

Improved BRCA Risk Screening Among Women in Primary Care Following Provider Education  
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### **Abstract**

This project to improve provider screening for breast cancer susceptibility (BRCA) gene mutations was implemented in a primary care clinic in Western Kansas. The purpose of this quality improvement project is to determine if a BRCA gene mutation educational session, discussing Hereditary Breast and Ovarian Cancers (HBOC), screening guidelines and implications of screening, among primary care providers, will increase provider's knowledge. Before and after the interventional BRCA educational session, the primary outcome, provider BRCA knowledge, was measured by use of a questionnaire titled "Questions for Survey for Birth Care Health Care Clinicians." With the use of the McNemar Statistical test, paired data was analyzed, but there was no statistically significant change from pre-education questionnaire to post-education questionnaire. A descriptive statistics table illustrates the impact on certain questions with the highest significance of 0.125. This topic is highly impactful because breast cancer is the second deadliest cancer among women, and possessing a mutation on either the BRCA 1 or BRCA 2 genes significantly increases a woman's risk for cancer in her lifetime. Regular, intermittent screening of women for HBOC syndrome risk, with an evidence-based tool at well-woman visits, should lead to earlier intervention for prevention and early detection of breast cancer and ovarian cancer in women at highest risk.

*Keywords:* BRCA screening, primary care, HBOC, barriers to screening, education for providers, strategies to improve provider compliance

### Improved BRCA Screening Among Women in Primary Care Following Provider Education

BRCA (BReast CAncer) genes, BRCA 1 and BRCA 2, work as tumor suppressors, which function by controlling the assembly of macromolecular structures that monitor segregation and duplication of chromosomes throughout the cell cycle (Venkitaraman, 2014). When these genes have a mutation, they are more susceptible to human malignancies, particularly breast and ovarian tumors (Venkitaraman, 2014). In the last 15 years, the rapid discovery of cancer-related genes has driven the field of hereditary risk assessment forward. As a result of this as well as media portrayal, more patients are learning about BRCA genetic testing and the vital role it has in prevention and diagnosis. Often, primary care providers' knowledge is incomplete when examining genetic testing views and targeted cancer screening (Hamilton, Abdiwahab, Edwards, Fang, Jdayani & Breslau, 2017).

### **Background and Significance**

The Department of Health and Human Services (HHS), *Healthy People 2020* has identified cancer care as one of the health concerns in the next 10 years to improve upon in America. More specifically, two objectives identified include reducing the death rate of female breast cancer and increasing the number of patients who were counseled about cancer screening consistent with current guidelines (DHHS, 2016). If this initiative is successful, a large portion of the United States population will be affected by improving prevention, detection, diagnosis and outcomes.

Currently, among women in the general population, 12% will be diagnosed with breast cancer and 1.3% will be diagnosed with ovarian cancer during her lifetime (National Cancer Institute, 2015). Contrariwise, 55-65% of women who possess a BRCA 1 and 45% of women

who possess a BRCA 2 mutation will be diagnosed with breast cancer in her lifetime. Ovarian cancer is most frequent among BRCA 1 mutation carriers with a lifetime risk of 39% and 11-17% risk for BRCA 2 mutation carriers (National Cancer Institute, 2015). According to an article published in the Pruthi, Gostout & Lindor (2010), “In the United States in 2009 alone, there were approximately 192,370 new cases of breast cancer and 21,550 new cases of ovarian cancer. That same year, 40,170 people died from breast cancer and ovarian cancer deaths were estimated at 14,600.” It is important to reiterate that although few breast cancers are attributable to inheritance of a mutation on the BRCA genes, the risk associated with a confirmed mutation is as high as 85% and can make a profound impact on the life of the patient with the mutation (Lipsky et al., 2009).

### **Economic Impact**

Death rates are notable when addressing female cancers, but economically, it is important to consider the economic impact when female patients are diagnosed with cancer. In an article published by the American Journal of Preventive Medicine, it was determined that between 1970 and 2008, there were 225,866 deaths associated with breast cancer, which could account for approximately 7.98 million years of potential life lost (YPLL) (Ekwueme et al., 2014). This same article utilized Joinpoint regression modeling to determine that in 2008 due to the YPLL, the estimated productivity loss was \$5.49 billion and approximately \$1.10 million in individual lifetime lost earnings from breast cancer specifically (Ekwueme et al., 2014).

The United States Preventive Services Task Force (USPSTF) (2015) issued recommendations for BRCA screening in the primary care setting. These recommendations outline that for any woman with a family history associated with an increased risk of mutations in the BRCA1 or BRCA2 gene, it is recommended with moderate certainty that the advantage of

screening, testing and subsequent early intervention is appropriate. This screening should begin once women have reached 18 years of age, the age of consent, and primary care clinicians should be regularly discussing changes in family history with these patients (USPSTF, 2015).

### **Local Issue**

Screening, by definition and for the purpose of this paper, is the evaluation of a patient's family history with the utilization of a tool to determine if she is at an increased risk of breast or ovarian cancer due to a deleterious mutation on the BRCA gene that predisposes women to HBOC cancers. For those providers who do not encounter this population of patients on a daily basis, and do not routinely utilize screening guidelines in conjunction with a screening tool, the guidelines may be difficult to interpret. This difficulty of interpretation could be a reason that very few primary care practitioners are evaluating patients for these deleterious mutations (Bellcross, Kolor, Goddard, Coates, Reyes & Khoury, 2011).

Specifically, rural communities such as Dodge City likely face barriers to receiving preventive care, specifically, monitoring for breast cancer, which decreases their chances of early detection (Lipsky et al., 2009). If providers further understand the implications of BRCA screening in the primary care setting, improvements in the identification of HBOC syndrome in patients is attainable (Nair et. al, 2015).

### **Diversity Considerations**

BRCA mutations can occur among any person with family history of deleterious mutations to this gene; however, there have been certain cultures among whom are considered to be at higher risk, including the Ashkenazi Jewish population (Ferla et al., 2007). The Washington State Nurses Association reports that barriers exist among rural practitioners, which prevent adequate healthcare administration (Lipsky et al., 2009). These barriers include:

negative patient attitude about mammography, lack of understanding regarding reimbursement for testing, lack of health insurance, lack of accessible imaging sites, physical disabilities, communication barriers and cultural norms and attitudes about disease processes (Lipsky et al., 2009). Furthermore, the population of rural communities is usually poorer, older and considerably less well educated compared to patients in urban communities (Lipsky et al., 2009).

The educational program was implemented at a family practice clinic in western Kansas. Of note, the city of project implementation has a 57.5% Hispanic population so cultural considerations were made (United States Census Bureau, 2016). The student investigator does not speak Spanish fluently, but the manager of the practice asserts that there is always someone available on staff to provide translation services to patients during the family history data collection, if necessary. According to Ramirez et al. (2013), breast cancer deaths rank higher in Latina women compared to Caucasian women, most likely because it is diagnosed and treated later when the cancer is more advanced and treatment is much more complex. Unfortunately, cultural barriers among Latina women have often been ignored because language barriers and social norms exist among this population, including respect, family-centeredness, dignity and a high value of being a dedicated wives and mothers, which make receiving timely treatment more difficult.

Another barrier to preventative care is that 21% of the population does not have health insurance in Dodge City, KS (United States Census Bureau, 2016). Because of this, uninsured patients may not seek counseling or follow-up visits as warranted (Sussner, Jandorf, Thompson & Valdimarsdottir, 2012). Another barrier among this population of patients is that 14.8% of patients are living in poverty (United States Census Bureau, 2016). If providers utilize a screening tool, such as the Ontario Family Health Assessment Tool (OFHAT) (see Appendix A)

to assess a family history that may be associated with an increased risk of a mutation on the BRCA gene, the guidelines outline that that patient should then be referred to a genetic counselor (USPSTF, 2015), which would be an additional cost to the patient. This may be a barrier to the referral process if the patient cannot afford to see a genetic counselor.

Rural practitioners often face barriers to providing adequate preventative health care and although Dodge City has access to BRCA testing kits through Myriad Genetics, and diagnostic imaging, mammography, ultrasonography, and MRI, there is no access to a genetic counselor in town. Because of this, patients would be referred to a genetic counselor in a larger urban area.

### **Problem & Purpose**

#### **Problem Statement & Purpose Statement**

Despite increasing knowledge and evidence regarding the use of genetic testing to assess a woman's predisposition to breast, ovarian, tubal and peritoneal cancers, significant barriers remain in appropriately screening women for their risk for having a BRCA gene mutation (Lipsky et al., 2009). Encouragingly, providers can take certain measures to ensure they are providing appropriate care to their patients, including: learning about the community, setting goals among staff and creating incentives for positive change in behavior (Lipsky et al., 2009). The purpose of this BRCA screening project was to determine if the BRCA screening educational session regarding hereditary breast and ovarian cancers, among primary care providers, will increase providers' knowledge related to BRCA risk screening.

#### **Intended Improvement**

The United States Preventive Services Task Force has provided guidelines for screening patients at added risk for breast, ovarian, tubal and peritoneal cancers (USPSTF, 2015). Bellcross et al. (2011) conducted a study among United States primary care providers, which

reported that out of 1,500 physician respondents in a primary care setting, 25% of providers reported having ordered at least one BRCA test within the last year. Excluding pediatricians from the results did improve these percentages to 93% aware of BRCA and 30% testing ordered (Bellcross et al., 2011). This further supports the hypothesis that although providers may read the new guidelines, most will not utilize the new guidelines if they are not comfortable with them (Bellcross et al., 2011).

In a recent study conducted regarding provider BRCA knowledge, Cohn (2014) reports that, generally speaking, primary care providers recognize their knowledge deficits regarding genetics testing and express an aspiration for further education. As such, health care providers in the primary care setting, especially those in rural communities, should be educated about the usefulness of family history screening and if positive response, a more in-depth screening with a tool (such as the OFHAT) would be warranted. Providers should also understand the utility of the results of the tool as well as the effect it can have on the future care for a woman with a deleterious mutation on BRCA genes. The focus of this project was primarily increasing provider knowledge regarding HBOC syndrome, BRCA screening and how to utilize the guidelines. A secondary purpose, which was not measured during this project, would be the consequences of providers understanding screening recommendations which would improve the number of patients who are being appropriately screened with a BRCA screening tool.

### **Facilitators and Barriers**

For the implementation of this project, there were facilitators and barriers alike. The family practice clinic in western Kansas, the location of project implementation, is a facilitator. Each provider with whom the student investigator works is a facilitator, and currently at this practice, there are 5 providers. The Advanced Practice Registered Nurse with whom the



student investigator worked is most notably a facilitator at this practice location because she worked closely with the student investigator to ensure that the project was implemented seamlessly.

One barrier that the student investigator faced was the inability of one provider to attend and listen to the educational opportunity regarding screening for BRCA mutations in the primary care setting. Certainly, agreeing to such an educational class not only takes time out of providers' days, but it also encourages them to practice differently, than perhaps the ways in which they are accustomed. Another barrier that exists is that of the language barrier. If the providers do not speak Spanish fluently, they will need to utilize a translator in order to ensure a thorough family history is obtained. Finally, there is not access to a genetic counselor to whom patients can be referred in the city of project implementation. Instead, they must first be seen by their practitioner and then referred to a genetic counselor in a larger town, which is a barrier.

If this project is found to make a significant difference in provider knowledge regarding BRCA gene mutation risk, it could be the impetus that such an educational class could be made available to other primary care offices across the country in order to provide the necessary educational information to providers. Factors that may inhibit sustainability of this intervention after the project are barriers previously discussed, as well as an inability of providers to dedicate time to the cause, unwillingness of providers to change their practice techniques, and lastly, if they see patients who are unaware of their family history. If a patient is unaware of her family history, use of the OFHAT screening tool or any other screening tool would not be useful in this patient.

## **Review of Evidence**

### **Primary PICOT**

Among providers who perform annual well-women exams, does an educational program about hereditary breast and ovarian cancer (HBOC) syndrome and the importance of screening for high-risk BRCA patients, compared to usual care, increase provider knowledge?

### **Search Strategies**

An extensive literature review was conducted using Cumulative Index to Nursing and Health Literature (CINAHL), PubMed, Medline databases and the use of Google Scholar search engine in preparation for the synthesis of evidence. Study designs that were utilized included seven cohort and observational studies (Level III evidence), seven guidelines, six non-randomized control trials (Level II evidence), three observational studies (Level IV evidence), two randomized control trials (Level I evidence) and one meta-analysis study (Level I evidence) (Appendix B). Key search words included: BRCA, screening, primary care setting, barriers to screening, randomized control trials and provider knowledge and HBOC Syndrome. Inclusion criteria included screening in the primary care setting, provider knowledge, risk assessment tools and original research data. Exclusion criteria included ethical considerations for genetic testing, and literature not in English. The guidelines utilized for this paper were provided by the United States Preventive Services Task Force (2013), The National Cancer Institute (2015) and the Centers for Disease Control and Prevention (2015).

### **Evidence**

#### **Screening Recommendation**

In 2013 the United States Preventive Services Task Force (USPSTF) published guidelines on the annual routine screening of adult patients who present to primary care clinics with a family history of cancers of breast, ovaries, fallopian tubes or peritoneum. Women with this family history should be screened with an approved screening tool (such as the OFHAT) to

identify a family history, which may be associated with a mutation on the BRCA1 or BRCA2 genes. The guideline further explains that should a patient positively screen with one of the approved tools, she should be referred for genetic counseling, and possible subsequent genetic testing (USPSTF, 2013).

It should be delineated that for those patients who do not have a direct family history of any of the aforementioned cancers, it is not recommended to screen these women with one of the approved screening tools outlined in the USPSTF guidelines; however, for women who have a family history associated with BRCA mutations, the USPSTF maintains with moderate certainty that the net advantage for genetic testing, and potentially, early intervention is considerable (USPSTF, 2013).

The National Cancer Institute (NCI) also approves of these guidelines (National Cancer Institute, 2011). According to an article published by the NCI, BRCA1 and BRCA2 gene mutations are moderately rare in the general population. Given this information, genetic testing for patients without cancer should be performed only if family history suggests a possible presence of a deleterious mutation (National Cancer Institute, 2011). The NCI also purports that screening tools, such as BRCA screening tools, are useful in identifying family history factors, which may indicate an increased likelihood of a BRCA mutation. These factors include: breast cancer diagnosed before age fifty, both breast and ovarian cancers in either the same woman or same family, cancer in both breasts in the same woman, multiple breast cancers, cases of male breast cancer, two or more primary types of BRCA1 or BRCA2-related cancers in a single family member, and Ashkenazi Jewish ethnicity (National Cancer Institute, 2011).

The NCI does not recommend genetic testing for a BRCA mutation without first discussing the testing with a genetic counselor (NCI, 2011). This is in alignment with the

USPSTF guidelines, in that, if a patient is positively screened in the primary care setting, she should be referred to genetic counseling prior to any genetic testing (USPSTF, 2013).

### **Rationale for Screening**

Kolor (2014) notes that while most cancers that occur in women are not hereditary, some certainly are. In fact, for those women who have a BRCA gene mutation, the lifetime risk of developing ovarian and breast cancers are greatly increased, specifically in the absence of intervention. In an effort to depict the importance of screening, a woman's risk of breast cancer increases from 45% to 65% by the age of 70 if there is a mutation on the BRCA gene (USPSTF, 2015). The USPSTF (2015) also determines that the overall benefit of testing for BRCA mutations is moderate, while the harms of detections are small.

In order to further provide rationale for screening with a screening tool, the National Cancer Institute (2011) notes that if a person screens positively with an approved family HBOC history screening tool (such as the OFHAT) for a BRCA genetic mutation, then undergoes genetic counseling and subsequent BRCA testing and is found to be positive, she now has the opportunity to utilize increased diagnostic imaging studies in order to diagnose a cancer in earlier stages, rather than late stages. Furthermore, if a patient is positive for a genetic mutation on the BRCA gene, she can then share this information with her family members who may be able to take advantage of increased monitoring and testing as well (NCI, 2011).

Lipsky et al. (2009) describes that breast cancer is the most common cancer in women, and in the United States a breast cancer is diagnosed every 3 minutes in women. Perhaps even more sobering, is that every 13 minutes, a woman dies from breast cancer. The student investigator outlines that a fundamental component to caring for patients is identifying those patients who are at increased risk of developing a cancer (Lipsky et al., 2009). Knowledge of an

individual's gene mutation status allows patients to utilize proactive medical management, which may include enhanced imaging, medical interventions or even prophylactic surgery (Cohn, 2014). One important piece to demarcate is that a genetic mutation cannot predict with certainty that a person will definitely develop cancer in the future. Instead, the mutation predisposes patients to BRCA-associated cancers, but knowledge of this may allow for prevention measures, which can improve patient outcomes (Loescher et al., 2009).

It could be argued by providers that they do not possess the time in a visit to utilize a screening tool with each woman with a family history of breast, ovarian, tubal or peritoneal cancers. Family history-screening questionnaires, such as the OFHAT tool have been underutilized for years, but according to a study published by Armel et al., (2011) in the Journal of Genetic Counselors, these family history-screening questionnaires are desirable to patients and may provide a more efficient means of counseling, by reducing the time spent by the provider. If these family history-screening questionnaires could be utilized more effectively in the primary care clinic, and providers understood the implications and utility of these tools, perhaps more providers would utilize these tools to aid in a smoother and prompter visit.

### **Provider Education**

A randomized control trial by Rubinstein et al. (2011) determined that family history is an established risk factor for breast cancer and ovarian cancer, but unfortunately, proper family health history is rarely obtained in practice and because of this, patients are not being routinely screened appropriately. McCarthy et al. (2013) performed a population-based study to determine whether or not provider recommendations played a vital role in subsequent BRCA testing. The study concluded that in fact, physician recommendations are a vital determinant in the use of genetic testing. Sadly, among high-risk women, failure to receive BRCA screening or a

recommendation for testing from their provider resulted in relatively late stage at diagnosis (McCarthy et al., 2013).

In a randomized control trial by Cox et al. (2012), of the providers who recommended any cancer screening and testing to their patients, it was for the following reasons: to guide future detection management (75%-80%), the patient met practice guidelines (82%-86%), to guide prophylactic management decisions (76%-80%), and because their patients requested the test (79%-81%). Although it is apparent that patient request certainly guides provider decisions, patient requests of testing is only valuable if the patient is aware of what the BRCA gene test is. In many populations, patients are completely unaware that he or she may be at an increased risk of cancer. In fact, Lipsky et al. (2009) explains that residents of rural areas face many barriers to obtaining cancer screening and this can be related to negative patient attitudes, cultural attitudes about disease processes, lack of health insurance, lack of understanding of insurance, lack of monetary means, and communication barriers, which is why the family screening tool is vital.

Bellcross et al. (2011) performed a study to determine the level of awareness and utilization of BRCA testing among United States primary care providers. This study did conclude that although utilization of BRCA testing has risen, many providers do not recognize that family history patterns dictate BRCA screening per the USPSTF guidelines. If providers are not identifying these high-risk individuals, a disservice is being done to the patient. Pruthi, Gostout & Lindor (2010) describe that obtaining a basic but comprehensive family history along with an evaluation of patient's risk factors are vital steps to assessing the risk of breast and ovarian cancer.

### **Theory**

The theory for this project is the Ace Star Model of Knowledge Transformation (Appendix C). In order for this project to be successful, an organizational change will need to occur among the practice and the providers. With the use of the Ace Star Model, five major stages of knowledge transformation will be delineated, which will aid in the successful transition to increased screening for potential BRCA mutation carriers, which will improve patient outcomes (Stevens, 2012). The five major stages include discovery, which is the knowledge generating stage. The student investigator has conducted a thorough review of literature to collect more knowledge about the topic. The second stage is evidence, which incorporates the knowledge into a meaningful statement. The student investigator created a problem statement to identify the current problem as well as the purpose statement to identify the need in the clinic. The third stage includes translation to guidelines, which has occurred by translating the evidence and guidelines into a solution to the problem. The fourth stage involves integration into practice, which will occur in the upcoming months as this project is implemented into practice. The final stage is that of outcome evaluation, which will occur at the end of the educational session with the providers and following statistical analysis (Stevens, 2012).

## **Methods**

### **IRB Approval, Ethical Issues, Funding**

Primary IRB approval was received from University of Missouri Kansas City (UMKC) Institutional Review Board (IRB) since the project site does not maintain their own IRB. The project was approved as non-human subjects quality improvement project. There are no known risks to the participants; the providers in this population will undergo no harm during this project and are free to withdraw from the project at any time with no repercussions. A flowchart depicting the project implementation is outlined in Appendix D. The total estimated cost of this

project is \$1,800 (Appendix E). The largest amount of funding will be used for development of the provider education program. The student investigator will prepare the educational program. The provider-training luncheon will amount to about \$200 and the handouts for providers are estimated to cost about \$200. No applications were submitted for scholarship or grants for project funds, though a \$500 scholarship was awarded to the student investigator to aid in the cost of dissemination.

### **Setting and Participants**

The setting of this project has taken place at a family practice clinic in western Kansas. This project involved an initial educational session with the providers individually to discuss HBOC Syndrome and the important role that screening women can play in clinical practice. Current guidelines set forth by the United States Preventive Services Task Force (USPSTF) (see Appendix F) was discussed regarding BRCA screening with the OFHAT tool, of any adult woman with a family history of breast, ovarian, tubal or peritoneal cancer for BRCA mutations (USPSTF, 2015). Inclusion criteria for this project included all providers within the participating clinic who perform wellness exams on adult women. Exclusion criteria included those providers who do not care for adult women patients, those providers who do not speak English, and those who do not wish to participate in the project or have not given consent to participate.

### **Evidence Based Practice Intervention**

The evidence based intervention for this project is provider education in order to promote knowledge about screening guidelines for patients who are at increased risk for BRCA mutations as well as the importance of collection of current family history data. Cohn et al. (2014) explains that few providers recognize the National Comprehensive Cancer Network's risk assessment guidelines for identifying BRCA mutation and thus, are unfamiliar with subsequent



management. Detailed family history is vital at routine medical visits in a primary care setting and if this occurs, more patients would be appropriately screened with a screening tool for deleterious mutations on the BRCA genes (Rubenstein et al., 2011). Specifically, when a patient presents for a routine wellness exam, the provider should be inquiring about recent changes in family history of cancer. If the patient has any family history of breast, ovarian, tubal or peritoneal cancer, she should then be further screened by the provider with one of many approved screening tools, such as the OFHAT tool, as outlined in the recommendation statement from the USPSTF. This project aims to educate providers about the importance of thorough family history data collection and screening for potential BRCA gene mutations while utilizing a screening tool, based on that family history data. Provider knowledge was measured by a pre-test before the educational intervention and a post-test directly after the educational session. The test that was utilized is titled the “Questions for Survey for Birth Health Care Clinicians” (QFSFBHCC) (Ledingham, 2014) (see Appendix G)

All providers at Medical Practice Associates of Western Kansas who see adult female patients for well woman exams were recruited to participate in this educational experience, though 5 participated. Initially, providers completed the QFSFBHCC pre-test regarding BRCA screening knowledge. Informed consent was implied when providers participated in the completion of the questionnaire. The student investigator then conducted the 20-minute BRCA Screening Educational Session with the recruited providers individually. Handouts provided by the American Cancer Society (see Appendix H) and the guidelines provided by the USPSTF (see Appendix F) were utilized to ensure retention of subject matter. Following the educational session, the providers were asked to fill out the QFSFBHCC post-education assessment in order to determine whether their understanding of BRCA screening changed. If the goal is met,

following the educational session, the providers should have a better understanding of which patients should be additionally screened with the OFHAT tool as well as what to do with the data once it is collected. Specifically, the OFHAT tool outlines that if a patient scores a value of 10 or greater, she should be referred for genetic counseling; this is considered a positive screen and is considered to be high-risk for potentially possessing a mutation on one of the BRCA genes.

The student investigator conducted recruitment for providers in this practice who care for this population of patients, so it could be replicated in any family practice or internal medicine clinic. The project implementation took about two months to complete and an addition 3 months for data analysis. Five providers participated in the project pretest, intervention, and posttest.

### **Change Process, EBP Model**

Along with utilizing the ACE Star Model of Knowledge Transformation to help guide this project, the student investigator will also utilize the Promoting Action on Research Implementation in Health Services (PARiHS) Method. This framework helped to guide the implementation of research into practice by the use of three key elements; evidence, context and facilitation (National Collaborating Centre for Methods and Tools, 2011). This model supports the intervention because it helps to describe how to properly and successfully implement research into practice by means of an organizational issue as opposed to and individual issues (National Collaborating Centre for Methods and Tools, 2011).

This PARiHS model also works well with this topic and project focus because it allows for reproducibility of the project in other clinics. Due to the low cost, reproducibility and the ease of use of this method, sustainability of this project is quite likely.

### **Study Design**

This project is a quality improvement project in order to improve provider knowledge. A single group pretest and posttest design on a convenience sample was utilized. Providers in the primary care practice were educated about the current guidelines regarding screening with the OFHAT tool for BRCA mutations in adult women. The student investigator compared the data from the QFSFBHCC pre-test and the QFSFBHCC post-test by use of the McNemar test to determine whether or not providers gained knowledge with the BRCA Screening Educational Session.

### **Validity**

The student investigator established internal validity by investigating the providers' understanding and knowledge of BRCA screening. Factors that may influence the internal validity of this project include providers' previous knowledge of BRCA screening, experience with BRCA screening in the past, and providers' personal experiences and attitudes toward the topic. Maturation is described in research as the changes in the dependent variable due to normal developmental processes. This likely would not cause a threat to internal validity due to the short project timeline. External validity can be achieved because of the reproducibility of this topic. Any clinic with providers willing to attend an educational session and those clinics with a patient population of adult, female women would be able to reproduce this project.

### **Outcomes to be Measured**

The primary outcome to be measured for this project is provider knowledge related to HBOC Syndrome and BRCA screening. Provider knowledge related to current guidelines will also be assessed with the pre and posttest provided to practitioners. An associated outcome that will not be measured for this project is education for providers regarding what to do with the information gained from utilizing a screening tool (see Appendix J).

### **Measurement Instruments**

The measurement instrument that will be used to assess provider knowledge regarding BRCA screening is the “Questions for Survey for Birth Care Health Care Clinicians” (Ledingham, 2014). Permission was received from the author for use of this tool for implementation of this project (Appendix K). This tool has been used before in similar research, but validity and reliability have not been determined at this time.

The BRCA risk assessment tool that will be discussed with providers during the education is the Ontario Family History Assessment Tool (OFHAT). This tool was developed for use by providers to determine those patients who should be referred for genetic counseling. The tool was indicated in the literature to be effective in identifying those patients who are later found to be mutation-positive (Gilpin, Carson & Hunter, 2000). The tool is identified in the USPSTF recommendation statement as an approved screening tool for use with women with an increased risk of BRCA gene mutation. Both validity and reliability have been established.

### **Quality of Data & Analysis Plan**

Following the recruitment period, quality of data was determined. Five total providers participated in this quality improvement project. Following data collection, SPSS was utilized to run McNemar’s test was utilized to analyze the participant’s responses pre and post intervention. Data was not statistically significant in this project. Future work should include further education with providers and interprofessional staff to ensure proper screening occurs according to guidelines.

## **Results**

### **Setting & Participants**

This quality improvement project was implemented at a family practice clinic in western

Kansas. The implementation was projected to span over one month's time, but the providers preferred that the student investigator discuss the topic with each provider individually instead of during one session. As such, the project timeline was expanded and lasted 4 months to obtain all data from each participant. The participants included 5 providers within the family practice clinic. There was one nurse practitioner and 4 physicians among the participants.

### **Intervention Course, Actual**

A major component of the intervention includes the educational session with each individual provider. Although the pre-educational questionnaire and post-educational questionnaire provide important information, given the fact that this project is a quality improvement effort, the education for providers is a vital component. This component occurred following the completion of the pre-educational session questionnaire by each provider. During educational sessions, information was provided to clinicians from the USPSTF, and the American Cancer Society to outline guidelines for screening for those patients who are at an increased risk of a deleterious mutation to the BRCA genes. The clinic where this project was implemented was quite busy, so the student investigator had to accommodate to each provider's schedule in order to obtain the data. There are six total providers in clinic, but one provider in the clinic was unable to take part, which left the final participant group at five providers.

### **Outcome Data**

The primary outcome that was measured in this quality improvement project was provider knowledge. Provider knowledge was initially assessed by use of the QFSFBHCC tool in order to gain an understanding of provider's knowledge of HBOC syndrome and better understand their practice preferences for BRCA screening and testing. Then, directly following the educational session with providers, they were asked to complete the QFSFBHCC

questionnaire again. Pre and post-test data was compared utilizing SPSS and the McNemar Test with binomial distribution. SPSS did not run data on those questions that showed no change between the pre and post-test, therefore, missing data was excluded from the data table (see Appendix L). The results of this quality improvement project are best displayed with use of descriptive statistics (see Appendix M). The table represents an abbreviation of the questions that are on the questionnaire to better understand the pre and post-test answers. Though the project did not yield statistically significant data, the providers in the clinic state that they are more aware of BRCA screening and testing guidelines and are more likely to utilize a genetic counselor prior to testing as recommended by the USPSTF.

## **Discussion**

### **Successes**

For this quality improvement project, the data retrieved was not statistically significant, however one vital success that was recognized following this project was an increase in provider's awareness regarding the importance of screening patients with an increased risk of possessing mutations on the BRCA genes. Prior to the educational sessions, through casual conversation with the student investigator, the providers had limited knowledge of the guidelines and were unaware of the importance of utilizing a genetic counselor. Although the data does not reflect significant knowledge increase, the providers have verbally expressed to the student investigator that they feel more comfortable using screening tools for this population of patients and are more likely to utilize the current guidelines from the USPSTF.

### **Study Strengths**

This study possessed elements that provided support for the proposed intervention. The first, and most important element was the provider and staff at the clinic with whom the student

investigator worked. All staff, whether involved in the project or not, were willing to assist in any way to make implementation of this project easier. The nurse practitioner in this practice was beyond helpful and assisted the student investigator in arranging meeting times with all providers who participated in the project. Another important element was the willingness of the participants to take time from their busy clinic day to discuss a quality improvement project with the student investigator. Finally, though the setting was in a rural area, which made implementation from a geographic perspective difficult, it was a helpful element for project implementation that the clinic was small and there were not large numbers of providers with whom to work.

### **Results Compared to Literature**

Results from this quality improvement project were similar to those found in the literature. According to Hamilton et al. (2016), there is a need to move beyond descriptive-type research questions regarding primary care provider's knowledge of genetic testing and instead, focus on the gaps related to the implementation of advanced interventions and educational platforms that would increase providers' knowledge regarding BRCA testing as well as promote effective, open communication between providers and patients. The data from this project was not statistically significant and the most important data was gained following the use of descriptive statistics to measure pre and post data following a questionnaire.

Genetic mutation screening tools were created to identify an increased risk of possessing a harmful mutation. According to Walker et al. (2015), risk assessment tools may increase patient intention to monitor for cancer, but additional interventions by the provider are necessary to increase appropriate screening behavior. This represents the importance of educating providers who care for adult women, as they need to understand the importance of utilizing

screening tools as well as discuss screening with the patient as well as the importance of risk-reduction strategies, if necessary.

### **Limitations**

#### **Internal and External Validity Effects**

Due to the descriptive nature of this project, the student investigator was not trying to identify a causal relationship between two variables and as such, the internal validity is not as relevant as in other types of studies. However, the student investigator was able to establish internal validity by only studying one variable, provider knowledge, which decreased the risk of confounding, thus promoting internal validity. Maturation was also avoided in this study due to the short project timeline. External validity can be gained because of the reproducibility of this topic. Any clinic could implement this project if the providers are willing to attend an educational session as well understand the importance of potentially augmenting their practice related to BRCA gene mutation screening and testing.

#### **Sustainability of Effects and Plans to Maintain Effects**

Sustainability of this project should be relatively easy to maintain as long as providers continue to stay current with guidelines for screening for this population of patients. Any new providers in the clinic should be educated about current practices for screening. Gains that were made should not weaken over time as long as providers are staying up-to-date on guideline recommendations.

#### **Efforts to Minimize Study Limitations**

Many efforts were taken for this quality improvement project in order to minimize study limitations, but unfortunately limitations did still occur. One impactful limitation was the small population size of only five providers. Due to the size of the clinic and the relatively rural area



of practice, the population size could only have been expanded if the student investigator included other internal medicine or family practice clinics, but given the short period of time to implement the project, this was not feasible. Another limitation of this study was the incremental findings following statistical data analysis. Some data was excluded from the final analysis because there was no change from the pretest to the posttest and the data that was analyzed did not represent significant increase in provider knowledge. Based on this information, follow-up research should focus on utilizing a less descriptive tool to measure pre and post knowledge, and perhaps an educational tool could be created to ensure all providers are being educated in exactly the same fashion with identical information presented. Data limitations existed in this project because the data that was collected was not as helpful as it could have been to best measure the provider's knowledge; however, the information is still helpful because it is widely-applicable for this population of patients in all parts of the world.

### **Interpretation**

#### **Expected & Actual Outcomes**

The student investigator expected to increase provider knowledge regarding screening adult women in the primary care setting for an increased risk of BRCA gene mutations, and while the reported data was not statistically significant, this outcome was met. Following the implementation, the student investigator discussed with the owner of the practice the possibility of building a screening tool into the electronic health record and the owner was receptive about this potential addition. One unexpected result from this project was the providers' interest in addressing gaps in their education regarding BRCA screening. Among all of the providers in the clinic, each person expressed to the student investigator that he or she should more closely follow the guidelines and was going to start utilizing genetic counseling as the guidelines

recommend. Initially, the student investigator planned to work with nurses as well as providers to increase compliance of screening, but due to a large Hispanic population of patients in this area, the translators who work with the nursing staff would also need to undergo Collaborative Institutional Training Initiative (CITI) education and there was little to no incentive for the translators to make this effort. As a result, the providers were the only staff members who received the educational intervention.

### **Intervention Effectiveness**

The project data did not yield statistically significant results, though the providers in the clinic did discuss with the student investigator that they have a better understanding of the guidelines for screening as well as those patients who should be referred for genetic counseling. Because of this, the student investigator infers that the intervention was effective in this type of setting. The setting in which this educational intervention would be most effective is any primary care setting in which providers care for adult women.

### **Intervention Revision**

One intervention modification that may have increased statistical improvement in the data would be to utilize a tool that was not descriptive, but instead had a right and wrong answer for each question that left no room for interpretation. Then, if the educational session was focused around each of these questions to ensure each question was addressed, perhaps pre and post data would have been more revealing.

### **Expected and Actual Impact to Health System, Costs and Policy**

The cost of project implementation in this clinic was higher for the student investigator because the clinic was a 5-hour drive from the city of residence for the student. Due to this, there was cost associated with travel including gas, wear on car and oil. Furthermore, lodging

and food while in Dodge City, KS was also a cause for increase in price. If staff of the clinic implemented this educational intervention in the future, these travel costs would be irrelevant. Economic sustainability for the intervention would be very likely due to the impact BRCA testing has on the economy. According to D'Andrea et al. (2016), family-history based screening is possibly highly cost-effective, though further studies identifying high-risk women need to be done. Moreover, Li et al. (2017) reports that testing breast cancer-associated genes could cost-effectively increase life expectancy for women at high risk for hereditary breast cancer.

## **Conclusion**

### **Practical Usefulness of Intervention**

This intervention improved provider knowledge and awareness about BRCA mutation screening in the primary care setting in western Kansas. If this project is successful in other clinics, providers would feel more aware and confident about BRCA screening techniques and incorporating BRCA screening in practice. Furthermore, if providers are educated appropriately regarding HBOC screening guidelines, this could lead to a decrease in the progression to advanced stage breast cancer, which leads to decreased health care costs (Birtwistle, 2014).

### **Further Study or Implementation of Intervention**

The provider educational session could be implemented in urban areas in primarily private insurance clinics. Then the levels of provider knowledge pre and post education could be compared to that in the rural areas. The education about BRCA screening guidelines could be presented at a free public offering to a high risk group of patients identified through cancer support groups along with a follow-up project to identify if requests for genetic referrals and BRCA testing in the area over the subsequent two months was statistically significant compared

to baseline requests for the same interventions over the prior two months.

### **Dissemination**

Dissemination plans are to present a poster presentation of the project at the National Nurse Practitioner Symposium from July 20-23, 2017 in Keystone, Colorado. The student investigator submitted an abstract (see Appendix N) that was accepted, and the poster will be displayed during the conference. The student investigator also applied for a scholarship from the National Nurse Practitioner Symposium to help with travel, lodging and dissemination costs, and was awarded a \$500 scholarship. Results and project poster will also be shared with UMKC faculty and students as part of degree requirements.

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## Appendix A

**Ontario Family History Assessment Tool (OFHAT)**

Table 1. Ontario Family History Assessment Tool\*

<b>Risk Factor</b>	<b>Points</b>
<b>Breast and ovarian cancer</b>	
Mother	10
Sibling	7
Second-/third-degree relative	5
<b>Breast cancer relative</b>	
Parent	4
Sibling	3
Second-/third-degree relative	2
Male relative (add to above)	2
<b>Breast cancer characteristics</b>	
Onset at age 20–29 y	6
Onset at age 30–39 y	4
Onset at age 40–49 y	2
Premenopausal/perimenopausal	2
Bilateral/multifocal	3
<b>Ovarian cancer relative</b>	
Mother	7
Sibling	4
Second-/third-degree relative	3
<b>Age at ovarian cancer onset</b>	
<40 y	6
40–60 y	4
>60 y	2
<b>Age at prostate cancer onset</b>	
<50 y	1
<b>Age at colon cancer onset</b>	
<50 y	1
<b>Family total</b>	
Referral†	≥10

\* From reference <sup>19</sup>.

† Referral with a score of ≥10 corresponds to doubling of lifetime risk for breast cancer (22%).

## Appendix B

**Table of Literature Review**

Reference	Research Design & Evidence Level	Measures & Reliability	Intervention	Results
<p>Armel, S., Hitchman, K., Millar, K., Zahavich, L., Demsky, R., Murphy, J., &amp; Rosen, B (2011). The use of family history questionnaires: An examination of genetic risks estimates and genetic testing eligibility in the non-responder population. <i>Journal of Genetic Counseling</i>, 20(4), 355-364. Retrieved from <a href="http://search.proquest.com.proxy.library.umkc.edu/docview/874904422?pq-origsite=summon&amp;accountid=14589">http://search.proquest.com.proxy.library.umkc.edu/docview/874904422?pq-origsite=summon&amp;accountid=14589</a></p>	<p>Cohort Study Level III</p>	<p>The Pearson Chi-square Test</p>	<p>This article explores the demographics of the non-responder population to assess genetic risk.</p>	
<p>Bellcross, C., Kolor, K., Goddard, K., Coates, R., Reyes, M., &amp; Khoury, M., (2011). Awareness and utilization of BRCA1/2 testing among U.S. primary care physicians. <i>American Journal of Preventative Medicine</i>, 49(1), 61-66. Retrieved from <a href="http://www.sciencedirect.com.proxy.library.umkc.edu/science/article/pii/S0749379710005520">http://www.sciencedirect.com.proxy.library.umkc.edu/science/article/pii/S0749379710005520</a></p>	<p>Cohort Study Level III</p>	<p>We used SPSS, version 17.0</p>	<p>Survey of providers</p>	<p>Of the 1500 physician respondents, 1300 (87%) were aware of <i>BRCA</i> testing and 375 (25%) reported having ordered at least one test in the past year.</p>

<p>Bernhardt, B., Zayak, C., Gordon, E., Wawak, L., Pyeritz, R., &amp; Gollust, S. (2012). Incorporating direct-to-consumer genomic information into patient care: attitudes and experiences of primary care physicians. NIH Public Access Author Manuscript, PMC 9(7), 683-692. Retrieved from <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3684987/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3684987/</a></p>	<p>Non-RCT Level II</p>		<p>Survey to PCP's</p>	<p>PCPs are open to BRCA testing, but education for providers is necessary.</p>
<p>Cox, S., Zlot, A., Silvey, K., Elliot, D., Horn, T., Johnson, A., &amp; Leman, R. (2012). Patterns of genetic testing: a randomized survey of Oregon clinicians. <i>Journal of Cancer Epidemiology</i>, 2012, 1-11. Retrieved from <a href="http://www.hindawi.com/journals/jce/2012/294730/">http://www.hindawi.com/journals/jce/2012/294730/</a></p>	<p>Non- RCT Level II</p>			<p>Reducing morbidity and mortality due to breast, ovarian, and colorectal cancers is goal.</p>
<p>Fletcher, S. (2012). Risk prediction models for breast cancer screening. Retrieved from <a href="http://cursoenarm.net/UPTODATE/contents/mobipreview.htm?32/63/33791?source=HISTORY">http://cursoenarm.net/UPTODATE/contents/mobipreview.htm?32/63/33791?source=HISTORY</a></p>	<p>Level III</p>			<p>Risk prediction model</p>
<p>Frank, T., Deffenbaugh, A., Reid, J., Hulick, M., Ward, B., Lingenfelter, B., Gumpper, L., Scholl, T., Taytigian, S., Pruss, D., &amp; Critchfield, G. (2002). Clinical Characteristics of Individuals with Germline Mutations in BRCA1 and</p>	<p>Observational Study Level IV</p>	<p>3 founder mutations prevalent in individuals of Ashkenazi Jewish ancestry</p>		<p>Overall, 1,731 deleterious mutations in <i>BRCA1</i> and <i>BRCA2</i> were identified.</p>

BRCA2: Analysis of 10,000 Individuals. Journal of Clinical Oncology, 20 (6), 1480-1490. Retrieved from <a href="http://jco.ascopubs.org.proxy.library.umkc.edu/content/20/6/1480.abstract">http://jco.ascopubs.org.proxy.library.umkc.edu/content/20/6/1480.abstract</a>				
National Cancer Institute (2011). Breast Cancer Risk Assessment Tool. Retrieved from <a href="http://www.cancer.gov/bcrisktool/Default.aspx">http://www.cancer.gov/bcrisktool/Default.aspx</a>	Level III			Breast Cancer risk assessment tool
McCarthy, A. M., Bristol, M., Fredricks, T., Wilkens, L., Roelfsema, I., Liao, K., Armstrong, K. (2014). Are physician recommendations for BRCA 1/2 testing among breast cancer patients appropriate? A population based study. <i>Cancer</i> , 119(20), 3596-3603. Retrieved from <a href="http://onlinelibrary.wiley.com.proxy.library.umkc.edu/doi/10.1002/cncr.28268/pdf">http://onlinelibrary.wiley.com.proxy.library.umkc.edu/doi/10.1002/cncr.28268/pdf</a>	Non-RCT Level II	T Tests and Chi-Square Tests	Among high risk women, age at diagnosis was the strongest predictor of not receiving a recommendation for testing.	<i>BRCA 1/2</i> testing was most common among older, low income, and employed women.
National Cancer Institute (2009). BRCA1 and BRCA2: Cancer risk and genetic testing. Retrieved from <a href="http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA">http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA</a>	Level III			In December 2013, the United States Preventive Services Task Force recommended that women who have family members with breast, ovarian, fallopian tube, or peritoneal cancer be evaluated to see if they have a family history that is associated with an increased risk of a harmful mutation in one of these genes.

<p>Pruthi, S., Gostout, B., &amp; Lindor, N. (2010). Identification and management of women with BRCA mutations or hereditary predisposition for breast and ovarian cancer. <i>Mayo Clinic Proceedings</i>, 85(12), 1111-1120. Retrieved from <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2996153/?tool=pmcentrez">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2996153/?tool=pmcentrez</a></p>	<p>Meta-analysis Level I</p>			<p>Breast health specialists, genetic counselors, gynecologic oncologists, and primary health care physicians all have an important role in discussing risk-reduction strategies with women at very high risk of breast and ovarian cancer.</p>
<p>Rubinstein, W. S., Acheson, L. S., O'Neill, S. M., Ruffin, M. T., IV, Wang, C., Beaumont, J. L., &amp; Rothrock, N. (2011). Clinical utility of family history for cancer screening and referral in primary care: A report from the Family Healthcare Impact Trial. <i>Journal of Genetic Medicine</i>, 13(11), 956-965. Doi: 10.1097/GIM.0b013e3182241d88</p>	<p>RCT Level I</p>	<p>Equation-based logistic regression model</p>	<p>24 women at strong risk of breast cancer, eligible for breast cancer screening earlier than 40 years of age. Of these, only four had received a mammogram before study enrollment.</p>	<p>Risk assessment was recommended based on family history but would not have been recommended for the general population</p>
<p>U.S. Preventive Services Task Force (2015). Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer in Women: Recommendation Statement. <i>American Family Physician</i> 91(2). Retrieved March 11, 2016.</p>	<p>Guideline</p>			<p>The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in <i>BRCA1</i> or <i>BRCA2</i> genes be referred for genetic counseling and evaluation for <i>BRCA</i> testing.</p>
<p>United States Department of Health and Human Services (2014). Cancer. Retrieved from <a href="https://www.healthypeople.gov/2020/topics-">https://www.healthypeople.gov/2020/topics-</a></p>	<p>Guideline</p>			



objectives/topic/cancer				
<p>Cohn, J., Blazey, W., Tegay, D., Harper, B., Koehler, S., Laurent, B., Chan, V., Jung, M., Krishnamachari, B. (2014). Physician Risk Assessment Knowledge Regarding BRCA Genetics Testing. <i>Journal of Cancer Education</i> 30(3), 573-579. Retrieved from <a href="http://link.springer.com.proxy.library.umkc.edu/article/10.1007%2Fs13187-014-0724-9">http://link.springer.com.proxy.library.umkc.edu/article/10.1007%2Fs13187-014-0724-9</a></p>	<p>Non-RCT Level II</p>		<p>Genetics training may be associated with knowledge of risk assessment for HBOC</p>	<p>Knowledge of an individual's gene mutation status may allow for proactive disease management.</p>
<p>Loescher, L. J., Lim, K. H., Leitner, O., Ray, J., D'Souza, J. (2009). Cancer Surveillance Behaviors in Women Presenting for Clinical BRCA Genetic Susceptibility Testing. <i>Oncology Nursing Forum</i> 36(2), E57-67. Retrieved from <a href="http://search.proquest.com.proxy.library.umkc.edu/docview/223114172?pq-origsite=summon&amp;accountid=14589">http://search.proquest.com.proxy.library.umkc.edu/docview/223114172?pq-origsite=summon&amp;accountid=14589</a></p>	<p>Non-RCT Level II</p>			<p>Healthcare providers should be aware of changing breast and ovarian cancer surveillance recommendations and counsel their at-risk patients accordingly.</p>

<p>Ferla, R., Calo, V., Cascio, S., Rinaldi, G., Badalamenti, G., Carreca, I., Surmacz, E., Colucci, G., Bazan, V., &amp; Russo, A., (2007). Founder mutations in BRCA1 and BRCA2 genes. <i>Annals of Oncology</i>, 18(6), 93-98. Retrieved from <a href="http://annonc.oxfordjournals.org/content/18/suppl_6/vi93.full.pdf+html">http://annonc.oxfordjournals.org/content/18/suppl_6/vi93.full.pdf+html</a></p>	<p>Non-RCT Level II</p>		<p>Identification of founder mutations in the various ethnic groups is an extremely important step towards the improvement of genetic counseling.</p>	<p>Differences in susceptibility and in age onset of cancer among carrier of a specific mutation could make it possible to define the role and importance of risk-modifying factors.</p>
<p>Centers for Disease Control and Prevention. Genomic testing. <a href="http://www.cdc.gov/genomics/gtesting/tier.htm">http://www.cdc.gov/genomics/gtesting/tier.htm</a></p>	<p>Level III</p>			
<p>Francke, U., Dijamco, C., Kiefer, A., Eriksson, N., Moiseff, B., Tung, J., Mountain, J. (2013). Dealing with the unexpected: Consumer Responses to Direct-Access BRCA Mutation Testing. <i>Peer Journal</i>, 12(1). Doi: 10.7717/peerj.8</p>	<p>RCT Level I</p>			
<p>Matloff, E. (2008). Direct to confusion; lessons learned from marketing BRCA testing. <i>The American Journal of Bioethics</i>, 8(6), 5-8. Retrieved from <a href="http://www-tandfonline-com.proxy.library.umkc.edu/doi/abs/10.1080/15265160802248179">http://www-tandfonline-com.proxy.library.umkc.edu/doi/abs/10.1080/15265160802248179</a></p>	<p>Observation-al Level IV</p>			<p>Ethical considerations: Monopoly on BRCA test</p>
<p>National Cancer Institute</p>	<p>Guidelines</p>			

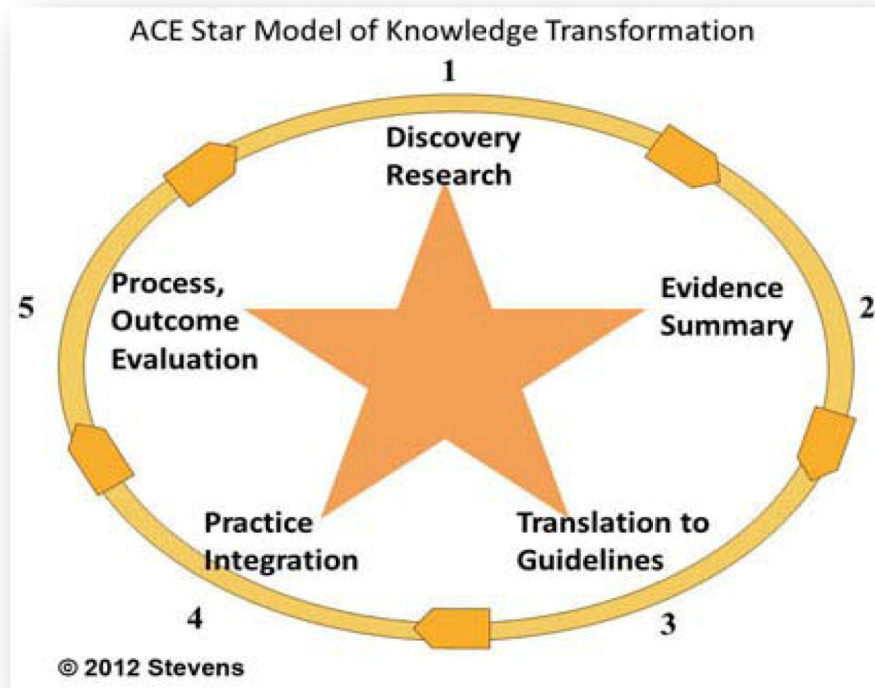
<p>(2016). Genetics of breast and ovarian cancer (PDQ). Retrieved from <a href="http://www.cancer.gov/types/breast/hp/breast-ovarian-genetics-pdq">http://www.cancer.gov/types/breast/hp/breast-ovarian-genetics-pdq</a></p>				
<p>National Cancer Institute (2013). Genetic Testing for Hereditary Cancer Syndromes. Retrieved from <a href="http://www.cancer.gov/about-cancer/causes-prevention/genetics/genetic-testing-fact-sheet">http://www.cancer.gov/about-cancer/causes-prevention/genetics/genetic-testing-fact-sheet</a></p>	Guidelines			
<p>Breast Cancer Genetics Screening Tool (2016). Health Care Providers. Retrieved from <a href="https://www.breastcancergenescreen.org/providers.aspx">https://www.breastcancergenescreen.org/providers.aspx</a></p>	Tool			
<p>Sifri, R., Gangadharappa, S., &amp; Acheson, L. (2004). Identifying and testing for hereditary susceptibility to common cancers. <i>Ca: a Cancer Journal for Clinicians</i>, 54(6), 309-326. Retrieved from <a href="http://pc8ga3qq6a.search.serialsolutions.com.proxy.library.umkc.edu/?genre=article&amp;atitle=Identifying and Testing for Hereditary Susceptibility to Common Cancers.&amp;title=CA: A">http://pc8ga3qq6a.search.serialsolutions.com.proxy.library.umkc.edu/?genre=article&amp;atitle=Identifying and Testing for Hereditary Susceptibility to Common Cancers.&amp;title=CA: A</a></p>	Observational Level IV			

<p>Cancer Journal for Clinicians&amp;issn=00079235 &amp;isbn=&amp;volume=54&amp;issue=6&amp;date=20041101&amp;aualast=Sifri, Randa&amp;spage=309&amp;pages=309-326&amp;sid=EBSCO:MasterFILE Premier:15345639</p>				
<p>Lipsky, M. S., Koenigs, M., Nora, R., Peralta, E., Zahasky, K. M. (2009). Breast Cancer Prevention for Rural Healthcare Practitioners. Retrieved from <a href="https://www.nphealthcarefoundation.org/ce/breast_cancer/downloads/article.pdf">https://www.nphealthcarefoundation.org/ce/breast_cancer/downloads/article.pdf</a></p>	<p>Level VII</p>			<p>Epidemiology in Rural Setting</p>
<p>Kolor, K. (2014). Genetics and BRCA in Primary Care. Retrieved from <a href="http://www.medscape.com/viewarticle/832522">http://www.medscape.com/viewarticle/832522</a></p>	<p>Level VII</p>			<p>Lists tools for BRCA screening in PC setting</p>

<p>Venkitaraman, A. (2014). Cancer suppression by the chromosome custodians, BRCA 1 and BRCA 2. <i>Science</i>, 343(6178), 1470-1475. doi: 10.1126/science.1252230</p>	<p>Observational Level III</p>			
<p>Lancaster, J. M., Powell, C. B., Chen, L., &amp; Richardson, D. L. (2014). Statement on risk assessment for inherited gynecologic cancer predispositions. <i>Gynecologic Oncology</i>, doi: 10.1016/j.ygyno.2014.09.009</p>	<p>Guideline</p>			
<p>Moyer, V. (2013). Risk assessment, genetic counseling, and genetic testing for BRCA-related cancer in women: U.S. preventive services task force recommendation statement. Retrieved from <a href="http://www.uspreventiveservicestaskforce.org/uspstf12/brcatest/brcatestfinalrs.pdf">http://www.uspreventiveservicestaskforce.org/uspstf12/brcatest/brcatestfinalrs.pdf</a></p>	<p>Guideline</p>			
<p>Ledingham, D. (2014). Incorporating BRCA1 and BRCA2 Testing into Clinical Practice. Retrieved March 13, 2016, from <a href="https://content.lib.utah.edu/utis/getfile/collection/ehsl-gradnu/id/90/filename/99.pdf">https://content.lib.utah.edu/utis/getfile/collection/ehsl-gradnu/id/90/filename/99.pdf</a></p>	<p>Previous project</p>			

Korde, L.A., Gadalla, S., M., (2009). Cancer Risk Assessment for the Primary Care Physician. <i>Primary Care: Clinics in Office Practice</i> 36(3), 471-488. Retrieved from <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2713871/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2713871/</a>	Non-RCT Level II			
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## Appendix C



### ACE Star Model of Knowledge Transformation Applied to BRCA Screening Project

Step 1: Discovery, research: Many primary care clinics are not following the guidelines for BRCA screening in the primary care setting as noted upon observation as well as per literature review.

Step 2: Evidence Summary: Conducted a thorough review of literature and it was determined that providers have room to improve in BRCA screening as warranted per USPSTF.

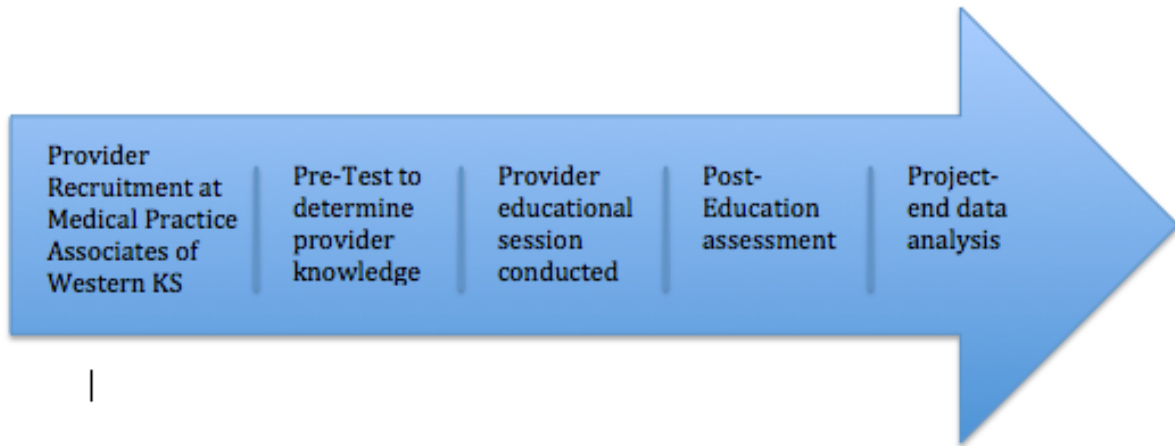
Step 3: Translation of Guidelines: Per guidelines, any woman with a family history of breast, ovarian, tubal or peritoneal cancers should be screened with an approved screening tool. It has been shown that providers lack this knowledge.

Step 4: Practice Integration: Now that it is known that providers lack this knowledge, we can take the appropriate steps to correct it, starting with an educational session to inform and educate. Once this is complete, improved screening for BRCA in the primary care will be possible.

Step 5: Process, Outcome evaluation: I can assess the outcomes after the educational session by administering a follow-up questionnaire to determine whether providers gained the knowledge they were previously lacking. It will also be evident in the number of referrals made to genetic counselors

Appendix D

**DNP Project Implementation Flow Chart**





## Appendix E

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<b>DNP Itemized Cost Table</b>	
<b>Provider Training Luncheon</b>	\$100
<b>Patient handouts</b>	\$100
<b>Provider handouts and questionnaire</b>	\$100
<b>Poster for Conference</b>	\$200
<b>Development of Provider education program</b>	\$1200 (approximately 120 hours at \$10/hour)
<b>Total Cost</b>	\$1700

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Appendix F

**USPSTF Screening Guidelines**

**Final Recommendation Statement**

***BRCA-related Cancer: Risk Assessment, Genetic Counseling and Genetic Testing, December 2013***

*Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.*

Table of Contents	
Recommendation Summary	Members of the U.S. Preventive Services Task Force
Preface	Copyright and Source Information
Rationale	Table 1. Ontario Family History Assessment Tool
Clinical Considerations	Table 2. Manchester Scoring System
Other Considerations	Table 3. Referral Screening Tool
Discussion	Table 4. Pedigree Assessment Tool
Update of Previous USPSTF Recommendation	Table 5. FHS-7
Recommendations of Other Groups	References

Recommendation Summary		
Summary of Recommendations and Evidence		
Population	Recommendation	Grade (What's This?)
Women who have Family Members with Breast, Ovarian, Tubal, or Peritoneal Cancer	The USPSTF recommends that primary care providers screen women who have family members with breast, ovarian, tubal, or peritoneal cancer with 1 of several screening tools designed to identify a family history that may be associated with an increased risk for potentially harmful mutations in breast cancer susceptibility genes ( <i>BRCA1</i> or <i>BRCA2</i> ). Women with positive screening results should receive genetic counseling and, if indicated after counseling, BRCA testing.	<b>B</b>

Women Whose Family History is not Associated with an Increased Risk	The USPSTF recommends against routine genetic counseling or BRCA testing for women whose family history is not associated with an increased risk for potentially harmful mutations in the <i>BRCA1</i> or <i>BRCA2</i> genes.	<b>D</b>
<a href="#">Return to Table of Contents ↗</a>		

## Preface

*The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific preventive care services for patients without related signs or symptoms.*

*It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.*

*The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.*

This article was first published in *Annals of Internal Medicine* on 24 December 2013. Select for [copyright and source information](#).

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## Rationale

### Importance

The cancer types related to potentially harmful mutations of the BRCA genes are predominantly breast, ovarian, and fallopian tube cancer, although other types are also associated<sup>1</sup>. In the general population, 12.3% of women will develop breast cancer during their lifetime and 2.74% will die of the disease, whereas 1.4% of women will develop ovarian cancer and 1.0% will die of the disease<sup>2</sup>. A woman's risk for breast cancer increases to 45% to 65% by age 70 years if there are clinically significant mutations in either BRCA gene<sup>3, 4</sup>. Mutations in the *BRCA1* gene increase ovarian cancer risk to 39% by age 70 years, and *BRCA2* mutations increase ovarian cancer risk to 10% to 17% by age 70 years<sup>3, 4</sup>. In the general population, these mutations occur in an estimated 1 in 300 to 500 women (0.2% to 0.3%)<sup>5-8</sup>. In a meta-analysis conducted for the USPSTF, the combined prevalence of *BRCA1* and *BRCA2* mutations was 2.1% in a general population of Ashkenazi Jewish women<sup>9</sup>.

### Detection of Potentially Harmful BRCA Mutations

Genetic risk assessment and BRCA mutation testing is generally a multistep process involving identification of individuals who may be at increased risk for potentially harmful mutations, followed by genetic counseling from suitably trained health care providers and genetic testing of selected high-risk individuals when indicated. Several familial risk stratification tools are clinically useful for selecting patients who should be offered genetic counseling to further determine their candidacy for possible BRCA mutation testing.

### Benefits of Testing for Potentially Harmful Mutations

For women whose family history is associated with an increased risk for potentially harmful mutations in the *BRCA1* or *BRCA2* genes, adequate evidence suggests that the benefits of testing for potentially harmful BRCA mutations are moderate.

For women whose family history is not associated with an increased risk for potentially harmful mutations in the *BRCA1* or *BRCA2* genes, there is adequate evidence that the benefits of testing for potentially harmful BRCA mutations are few to none.

### Harms of Detection of Potentially Harmful BRCA Mutations and Early Intervention and Treatment

Adequate evidence suggests that the overall harms of detection of and early intervention for potentially harmful BRCA mutations are small to moderate.

### USPSTF Assessment

For women whose family history is associated with an increased risk for potentially harmful mutations in the *BRCA1* or *BRCA2* genes, there is moderate certainty that the net benefit of testing for potentially harmful BRCA mutations and early intervention is moderate.

For women whose family history is not associated with an increased risk for potentially harmful mutations in the *BRCA1* or *BRCA2* genes, there is moderate certainty that the net benefit of testing for potentially harmful BRCA mutations and early intervention ranges from minimal to potentially harmful.

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## Clinical Considerations

### ***Patient Population Under Consideration***

This recommendation applies to asymptomatic women who have not been diagnosed with BRCA-related cancer.

Women who have 1 or more family members with a known potentially harmful mutation in the *BRCA1* or *BRCA2* genes should be offered genetic counseling and testing.

The USPSTF recognizes the potential importance of further evaluating women who have a diagnosis of breast or ovarian cancer. Some women receive genetic testing as part of a cancer evaluation at the time of diagnosis of breast cancer. The USPSTF did not review the appropriate use of BRCA testing in the evaluation of women who are newly diagnosed with breast cancer. That assessment is part of disease management and is beyond the scope of this recommendation. Women who have been diagnosed with breast cancer in the past and who did not receive BRCA testing as part of their cancer care but have a family history of breast or ovarian cancer should be encouraged to discuss further evaluation with their clinician.

These recommendations do not apply to men, although male family members may be identified for testing during evaluation.

### ***Family History Screening and Risk Assessment***

Mutations in the BRCA genes cluster in families, exhibiting an autosomal dominant pattern of transmission in maternal or paternal lineage. During standard elicitation of family history information from patients, primary care providers should ask about specific types of cancer, primary cancer sites, which family members were affected, relatives with multiple types of primary cancer, and the age at diagnosis and sex of affected family members.

For women who have at least 1 family member with breast, ovarian, or other types of BRCA-related cancer, primary care providers may use 1 of several brief familial risk stratification tools to determine the need for in-depth genetic counseling.

Although several risk tools are available, the tools evaluated by the USPSTF include the Ontario Family History Assessment Tool (Table 1), Manchester Scoring System (Table 2), Referral Screening Tool (Table 3), Pedigree Assessment Tool (Table 4), and FHS-7 (Table 5)<sup>10-19</sup>. The Referral Screening Tool (an updated version, the B-RST, is available at [www.breastcancergenescreeen.org](http://www.breastcancergenescreeen.org))<sup>20</sup> and FHS-7 are the simplest and quickest to administer. All of these tools seem to be clinically useful predictors of which women should be referred for genetic counseling due to increased risk for potentially harmful BRCA mutations (most sensitivity estimates were >85%), although some models have been evaluated in only 1 study<sup>9, 20</sup>. To determine which patients would benefit from BRCA risk assessment, primary care providers should not use general breast cancer risk assessment models (for example, the National Cancer Institute Breast Cancer Risk Assessment Tool, which is based on the Gail model) because they are not designed to determine which women should receive genetic counseling or BRCA testing.

In general, these tools elicit information about factors that are associated with increased likelihood of BRCA mutations. Family history factors associated with increased likelihood of potentially harmful BRCA mutations include breast cancer diagnosis before age 50 years, bilateral breast cancer, presence of breast and ovarian cancer, presence of breast cancer in 1 or more male family members, multiple cases of breast cancer in the family, 1 or more family members with 2 primary types of BRCA-related cancer, and Ashkenazi Jewish ethnicity. The USPSTF recognizes that each risk assessment tool has limitations and found insufficient comparative evidence to recommend one tool over another. The USPSTF also found insufficient evidence to support a specific risk threshold for referral for testing.

### ***Genetic Counseling***

Genetic counseling about BRCA mutation testing may be done by trained health professionals, including trained primary care providers. Several professional organizations describe the skills and training necessary to provide comprehensive genetic counseling. The process of genetic counseling includes detailed kindred analysis and risk assessment for potentially harmful BRCA mutations; education about the possible results of testing and their implications; identification of affected family members who may be preferred candidates for testing; outlining options for screening, risk-reducing medications, or surgery for eligible patients; and follow-up counseling for interpretation of test results.



### ***BRCA Mutation Testing***

Adequate evidence suggests that current genetic sequencing tests can accurately detect BRCA mutations. Testing for BRCA mutations should be done only when an individual has personal or family history that suggests an inherited cancer susceptibility, when an individual has access to a health professional who is trained to provide genetic counseling and interpret test results, and when test results will aid in decision making. Initial testing of a family member who has breast or ovarian cancer is the preferred strategy in most cases, but it is reasonable to test if no affected relative is available. It is essential that before testing, the individual is fully informed about the implications of testing and has expressed a desire for it.

The type of mutation analysis required depends on family history. Individuals from families with known mutations or from ethnic groups in which certain mutations are more common (for example, Ashkenazi Jewish women) can be tested for these specific mutations.

Individuals without linkages to families or groups with known mutations receive more comprehensive testing. In these cases, when possible, testing should begin with a relative who has breast or ovarian cancer to determine whether affected family members have a clinically significant mutation.

Tests for BRCA mutations are highly sensitive and specific for known mutations, but interpretation of results is complex and generally requires posttest counseling. Test results for genetic mutations are reported as positive (that is, potentially harmful mutation detected), variants of uncertain clinical significance, uninformative-negative, or true-negative. Women who have relatives with known BRCA mutations can be reassured about their inherited risk for a potentially harmful mutation if the results are negative (that is, a true negative). Some studies suggest increased breast cancer risk in some women with true-negative results<sup>21-24</sup>. However, a comprehensive meta-analysis conducted for the USPSTF that included these studies found that breast cancer risk is generally not increased in women with true-negative results<sup>9</sup>. An uninformative-negative result occurs when a woman's test does not detect a potentially harmful mutation but no relatives have been tested or no mutations have been detected in tested relatives. Available tests may not be able to identify mutations in these families. Risk for breast cancer is increased in women with uninformative-negative results<sup>9</sup>.

### ***Timing of Screening***

Consideration of screening for potentially harmful BRCA mutations should begin once women have reached the age of consent (18 years). Primary care providers should periodically assess all patients for changes in family history (for example, comprehensive review at least every 5 to 10 years<sup>25</sup>).

### ***Interventions for Women Who Are BRCA Mutation Carriers***

Interventions that may reduce risk for cancer or cancer-related death in women who are BRCA mutation carriers include earlier, more frequent, or intensive cancer screening; risk-reducing medications (for example, tamoxifen or raloxifene); and risk-reducing surgery (for example, mastectomy or salpingo-oophorectomy). However, the strength of evidence varies across the types of interventions.

Evidence is lacking on the effect of intensive screening for BRCA-related cancer on clinical outcomes in women who are BRCA mutation carriers. Medications, such as tamoxifen and raloxifene, have been shown to reduce the incidence of invasive breast cancer in high-risk women in the general population, but they have not been studied specifically in women who are BRCA mutation carriers<sup>9, 20, 26</sup>.

In high-risk women and those who are BRCA mutation carriers, cohort studies of risk-reducing surgery (mastectomy and salpingo-oophorectomy) showed substantially reduced risk for breast or ovarian cancer. Breast cancer risk was reduced by 85% to 100% with mastectomy<sup>27-29</sup> and by 37% to 100% with oophorectomy, and ovarian cancer risk was reduced by 69% to 100% with oophorectomy or salpingo-oophorectomy<sup>26</sup>. Salpingo-oophorectomy was also associated with a 55% relative reduction in all-cause mortality (as measured during the course of the study) in women with *BRCA1* or *BRCA2* mutations and without a history of breast cancer<sup>27</sup>.

### **Other Approaches to Prevention**

The USPSTF recommendations on medications for breast cancer risk reduction are available on the USPSTF Web site ([www.uspreventiveservicestaskforce.org](http://www.uspreventiveservicestaskforce.org)).

The USPSTF recommends against screening for ovarian cancer in women. This recommendation does not apply to women with known genetic mutations that increase their risk for ovarian cancer (for example, BRCA mutations).

### **Useful Resources**

The National Cancer Institute Cancer Genetics Services Directory provides a list of professionals who offer services related to cancer genetics, including cancer risk assessment, genetic counseling, and genetic susceptibility testing (available at <http://www.cancer.gov/cancertopics/genetics/directory>).

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## **Other Considerations**

Although some studies have reported that women prefer in-person genetic counseling, telephone- or computer-based counseling may be considered for women who would not otherwise have access to these services.

### **Research Needs and Gaps**

Research on risk assessment and testing for BRCA mutations has focused on short-term outcomes for highly selected women in referral centers. Additional studies are needed, including comparative effectiveness trials of approaches to risk screening and strategies to improve access to genetic counseling and BRCA testing for high-risk individuals.

Another unresolved question is what specific training is needed (for persons other than trained genetic counselors) to provide genetic counseling. It would be helpful to understand which methods of delivery of genetic counseling are most effective, including those that can increase access to genetic counseling in rural or other settings. Trials comparing types of providers and protocols could address these questions.

What happens after patients are identified as high-risk in clinical settings is unknown. The consequences of genetic testing for individuals and their relatives require more study. Well-designed investigations using standardized measures and diverse study populations are needed.

An expanded database or registry of patients receiving genetic counseling for inherited breast and ovarian cancer susceptibility or who are tested for BRCA mutations would provide useful information about predictors of cancer and response to interventions. Additional data are needed from women of varying socioeconomic, racial, and ethnic groups.

For women who are mutation carriers, studies about the effectiveness of intensive cancer screening and risk-reducing medications and the effects of age at intervention on improving long-term outcomes are needed. This research would increase knowledge of the relative benefits and harms of interventions that are provided on the basis of genetic risk information.

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## **Discussion**

### **Burden of Disease**

Breast cancer is the second most common cancer in women in the United States and is the second leading cause of cancer death<sup>30, 31</sup>. In 2013, an estimated 232,340 women in the United States will be diagnosed with breast cancer and 39,620 women will die of the disease<sup>32</sup>. According to lifetime risk estimates for the general population, 12.3% of women will develop breast cancer during their lives and 2.74% will die of it<sup>2</sup>.

Ovarian cancer is the fifth leading cause of cancer death in women in the United States<sup>31</sup>, accounting for an estimated 22,240 new cases and 14,030 deaths in 2013<sup>33</sup>. According to lifetime risk estimates for the general population, 1.4% of women will develop ovarian cancer during their lives and 1.0% will die of it<sup>2</sup>.

Estimates of the prevalence of potentially harmful BRCA mutations vary by population. The estimated prevalence is 0.2% to 0.3% in the general population of women<sup>5-8</sup>, 6.0% in women with cancer onset before age 40 years<sup>9, 34, 35</sup>, and 2.1% in the general population of Ashkenazi Jewish women<sup>36-39</sup>. In a meta-analysis of studies in which recruitment was based on family history of breast or ovarian cancer, BRCA1 mutation prevalence was 13.6%, BRCA2 mutation prevalence was 7.9%, and prevalence of either mutation was 19.8%<sup>9</sup>.

### **Scope of Review**

This recommendation applies to women who have no signs or symptoms of BRCA-related cancer. For its updated evidence review, the USPSTF considered risk assessment, genetic counseling, and genetic testing for potentially harmful BRCA1 or BRCA2 mutations in asymptomatic women with a family history of breast or ovarian cancer but no personal history of cancer or known potentially harmful BRCA mutations in their family. The USPSTF also reviewed interventions aimed at reducing the risk for BRCA-related cancer in women with potentially harmful BRCA mutations, including intensive cancer screening (for example, earlier and more frequent mammography or magnetic resonance imaging of the breast), medications (for example, tamoxifen or raloxifene), and risk-reducing surgery (for example, mastectomy or oophorectomy). Studies about patients with current or past breast or ovarian cancer were excluded unless they were designed to address screening issues in women without cancer (for example, retrospective or case-control studies).

### **Accuracy of Familial Risk Assessment**

The USPSTF reviewed several tools that could be used in primary care settings to predict individual risk for breast cancer and potentially harmful BRCA mutations.

Tools specifically designed to determine risk for BRCA-related cancer are primarily intended for use by nongeneticist health care providers to guide referral to genetic counselors for more definitive evaluation. Models that have been validated in studies include the Ontario Family History Assessment Tool (Table 1), Manchester Scoring System (Table 2), Referral Screening Tool (Table 3), Pedigree Assessment Tool (Table 4), and FHS-7 (Table 5)<sup>10-19</sup>. In general, these tools elicit information about factors associated with increased likelihood of BRCA mutations. They are clinically useful predictors of which women should be referred for genetic counseling because of increased risk for potentially harmful BRCA mutations (most sensitivity estimates were >85%), although some models have been evaluated in only 1 study<sup>9, 20</sup>. The USPSTF recognizes that each risk assessment tool has limitations and found insufficient evidence to recommend one tool over another.

### **Accuracy of BRCA Mutation Testing**

The type of mutation analysis done depends on family history. Individuals from families with known mutations or from ethnic groups with common mutations (for example, Ashkenazi Jewish women) can be tested specifically for these mutations. The sensitivity and specificity of analysis techniques are measured by individual clinical laboratories and are not publicly available. Individuals without linkages to families or groups with known mutations receive more comprehensive testing. In these cases, guidelines recommend initial testing of a relative with known breast or ovarian cancer, when possible, to check for the presence of clinically significant mutations.

### **Effectiveness of BRCA Mutation Testing and Early Detection and Treatment**

To understand the potential benefits and harms of genetic counseling, the USPSTF reviewed 18 studies<sup>40-57</sup> published since its previous review. Studies generally reported positive (or no negative) psychological effects, increased accuracy of risk perception, or decreased intention to have genetic testing.

Genetic counseling significantly decreased breast cancer worry in 8 studies<sup>44-46, 48, 50, 53-55</sup>. Three studies<sup>41, 44, 49</sup> reported decreased or no changes in general anxiety and depression after genetic counseling, whereas other studies found no significant differences in anxiety scores<sup>48, 50</sup>. However, 1 of these studies noted an increase in state anxiety scores after genetic counseling<sup>44</sup>. Eight studies published since 2004 reported improved accuracy of risk perception after genetic counseling<sup>41, 42, 44-47, 49, 50, 52</sup>. Two studies reported decreased intention to have genetic testing after genetic counseling<sup>45, 46</sup>.



Interventions that may reduce risk for cancer in women who are BRCA mutation carriers include: earlier, more frequent, or intensive cancer screening; use of selective estrogen receptor modulators as risk-reducing medications (for example, tamoxifen or raloxifene); and risk-reducing surgery (for example, mastectomy or salpingo-oophorectomy).

Evidence is lacking on the effect of intensive screening for BRCA-related cancer on clinical outcomes in women who are BRCA mutation carriers.

Selective estrogen receptor modulators reduced the incidence of invasive breast cancer in several randomized, controlled trials<sup>58-64</sup>, although clinical trials of tamoxifen and raloxifene have not been conducted specifically in women who are BRCA mutation carriers. In a meta-analysis of trials published to date<sup>26, 65</sup>, tamoxifen and raloxifene reduced the incidence of estrogen receptor–positive invasive breast cancer, with 7 fewer events per 1000 women for tamoxifen (4 trials) and 9 fewer events per 1000 women for raloxifene (2 trials), assuming 5 years of treatment. Selective estrogen receptor modulators do not reduce risk for estrogen receptor–negative breast cancer, which includes 69% of breast cancer cases associated with *BRCA1* mutations and 16% associated with *BRCA2* mutations<sup>66</sup>.

In cohort studies of high-risk women and those who are BRCA mutation carriers, risk-reducing surgery (for example, mastectomy or salpingo-oophorectomy) substantially reduced risk for breast or ovarian cancer. Mastectomy reduced breast cancer risk by 85% to 100%, and oophorectomy or salpingo-oophorectomy reduced ovarian cancer risk by 69% to 100% and breast cancer risk by 37% to 100%<sup>9</sup>. In 1 fair-quality prospective cohort study<sup>27</sup>, salpingo-oophorectomy was also associated with a 55% relative reduction in all-cause mortality (as measured during the course of the study) in women with *BRCA1* and *BRCA2* mutations without a history of breast cancer. Breast cancer risk reduction associated with oophorectomy was more pronounced in women who were premenopausal at the time of surgery<sup>27, 67</sup>.

### **Potential Harms of Cancer Screening and Treatment**

Intensive screening for breast and ovarian cancer is associated with false-positive results, unnecessary imaging, and unneeded surgery. In 2 studies comparing mammography with magnetic resonance imaging for breast cancer screening in which 18% to 100% of study participants were BRCA mutation carriers, mammography was associated with higher false-positive rates (14% vs. 5.5% in the first round of screening;  $P < 0.001$ <sup>68</sup>; 15% vs. 11% in another study<sup>69</sup>) and more false-negative results (12 vs. 1 case in the first round of screening; 12 vs. 4 cases in subsequent rounds<sup>68</sup>). In a retrospective analysis of a cohort of women with potentially harmful BRCA mutations or first-degree relatives with BRCA mutations, those who were screened with mammography were more likely to have unneeded imaging than those who were screened with magnetic resonance imaging; however, rates of unneeded biopsy were similar<sup>69</sup>.

Risk-reducing medications (for example, tamoxifen or raloxifene) can increase risk for thromboembolic events (4 to 7 events per 1000 women over 5 years). Tamoxifen increased the risk for endometrial cancer (4 to 5 cases per 1000 women) compared with placebo or raloxifene, and it also increased risk for cataracts (15 per 1000 women) compared with raloxifene<sup>26, 65</sup>.

Data on the long-term physical harms of risk-reducing mastectomy are limited. In high-risk women having risk-reducing mastectomy with immediate reconstruction, 21% in 1 series had complications (for example, hematoma, contracture, or implant rupture)<sup>70</sup>. In another series, 64% reported postsurgical symptoms (for example, numbness, pain, tingling, infection, swelling, breast hardness, bleeding, organizing hematoma, failed reconstruction, breathing problems, thrombosis, and pulmonary embolism)<sup>71</sup>. After risk-reducing oophorectomy, 5% of women in 1 study had postsurgical complications (for example, wound infection, bladder or uterine perforation, or small-bowel obstruction)<sup>72</sup>.

Seven observational studies provided data on psychological distress due to risk-reducing mastectomy<sup>73, 74</sup> or oophorectomy<sup>25, 77</sup>. In 1 study of 90 women who had risk-reducing bilateral mastectomy<sup>73, 74</sup>, there were significant reductions in scores for anxiety and sexual pleasure and no significant differences in depression scores, body image concerns, or other measures. In another study<sup>75</sup>, there were no significant differences in psychological measures between women who had risk-reducing mastectomy and a reference sample that did not have the procedure. Ten years after risk-reducing mastectomy, most women in another study reported that their family lives were unchanged, but 39% reported negative effects on spousal relationships because of decreased sensation and changed body appearance<sup>76</sup>. After risk-reducing salpingo-oophorectomy, premenopausal women reported significant worsening of vasomotor symptoms and decreased sexual function<sup>77</sup>.



### **Estimate of Magnitude of Net Benefit**

For women whose family history is associated with an increased risk for potentially harmful mutations in the *BRCA1* or *BRCA2* genes, the USPSTF found adequate evidence that the benefits of testing, detection, and early intervention are moderate. For women whose family history is not associated with an increased risk for potentially harmful mutations in the *BRCA1* or *BRCA2* genes, the USPSTF found adequate evidence that the benefits of testing, detection, and early intervention are few to none. The USPSTF found adequate evidence that the overall harms of testing, detection, and early intervention are small to moderate.

For women whose family history is associated with an increased risk for potentially harmful mutations in the *BRCA1* or *BRCA2* genes, the USPSTF concludes with moderate certainty that the net benefit of testing, detection, and early intervention is moderate. For women whose family history is not associated with an increased risk for potentially harmful mutations in the *BRCA1* or *BRCA2* genes, the USPSTF concludes with moderate certainty that the net benefit of testing, detection, and early intervention ranges from minimal to potentially harmful.

### **How Does Evidence Fit With Biological Understanding?**

The *BRCA1* and *BRCA2* genes are tumor suppressor genes. Mutations of these genes have been linked to hereditary breast and ovarian cancer. Risks for breast, ovarian, and other types of BRCA-related cancer are greatly increased in patients who have inherited potentially harmful *BRCA1* or *BRCA2* mutations. Genetic testing may identify such mutations. Several options are available to manage cancer risk in patients who are found to be mutation carriers.

### **Response to Public Comments**

A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from 2 April through 29 April 2013. In response to comments, the USPSTF clarified that this recommendation statement applies to women. It also expanded the recommendation to include women who have family members with tubal or peritoneal (in addition to breast or ovarian) cancer. The USPSTF clarified that it recognizes the potential importance of further evaluating women who have a diagnosis of breast or ovarian cancer; however, that assessment is part of disease management and is beyond the scope of this recommendation.

The USPSTF added that it found insufficient evidence to recommend one risk assessment tool over another or to support a specific risk threshold for referral for genetic counseling and BRCA testing. It also added a compilation of risk assessment tools (Tables 1 to 5). Although the preferred BRCA testing strategy is initial testing of a family member with breast or ovarian cancer, the USPSTF clarified that it is reasonable to start testing in an unaffected individual if no affected relative is available. Because of the complexity of BRCA test results, the USPSTF also suggests posttest counseling. It also clarified and updated information on BRCA testing, other resources, and recommendations of other groups.

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## **Update of Previous USPSTF Recommendation**

In 2005, the USPSTF recommended that women whose family history is associated with an increased risk for potentially harmful mutations in the *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for BRCA testing. It also recommended against routine referral for genetic counseling or routine BRCA testing for women whose family history is not associated with an increased risk for potentially harmful mutations in the *BRCA1* or *BRCA2* genes<sup>78</sup>.

This recommendation statement reaffirms the USPSTF's previous recommendation. Since 2005, family history risk stratification tools have been developed and validated for use in primary care practice to guide referral for BRCA genetic counseling (Tables 1 to 5). In addition, the potential benefits and harms of medications for breast cancer risk reduction have been studied for longer follow-up periods, and more information is available about the potential psychological effects of genetic counseling and risk-reducing surgery.

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## Recommendations of Other Groups

The National Comprehensive Cancer Network provides specific criteria for genetic counseling and testing<sup>1</sup>. The American Congress of Obstetricians and Gynecologists recommends genetic risk assessment for women who have more than a 20% to 25% risk for an inherited predisposition to breast and ovarian cancer and states that it may be helpful for patients with more than a 5% to 10% risk<sup>79</sup>. The American Society of Clinical Oncology recommends genetic testing when there is personal or family history suggestive of genetic cancer susceptibility, the test can be adequately interpreted, and the results will aid in diagnosis or medical management of the patient or family member who has hereditary risk for cancer. It also recommends genetic testing only when pretest and posttest counseling are included<sup>80</sup>. The National Society of Genetic Counselors has issued practice guidelines for risk assessment and genetic counseling for hereditary breast and ovarian cancer. It recommends that genetic testing should be offered to individuals with a personal or family history suggestive of an inherited cancer syndrome, when the test can be adequately interpreted, if testing will influence medical management of the patient or relative, when potential benefits outweigh potential risks, if testing is voluntary, and when the individual seeking testing or a legal proxy can provide informed consent<sup>81</sup>. The European Society for Medical Oncology recommends that all patients who may be referred for BRCA testing should first complete informed consent and genetic counseling and patients who are mutation carriers should be encouraged to advise close family members to obtain genetic counseling<sup>82</sup>. The Society of Gynecologic Oncologists recommends genetic risk assessment for individuals with a personal risk of more than approximately 20% to 25% for an inherited predisposition to cancer and states that it may be helpful for patients with more than approximately 5% to 10% risk. Genetic testing for cancer predisposition requires informed consent that should encompass pretest education and counseling about the risks, benefits, and limitations of testing, including the implications of both positive and negative genetic test results<sup>83</sup>.

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## Members of the U.S. Preventive Services Task Force

Members of the U.S. Preventive Services Task Force at the time this recommendation was finalized† are Virginia A. Moyer, MD, MPH, *Chair* (American Board of Pediatrics, Chapel Hill, North Carolina); Michael L. LeFevre, MD, MSPH, *Co-Vice Chair* (University of Missouri School of Medicine, Columbia, Missouri); Albert L. Siu, MD, MSPH, *Co-Vice Chair* (Mount Sinai School of Medicine, New York, and James J. Peters Veterans Affairs Medical Center, Bronx, New York); Linda Ciofu Baumann, PhD, RN (University of Wisconsin, Madison, Wisconsin); Kirsten Bibbins-Domingo, PhD, MD (University of California, San Francisco, San Francisco, California); Susan J. Curry, PhD (University of Iowa College of Public Health, Iowa City, Iowa); Mark Ebell, MD, MS (University of Georgia, Athens, Georgia); Glenn Flores, MD (University of Texas Southwestern, Dallas, Texas); Francisco A.R. García, MD, MPH (Pima County Department of Health, Tucson, Arizona); Adelita Gonzales Cantu, RN, PhD (University of Texas Health Science Center, San Antonio, Texas); David C. Grossman, MD, MPH (Group Health Cooperative, Seattle, Washington); Jessica Herzstein, MD, MPH (Air Products, Allentown, Pennsylvania); Wanda K. Nicholson, MD, MPH, MBA (University of North Carolina School of Medicine, Chapel Hill, North Carolina); Douglas K. Owens, MD, MS (Veterans Affairs Palo Alto Health Care System, Palo Alto, and Stanford University, Stanford, California); William R. Phillips, MD, MPH (University of Washington, Seattle, Washington); and Michael P. Pignone, MD, MPH (University of North Carolina, Chapel Hill, North Carolina).

† For a list of current Task Force members, go to [www.uspreventiveservicestaskforce.org/members.htm](http://www.uspreventiveservicestaskforce.org/members.htm).

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**Table 1. Ontario Family History Assessment Tool**

Table 1. Ontario Family History Assessment Tool*	
Risk Factor	Points
<b>Breast and ovarian cancer</b>	
Mother	10
Sibling	7
Second-/third-degree relative	5
<b>Breast cancer relative</b>	
Parent	4
Sibling	3
Second-/third-degree relative	2
Male relative (add to above)	2
<b>Breast cancer characteristics</b>	
Onset at age 20–29 y	6
Onset at age 30–39 y	4
Onset at age 40–49 y	2
Premenopausal/perimenopausal	2
Bilateral/multifocal	3
<b>Ovarian cancer relative</b>	
Mother	7
Sibling	4
Second-/third-degree relative	3
<b>Age at ovarian cancer onset</b>	
<40 y	6
40–60 y	4
>60 y	2
<b>Age at prostate cancer onset</b>	
<50 y	1
<b>Age at colon cancer onset</b>	
<50 y	1
<b>Family total</b>	
Referral†	≥10

\* From reference <sup>19</sup>.

† Referral with a score of ≥10 corresponds to doubling of lifetime risk for breast cancer (22%).

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**Table 2. Manchester Scoring System**

\*  
Table 2. Manchester Scoring System\*

Risk Factor	BRCA1 Score	BRCA2 Score
<b>Age at onset of female breast cancer†</b>		
<30 y	6	5
30–39 y	4	4
40–49 y	3	3
50–59 y	2	2
≥60 y	1	1
<b>Age at onset of male breast cancer†</b>		
<60 y	5‡	8§
≥60 y	5‡	5§
<b>Age at onset of ovarian cancer†</b>		
<60 y	8	5
≥60 y	5	5
<b>Pancreatic cancer</b>	0	1
<b>Age at onset of prostate cancer†</b>		
<60 y	0	2
≥60 y	0	1

\* From reference <sup>13</sup>. Developed so that a score of 10 in either column or a combined score of 15 for both columns would be equivalent to a 10% chance of identifying a *BRCA1* or *BRCA2* mutation.

† For relatives in direct lineage.

‡ If *BRCA2* tested.

§ If *BRCA1* tested.

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**Table 3. Referral Screening Tool**

Table 3. Referral Screening Tool\*

Risk Factor	Breast Cancer at Age ≤50 y	Ovarian Cancer at Any Age
Yourself		
Mother		
Sister		
Daughter		
Mother's side		
Grandmother		
Aunt		
Father's side		
Grandmother		
Aunt		
≥2 cases of breast cancer after age 50 y on the same side of the family		
Male breast cancer at any age in any relative		
Jewish ancestry		

\* From reference <sup>16</sup>. A patient completes the checklist if she has a family history of breast or ovarian cancer and receives a referral if she checks ≥2 items.

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**Table 4. Pedigree Assessment Tool**

Table 4. Pedigree Assessment Tool\*

Risk Factor	Score†
Breast cancer at age ≥50 y	3
Breast cancer at age <50 y	4
Ovarian cancer at any age	5
Male breast cancer at any age	8
Ashkenazi Jewish heritage	4

\* From reference <sup>17</sup>. A score of ≥8 is the optimum referral threshold.

† For every family member with a breast or ovarian cancer diagnosis, including second- or third-degree relatives.

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**Table 5. FHS-7**

Did any of your first-degree relatives have breast or ovarian cancer?
Did any of your relatives have bilateral breast cancer?
Did any man in your family have breast cancer?
Did any woman in your family have breast and ovarian cancer?
Did any woman in your family have breast cancer before age 50 y?
Do you have 2 or more relatives with breast and/or ovarian cancer?
Do you have 2 or more relatives with breast and/or bowel cancer?

\* From reference <sup>18</sup>. One positive response initiates referral.

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Please read the following clinical scenarios and answer who you would consider for referral/testing for BRCA1/2.

- |  |     |    |
|--|-----|----|
| 1. Any adult woman with breast cancer  | yes | no |
| 2. Any adult woman with any family history of breast cancer  | yes | no |
| 3. Any adult woman with any family history of ovarian cancer   | yes | no |
| 4. Any adult woman with any family history of breast cancer, including at least three affected close relatives | yes | no |
| 5. A close adult female relative of a person who has tested positive for a BRCA1 or BRCA2 mutation             | yes | no |
| 6. Any adult woman with $\geq 2$ first-degree relatives diagnosed with breast cancer at age $<50$              | yes | no |
| 7. Any adult woman with a first-degree relative with bilateral breast cancer                                   | yes | no |
| 8. Any adult woman with a family history of male breast cancer   | yes | no |
| 9. Do you know of any racial/ethnic groups who are at higher risk for BRCA1/2 mutations?                       | yes | no |

10. If you answered yes to question 9, please identify the relevant racial/ethnic groups.

## Appendix H

**Education for Providers During Educational Session**

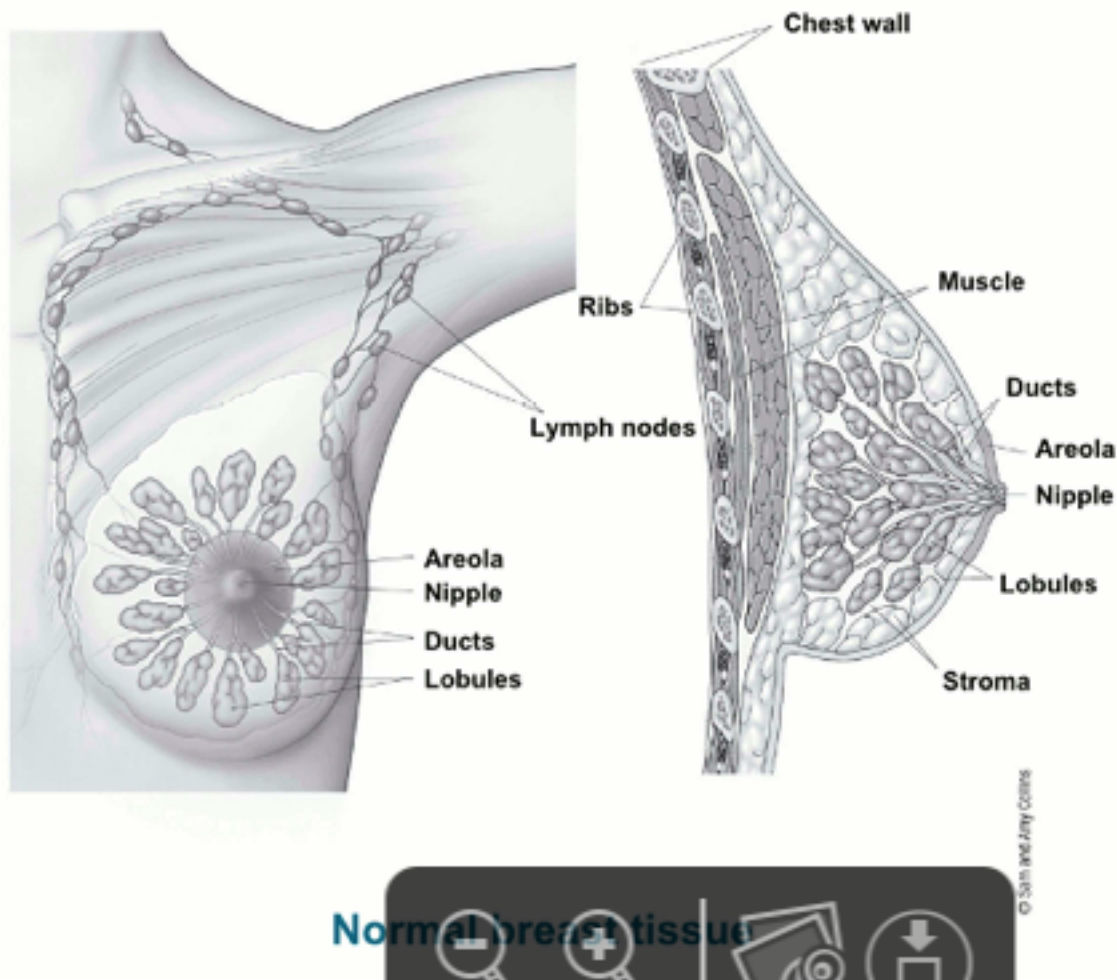
# **Breast Cancer Prevention and Early Detection**

## **What is breast cancer**

Breast cancer is a malignant tumor that starts in the cells of the breast. A malignant tumor is a group of cancer cells that can grow into (invade) nearby tissues or spread (metastasize) to distant parts of the body. Breast cancer happens mostly in women, but men can get it, too.

## **The normal breast**

To understand breast cancer, it helps to know about the normal structure of the breasts.



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The female breast is made up mainly of:

- Lobules – milk-producing glands
- Ducts – tiny tubes that carry the milk from the lobules to the nipple
- Stroma – fatty tissue and connective tissue, blood vessels, and lymphatic vessels

Most breast cancers start in the cells that line the ducts (*ductal* cancers). Some start in the cells that line the lobules (*lobular* cancers), while a small number start in other tissues.

## What are the risk factors for breast cancer?

A risk factor is anything that affects your chance of getting a disease such as cancer. Most women who have one or more breast cancer risk factors never develop breast cancer, while many women with breast cancer have no known risk factors (other than being a woman and growing

older). Even when a woman with risk factors develops breast cancer, it's hard to know just how much these factors might have contributed.

Some risk factors can't be changed – like a person's age or race. Other risk factors are lifestyle-related, such as cancer-causing factors in the environment or personal behaviors, such as smoking, drinking, and diet. Some factors influence risk more than others, and your risk for breast cancer can change over time, due to things like aging or lifestyle.

You may also hear about risk factors with unclear effects on breast cancer risk, or risk factors that are controversial or have been disproven.

## Breast cancer risk factors you cannot change

### Gender

Simply being a woman is the main risk factor for developing breast cancer. Men can develop breast cancer, but it's about 100 times more common among women than men. This is probably because men have less breast tissue, as well as less of the female hormones estrogen and progesterone, which can promote breast cancer cell growth.

### Aging

Your risk of developing breast cancer goes up as you get older. About 1 out of 8 invasive breast cancers are found in women younger than 45, while about 2 of 3 invasive breast cancers are found in women age 55 or older.

### Inheriting certain genes

About 5% to 10% of breast cancer cases are thought to be hereditary, meaning that they are caused by gene defects (called *mutations*) passed on from a parent.

***BRCA1* and *BRCA2* gene changes:** The most common cause of hereditary breast cancer is an inherited mutation in the *BRCA1* or *BRCA2* gene. In normal cells, these genes help prevent cancer by making proteins that help keep the cells from growing out of control. If you inherited a mutated copy of either gene from a parent, you have a high risk of developing breast cancer during your lifetime.

Although in some families with *BRCA1* mutations the lifetime risk of breast cancer is as high as 80%, on average this risk seems to be in the range of 55 to 65%. For *BRCA2* mutations the risk is lower, around 45%.

Breast cancers linked to these mutations occur more often in younger women and more often affect both breasts than cancers not linked to these mutations. Women with these inherited mutations also have an increased risk for developing other cancers, particularly ovarian cancer.

In the United States, *BRCA* mutations are more common in Jewish people of Ashkenazi (Eastern Europe) origin than in other racial and ethnic groups, but they can occur in anyone.

**Changes in other genes:** Other inherited gene mutations can also lead to breast cancer. These gene mutations are much less common and often do not increase the risk of breast cancer as much as the *BRCA* genes.

□ *ATM*: The *ATM* gene makes a protein that normally helps repair damaged DNA. Inheriting 2 abnormal copies of this gene (one from each parent) causes the disease *ataxia-telangiectasia*. Inheriting one abnormal copy of this gene has been linked to a high rate of breast cancer in some families.

□ *TP53*: The *TP53* gene makes a protein called *p53* that helps stop the growth of abnormal cells. Inherited mutations of this gene cause *Li-Fraumeni syndrome*. People with this syndrome have an increased risk of breast cancer, as well as other cancers such as leukemia, brain tumors, and sarcomas (cancers of bones or connective tissue). This is a rare cause of breast cancer.

□ *CHEK2*: The *Li-Fraumeni syndrome* can also be caused by inherited mutations in the *CHEK2* gene. Even when it doesn't cause this syndrome, it can increase breast cancer risk when it's mutated.

□ *PTEN*: The *PTEN* gene normally helps regulate cell growth. Inherited mutations in this gene cause *Cowden syndrome*, a rare disorder in which people are at increased risk for both benign and malignant breast tumors, as well as growths in the digestive tract, thyroid, uterus, and ovaries. Defects in this gene can also cause a different syndrome called *Bannayan-Riley-Ruvalcaba syndrome* that's not thought to be linked to breast cancer risk. The syndromes caused by mutations in *PTEN* can be grouped together as PTEN Tumor Hamartoma Syndrome.

□ *CDH1*: Inherited mutations in this gene cause *hereditary diffuse gastric cancer*, a syndrome in which people develop a rare type of stomach cancer at an early age. Women with mutations in this gene also have an increased risk of invasive lobular breast cancer.

□ *STK11*: Defects in this gene can lead to *Peutz-Jeghers syndrome*. People affected with this disorder develop pigmented spots on their lips and in their mouths, polyps in the urinary and gastrointestinal tracts, and have an increased risk of many types of cancer, including breast cancer.

□ *PALB2*: The *PALB2* gene makes a protein that interacts with the protein made by the *BRCA2* gene. Defects in this gene can lead to an increased risk of breast cancer. It isn't yet clear if *PALB2* gene mutations also increase the risk for ovarian cancer and male breast cancer.

**Genetic testing:** Genetic testing can be done to look for mutations in the *BRCA1* and *BRCA2* genes (or less commonly in other genes such as *PTEN* or *TP53*). Although testing can be helpful in some situations, the pros and cons need to be considered carefully.

If you are thinking about genetic testing, it's strongly recommended that first you talk to a genetic counselor, nurse, or doctor qualified to explain and interpret the results of these tests. It's very important to understand what genetic testing can and can't tell you, and to

carefully weigh the benefits and risks of genetic testing before these tests are done. Testing is expensive and might not be covered by some health insurance plans.

For more information, see *Genetic Testing: What You Need to Know*. You might also want to visit the National Cancer Institute website.

### **Family history of breast cancer**

Breast cancer risk is higher among women whose close blood relatives have this disease.

Having a first-degree relative (mother, sister, or daughter) with breast cancer about doubles a woman's risk. Having 2 first-degree relatives increases her risk about 3-fold.

Although the exact risk is not known, women with a family history of breast cancer in a father or brother also have an increased risk of breast cancer.

Overall, less than 15% of women with breast cancer have a family member with this disease. This means that most (85%) women who get breast cancer *do not* have a family history of this disease.

### **Personal history of breast cancer**

A woman with cancer in one breast has an increased risk of developing a new cancer in the other breast or in another part of the same breast. (This is different from a recurrence (return) of the first cancer.) This risk is even higher if breast cancer was diagnosed at a younger age.

### **Race and ethnicity**

Overall, white women are slightly more likely to develop breast cancer than are African-American women, but African-American women are more likely to die of this cancer. In women under 45 years of age, however, breast cancer is more common in African-American women. Asian, Hispanic, and Native American women have a lower risk of developing and dying from breast cancer.

### **Dense breast tissue**

Breasts are made up of fatty tissue, fibrous tissue, and glandular tissue. A woman is said to have dense breasts (on a mammogram) when she has more glandular and fibrous tissue and less fatty tissue. Women with dense breasts on a mammogram have a risk of breast cancer that is 1.2 to 2 times that of women with average breast density. Unfortunately, dense breast tissue can also make mammograms less accurate.



A number of factors can affect breast density, such as age, menopausal status, the use of certain drugs (including menopausal hormone therapy), pregnancy, and genetics.

### **Certain benign breast conditions**

Women diagnosed with certain benign breast conditions may have an increased risk of breast cancer. Some of these conditions are more closely linked to breast cancer risk than others. Doctors often divide benign breast conditions into 3 general groups, depending on how they affect this risk.

**Non-proliferative lesions:** These are not associated with overgrowth of breast tissue. They do not seem to affect breast cancer risk, or if they do, it's to a very small extent. They include:

- Fibrosis and/or simple cysts (sometimes called *fibrocystic changes* or *disease*)
- Mild hyperplasia
- Adenosis (non-sclerosing)
- Phyllodes tumor (benign)
- A single papilloma
- Fat necrosis
- Duct ectasia
- Periductal fibrosis
- Squamous and apocrine metaplasia
- Epithelial-related calcifications
- Other benign tumors (such as lipoma, hamartoma, hemangioma, neurofibroma, adenomyoepithelioma)

Mastitis (infection of the breast) is not a lesion, and it doesn't increase the risk of breast cancer.

**Proliferative lesions without atypia:** These conditions show excessive growth of cells in the ducts or lobules of the breast tissue. They seem to raise a woman's risk of breast cancer slightly (1/2 to 2 times normal). They include:

- Usual ductal hyperplasia (without atypia)  Fibroadenoma
- Sclerosing adenosis
- Several papillomas (called *papillomatosis*)

Radial scar

**Proliferative lesions with atypia:** In these conditions, there's excessive growth of cells in the ducts or lobules of the breast tissue, and some of the cells do not look normal. These have a stronger effect on breast cancer risk, raising it about 4 to 5 times higher than normal. These types of lesions include:

Atypical ductal hyperplasia (ADH)

### □ Atypical lobular hyperplasia (ALH)

Women with a family history of breast cancer and either hyperplasia or atypical

hyperplasia have an even higher risk of developing a breast cancer.

For more information on these conditions, see *Non-cancerous Breast Conditions*.

### **Lobular carcinoma in situ**

In lobular carcinoma in situ (LCIS), cells that look like cancer cells are growing in the lobules of the milk-producing glands of the breast, but they have not grown through the wall of the lobules. LCIS (also called *lobular neoplasia*) is sometimes grouped with ductal carcinoma in situ (DCIS) as a non-invasive breast cancer, but it differs from DCIS in that it doesn't seem to become invasive cancer if it isn't treated.

Women with LCIS have a 7- to 11-fold increased risk of developing cancer in either breast.

### **Starting menstruation before age 12**

Women who have had more menstrual cycles (periods) because they started menstruating early (before age 12) have a slightly higher risk of breast cancer. The increase in risk may be due to a longer lifetime exposure to the hormones estrogen and progesterone.

### **Going through menopause after age 55**

Women who have had more menstrual cycles because they went through menopause later (after age 55) have a slightly higher risk of breast cancer. The increase in risk may be due to a longer lifetime exposure to the hormones estrogen and progesterone.

### **Previous chest radiation**

Women who as children or young adults were treated with radiation therapy to the chest area for another cancer (such as Hodgkin disease or non-Hodgkin lymphoma) have an increased breast cancer risk. This varies with the patient's age when they got radiation. The risk is highest if the radiation was given during adolescence, when the breasts were

still developing. Radiation treatment after age 40 does not seem to increase breast cancer risk.

### **Diethylstilbestrol (DES) exposure**

From the 1940s through the early 1970s some pregnant women were given DES, an estrogen-like drug, because it was thought to lower their chances of losing the baby (miscarriage). These women have a slightly increased risk of developing breast cancer. Women whose mothers took DES during pregnancy may also have a slightly higher risk of breast cancer. For more information, see *DES Exposure: Questions and Answers*.

## Lifestyle-related risk factors for breast cancer

### **Drinking alcohol**

Drinking alcohol is clearly linked to an increased risk of breast cancer. The risk increases with the amount of alcohol consumed. Excessive alcohol consumption is also known to increase the risk of developing several other cancers.

### **Being overweight or obese**

Being overweight or obese after menopause increases breast cancer risk. Before menopause your ovaries make most of your estrogen, and fat tissue makes a small amount. After menopause (when the ovaries stop making estrogen), most of a woman's estrogen comes from fat tissue. Having more fat tissue after menopause can increase your chance of getting breast cancer by raising estrogen levels. Also, women who are overweight tend to have higher blood insulin levels. Higher insulin levels have also been linked to some cancers, including breast cancer.

The connection between weight and breast cancer risk is complex. For instance, risk appears to be increased for women who gained weight as an adult but may not be increased in those who have been overweight since childhood. Also, excess fat in the waist area may affect risk more than the same amount of fat in the hips and thighs. Researchers believe that fat cells in various parts of the body have subtle differences that may explain this.

### **Physical activity**

Evidence is growing that physical activity in the form of exercise reduces breast cancer risk. The main question is how much exercise is needed. In one study from the Women's Health Initiative, as little as 1 1/4 to 2 1/2 hours per week of brisk walking reduced a woman's risk by 18%. Walking 10 hours a week reduced the risk a little more.

### **Having children**

Women who have not had children or who had their first child after age 30 have a slightly higher breast cancer risk overall. Having many pregnancies and becoming pregnant at an early age reduces breast cancer risk overall. Still, the effect of pregnancy is different for different types of breast cancer.

### **Birth control**

**Oral contraceptives:** Studies have found that women using oral contraceptives (birth control pills) have a slightly greater risk of breast cancer than women who have never used them. This risk seems to go back to normal over time once the pills are stopped. Women who stopped using oral contraceptives more than 10 years ago don't appear to have any increased breast cancer risk.

**Depot-medroxyprogesterone acetate (DMPA; Depo-Provera):** This is an injectable form of progesterone that is given once every 3 months as birth control. A few studies have looked at the effect of DMPA on breast cancer risk. Women currently using DMPA seem to have an increase in risk, but the risk doesn't seem to be increased if this drug was used more than 5 years ago.

## Hormone therapy after menopause

Hormone therapy with estrogen (often combined with progesterone) has been used for many years to help relieve symptoms of menopause and to help prevent osteoporosis (thinning of the bones). This treatment goes by many names, such as *post-menopausal hormone therapy* (PHT), *hormone replacement therapy* (HRT), and *menopausal hormone therapy* (MHT).

There are 2 main types of hormone therapy:

- For women who still have a uterus (womb), doctors generally prescribe estrogen and progesterone (known as *combined hormone therapy* or HT). Progesterone is needed because estrogen alone can increase the risk of cancer of the uterus.
- For women who've had a hysterectomy (those who no longer have a uterus), estrogen alone can be prescribed. This is commonly known as *estrogen replacement therapy* (ERT) or just *estrogen therapy* (ET).

**Combined hormone therapy (HT):** Use of combined hormone therapy increases the risk of getting breast cancer. It may also increase the chances of dying from breast cancer.

**Estrogen therapy (ET):** The use of estrogen alone after menopause does not appear to increase the risk of developing breast cancer.

For more information about this topic, see *Menopausal Hormone Therapy and Cancer Risk*.

## Breastfeeding

Some studies suggest that breastfeeding may slightly lower breast cancer risk, especially if it's done for at least a year. But this has been hard to study, especially in countries like the United States, where breastfeeding for this long is uncommon.

The reason for this possible effect may be that breastfeeding reduces a woman's total number of lifetime menstrual cycles (the same as starting menstrual periods at a later age or going through early menopause).

## Factors with unclear effects on breast cancer risk

For some factors, the research is not yet clear on whether they influence breast cancer risk.

## Diet and vitamin intake

Many studies have looked for a link between certain diets and breast cancer risk, but so far the results have been conflicting. Some studies have shown that diet may play a role, while others have not found that diet impacts breast cancer risk.

Studies have also looked at vitamin levels, again with mixed results. Some studies have actually found an increased risk of breast cancer in women with higher levels of certain nutrients. So far, no study has shown that taking vitamins reduces breast cancer risk.

Most studies have found that breast cancer is less common in countries where the typical diet is low in total fat, low in polyunsaturated fat, and low in saturated fat. But many studies of women in the United States have not linked breast cancer risk to fat in the diet. Researchers are still not sure how to explain this. It may be at least partly due to the effect of diet on body weight. Also, studies comparing diet and breast cancer risk in different countries are complicated by other differences (such as activity level, intake of other nutrients, and genetic factors) that might also alter breast cancer risk.

More research is needed to better understand the effect of the types of fat eaten on breast cancer risk. But it's clear that calories do count, and fat is a major source of calories. High-fat diets can lead to being overweight or obese, which is a breast cancer risk factor. A diet high in fat has also been shown to influence the risk of developing several other types of cancer, and intake of certain types of fat is clearly related to heart disease risk.

## **Chemicals in the environment**

A great deal of research has been reported and more is being done to understand possible environmental influences on breast cancer risk.

Chemicals in the environment that have estrogen-like properties are of special interest. For example, substances found in some plastics, certain cosmetics and personal care products, pesticides, and PCBs (polychlorinated biphenyls) seem to have such properties. These could in theory affect breast cancer risk.

This issue understandably invokes a great deal of public concern, but at this time research does not show a clear link between breast cancer risk and exposure to these substances. Unfortunately, studying such effects in humans is difficult. More research is needed to better define the possible health effects of these and similar substances.

## **Tobacco smoke**

In recent years, some studies have found that long-term heavy smoking might be linked to a higher risk of breast cancer. Some studies have found that the risk is highest in certain groups, such as women who started smoking before they had their first child. The 2014 US Surgeon General's report on smoking concluded that there is "suggestive but not sufficient" evidence that smoking increases the risk of breast cancer.

**Secondhand smoke:** An active focus of research is whether secondhand smoke increases the risk of breast cancer. Both mainstream and secondhand smoke contain chemicals that, in high concentrations, cause breast cancer in rodents. Chemicals in tobacco smoke reach breast tissue and are found in breast milk.

The evidence on secondhand smoke and breast cancer risk in human studies is unclear, at least in part because the link between smoking and breast cancer is also not clear. One possible explanation for this is that tobacco smoke may have different effects on breast cancer risk in smokers compared to those who are just exposed to secondhand smoke.

A report from the California Environmental Protection Agency in 2005 concluded that the evidence about secondhand smoke and breast cancer is “consistent with a causal association” in younger, mainly pre-menopausal women. The 2014 US Surgeon General’s report concluded that there is “suggestive but not sufficient” evidence of a link at this point. In any case, this possible link to breast cancer is yet another reason to avoid secondhand smoke.

## **Night work**

Several studies have suggested that women who work at night may have an increased risk of breast cancer. This is a fairly recent finding, and more studies are looking at this issue. Some researchers think the effect may be due to changes in levels of melatonin, a

hormone whose production is affected by the body’s exposure to light. Other hormones are also being studied.

## **Disproven or controversial breast cancer risk factors**

There are many factors that research has shown are not linked to breast cancer. You may see information online or hear about these disproven or controversial risk factors, but it’s important to learn the facts.

### **Antiperspirants**

Internet and e-mail rumors have suggested that chemicals in underarm antiperspirants are absorbed through the skin, interfere with lymph circulation, and cause toxins to build up in the breast, over time leading to breast cancer.

Based on the available evidence (including what we know about how the body works), there’s little if any reason to believe that antiperspirants increase the risk of breast cancer. For more information, see *Antiperspirants and Breast Cancer Risk*.

### **Bras**

Internet and e-mail rumors and at least one book have suggested that bras cause breast cancer by blocking lymph flow. There's no good scientific or clinical basis for this claim, and a recent study of more than 1,500 women found no link between wearing a bra and breast cancer risk.

### **Induced abortion**

Several studies have provided very strong data that neither induced abortions nor spontaneous abortions (miscarriages) have an overall effect on the risk of breast cancer. For more detailed information, see *Is Abortion Linked to Breast Cancer?*

### **Breast implants**

Several studies have found that breast implants do not increase the risk of breast cancer. Implants can make breast tissue harder to see on standard mammograms, but extra x-ray pictures called *implant displacement views* can be used to examine the breast tissue more completely.

Breast implants might be linked to a rare type of lymphoma called *anaplastic large cell lymphoma*. This lymphoma has rarely been found in the breast tissue around the implants. So far, though, there are too few cases to know if the risk of this lymphoma is really higher in women with implants.

## **Can breast cancer be prevented?**

There is no sure way to prevent breast cancer. But there are things all women can do to help reduce their risk and help increase the odds that if cancer does occur, it will be found at an early, more treatable stage.

### **Lowering your risk**

You can lower your risk of breast cancer by changing those risk factors that can be changed. (See [“What are the risk factors for breast cancer?”](#))

[Body weight](#), [physical activity](#), and [diet](#) have all been linked to breast cancer, so these might be areas where you can take action.

Both increased body weight and weight gain as an adult are linked with a higher risk of breast cancer after menopause. [Alcohol](#) also increases risk of breast cancer. Even low levels of alcohol intake have been linked with an increase in risk.

Many studies have shown that moderate to vigorous physical activity is linked with lower breast cancer risk.

A diet that's rich in vegetables, fruit, poultry, fish, and low-fat dairy products has also been linked with a lower risk of breast cancer in some studies. But it's not clear if specific vegetables,

fruits, or other foods can lower risk. Most studies have not found that lowering fat intake has much of an effect on breast cancer risk.

At this time, the best advice about diet and activity to possibly reduce the risk of breast cancer is to:

- Get regular, intentional physical activity. To help reduce your risk of breast cancer, the American Cancer Society recommends that adults get at least 150 minutes of moderate intensity or 75 minutes of vigorous intensity activity each week (or a combination of these), preferably spread throughout the week.
- Reduce your lifetime weight gain by limiting your calories and getting regular physical activity.
- Avoid or limit your alcohol intake. The American Cancer Society recommends that women have no more than 1 alcoholic drink a day.

For more, see [\*American Cancer Society Guidelines on Nutrition and Physical Activity for Cancer Prevention\*](#).

Women who choose to breastfeed for at least several months may also get an added benefit of reducing their breast cancer risk.

Not using [hormone therapy after menopause](#) can help you avoid raising your risk.

It's not clear at this time if environmental chemicals that have estrogen-like properties (like those found in some plastic bottles or certain cosmetics and personal care products) increase breast cancer risk. If there is an increased risk, it's likely to be very small. Still, women who are concerned may choose to avoid products that contain these substances when possible.

## For women who are or may be at increased risk

If you are a woman at increased risk for breast cancer (for instance, because you have a strong family history of breast cancer, a known genetic mutation of a *BRCA* gene (*BRCA1* or *BRCA2*), or you have had DCIS, LCIS, or biopsies that have shown pre-cancerous changes), there may be some things you can do to help reduce your chances of developing breast cancer. Before deciding which, if any, of these may be right for you, talk with your health care provider to understand your risk and how much any of these approaches might lower this risk.

### Genetic testing for *BRCA* gene mutations

Having an inherited mutation in one of the *BRCA* genes greatly increases a woman's risk of getting breast cancer (and some other cancers). Many women may have relatives with breast cancer, but in most cases this is not the result of *BRCA* gene mutations. Genetic testing for these mutations can be expensive, and the results are often not clear cut. Testing can have a wide range of consequences that need to be considered. It should only be done when there's a reasonable suspicion that a mutation may be present.



Different expert groups have different recommendations about who should be considered for genetic testing.

For example, the US Preventive Services Task Force (USPSTF) has guidelines aimed at women without a history of cancer. The USPSTF recommends that women with an increased risk of having a *BRCA* mutation based on a family history of breast, ovarian, fallopian tube, and/or primary peritoneal cancer should be referred to a genetics professional. The genetics professional can evaluate that risk further, discuss the pros and cons of testing if the woman is at high risk (this is called genetic counseling), and arrange for the test if the patient wishes to proceed. It's important to know that *BRCA* mutations are rare, and only a small fraction of women who have a family history of breast cancer should be referred for genetic counseling and testing.

Other medical groups offer guidelines that include women with cancer. For example, the National Comprehensive Cancer Network (NCCN) guidelines advise referring women 60 and under who have triple-negative breast cancer for genetic counseling and testing.

If you are considering genetic testing, it's strongly recommended that you talk first to a genetic counselor, nurse, or doctor qualified to explain and interpret the results of these tests. It's very important to understand what genetic testing can and can't tell you, and to

carefully weigh the benefits and risks of testing before these tests are done. You also need to know that testing is expensive and may not be covered by some health insurance plans.

Most large cancer centers employ a genetic counselor who can assess your risk of carrying a mutated *BRCA* gene, explain the risks and benefits of testing, and check with your insurance company to see if they will cover the test.

For more information, see [Genetic Testing: What You Need to Know](#). You might also want to visit the [National Cancer Institute website](#).

## **Breast cancer chemoprevention**

Chemoprevention is the use of drugs to reduce the risk of cancer.

The drugs tamoxifen and raloxifene can be used to help lower breast cancer risk in certain women. These drugs block the action of estrogen in breast tissue. Raloxifene is only used in women who have gone through menopause, while tamoxifen can be used in women even if they haven't gone through menopause. Experts recommend that these drugs only be used to lower breast cancer risk in women who are known to be at increased risk of the disease. These drugs can also have some side effects, so it's important to understand the possible benefits and risks of taking one of the drugs.

Other drugs are being studied to see if they can lower the risk of breast cancer.

For more information on the possible benefits and risks of chemopreventive drugs, see

### *Medicines to Reduce Breast Cancer Risk.*

#### **Preventive surgery for women with very high breast cancer risk**

For the few women who have a very high risk for breast cancer, surgery to remove the breasts or ovaries may be an option.

**Preventive (prophylactic) mastectomies:** Removing both breasts before cancer is diagnosed can greatly reduce the risk of breast cancer (by up to 97%). Some women diagnosed with cancer in one breast choose to have the other, healthy breast removed as well to help prevent a second breast cancer. Breast removal does not completely prevent breast cancer because even a very careful surgeon will leave behind at least some breast cells, which might go on to become cancer.

Some of the reasons for considering this type of surgery may include:

- Mutated *BRCA* genes found by genetic testing
- Strong family history (such as breast cancer in several close relatives)  Lobular carcinoma in situ (LCIS) seen on biopsy
  
- Previous cancer in one breast (especially in someone with a strong family history)

This type of surgery has been shown to be helpful in studies of large groups of women with certain conditions, but there's no way to know ahead of time if this surgery will benefit any one woman. Some women with *BRCA* mutations will develop breast cancer early in life, and have a very high risk of getting a second breast cancer. A prophylactic mastectomy before the cancer occurs might add many years to their lives. But while most women with *BRCA* mutations develop breast cancer, some don't. These women would not benefit from the surgery, but they would still have to deal with its aftereffects. Second opinions are strongly recommended before any woman decides to have this surgery.

**Prophylactic oophorectomy (removal of the ovaries):** Women with a *BRCA* mutation may reduce their risk of breast cancer by 50% or more by having their ovaries surgically removed before menopause. This is likely because the ovaries are the main sources of estrogen in the body.

It's important that women with a *BRCA* mutation recognize they also have a high risk of developing [ovarian cancer](#). Most doctors recommend that women with *BRCA* mutations have their ovaries surgically removed once they finish having children to lower this risk.

## **Signs and symptoms of breast cancer**

Widespread use of screening mammograms has increased the number of breast cancers found before they cause any symptoms. Still some breast cancers are not found by mammograms, either because the test was not done or because even under ideal conditions mammograms do not find every breast cancer.

### **Breast lump or mass**

The most common symptom of breast cancer is a new lump or mass. A mass that's painless, hard, and has irregular edges is more likely to be cancer, but breast cancers can be tender, soft, or rounded. They can even be painful. For this reason, it's important to have any new breast mass, lump, or change checked by a health care provider experienced in diagnosing breast diseases.

### **Other symptoms**

Other possible symptoms of breast cancer include:

- Swelling of all or part of a breast (even if no distinct lump is felt)  Skin irritation or dimpling
- Breast or nipple pain
  
- Nipple retraction (turning inward)
- Redness, scaliness, or thickening of the nipple or breast skin  A nipple discharge other than breast milk

Sometimes breast cancer can spread to lymph nodes under the arm or around the collar bone and cause a lump or swelling there, even before the original tumor in the breast tissue is large enough to be felt.

Although any of these symptoms can be caused by things other than breast cancer, if you have them, see your health care provider so that he or she can find the cause.

## **American Cancer Society recommendations for early breast cancer detection in women without breast symptoms**

### **The importance of finding breast cancer early**

The goal of screening tests for breast cancer is to find it before it causes symptoms (like a lump that can be felt). *Screening* refers to tests and exams used to find a disease in people who don't have any symptoms. *Early detection* means finding and diagnosing a disease earlier than might have happened if you'd waited for symptoms to start.

Breast cancers found during screening exams are more likely to be smaller and still confined to the breast. The size of a breast cancer and how far it has spread are some of the most important factors in predicting the *prognosis* (outlook) of a woman with this disease.

Most doctors feel that early detection tests for breast cancer help save thousands of lives each year, and that many more lives could be saved if even more women and their health care providers took advantage of these tests. Following the American Cancer Society's guidelines for the early detection of breast cancer improves the chances that breast cancer can be found early and treated successfully.

## For women at average risk

**These guidelines are for women at average risk for breast cancer.** Women with a personal history of breast cancer, a family history of breast cancer, a genetic mutation known to increase risk of breast cancer (such as BRCA), and women who had radiation therapy to the chest before the age of 30 are at higher risk for breast cancer, not average-risk. (See below for guidelines for women at higher than average risk.)

**Women ages 40 to 44** should have the choice to start annual breast cancer screening with mammograms if they wish to do so. The risks of screening as well as the potential benefits should be considered.

**Women age 45 to 54** should get mammograms every year.

**Women age 55 and older** should switch to mammograms every 2 years, or have the choice to continue yearly screening.

Screening should continue as long as a woman is in good health and is expected to live 10 more years or longer.

**All women** should be familiar with the known benefits, limitations, and potential harms associated with breast cancer screening. They should also be familiar with how their breasts normally look and feel and report any changes to a health care provider right away.

## Mammograms

Regular mammograms can often help find breast cancer at an early stage, when treatment is most likely to be successful. A mammogram can find breast changes that could be cancer years before physical symptoms develop. Results from many decades of research clearly show that women who have regular mammograms are more likely to have breast cancer found early, less likely to need aggressive treatment (like surgery to remove the entire breast [mastectomy] and chemotherapy), and more likely to be cured.

Mammograms are not perfect. They miss some cancers. And sometimes more tests will be needed to find out if something found on a mammogram is or is not cancer. There's also a small possibility of being diagnosed with a cancer that never would have caused any problems had it not been found during screening. It's important that women getting mammograms know what to expect and understand the benefits and limitations of screening.

## Clinical breast exam and breast self-exam

Research does not show a clear benefit of physical breast exams done by either a health professional or by yourself for breast cancer screening. Due to this lack of evidence, regular clinical breast exam and breast self-exam are not recommended. Still, all women should be

familiar with how their breasts normally look and feel and report any changes to a health care provider right away.

## For women at higher than average risk

**Women who are at high risk for breast cancer based on certain factors** should get an MRI and a mammogram every year. This includes women who:

- Have a lifetime risk of breast cancer of about 20% to 25% or greater, according to risk assessment tools that are based mainly on family history (such as the Claus model – see below)
- Have a known *BRCA1* or *BRCA2* gene mutation
- Have a first-degree relative (parent, brother, sister, or child) with a *BRCA1* or *BRCA2* gene mutation, and have not had genetic testing themselves
- Had radiation therapy to the chest when they were between the ages of 10 and 30 years
- Have Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome, or have first-degree relatives with one of these syndromes

**The American Cancer Society recommends against MRI screening for women whose lifetime risk of breast cancer is less than 15%.**

**There's not enough evidence to make a recommendation for or against yearly MRI screening for women who have a moderately increased risk of breast cancer (a lifetime risk of 15% to 20% according to risk assessment tools that are based mainly on family history) or who may be at increased risk of breast cancer based on certain factors, such as:**

- Having a personal history of breast cancer, ductal carcinoma in situ (DCIS), lobular carcinoma in situ (LCIS), atypical ductal hyperplasia (ADH), or atypical lobular hyperplasia (ALH)
- Having dense breasts (“extremely” or “heterogeneously” dense) as seen on a mammogram

If MRI is used, it should be in addition to, not instead of, a screening mammogram. This is because although an MRI is a more sensitive test (it's more likely to detect cancer than a mammogram), it may still miss some cancers that a mammogram would detect.

For most women at high risk, screening with MRI and mammograms should begin at age 30 years and continue for as long as a woman is in good health. But because the evidence is limited about the best age at which to start screening, this decision should be based on shared decision-making between patients and their health care providers, taking into account personal circumstances and preferences.

## Tools used to assess breast cancer risk

Several risk assessment tools, with names such as the Gail model, the Claus model, and the Tyrer-Cuzick model, are available to help health professionals estimate a woman's breast cancer risk. These tools give approximate, rather than precise, estimates of breast cancer risk based on different combinations of risk factors and different data sets.

Because the different tools use different factors to estimate risk, they may give different risk estimates for the same woman. For example, the Gail model bases its risk estimates on certain personal risk factors, like current age, age at first menstrual period and history of prior breast biopsies, along with any history of breast cancer in first-degree relatives. In contrast, the Claus model estimates risk based only on family history of breast cancer in both first and second-degree relatives. These 2 models could easily give different estimates for the same person.

Risk assessment tools (like the Gail model, for example) that are not based mainly on family history are not appropriate to use with the ACS guidelines to decide if a woman should have MRI screening. The use of any of the risk assessment tools and its results should be discussed by a woman with her health care provider.

### **More on MRI as a screening test**

It's recommended that women who get a screening MRI do so at a facility that can do an MRI-guided breast biopsy at the same time if needed. Otherwise, the woman will have to have a second MRI done at another facility when she has the biopsy.

There's no evidence right now that MRI is an effective screening tool for women at average risk. While MRI is more sensitive than mammograms, it also has a higher false-positive rate. (This means it's more likely to find something that turns out not to be cancer.) This would lead to unneeded biopsies and other tests in many of the women screened, which can lead to a lot of worry and anxiety.

The American Cancer Society believes the use of mammograms and MRI (in women at high risk), according to the recommendations outlined above, offers women the best chance to reduce their risk of dying from breast cancer. This approach is clearly better than any one exam or test alone.

See *Mammograms and Other Breast Imaging Tests* for more details on mammograms, breast MRI, breast ultrasound, and other tests that might be used to diagnose breast cancer or find it early.

## **Paying for breast cancer screening**

In the United States, certain laws require most private health plans, Medicaid, and Medicare to cover early detection services for breast cancer screening.

## Laws requiring coverage for breast cancer screening

### Federal law

Coverage of mammograms for breast cancer screening is mandated by the Affordable Care Act, which provides that these be given without a co-pay or deductible in plans that started after August 1, 2012. This doesn't apply to health plans that were in place before the law was passed (called *grandfathered* plans). You can find out the date your insurance plan started by contacting your health insurance plan administrator. Even grandfathered plans may still have coverage requirements based on state laws, which vary, and other federal laws.

### State laws

Many states require that private insurance companies, Medicaid, and public employee health plans provide coverage and reimbursement for specific health services and procedures. The American Cancer Society (ACS) supports these kinds of patient protections, particularly when it comes to evidence-based cancer prevention, early detection, and treatment services.

The only state without a law ensuring that private health plans cover or offer coverage for screening mammograms is Utah. Laws on coverage vary slightly from state to state, so check with your insurer to see what's covered.

**Note:** State laws don't affect self-insured (self-funded) health plans.

## Insurance coverage for breast cancer screening

### Self-insured (self-funded) plans

Many employers offer self-insured (self-funded) plans. These plans pay employee health care costs from the employer's own funds, even though they usually contract with another company to track and pay claims.

Self-insured or self-funded plans do not have to follow state laws about breast cancer screening. Instead, they are governed by the Affordable Care Act (ACA), and are required to cover breast cancer screening. The exception is any self-insured plan that was in effect before the ACA was passed. These plans are called *grandfathered*, and they don't have to provide coverage based on what the ACA says.

You can find out if your health plan is self-insured by contacting your insurance administrator at work or reading your Summary of Plan Benefits. Women covered by self-insured employer plans should check to find out what breast cancer early detection services are covered.

### Medicare

As a part of the Affordable Care Act, Medicare covers the full cost of a screening mammogram once every 12 months for all women with Medicare aged 40 and over. Diagnostic mammograms are covered with a 20% co-pay after the part B deductible is met.

## **Medicaid**

All state Medicaid programs plus the District of Columbia cover screening mammograms. This coverage may or may not conform to American Cancer Society guidelines. State Medicaid offices should be able to give you details about screening coverage in your state.

## **National Breast and Cervical Cancer Early Detection Program**

States are making breast cancer screening more available to medically underserved women through the Centers for Disease Control and Prevention's (CDC's) National Breast and Cervical Cancer Early Detection Program (NBCCEDP). The NBCCEDP attempts to reach as many women in medically underserved communities as possible, including older women, women without health insurance, and women who are members of racial and ethnic minorities. Age and income requirements vary by state.

The program provides both screening and diagnostic services to low-income, uninsured, and underserved women for free or at very low cost, including:

- Mammograms
- Diagnostic testing for women whose screening results are abnormal
- Surgical consultations
- Referrals to treatment

Each state's Department of Health will have information on how to contact the nearest NBCCEDP screening and early detection program in your area. To learn more, contact the CDC at 1-800-CDC-INFO (1-800-232-4636) or online at [www.cdc.gov/cancer/nbccedp](http://www.cdc.gov/cancer/nbccedp).

We have a lot more information you might find helpful. You can read more online or call one of our cancer information specialists at 1-800-227-2345 any time, day or night.

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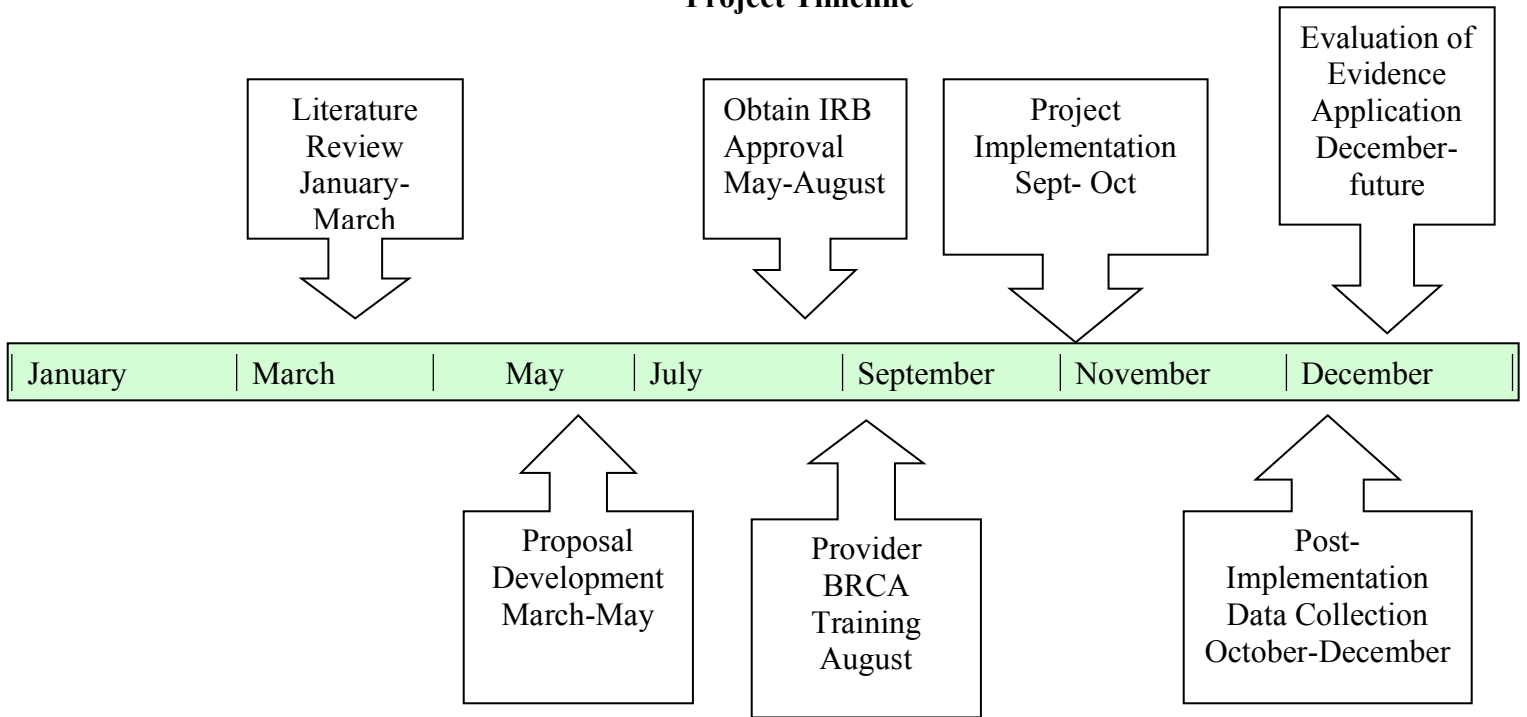
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**Last Medical Review: 10/9/2015 Last Revised: 10/20/2015**

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Appendix I

**Project Timeline**



Appendix J

Logic Model for DNP Project

Rev. 7/09, 1/2015...  
[http://www.umkc.edu/ces/umcourse/interface/coop\\_M1\\_Overview.htm](http://www.umkc.edu/ces/umcourse/interface/coop_M1_Overview.htm)  
 Logic-Model Worksheet content revisions by Lyla Lindholm for DNP Project. Not to be placed on web for public use. Esp. UMKC DNP coursework only.

Logic Model for DNP Project

**Student:** Jentry Wheaton, RN, BSN

**PICOTS:** In providers that perform annual exams (P), does an educational program and implementation of a family history screening

questionnaire in women with a family history of breast, ovarian, tubal and peritoneal (I) compared to usual care (C) increase referral for BRCA

testing (O) during 3 months (T) In a Primary Care practice (S)?

	Intervention(s) <i>Activities</i>	Outputs <i>Participation</i>	Outcomes -- Impact		
			Short <i>(Completed as student)</i>	Medium <i>(after student DNP)</i>	Long <i>(after student DNP)</i>
<b>Evidence, sub-topics</b> 1.Provider education 2.Rationale for 3.Screening USPSTF Guidelines  <b>Major Facilitators or Contributors</b> Primary Care Providers who are utilizing screening tools to assess patients for a potential BRCA mutation  <b>Major Barriers or Challenges</b> Those providers who are not screening patients appropriately	<b>EBP Intervention which is supported by the evidence in the Input column</b> Implementation of educational session with PC providers in order to ensure they are knowledgeable about the importance of BRCA screening in the PC setting.  <b>Major steps of the intervention</b> <ol style="list-style-type: none"> <li>1. Discovery</li> <li>2. Evidence summary</li> <li>3. Translation to guidelines</li> <li>4. Practice integration</li> <li>5. Process, outcome evaluation</li> </ol>	<b>The participants (subjects)</b> Primary Care Providers  <b>Site</b> Family Practice Associates of Western KS  <b>Time Frame</b> 3 months  <b>Consent Needed or other</b> The above mentioned clinic and providers who work at that clinic  <b>Person(s) collecting data</b> Jentry Wheaton  <b>Others directly involved</b> Dr. Renee Endicott-faculty at UMKC	<b>Outcome(s) to be measured with valid &amp; reliable tool(s)</b>  Primary Care providers who are utilizing an approved screening tool for patients who present with family history of breast, ovarian, tubal and peritoneal cancers.  <b>Statistical analysis to be used</b>  Analysis of data collected	<b>Outcomes to be measured</b>	<b>Outcomes that are potentials</b>

## Appendix K

**Permission for Use of Tool****Debra Ledingham**

To: Jentry Wheaton

RE: DNP BRCA request for use of your material

May 4, 2016 10:01 PM

[Hide Details](#)[All Mail \(Gmail\) - Gmail \(All Mail\)](#)

Hi Jentry,

You are welcome to use any resources that you would like to from my project. After all I spent over 360 hours doing it and am happy to share this with you. I can honestly tell you that I really enjoyed my project and feel passionate about the subject like you. I am sorry to hear that you have personal experience with it. Luckily advances have been made for testing women in the clinical setting. Feel free to contact me if you have any further questions.

Debra Ledingham, DNP, WHNP

[See More from Jentry Wheaton](#)

## Appendix L

**Pre- Post Knowledge**

	Q1	Q2	Q4	Q5	Q7	Q9	Q11	Q12	Q13	Q18	Q19
N	5	5	5	5	5	5	5	5	5	5	5
Exact Sig. (2-tailed)	1.000 <sup>b</sup>	1.000 <sup>b</sup>	1.000 <sup>b</sup>	1.000 <sup>b</sup>	1.000 <sup>b</sup>	1.000 <sup>b</sup>	1.000 <sup>b</sup>	1.000 <sup>b</sup>	1.000 <sup>b</sup>	.500 <sup>b</sup>	.125 <sup>b</sup>

No change pre-post in questions not listed

## Appendix M

Question Abbreviation	Yes Pre	Yes Post	No Pre	No Post	P-Value	No answer, or list answer
Guidelines for referral for genetic counseling/BRCA testing	4	5	1	0	1.000	
Asking patient about personal/family hx of breast/ovarian cancer	5	5	0	0	1.000	
Referral for genetic counseling in last year	2	2	3	3		
BRCA testing in last year	3	3	2	2	1.000	
If yes to previous question, guidelines used?	3	3			1.000	Pre: 2 No answer Post: 2 No answer
If yes, list guidelines						USPSTF, NCCN, ACS- No change pre to post
If yes, were guidelines helpful?	3	3			1.000	Pre: 2 No Answer Post: 2 No Answer
If no to question 7, how to improve?						Pre and Post: 5 No Answer
Barriers to genetic counseling/testing	4	4			1.000	Pre and Post: 1 No Answer
If yes, list barriers						Pre and Post: 2 cost, 2 insurance, 1 no answer
For the below, list clinical scenarios who you would consider for BRCA referral/testing						
Any adult woman with Breast CA	1	2	4	3	1.000	
Adult woman with family hx of Breast CA	1	2	4	3	1.000	
Adult woman with family hx of Ovarian CA	4	5	1	0	1.000	
Family hx of 3 affected close relatives with Breast CA	5	5	0	0		
Adult female with BRCA1 or BRCA2 mutation	5	5	0	0		
Woman with > 2 relatives with Breast CA	5	5	0	0		
Woman with relative with bilateral Breast CA	5	5	0	0		
Woman with family hx of male Breast CA	3	5	2	0	.500	
Racial/ethnic groups at higher risk of BRCA mutation	1	5	4	0	.125	
If yes, list groups						Pre: 1- Ashkenazi Jewish Post: 5 Ashkenazi Jewish

## Appendix N

## Abstract for Dissemination

**Improved BRCA Risk Screening Among Women in Primary Care Following Provider Education**

**Jentry Wheaton, RN, BSN, DNP Student  
University of Missouri-Kansas City  
Kansas City, MO**

**Objective:** The purpose of this project is to determine if a BRCA gene mutation educational session regarding hereditary breast and ovarian cancers, among primary care providers will increase provider's knowledge related to Hereditary Breast and Ovarian Cancer (HBOC) Syndrome.

**Background/Significance:** There are two types of BRCA (BREast CAncer) genes, BRCA 1 and BRCA 2. The BRCA genes work as tumor suppressors, which function by controlling the assembly of macromolecular structures that monitor segregation and duplication of chromosomes. When these genes are malfunctioning, or have a mutation, they are more susceptible to human malignancies, particularly breast and ovarian tumors.

**Design:** The project is a quality improvement project in order to assess provider knowledge before and after educational intervention.

**Methodology:** Providers within the primary care clinic will complete a questionnaire to determine their current level of understanding regarding screening for increased risk of BRCA mutations. Directly following, an educational session will be provided to discuss current screening guidelines from the United States Preventive Services Task Force as well as the American Cancer Society and implications of BRCA gene mutations for female patients. Next, providers will complete the same questionnaire to determine if their knowledge has increased following the educational session.

**Results:** It is expected that providers will better understand the purpose of screening for BRCA mutations in the primary care setting. Data analysis will begin January 2017.

**Implications for Nursing Practice:** The usefulness of this intervention has the potential to improve provider knowledge and awareness about BRCA mutation screening in the primary care setting. If this project is successful, this could lead to a decrease in the diagnosis of advanced stage breast cancer, which leads to decreased health care costs.