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High-Risk Breast Clinic

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Authors' disclosures of conflicts of interest are found at the end of this article.

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Abstract

Individuals who are at a high risk for breast cancer are a unique population. These women and men may be eligible for additional screenings for breast cancer and require education that can help reduce the risk of breast cancer. There are several risk factors, such as smoking and obesity, that can be modifiable to help reduce the risk for developing breast cancer. Currently, there are limited data on the number of high-risk programs that provide additional screening recommendations and education to patients in this population, across the country. The need to create a thorough and inclusive program that includes education for providers and patients, the latest technology in mammography, and other breast screening techniques and routine clinic visits for high-risk breast cancer patients was recognized at a cancer center in southeast Louisiana. The creation of the high-risk breast (HRB) clinic has helped ensure patients are receiving the standard of care, ensure providers are up to date on the latest guidelines, and has improved patient satisfaction across this population. The creation of this clinic has evolved over the past 3 years, including a standardization model for this population, an increase in weight loss referrals prompting interest in a weight loss clinic within the HRB clinic, and multidisciplinary monthly team meetings.

Breast cancer is a leading concern among women due to its high mortality and morbidity rate. One in eight women is diagnosed with breast cancer in their lifetime (ACS, 2024). Research shows screening and early detection of breast cancer leads to effective management and increases overall survival. Management should start from the beginning and include a stringent cancer screening and surveillance program or specialty clinic. There is a population of women that falls into high risk for breast cancer based on their risk scores. Currently, there are between 800 and 1,000 women yearly who have an elevated risk for breast cancer across the New Orleans region who are within the Ochsner Health System. This was calculated using Tyrer-Cuzick (TC) score data from women's mammogram reports in the Ochsner system. At Ochsner, the medical oncology advanced practice providers (APPs) within Ochsner's Gayle and Tom Benson Cancer Center formed a high-risk breast (HRB) clinic with support from breast surgical oncology, radiation (with a focus of breast imaging), and administration.

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An extensive breast cancer information program or clinic can create awareness regarding the risk factors and incidence of breast cancer. In addition, screening programs are essential for early detection to reduce the burden of breast cancer incidence and mortality (Mathur et al., 2020). The purpose of the HRB clinic is to identify individuals who are at high risk for developing a breast cancer in their lifetime, formulate an individualized plan to help lower their risk, and identify those who may benefit from supplemental screening tests. Certain risk factors (modifiable and nonmodifiable) can increase a woman's risk. It should be noted that there is a small population of men with a *BRCA1* or *BRCA2* gene mutation who are also followed within the HRB clinic.

CLINIC FORMATION

To have this clinic be successful, it was necessary to identify the population who is at high risk for breast cancer. There are several risk calculators that can be used to predict an individual's lifetime and 5-year risk of breast cancer (Table 1). There are limitations to each of these risk calculators. In addition, the demographics of the population seen in this clinic are racially diverse. The data center analysis of the US Census Bureau data from 2000 and population estimates from 2023 reported the metro area population as 34% Black, 49% White, 12% Hispanic, and 3% Asian. When a mammogram is performed on a woman within the Ochsner Health system, she receives a questionnaire that consists of information regarding personal and family history. With this information, a radiology technician enters the data into the system. A TC score is calculated by CRA Health and then interfaced over to Epic. Any woman who is identified to have a score equal to or greater than 20% will have a referral placed by the provider who ordered the mammogram, typically the gynecologist (GYN) or primary care physician. This process has created a referral base of patients. Other referrals may be placed by cancer genetics APPs, outside referrals from other physicians, or patient self-referrals.

With administrative help, a visit type was created, and a navigator was hired to work the queue from the referrals placed, both of which help track this patient population. Education was provided, in lecture form, to the medical oncology APPs by a breast medical oncologist and by shadowing the breast surgical APPs who had previously been designated to assist with this patient population. The medical oncology APPs also obtained education and up-to-date guidelines from the National Comprehensive Cancer Network (NCCN). The clinic was formed in October 2020 originally utilizing two medical oncology APPs

Table 1. Breast Cancer Risk Calculators

Gail Model	Claus Model	BRCAPRO Model	Tyrer-Cuzick Model	BOADICEA Model
• Age of the person • Age at menarche • Age at first live birth • Breast biopsies (AH) • Family history (first-degree relative)	• Age of the person • Age at menarche • Age at first live birth • Family history (first-degree relatives and second-degree relatives)	• Age of the person • Family history (first-degree relatives, second-degree relatives, third-degree relatives, age at onset of breast cancer, bilateral breast cancer, ovarian cancer, male breast cancer)	• Age of the person • Body mass index • Age at menarche • Age at first live birth • Age at menopause • Hormone replacement therapy use • Breast biopsies (ADH, LCIS) • Family history (first-degree relatives, second-degree relatives, age at onset of breast cancer, bilateral breast cancer, ovarian cancer)	• Age of the person • Family history (first-degree relatives, second-degree relatives, third-degree relatives, age at onset of breast cancer, bilateral breast cancer, ovarian cancer, male breast cancer)

Note. BOADICEA = breast and ovarian analysis of disease incidence and carrier estimation algorithm; ADH = atypical ductal hyperplasia; LCIS = lobular carcinoma in situ. Information from NCCN (2023).

schedules to support this population. There are now three medical oncology APPs who practice independently and three medical oncology physicians with this visit type on their daily schedules. All providers involved in the clinic also see other types of patients, such as those with breast cancer, history of breast cancer, etc. There is a monthly multidisciplinary meeting with the scheduling team, medical oncology APPs, oncology navigation manager, and breast radiology physician lead where the clinic is routinely discussed, improvement recommendations are given, and new educational material is presented. Improvements and changes to the clinic ensure the patients referred to and established in the clinic receive the highest quality of evidence-based care.

METHODS

Once an individual is scheduled for an HRB clinic visit, they can anticipate an hour-long appointment, which will include a recalculation of the TC score as well as a calculation of a Breast Cancer Risk Assessment Tool (BCRAT or the Gail Model) score, extensive education on nonmodifiable and modifiable risk factors, diet and lifestyle recommendations, screening recommendation, and a chemoprevention discussion. Follow-up typically occurs every 6 months or every year. The first step is to gather a personal history of the patient and detailed family history specifically addressing family members with breast or ovarian cancer (Table 2).

A recalculation score is supported by the clarification of the information provided on the questionnaire at the time of the mammogram. The addition of the BCRAT risk assessment tool is supported by the difference in recommendation of the use of chemoprevention given by the NCCN Guidelines. A TC score is used to determine the screening recommendations (mammogram and MRI), while the BCRAT screening tool is used to determine the consideration of chemoprevention. Once a high-risk score is confirmed by either model, the educational piece of the visit begins for the patient. The provider will educate the individual on the appropriate screening recommendations based on their TC and/or Gail Model scores. All individuals, regardless of their risk factors, should be educated on breast health and breast awareness. The current guidelines do not recommend monthly breast exams but do recommend monthly breast awareness. Breast awareness should include individuals viewing themselves in the mirror and checking for any skin or nipple changes including (but not limited to) nipple discharge and nipple or skin retraction. Additionally, those individuals who are at high risk for breast cancer should also receive two clinical breast exams a year, preferably 6 months apart. The patient is eligible for mammograms and MRIs based on

Table 2. Ochsner Health's Personal and Family History of High-Risk Breast Clinic Patients

Current: age, height, and weight	Cancer genetic testing history
Age of menstruation	Personal history of cancer
Age of menopause (if applicable)	Previous chest wall radiation
Breast density per Breast Imaging-Reporting and Data System A. Almost entirely fatty B. Scattered fibroglandular density C. Heterogeneously dense D. Extremely dense	Personal history of breast biopsy A. Location (right or left) B. Results 1. Benign 2. Atypia 3. Lobular carcinoma in situ
Number of pregnancies Age at first live birth	Ashkenazi Jewish heritage
History of breast feeding (number of months or years)	Family history of cancer A. Breast cancer B. Ovarian cancer
Uterus and ovaries intact A. Uterus removed B. Ovaries removed C. Uterus and ovaries removed	Hormone replacement therapy A. Current and planning to use for how long B. History, what time length used for C. Combination or estrogen alone

their unique personal and family history. For most individuals, mammograms will begin at age 40 and MRIs at age 35; however, for those who have a family history of a woman with a breast cancer under the age of 50, their screenings will begin 10 years prior to when the youngest family member was diagnosed with breast cancer. Again, as with the clinical breast exams, the mammograms and MRIs should be yearly but alternating so the patient receives imaging every 6 months.

There are several nonmodifiable and modifiable risk factors that are discussed throughout an HRB clinic visit. While discussing nonmodifiable risk factors is important, there is no action that can be taken. Therefore, the bulk of lifestyle recommendations is on modifiable risk factors. The main modifiable risk factors include tobacco use, alcohol use, exercise, and obesity.

Smoking has been shown to increase the risk of several cancers, including breast cancer. Smoking was associated with a modest but significantly increased risk of breast cancer, particularly among women who started smoking at adolescent or perimenarcheal ages (Jones et al., 2017). The relative risk of breast cancer associated with smoking was greater for women with a family history of the disease (Jones et al., 2017). Patients are offered a referral to our smoking cessation program.

Alcohol use has also been linked to an increased risk of breast cancer. Moderate alcohol consumption has been linked to an approximate 30% to 50% increased risk of breast cancer. This risk is seen when a woman has 15 g to 30 g per day of alcohol (1–2 drinks per day). Given the prevalence of drinking in women in the US, many could benefit from staying within the drinking guidelines of ≤ 1 drink a day for overall health and consider stopping entirely to reduce the risk of breast cancer (McDonald et al., 2013).

The last two modifiable risk factors are related: elevated body mass index (obesity) and physical inactivity. It has long been recognized that overweight and obesity (and adult weight gain) are associated with an increased risk of postmenopausal breast cancer, notably hormone receptor–positive cancers (Jiralerspong & Goodwin, 2016). Patients are offered a referral to our nutritionist, weight management, or bariatric clinic. Physical inactivity, an attribute linked to obesity, has been associated with a higher risk of breast cancer regardless of menopausal status. Physical activity may offer an acceptable means of reducing breast cancer risk for postmenopausal women who are not at a high enough risk for the benefits to outweigh the adverse effects of chemoprevention options that are currently under investigation, particularly given the broad health benefits associated with regular exercise (Friedenreich et al., 2010). The recommendation for women is to exercise at least 150 minutes (2 and a half hours) at moderate intensity per week or to have at least 75 minutes of vigorous exercise per week. Moderate-intensity activity is usually made up of exercises that get the heart rate up to 50% to 60% higher than its rate when at rest, such as walking 2 miles in 30 minutes. For high-intensity exercise at which the heart is working at 80% to 95% of the maximum heart rate, an example would be a Tabata workout (20 seconds of exercise followed by 10 seconds of rest for a certain number of rounds). Regular exercise, both moderate and vigorous, has been shown to reduce the relative risk for breast cancer by 18% to 20%.

Lastly, breastfeeding has also been shown to reduce the risk of breast cancer by 4.3% for every 12 months of breastfeeding, which is in addition to the 7% decrease in risk observed for each birth (Stordal, 2023). While this may not be modifiable for many of the patients seen in the HRB clinic, it is an important education piece for those who are still of childbearing age and women who have daughters that are of childbearing age and have an increased risk for breast cancer (Table 3).

CHEMOPREVENTION

Individuals are educated on the use of aromatase inhibitors (AIs) and selective estrogen receptors modulators (SERMs) as chemoprevention. For women at high risk for breast cancer on the Gail Model, endocrine therapy can reduce the risk of developing an estrogen receptor (ER)-positive breast cancer (invasive and/or in situ). Current research supports the use of tamoxifen for pre- or postmenopausal women, and the use of raloxifene or exemestane and anastrozole for postmenopausal women. Risk-reduction agents are recommended for individuals > 35 years of age only, as the utility of these agents in those younger than 35

Table 3. Ochsner Health's Nonmodifiable and Modifiable Breast Cancer Risk Factors

Nonmodifiable	Modifiable
Family history	Lifestyle factors • Increased body mass index • Alcohol intake • Smoking • Hormone replacement therapy use
Increasing age	
Ethnicity/race	
Prior estrogen and progesterone hormone	
Reproductive history • Younger age at menarche • Nulliparity/lower parity • Older age at first live birth • Older age at menopause	Elements that reduce risk (not included in risk-evaluating models as reducing risk, but have research supporting risk reduction) • Menopause before 45 years old • Exercise • Breast feeding • Risk-reducing agent
History of lobular carcinoma in situ/atypical hyperplasia (ductal and/or lobular)	
Number of prior breast biopsies	
Breast density	
Prior thoracic radiation therapy < 30 years of age	

years is unknown (NCCN, 2023). Chemoprevention is not indicated in men.

When considering the use of endocrine therapy, a provider must educate the individual on the potential side effects. Most side effects can be the same for AI or SERM therapy. The major side effects noted were hot flashes, vaginal dryness, midabdominal weight gain, and hair thinning. For the reasons above, the provider must know which patients are candidates for which therapies and when the risks of the potential side effects may outweigh the benefit of chemoprevention. Chemoprevention is not indicated for every individual at an increased risk for breast cancer. Women who opt for chemoprevention are followed in clinic at least every 6 months.

Tamoxifen and Raloxifene

The use of tamoxifen in women who have an ER-positive breast cancer has been widely published. The results of the P-1 study showed that treatment with tamoxifen reduced the short-term risk of breast cancer by 49% in healthy individuals aged 35 years or older who had an increased risk of the disease (Fisher et al., 1998). This risk reduction was demonstrated in all age groups, across pre- and postmenopausal patients. An additional benefit noted with tamoxifen was the reduction in bone fractures. However, women who were diagnosed with a breast cancer after the use of preventative tamoxifen did not see improved overall survival after their breast cancer diagnosis. It should also be noted that certain CYP2D6 genotypes are markers of poor tamoxifen metabolisms, and for this reason genomic testing should be considered when using tamoxifen. The Breast Cancer Risk Reduction Panel strongly recommends that tamoxifen is a superior choice of risk-reduction agent for most postmenopausal patients desiring nonsurgical risk-reduction therapy (Vogel, 2009). The use of raloxifene in the high-risk breast population has been studied in postmenopausal women who are over the age of 35 and have a 1.7% or higher Gail Model score or who have a biopsy proven to be lobular carcinoma in situ (LCIS). A crucial factor is that SERM therapy can increase the risk of venous thromboembolism (VTE), so education must be provided to individuals who choose to take a SERM. Individuals with a history of VTE or a family history of VTE may not be candidates for SERM use. Lastly, tamoxifen has been shown to increase the risk of invasive endometrial cancer in postmenopausal women > 49 years of age (2.3/1,000 compared to 0.9/1,000; Emons et al., 2020). It is imperative that women are educated to continue to follow up with a GYN yearly while on tamoxifen.

Exemestane and Anastrozole

The MAP.3 trial and IBIS-II trial have proven the use of exemestane and anastrozole in postmenopausal individuals desiring nonsurgical risk-

reduction therapy (Cuzick et al., 2014). This data is limited to women who are over the age of 35 and postmenopausal with a Gail Model 5-year risk score > 1.66%. Unique to AI therapy is the loss of bone, requiring a dual-energy X-ray absorptiometry (DEXA) scan every other year and possibly requiring the use of bisphosphonate therapy. Aromatase inhibitors can cause or increase the severity of arthralgias in some patients. Exemestane and anastrozole are not approved by the US Food and Drug Administration (FDA) for breast cancer risk reduction, but published studies support the use of AIs. The NCCN Guidelines (2023) also support the use of AIs in this population.

SPECIAL POPULATIONS

Atypical Ductal or Lobular Hyperplasia and Lobular Carcinoma in Situ

Women who are seen in the HRB clinic for a history of a breast biopsy that is positive for atypical ductal hyperplasia (ADH), atypical lobular carcinoma (ALH), or lobular carcinoma in situ (LCIS) are educated on the screening process and the use of endocrine therapy. The lifetime risk for breast cancer for this population is elevated, as ADH, ALH, or LCIS all significantly increase a female's risk for breast cancer. Women who choose to take endocrine therapy with a diagnosis of ADH, ALH, or LCIS can see up to an 86% risk reduction for breast cancer. Therefore, unless contraindicated, endocrine therapy is highly recommended in this population. Overall, risk-reduction therapy with tamoxifen and raloxifene has been vastly underutilized (Bevers, 2015). The benefits of risk-reduction therapy far outweigh the harms for those with atypical hyperplasia (AH; both ductal and lobular types) and LCIS. Despite the current research supporting the use of endocrine therapy or SERMs, a study has documented that only 44% of individuals with AH or LCIS received risk-reduction therapy (Coopey et al., 2012).

BRCA1 and *BRCA2* Gene Mutations

Populations with *BRCA1* and *BRCA2* mutations are unique when it comes to chemoprevention. An evaluation of this subset revealed that breast cancer risk was reduced by 62% in study individuals with a *BRCA2* mutation receiving tamoxifen compared with placebo. However, tamoxifen use was not associated with a reduction in breast cancer risk in patients with a *BRCA1* mutation (King et al., 2021). The provider must educate the individual to make the best decision for themself. It is recommended per the NCCN Guidelines that women with a *BRCA1/2* gene mutation have a surgical consult to discuss bilateral mastectomies for risk reduction. There is no data currently to support the use of raloxifene in the *BRCA1/2* population.

Men With *BRCA1* and *BRCA2* Gene Mutations

Men with *BRCA1/2* gene mutations may be seen in the HRB clinic as well. For men, breast self-exam training and education as well as a clinical breast exam yearly should start at age 35. An annual mammogram can be considered, especially for those with *BRCA2* pathogenic and likely pathogenic variants in whom the lifetime risk of breast cancer is up to 7%, starting at age 50 or 10 years before the earliest known male breast cancer in the family (whichever comes first). There is a lack of screening for men who are at an increased risk for breast cancer, which often causes men to be diagnosed at a more advanced stage. In males, breast cancer risk in *BRCA1* carriers is lower than in *BRCA2* carriers (NCCN, 2023, p. 50).

RECOMMENDATIONS

Plans for the HRB clinic are to expand it to all Ochsner campuses across the Southeast region. Improvements to the workflow are in progress, such as a questionnaire through the electronic medical record (EMR) prior to the individual's arrival in the clinic that contains the information needed to calculate the TC and Gail Models score. Including the TC and Gail Model scores in the EMR is in progress as well. Additional educational information and research from the clinic is linking obesity with individuals at higher risk for breast cancer. This information is currently being reviewed and may prompt a need for APPs at the center to obtain a Certificate of Advanced Education in Obesity Medicine in an effort to treat obesity for women at high risk for breast cancer. Other information to review includes the time from diagnosis of a breast cancer to treatment since the patient is already established within the medical oncology team, number of patients diagnosed with ADH/ALH, LCIS, and even ductal carcinoma in situ and early-stage breast cancer, and the

number of genetic mutations found in those individuals already established with the HRB clinic. Importantly, as the high-risk program grows, the need for other services such as genetics, nutrition, weight management, and surgical referrals will increase within the Ochsner system.

Disclosure

The authors have no conflicts of interest to disclose.

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