects mattered most.					
56f. I was clear about which was more important to me (the benefits or the risks and side effects).					

Appendix J: Decision Conflict Scale (Continued)

57 How did you feel about making a decision about which risk-reducing option to choose?

	Strongly Agree	Agree	Neither Agree Or Disagree	Disagree	Strongly Disagree
a. I had enough support from others to make a choice.					
b. I chose without pressure from others.					
c. I had enough advice to make a choice.					
d. I was clear about the best choice for me.					
e. I felt sure about what to choose.					
f. This decision was easy for me to make.					
g. I felt I made an informed choice.					
h. My decision shows what is important to me.					
i. I expect to stick with my decision.					
j. I am satisfied with my decision.					

Appendix K: Decision Regret Scale

58. Please reflect on the decision you have made about whether or not to undergo prophylactic mastectomy. Please show how strongly you agree or disagree with these statements by selecting the response that best fits your views about your decision.

58a. It was the right decision..... ρρρρρ

58b. I regret the choice that was made..... ρρρρρ

58c. I would go for the same choice if I had to do it over again..... ρρρρρ

58d. The choice did me a lot of harm ..... ρρρρρ

58e. The decision was a wise one..... ρρρρρ

Appendix L: Center for Epidemiologic Studies, Depression Scale (CES-D)

For each statement below, make an **"X"** in the box which best describes how often you felt or behaved this way. **DURING THE PAST WEEK, INCLUDING TODAY.**

	None of the Time	A Little of the Time	A Moderate Amount of Time	Most of the Time
59a. I was bothered by things that usually don't bother me.	ρ	ρ	ρ	ρ
59b. I did not feel like eating; my appetite was poor.	ρ	ρ	ρ	ρ
59c. I felt that I could not shake off the blues even with help from my family or friends.	ρ	ρ	ρ	ρ
59d. I felt that I was just as good as other people.	ρ	ρ	ρ	ρ
59e. I had trouble keeping my mind on what I was doing.	ρ	ρ	ρ	ρ
59f. I felt depressed.	ρ	ρ	ρ	ρ
59g. I felt that everything I did was an effort.	ρ	ρ	ρ	ρ
59h. I felt hopeful about the future.	ρ	ρ	ρ	ρ
59i. I thought my life had been a failure.	ρ	ρ	ρ	ρ
59j. I felt fearful.	ρ	ρ	ρ	ρ
59k. My sleep was restless.	ρ	ρ	ρ	ρ
59l. I was happy.	ρ	ρ	ρ	ρ
59m. I talked less than usual.	ρ	ρ	ρ	ρ
59n. I felt lonely.	ρ	ρ	ρ	ρ
59o. People were unfriendly.	ρ	ρ	ρ	ρ
59p. I enjoyed life.	ρ	ρ	ρ	ρ
59q. I had crying spells.	ρ	ρ	ρ	ρ
59r. I felt sad.	ρ	ρ	ρ	ρ
59s. I felt that people disliked me.	ρ	ρ	ρ	ρ
59t. I could not "get going."	ρ	ρ	ρ	ρ

60. Vividly imagine that you are <u>afraid</u> of the dentist and have to get some dental work done. Which of the following would you do? Check <u>all</u> of the statements that might apply to you.

_____ I would ask the dentist exactly what he was going to do.

_____ I would take a tranquilizer or have a drink before going.

_____ I would try to think about pleasant memories.

_____ I would want the dentist to tell me when I would feel pain.

_____ I would try to sleep.

_____ I would watch all the dentist's movements and listen for the sound of his drill.

_____ I would watch the flow of water from my mouth to see if it contained blood.

_____ I would do mental puzzles in my mind.

61. Vividly imagine that you are being held hostage by a group of armed terrorists in a public building. Which of the following would you do? Check <u>all</u> of the statements that might apply to you.

_____ I would sit by myself and have as many daydreams and fantasies as I could.

_____ I would stay alert and try to keep myself from falling asleep.

_____ I would exchange life stories with the other hostages.

_____ If there was a radio present, I would stay near it and listen to the bulletins what the police were doing.

_____ I would watch every movement of my captors and keep an eye on their weapons.

_____ I would try to sleep as much as possible.

_____ I would think about how nice it's going to be when I get home.

_____ I would make sure I knew where every possible exit was.

62. Vividly imagine that, due to a large drop in sales, it is rumored that several people in your department at work will be laid off. Your supervisor has turned in an evaluation of your work for the past year. The decision about lay-offs has been made and will be announced in several days. Check all of the statements that might apply to you.

_____ I would talk to my fellow workers to see if they knew anything about what the supervisor's evaluation of me said.
_____ I would review the list of duties for my present job and try to figure out if I had fulfilled them all.
_____ I would go to the movies to take my mind off things.
_____ I would try to remember any arguments or disagreements I might have had with the supervisor that would have lowered his opinion of me.
_____ I would push all thoughts of being laid off out of my mind.
_____ I would tell my spouse that I'd rather not discuss my chances of being laid off.
_____ I would try to think which employees in my department the supervisor might have thought had done the worst job.
_____ I would continue doing my work as if nothing special was happening.

63. Vividly imagine that you are on an airplane, thirty minutes from your destination, when the plane unexpectedly goes into a deep dive and then suddenly levels off. After a short time, the pilot announces that nothing is wrong, although the rest of the ride may be rough. You, however, are not convinced that all is well. Check all of the statements that might apply to you.

_____ I would carefully read the information provided about safety features in the plane and make sure I knew where the emergency exits were.
_____ I would make small talk with the passenger beside me.
_____ I would watch the end of the movie, even if I had seen it before.
_____ I would call the stewardess and ask her exactly what the problem was.
_____ I would order a drink or tranquilizer from the stewardess.
_____ I would listen carefully to the engines for unusual noises and would watch the crew to see if their behavior was out of the ordinary
_____ I would talk to the passenger beside me about what might be wrong.
_____ I would settle down and read a book or magazine or write a letter.

About the Author

Heidi King was born and raised in Cleveland, OH. In 1995, she received her BA from the University of Pennsylvania. She began her graduate work at the University of South Florida in 2000 under the mentorship of Paul Jacobsen. She currently resides in Tampa, Florida with her family.