A large, diverse crowd of people is arranged in a large 'U' shape on a white background. The people are of various ages, ethnicities, and are wearing colorful clothing. The 'U' shape is open at the bottom, and the text is centered within the curve of the 'U'.

A Pathway for Identifying Women at Increased Risk for Breast Cancer...



...and Providing Personalized Management and Risk Reduction

In the summer of 2014 staff at the Novant Health Derrick L. Davis Cancer Center (NHDLD Cancer Center), Winston-Salem, N.C., developed a screening method aimed at detecting women in our community who are at increased risk for breast cancer. After several months of planning, the six-week pilot launched in November 2014. Following the success of this pilot, over the course of the next year, the NHDLD Cancer Center implemented a Women's Risk Assessment Survey process and Cancer Prevention and Wellness Clinic to first identify women at an increased risk for breast cancer and then address this risk with appropriate interventions.

The Impact of Breast Cancer

Breast cancer is the second leading cause of cancer death in women, exceeded only by lung cancer. In 2015 at the NHDLD Cancer Center, 574 invasive breast cancers were diagnosed, 113 in situ breast cancers were diagnosed, and 211 women died of the disease. The local breast cancer incidence in Forsyth County where our center is located is 166.9/100,000, which is higher than both the state of North Carolina average incidence (157.4/100,000) and the U.S. average incidence (125.0/100,000).¹

Due to the impact of this disease, much research has gone into understanding the risk factors for breast cancer development. Women at the highest risk for breast cancer include those with a personal history of atypia or lobular carcinoma in situ. Other factors that impact breast cancer risk include age, gender, genetics, personal and family history of breast cancer, breast density, race, age at menarche, age at menopause, prior chest radiation,

There are many barriers to assessing a patient's risk for breast cancer, including inadequate documentation of family history, the complexity of risk calculation and model selection, and a lack of awareness of risk on the part of the patients and/or providers.

diethylstilbestrol (DES) exposure, alcohol use, weight, physical activity, birth control use, hormone therapy use, pregnancy history, breast feeding history, and number of past breast biopsies.²

Individual Breast Cancer Risk: An Underutilized Tool

The best first step in managing patients' breast cancer risk is to assess this risk using a model that is largely dependent on family history, as recommended by National Comprehensive Cancer Network (NCCN) guidelines. There are several different recommended models for calculating a patient's breast cancer risk, and results from these risk calculations can help better determine who might be referred for additional management. The models directly mentioned by NCCN include Claus, BOADICEA, BRCAPRO,



Process development team. Front row (L to R): Megan Mortenson, genetic counselor; Betsy Johnson, Cancer Center director; Kate Hughes, genetic counselor. Back row (L to R): Laurie Mathis, nurse navigator; Jamie Flaherty, nurse navigator; Erica Cousins, genetic counselor; Carol Holt, physician's assistant; Kimberly Cannon, Novant Health Breast Center manager.

and Tyrer-Cuzick.³ The Claus and BRCAPRO models take into account only family cancer history information, while models like BOADICEA and Tyrer-Cuzick take family history, as well as personal history data points, into consideration when calculating breast cancer risk.⁴

Once information on breast cancer risk is collected, action must be taken to make patients and providers aware of appropriate healthcare management changes. NCCN recommends that women with a 20 percent or higher lifetime breast cancer risk consider the following options:³

- Breast self-awareness
- Annual mammogram and clinical breast exams every 6 to 12 months beginning at age 30
- Annual breast MRI beginning at age 30
- Consideration of risk-reduction strategies, including agents such as tamoxifen, raloxifene, or an aromatase inhibitor.

Hereditary Breast Cancer Risk: An Overlooked Component

In addition to general breast cancer risk, another aspect of risk assessment to consider is the chance of a hereditary breast cancer predisposition, with hereditary breast and ovarian cancer syndrome (HBOC) caused by the BRCA1 and BRCA2 genes being the most widely-known example. Previous studies have shown that 6.2 percent of women in a screening mammography popu-

lation were at “high risk” of HBOC Syndrome and would be candidates for genetic testing.⁵ However, eligibility for genetic testing is often overlooked in healthcare settings. One study showed that of 8.9 percent of individuals eligible for genetic testing for HBOC Syndrome, less than 2 percent had undergone genetic testing.⁶

Development of Our Pilot Program

There are many barriers to assessing a patient’s risk for breast cancer, including inadequate documentation of family history, the complexity of risk calculation and model selection, and a lack of awareness of risk on the part of the patients and/or providers. Staff at the NHDLD Cancer Center believed that our patient population was being under-assessed for breast cancer risk and genetic testing eligibility, and we felt it was an opportune time to identify these women and offer appropriate interventions. In the summer of 2014 we began to develop a program that would allow us to assess risk for all women who come through the Novant Health Breast Center to determine the potential patient volumes the program would create. If this process was feasible, we would then develop a pathway to appropriately navigate these patients to a healthcare team at the NHDLD Cancer Center that would provide a comprehensive approach to breast cancer risk management.

The first step was to identify the breast cancer risk calculation

model that would best fit our needs. After research, internal discussion, and discussion with colleagues at other cancer centers, it was decided that the Tyrer-Cuzick (version 7) model was the best fit. While there are a few data points that cannot be collected with this tool, overall we felt it provided the most comprehensive model to gather information that includes both the patient's personal and family breast and/or ovarian cancer history and crucial personal breast cancer risk factors.

Next, we used the Tyrer-Cuzick model to develop a questionnaire that would be distributed to all patients being seen at the Novant Health Breast Center. This questionnaire, titled the Women's Risk Assessment Survey, addresses all of the data points necessary to calculate lifetime breast cancer risk using the Tyrer-Cuzick model. In the six-week pilot program, a mammogram technologist calculated breast cancer risk and generated a paper printout. Mammography technologists then sorted patients by those with a lifetime risk of 20 percent or higher and those who were under the 20 percent threshold, placing their paper printouts into collection bins. One of our breast cancer nurse navigators collected the risk printouts, reviewing the forms of those patients who have a lifetime risk of 20 percent or higher, as well as patients with a prior breast cancer diagnosis. Specifically, breast cancer survivors were reviewed to determine if they were eligible for genetic testing based on their prior diagnosis and/or family history.

Of the 668 patients assessed in the pilot, 120 (18 percent) required additional work to determine if follow-up was needed. This work included tasks such as recalculation after survey answers were clarified and investigation to determine if prior genetic testing had been completed. The results:

- 19 breast cancer survivors were eligible for genetic testing
- 40 patients (6 percent) qualified for MRI
- 37 patients (5.5 percent) qualified for genetic counseling.

When these percentages were projected onto the total annual number of women screened at the Novant Health Breast Center, our staff agreed that the pilot should be developed into a clinic program to make a meaningful positive impact on identifying women with an increased breast cancer risk in our communities.

Novant Health Breast Center: Current Process

From January 2015 through October 2015, our team developed the pilot into a streamlined breast cancer risk assessment program located at the Novant Health Breast Center. The program aligns seamlessly with the newly-created Novant Health Cancer Prevention and Wellness Clinic, located at the NHDLD Cancer Center and designed to manage women with increased breast cancer risk. The team who developed this process included management from both the Novant Health Breast Center and the NHDLD Cancer Center, breast cancer nurse navigators, and genetic counselors. In brief, here's how the process works.

It begins when patients check in to their appointment at the Novant Health Breast Center or its mobile mammography unit. Patients are handed a Women's Risk Assessment Survey to com-

plete in addition to their routine visit paperwork, which is collected by staff at the front desk for risk calculation. From the pilot, we recognized that the mammography technologists would be unable to calculate breast cancer risk while also keeping the mammogram schedule running on time, so the decision was made to hire and train several FTE data specialists to complete the Tyrer-Cuzick risk calculation. If any items completed on the survey are unclear or confusing, data specialists call the patients for clarification. One item on the survey is history of breast biopsies and the results of these biopsies, so data specialists have access to the electronic health record (EHR) to look up past breast biopsy results if necessary. We quickly learned that access to pathology reports was vital to calculating accurate lifetime breast cancer risk, as misinformation about biopsy findings can result in over- or under-calculation. The scenario we saw most often was miscalculation when selecting between the options of "no benign disease" and "unknown benign disease" in the Tyrer-Cuzick model.

Data specialists pull the surveys and risk calculations for all women with a ≥ 20 percent lifetime risk, and these patients are initially stratified according to mammography Breast Imaging Reporting and Data System (BI-RADS) code. High-risk patients with a BI-RADS code of 0, 4, or 5 are held and not contacted by staff until resolved as more imaging (0) or biopsy (4 and 5) are indicated. Should a cancer or other high-risk lesion be detected, patients will be followed at the NHDLD Cancer Center appropriately. The remaining patient charts are provided to a designated breast oncology nurse navigator located at the NHDLD Cancer Center.

One goal of our process was to identify women who are eligible for genetic testing, as these patients are often under-referred by their healthcare providers. For patients who have a lifetime risk lower than 20 percent and, therefore, are not eligible for the Novant Health Cancer Prevention and Wellness Clinic, data specialists flag the charts of those who may be eligible for hereditary cancer genetic testing based on family history alone. These patients include women reporting a family history of ovarian cancer, male breast cancer, known hereditary cancer mutations, or breast cancer in the setting of Ashkenazi Jewish ancestry. For these patients, a "Frequently Asked Questions" fact sheet is documented in the EHR and mailed directly to patients. This FAQ sheet provides basic information about hereditary cancer genetics and genetic counseling, including a direct phone number to call for additional information and appointment scheduling. These patients are seen in the Cancer Genetics Clinic at the NHDLD Cancer Center.

Data specialists pull all patients who indicated that they have a personal history of breast or ovarian cancers, and pass these charts to the genetic counseling team for review. Eligible patients are contacted directly, and offered appointments in the genetics clinic if they are interested. For patients who cannot be reached after two phone call attempts over a two-week period, genetic counselors mail a letter to the patient recommending further conversation about the personal and family history of breast and ovarian cancer with contact information, documenting the letter in the EHR.



Carol Holt, PA-C, provides breast health education to a patient at the Novant Health Cancer Prevention and Wellness Clinic.

NHDLD Cancer Center: Current Process

Once staff from the Novant Health Breast Center provides the charts for women with an increased risk of breast cancer to the designated breast oncology nurse navigator, the process of reviewing charts and contacting patients begins. The breast navigator calls every patient who meets the 20 percent risk threshold; the genetic counseling team helps contact patients when needed. This conversation is documented in the EHR and includes:

- Discussion of the patient's calculated breast cancer risk
- Factors contributing to this risk
- Family history
- NCCN recommendations for women at an increased risk for breast cancer.

For patients who cannot be reached after two phone call attempts over a two-week period, the nurse navigator mails a letter to patients that informs them that we have calculated their lifetime breast cancer risk and to call the breast navigator to discuss this information. The letter is documented in the EHR. If patients are interested in a conversation about their breast risk and management options, the breast navigator schedules them for a clinic visit in the newly-created Novant Health Cancer Prevention and Wellness Clinic. Two types of appointments are available to patients, depending on patient family cancer history. The first visit type is for patients who have a family history that indicates a conversation about genetic testing is appropriate, and these patients also see a member of the genetic counseling team during their visit. The second visit type is for patients for whom genetic testing is not indicated, and these patients are not seen by genetic counseling staff during their visit.

Cancer Prevention and Wellness Clinic Visit

Our initial vision did not merely include the identification of women with increased breast cancer risk; it also included the development of a clinic that these women could call home for risk management. Accordingly, the Novant Health Cancer Prevention and Wellness Clinic was created to manage women identified as having an increased breast cancer risk at the Novant Health Breast Center and also for women with an increased breast cancer risk due to a genetic predisposition who are identified in the Novant Health Cancer Genetics Clinic.

The Novant Health Cancer Prevention and Wellness Clinic operates three days a week, and is housed inside the NHDLD Cancer Center. Patients meet first with an oncology physician's assistant (PA); a medical oncologist provides oversight for this PA. The PA has a thorough discussion of the patient's risk and contributing factors, as well as a discussion of management options, such as mammography, breast MRI, and/or chemoprevention. Patients also receive education about healthy lifestyle modifications that may help lower their breast cancer risk, such as diet, exercise, and smoking cessation. Handouts are provided to the patient summarizing these lifestyle recommendations as well.

When appropriate, patients are also seen by a member of the genetic counseling team. A certified genetic counselor collects a three-generation pedigree, discusses hereditary cancer genetic testing in detail, and coordinates testing if indicated. Together, the patient, PA, and genetic counselor formulate a care plan that includes a breast screening protocol, genetic testing selection, and lifestyle changes. We sometimes use a risk assessment tool (the Gail model) to help in the patient decision-making process on whether to use chemo prevention. If patients elect to use medication, the prescription is generated by the PA and follow-up monitoring for side effects and toleration is included in their care. Patients are also offered access to a registered dietitian, oncology family and marriage therapist, and/or oncology chaplain if indicated.

Patients are then followed in the Novant Health Cancer Prevention and Wellness Clinic every 6 to 12 months or more frequently if needed, and their breast screening is managed by clinic staff. For patients who pursue genetic testing, their genetic counselor contacts them by phone with their results. The breast screening protocol is adjusted as needed based on genetic results, and referrals to additional healthcare providers are arranged as well. Throughout the process, the patient's primary care and gynecologic care providers are sent copies of clinic notes so that they are informed of the assessments and care plan. The Novant Health Cancer Prevention and Wellness Clinic employs administrative staff that assists with appointment scheduling and pre-certification for breast MRI and other insurance needs.

Outcome Data

Our screening process was formally initiated on October 19, 2015, and we have included outcome data through August 31, 2016 (Table 1, right). Of all women screened using the Women's Risk Assessment at the Novant Health Breast Center, 1,120 have been contacted to discuss a breast cancer risk ≥ 20 percent. Approximately 426 women have been scheduled to be seen in the Novant

Health Cancer Prevention and Wellness Clinic, and of those women 333 have attended their visit, resulting in a no-show rate of 21.8 percent. A high no-show rate is one challenge that we face with the clinic, which is not a surprise as we are dealing with a healthy population in a preventive setting. One hundred and four MRIs have been ordered for patients, and roughly 50 MRIs have been completed to date. This number is lower than the number ordered at the current time as patients began having MRIs in April/May of 2016 due to most MRIs being ordered for six months after the patient's mammogram. Five biopsies have been completed based on findings on screenings ordered in the Novant Health Cancer Prevention and Wellness Clinic, and one breast cancer was identified on a screening breast MRI, but was undetected on 3D mammography weeks earlier. We have also identified one patient with an area of hyperplasia, and one patient with a papilloma.

Of the women seen in the clinic, 119 have undergone genetic testing due to family history of breast and/or ovarian cancer. Of these women, five (4.2 percent) had positive genetic test results and three of the five positive results had mutations that warranted

breast health medical management changes. Two of these women were found to have mutations in their CHEK2 genes, with medical management recommendation changes including annual breast MRI alternating with mammography and initiating more frequent colonoscopies at a younger age. One BRCA1 mutation carrier was identified, and this patient has already completed her recommended MRI and is currently contemplating her ovarian cancer risk reduction options.

We have also collected data on women who were seen in the Cancer Genetics Clinic based on personal or family history information gathered using the Women's Risk Assessment. Sixty-eight patients have been seen in the Cancer Genetics Clinic: 53 breast cancer survivors, 2 ovarian cancer survivors, and 13 with a suspicious family history. Three of these women had positive genetic test results, with two of the breast cancer survivors and one of the ovarian cancer survivors testing positive. One CHEK2 mutation carrier was identified; she was diagnosed with a second breast cancer from the mammogram where her survey was completed and flagged. One BRCA2 mutation carrier was identified and she is currently in the process of scheduling bilateral mastec-

Table 1. Outcome Data October 19, 2015 to August 31, 2016

WOMEN WITH ≥20% LIFETIME BREAST CANCER RISK	
Total number seen at the Cancer Genetics Clinic	1,120
Scheduled for the Novant Health Cancer Prevention and Wellness Clinic	426
Seen in the Novant Health Cancer Prevention and Wellness Clinic	333
MRIs	50
Biopsies	5
Breast cancers found	1
Underwent genetic testing	119
Positive genetic test	5
WOMEN LESS THAN A 20% RISK BUT ELIGIBLE FOR GENETIC TESTING	
Total Number	68
Breast cancer survivors	53
Breast cancer survivors (positive)	2
Ovarian cancer survivors	2
Ovarian cancer survivors (positive)	1
Suspicious family history	13
Suspicious family history (positive)	0

OUR PROGRAM AT-A-GLANCE

Accredited by both the American College of Surgeons Commission on Cancer and the National Accreditation Program for Breast Centers (NAPBC), the Novant Health Derrick L. Davis Cancer Center is a community cancer center in Winston-Salem, N.C., with a primary service area of 800,575 people across 7 counties. It houses 13 medical oncologists, 15 medical oncology mid-level providers, 5 gynecologic oncologists, 4 gynecologic oncology mid-level providers, and 5 radiation oncologists. The cancer center also has a support staff of 18 individuals, including site-specific cancer navigators, genetic counselors, tumor board staff, an oncology dietitian, a chaplain, a resource specialist, and a family and marriage therapist. The NHDLD Cancer Center works closely with the Novant Health Breast Center, which manages all aspects of breast screening and

imaging in our market. The Novant Health Breast Center is NAPBC-accredited and an American College of Radiology (ACR) Breast Imaging Center of Excellence that has a primary service area of roughly 1.9 million people across 16 counties, providing breast imaging services including:

- Screening and diagnostic mammography
- Breast tomosynthesis (3D mammography)
- Mobile screening mammography
- Breast ultrasound
- Special procedures (breast biopsies and aspirations).

If indicated based on findings at the Novant Health Breast Center, patients are referred to other Novant Health facilities for breast MRI or abbreviated breast MRI.

tomies followed by bilateral salpingo-oophorectomies to reduce her cancer risks. One BRCA1 mutation carrier was identified as well. The identification of these patients highlights the importance of appropriately offering testing to those who are eligible to hopefully avoid second cancer diagnoses when possible.

Pathway Benefits

The pathway that we have created has the potential to greatly benefit the women in our community (see Figures 1-4, pages 45-47). It allows us to identify patients at an increased risk for breast cancer and join with these women to develop customized screening and management plans. We also empower our patients to take personal control through education about risk factors and management of these risks. Using these risk-reducing interventions we hope to impact not only individual patients but the community as a whole with an eventual reduction in breast cancer diagnoses. It is important to note that for patients who are identified as having a genetic predisposition to breast and/or other cancers, the benefit reaches beyond the individual to their extended family members. We are able to offer genetic testing for the familial mutation to at-risk relatives to identify who in the family is also at an increased risk and provide tailored risk management plans.

Our pathway also has many benefits to the NHDLD Cancer Center. It increases the confidence that patients and providers in our community have in the cancer center, which has the potential to attract patients and increase provider referrals. Since the development of the pathway and the Novant Health Cancer Prevention and Wellness Clinic, we have already seen an increase in referrals from local providers—both within the Novant Health network and outside our network. The pathway allows for continuity of care and a fluid transition of care to our surgical oncology, medical oncology, and radiation oncology teams in the event that a breast

cancer is diagnosed in one of the high-risk women followed in the Novant Health Cancer Prevention and Wellness Clinic. We are also able to increase revenue in our system through Novant Health Cancer Prevention and Wellness Clinic visits, MRIs, and surgical interventions if needed by patients found to have hereditary cancer predispositions (for example, risk reducing bilateral mastectomies in a woman with a BRCA1/2 mutation).

Future Directions

Now that we have established this pathway and determined that it is successful, we are excited to grow the program in new directions. Our current paper process requires several staff members and many man-hours to manually enter the risk calculations into the Tyrer-Cuzick model, and we have investigated ways to streamline this process. One consideration would be investing in a tablet-based risk assessment program that would allow patients to enter their personal and family history information and would automatically calculate their breast cancer risk, thereby eliminating the manual calculation process. We soon plan to branch out and begin calculating breast cancer risk at other breast imaging centers in the Novant Health system. In order to determine the true impact of this pathway and our new Novant Health Cancer Prevention and Wellness Clinic on cancer incidence and outcomes, we will continue to track and analyze our long-term data. This reporting will include an assessment of impact on our local breast cancer incidence, as well as an analysis to determine if breast cancers diagnosed through this pathway are detected at earlier stages than average. We also hope to open our Novant Health Cancer Prevention and Wellness Clinic to other cancer disease sites in the future, such as for CT lung screening or management of individuals with increased risk for other cancers.

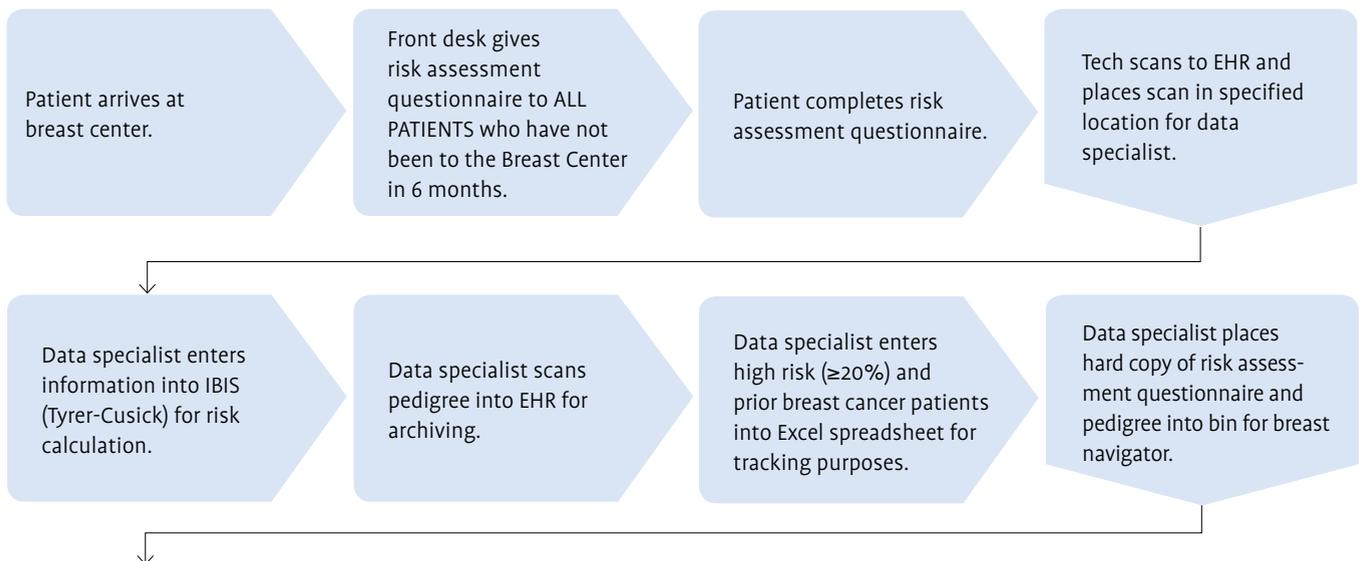
We have created a service that has the potential to identify patients at increased risk for breast cancer before diagnosis is made. Through early detection of risk we are aligning our breast care services with current population health initiatives and are hoping to reduce the incidence of breast cancer morbidity and mortality in our community. We are accomplishing this through detection of—and intervention with—women at an increased risk for breast cancer through the development of customized screening and management plans. In our Novant Health Cancer Prevention and Wellness Clinic, we aim to empower women by giving them the information needed to reduce their breast cancer risk through lifestyle education and modification. Bottom line: this pathway promotes awareness of risk levels, helps our patients take appropriate action for their breast health, attracts patients to our system, and increases revenue. 

S. Kate Hughes, MS, CGC, is a genetic counselor at the Novant Health Derrick L. Davis Cancer, part of Novant Health Forsyth Medical Center, Winston-Salem, N.C.

References

1. National Cancer Institute Surveillance, Epidemiology, and End Results Program (2016). SEER Stat Fact Sheets: Female Breast Cancer. Available online at: seer.cancer.gov/statfacts/html/breast.html. Last accessed Jan. 20, 2017.
2. American Cancer Society. What are the Risk Factors for Breast Cancer? Available online at: cancer.org/cancer/breastcancer/detailed-guide/breast-cancer-risk-factors. Last accessed Jan. 20, 2017.
3. Bevers T. Breast Cancer Risk Reduction, V 1.2016. National Comprehensive Cancer Network. Available online: nccn.org/professionals/physician_gls/pdf/breast_risk.pdf. Last accessed Jan. 20, 2017.
4. Ozanne E, Drohan B, Bosinoff P, et al. Which risk model to use? Clinical implications of the ACS MRI Screening Guidelines. *Cancer Epidemiol Biomarkers Prev.* 2013;22(1):146-149.
5. Bellcross CA, et al. Evaluation of a breast/ovarian cancer genetics referral screening tool in a mammography population. *Genetics in Med.* 2009;11(11):783-789.
6. Hall IJ, Middlebrooks A, Coughlin SS. Population prevalence of first-degree family history of breast and ovarian cancer in the United States: implications for genetic testing. *Open Health Services and Policy Journal.* 2008;1:4-37.

Figure 1. Pathway—Novant Health Breast Center Workflow



Breast navigator stratifies risk assessment questionnaires by BI-RADS and cancer history status (see Figure 2. Breast Cancer History Workflow, Figure 3. Novant Health Prevention & Wellness Clinic Workflow, and Figure 4. High-Risk Workflow).

Note: Low-risk patients receive standard lay letter with the following verbiage: “If you completed the family history questionnaire during your visit, your lifetime risk of breast cancer was calculated and the result sent to the Novant Health Prevention & Wellness Clinic. If your risk was 20% or greater, you will be contacted within the next several weeks by our breast navigator and/or genetics counselor. For questions, please call [phone number].”

Figure 2. Pathway—Breast Cancer History Workflow

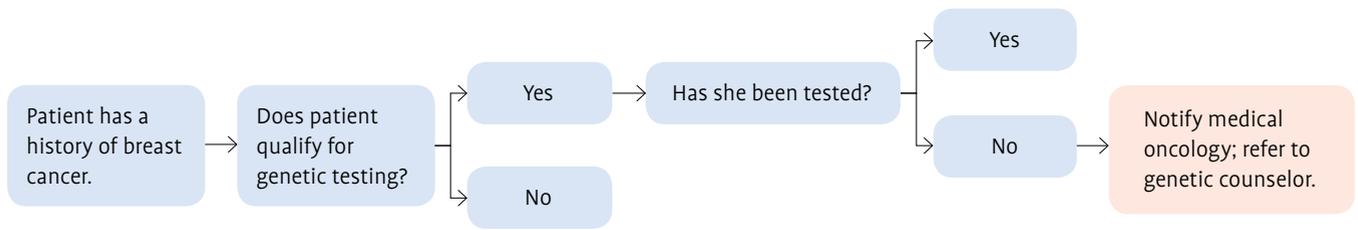
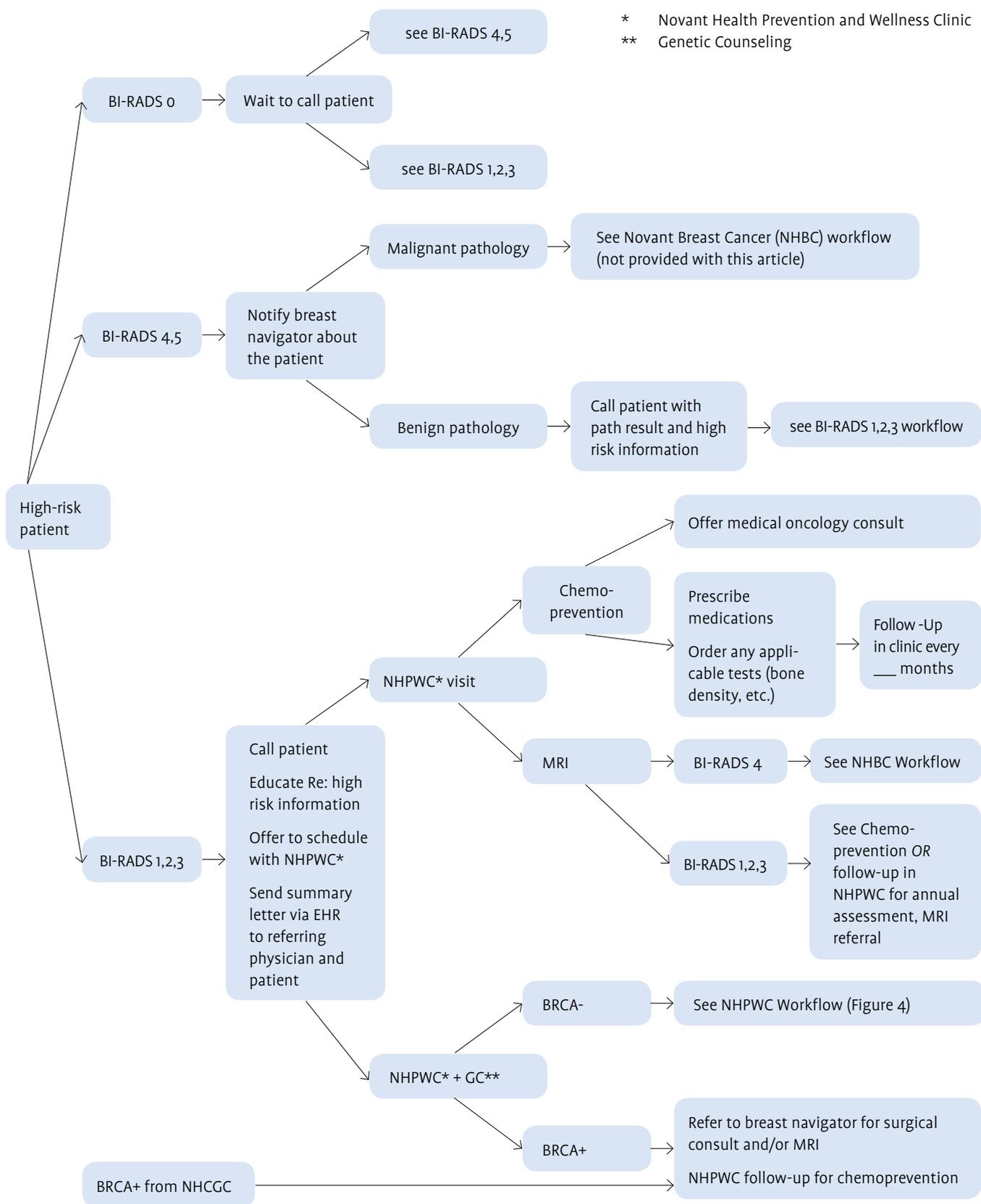


Figure 3. Pathway—Novant Health Prevention & Wellness Clinic Workflow



Figure 4. Pathway—High-Risk Workflow



* Novant Health Prevention and Wellness Clinic
 ** Genetic Counseling