High Risk **Breast & Ovarian**

The experience of one community-based teaching hospital and cancer center

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All women face some risk, but the likelihood of developing breast or ovarian cancer is much higher in those who carry an alteration in the BRCA1 or BRCA2 gene. For these women, the lifetime risk of developing breast cancer is as high as 85 percent, and cancer can occur at a much younger age. Depending on which gene alterations a woman carries, her risks for developing ovarian cancer are between 15 and 60 percent.[1] Also, the risks to those who carry BRCA 1/2 alterations are higher for developing a second breast cancer within five years. Their lifetime risk also increases for pancreatic cancer, and the BRCA 1/2 alteration may be associated with an increased risk for other cancers such as fallopian tube, gallbladder, bile duct, stomach, and melanoma; however, data on the last three cancers have been inconsistent.[2]

Based in Wilmington, Del., the not-for-profit Christiana Care Health System serves all of Delaware and bordering counties in Pennsylvania, Maryland, and New Jersey. The Christiana Care family of services includes two [teaching] hospitals, Christiana Hospital and Wilmington Hospital, with nearly 1,100 licensed beds, as well as the Helen F. Graham Cancer Center, a National Cancer Institute (NCI) Community Cancer Center with funding for a Community Clinical Oncology Program (CCOP) for clinical trials. The Breast Center and the Genetic Risk Assessment Program are part of the comprehensive service line at the Helen F. Graham Cancer Center.

After hearing from patients who carry BRCA 1/2 mutations that an opportunity existed to fill gaps in surveillance and supportive care recommendations, Christiana Care Health System established the High Risk Breast and Ovarian Cancer Surveillance Program. In concert with best practice guidelines, this new service line offering opened in 2007. Today, the program is a conduit for at-risk individuals to benefit from: 1) personalized cancer risk assessment, 2) convenient, same-day screening, and 3) specialized consultation services. All services are integrated with targeted risk-reduction strategies aimed at the prevention and early detection of breast and ovarian cancer.

Our Program

Clinical management of women who face an increased risk of developing breast and/or ovarian cancer can be complex and requires an individualized prevention and treatment strategy that incorporates multiple specialists.[3] Our High Risk Breast and Ovarian Cancer Surveillance Program offers these patients the opportunity to work with a team of cancer care professionals in a specialized clinical setting to receive comprehensive cancer risk assessment, screening, evaluation, education, counseling, and referrals for information about and access to the latest cancer risk-reduction strategies. Our clinical specialists work as a team to offer accurate interpretation of screening and testing results, which is critical to patient decision making regarding medical management.[4]

Historically, at our institution and others, oncology nurses have played a crucial role in coordinating staff and connecting cancer patients to resources and information related to their cancer diagnosis and treatment.[5] The contribution of a clinical nurse specialist in helping patients "navigate" the pathway of ongoing breast and ovarian cancer surveillance is also important and has been equally effective.[6] At our program, a clinical nurse specialist, certified in oncology and breast health, coordinates the resources of a multidisciplinary team of physicians, nurses, certified genetic counselors, and other health professionals to assist patients in accessing laboratory and screening tests, counseling, consultative care, and any other services they may need. Most of these services are provided in one day at one centralized location.

Initial screening is conducted through the Breast Center, where patients are seen on the first or third Thursday of each month. A clinical nurse specialist handles intake calls, screening patients to determine whether they have had genetic counseling and/or testing. Individuals who are concerned about their risks for breast and ovarian cancer who have not had genetic counseling and/or testing are referred to a certified adult genetic counselor at the Helen F. Graham Cancer Center to have their individual risk-factor profile evaluated.

Risk-factor assessment for participation in the High Risk Breast and Ovarian Cancer Surveillance Program is determined according to the current standards set forth by the National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology for Genetic/Familial High Risk Assessment of Breast and Ovarian Cancer.[7] Based on

these guidelines, individuals determined to have a BRCA1/2 mutation or a mutation of unknown clinical significance have the opportunity to participate in the High Risk Breast and Ovarian Cancer Surveillance Program. In the absence of a confirmed genetic mutation, participation in the program by individuals determined to be at above-average risk is based on an assessment of the following characteristics:

- Family or personal history of breast or ovarian cancer
- Previous breast biopsy that identified atypical cells
- Previous diagnosis of lobular carcinoma in situ (LCIS)
- Family history of known/suspected gene mutations associated with breast cancer risk
- A history of therapeutic irradiation to the chest.

Comprehensive Risk-Factor Assessment

Through the High Risk Breast and Ovarian Cancer Surveillance Program, individuals at high risk for breast and ovarian cancers access screening services at the Breast Center. Screening schedules follow current NCCN guidelines.[8] These include a clinical breast exam with breast self-examination instruction, a digital mammogram, and a breast MRI. Same day results are available for these imaging studies, and women have the opportunity to meet onsite with the participating radiologist to discuss any findings. Additional testing may include a CA-125 blood test and a pelvic and transvaginal ultrasound. NCCN guidelines currently recommend concurrent transvaginal ultrasound plus CA-125 screening every 6 months starting at age 35 years or 5 to 10 years earlier than the earliest age of first diagnosis of ovarian cancer in the family, and preferably on day one through 10 of the cycle for premenopausal women.[7,8]

Women who are found to be BRCA 1/2 mutation carriers are referred to a breast specialist familiar with high-risk patients.[3] A consultation with a board-certified general surgeon with a focused practice in breast diseases is scheduled on the same day and includes a physical exam and skin screening along with a personal and family medical history. At the conclusion of the surgical consultation, each patient receives a visit summary completed by the clinical nurse specialist in collaboration with the surgeon. This summary includes follow-up recommendations.

Discussions with patients about their risk factors include consideration of early detection and risk-reduction strategies that are determined to be best for them. These follow current NCI recommendations and may include lifestyle modification, the latest chemopreventive medications found to decrease the risk of breast or ovarian cancer, and prophylactic surgery, if indicated.[1] Advice about the risks to relatives is also provided, as well as a reference to NCCN guidelines for other cancer screenings. Referrals to see a medical oncologist, gynecologic oncologist, plastic surgeon, gastroenterologist, health psychologist, registered dietitian, clinical trials nurse, or other specialists may also be recommended. These referrals are often arranged the same day.

While physician recommendations can be a key predictor of future health promoting behaviors, studies have shown that patient recall can be limited or inaccurate regarding these recommendations.[9] To help ensure that women at high risk are not avoiding or neglecting potentially life-saving healthcare recommendations, our High Risk Breast and Ovarian Surveillance Program does long-term follow-up with participants. One month after the initial visit, each patient receives a follow-up phone call from the clinical nurse specialist who will review recommendations, answer questions, or address any concerns the patient may have. At the recommended surveillance intervals, the patient receives a reminder phone call one month prior to the time she should schedule her next visit.

Referrals and Financial Assistance

Patients may request a consultation appointment themselves, or they may be referred by their primary care physician or other specialist. The Genetic Risk Assessment Program also refers patients to the High Risk Breast and Ovarian Cancer Surveillance Program. Patients are reminded to bring any necessary insurance referrals for imaging tests or physician appointments on their scheduled appointment date. Prior to their appointment, patients are mailed a packet that identifies the date and time of each test scheduled. A Special Needs Fund is available through the Breast Center and the Helen F. Graham Cancer Center to cover the costs of imaging tests and/or the surgical consultation for eligible patients with no insurance coverage or insufficient coverage to meet these expenses. Determination of eligibility to access the fund is made by the director of the Breast Center.

Results from the Pilot Phase

Currently our High Risk Breast and Ovarian Cancer Program is in its pilot phase. (The pilot program was unrolled April 1, 2007.) As part of the pilot phase, patients are seen on the first and third Thursdays of each month between 7:30 am and 4:00 pm at the Christiana Care Breast Center and at other onsite imaging facilities.

In the first year of the pilot program, 14 individuals were evaluated and provided services through the program. No breast, ovarian, or skin cancers were found among this group. Suspicious findings appeared on a breast MRI for two individuals and on a pelvic/transvaginal ultrasound for another. Further tests for these three individuals came back negative.

Five individuals requested consultation with the team

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gynecologic oncologist to discuss prophylactic hysterectomy and oophorectomy. Two individuals screened requested information about a prophylactic mastectomy, and of those, one requested a consult with the team plastic surgeon. Among this group, no one requested a referral to another specialist or accepted the offer to speak with a clinical trials nurse.

Demographically, program participants ranged in age from 26 to 65 with a median age of 49. One was African American, the others, Caucasian. Two had a previous breast cancer, and one patient had had a total hysterectomy and oophorectomy.

During the pilot phase, all patients but one had their surveillance exams covered by their commercial insurance carriers. The Special Needs Fund was used to cover the cost of one surveillance MRI denied by insurance.

Lessons Learned

Developing and implementing our High Risk Breast and Ovarian Cancer Program has not been without challenges. For example, providing convenient screening and consultative services at one centralized location with same day test results required cooperation from the entire multidisciplinary team of specialists and imaging providers. We solved the problem of scheduling successive appointments with multiple providers by asking providers to commit to a series of appointment time slots on one day every two weeks to accommodate the women in the program. To cover appointment gaps, a one-week release was negotiated with both Christiana Care Imaging Services and participating physicians. In other words, one week prior, physicians can fill schedule gaps with patients outside of the High Risk Breast and Ovarian Cancer Program. Having both a dedicated, onsite radiologist and breast surgeon on duty at the Breast Center every day was an additional advantage. This practice set the standard to broaden the team of specialists located in close proximity to block a series of available appointments on the day of the program.

Standardizing the daily schedule was also helpful. For example, the CA-125 test requires no prep and is scheduled first thing in the morning, followed by the pelvic/transvaginal ultrasound. A meeting with the clinical nurse specialist includes the clinical breast exam with self-exam instruction and is followed by a mammogram and breast MRI. The surgical consult is scheduled after lunch.

The High Risk Breast and Ovarian Cancer Program also faced administrative challenges related to paperwork. An effort is currently underway to streamline the paperwork involved with the program. For example, we eliminated duplicate intake and consent forms for all services provided on the day of the program. This area continues to be a work in progress. Collaboration with Christiana Care Information Services will enable us eventually to offer patients a convenient one-time registration process for the laboratory and imaging exams ordered through the program.

Another challenge is related to prevention efforts. One goal of the High Risk Breast and Ovarian Cancer Surveillance Program is to encourage participants to become educated about their individual risk factors and to avail themselves of the preventive screening and lifestyle modification counseling available through the program. Although all participants were made aware of these services, the rate of referrals accepted to our dietitian, health psychologist, clinical trials nurse, and other health professionals on the team remained low during the pilot phase. We are considering new initiatives to encourage these important connections.

Anecdotally, many patients have expressed appreciation for the services offered and the compassionate care received at our High Risk Breast and Ovarian Cancer Program. As the program continues and the number of participants expands, it may be useful to devise a more formalized mechanism for assessing patient satisfaction.

For community cancer centers interested in developing a similar program, it is our belief that Christiana Care's High Risk Breast and Ovarian Cancer Surveillance Program can be easily replicated. In other words, smaller, community hospitals—not necessarily affiliated with a university or major academic center—could take a similar proactive approach to breast and ovarian cancer surveillance largely through coordination of existing programs and services within their own hospital or community.

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References

[1]National Cancer Institute. *Genetic Testing for BRCA1 and BRCA2: It is Your Choice*. Available online at: *http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA*. Last Accessed 12/02/08.

[2]Lindor NM, McMastor ML, Lindor CJ, Greene MH. The concise handbook of familial cancer susceptibility syndromes, 2nd ed. *J Natl Cancer Inst. Monographs*. 2008;38:22-29.

[3]Fatouros M, Baltoyiannis G, Roukos DH. The predominant role of surgery in the prevention and new trends in the surgical treatment of women with BRCA1/2 mutations. *Ann Surg Oncol.* 2007;15(1):21-33.

[4]Nusbaum R, Isaacs C. Management updates for women with BRCA1 or BRCA2 mutation. *Mol Diag Ther.* 2007;11(3):133-144.

[5]Frelick RW, Strusowski P, Petrelli N, Grusenmeyer P. Oncology nurse care coordinators as "navigators": improving cancer disease management and patient experience. *Oncol Issues.* July/August 2006;20(4):26-30.

[6]Grusenmeyer PA, Petrelli NJ, Strusowski P. Developing and operating multidisciplinary disease-specific clinics. *Community Oncology.* June 2006; 3(6):385-387.

[7]National Comprehensive Cancer Network. Genetic/familial high-risk assessment: breast and ovarian. NCCN Clinical Practice Guidelines in Oncology-V.I.2008. Available online at: *http://www.nccn.org/professionals/physician_gls/PDF/genetics_screening.pdf* Last accessed 12/02/08.

[8]Pavelka JC, Andrew JL, Karlan BY. Hereditary ovarian cancer – assessing risk and prevention strategies. *Obstet Gynecol Clin NAM*. 2007;34:651-665.

[9]Bober SL, Hoke LA, Duda RB, Tung NM. Recommendation recall and satisfaction after attending breast/ovarian cancer risk counseling. *J Genet Counsel.* 2007;16:755-762.