PHY SIE FAN COLLABORATION

Implementing a Community-Based Breast Cancer Risk-Assessment Model

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*In 2010 approximately 207,090 women were diagnosed with breast cancer.*¹

In 1998 and 2006, two well-designed clinical trials [Breast Cancer Prevention Trial (BCPT), NSABP, P-1 in 1998 and the STAR trial in 2006] demonstrated that prevention of breast cancer is possible. Two anti-estrogenic medications, Tamoxifene and Raloxifene, were shown to reduce the risk of breast cancer in women at high risk by almost 50 percent.^{2,3} While the trials were expensive to design and execute, the findings could potentially reduce healthcare costs significantly.

Despite compelling data from the BCPT and STAR trials, FDA approvals, and published guidelines, chemoprevention has not been used significantly in the community setting. The nursing and medical communities have failed to integrate the findings from these trials into clinical practice, and there has not been a coordinated educational initiative focused on breast cancer prevention for the population. These studies have not been accepted into clinical practice for a variety of reasons, including:

- A lack of awareness about the availability and efficacy of breast cancer prevention on the part of the general public. Few people request risk assessment from their healthcare provider(s).
- A lack of education on the part of primary healthcare providers.⁴
- Insufficient time to perform the risk assessment by primary care physicians, as well as a lack of reimbursement for these services.^{4,5}
- Clinicians who are familiar with the data, namely, oncologists, are not sought out by people who may be at high risk but have no history of oncologic disease.
- Some patients experience adverse medication effects.^{2,6}
- Studies have shown that women are reluctant to take a drug to prevent cancer.^{7,8}

Cognizant of these barriers, members of the Cancer Committee at Huntington Hospital, a community notfor-profit, 408-bed hospital in the suburban area of Long Island, N.Y., sought to find a way to incorporate breast cancer risk screening and breast cancer prevention education into the yearly physical examinations of its patients.

Our Methods

Our first approach was to assess our clinician's knowledge base of breast cancer risk assessment. We distributed a questionnaire to physicians (page 40) involved in the care of women, including breast surgeons, general surgeons, internists, general practitioners (GPs), and gynecologists. We distributed 200 surveys; 41 were returned (20.5 percent return rate). Of respondent breast surgeons, 100 percent (n=2) stated they were familiar with the Gail model (see box on page 39) and used the model in their practice. Of the 16 GPs and internists who returned the survey, only 3 stated being familiar with the model and 1 reported using the Gail model. Of the 9 gynecologists who responded, all 9 were familiar with the Gail model but only 2 reported using the Gail model in their practice.

Based on the survey results, the Cancer Committee decided to focus its attention on educating gynecologists and nurse practitioners on breast cancer risk screening using the Gail model. The Breast Cancer Risk Assessment Tool (see Table 1, page 38) is an interactive tool designed by scientists at the National Cancer Institute (NCI) and the National Surgical Adjuvant Breast and Bowel Project (NSABP) to estimate a women's risk of developing invasive breast cancer. The tool is available online at: http://www. cancer.gov/bcrisktool.¹¹

Our team theorized that gynecologists might not be familiar with the details of prevention, including the available interventions, their benefits, and side effects. This group was an ideal one to approach for professional education since their specialty concerns women's health. These clinicians also see relatively healthy patients on a yearly basis.

In order to educate gynecologists, we held a Medical Grand Rounds specifically for gynecologists. Topics were:

- Breast cancer risks
- The Gail model
- How to calculate breast cancer risk using the online Gail tool available on the NCI website
- Preventive strategies and data regarding medical interventions.

One month after the Grand Rounds education session for gynecologists, we sent out a second survey (page 41) to evaluate what the clinicians had learned and to measure their comfort in assessing risk and making recommendations for risk-reducing therapy. Our team was also interested in learning if gynecologists would now consider using the Gail model in their practice.

Here's what we found. Prior to the presentation only two gynecologists were using the Gail model. Following the presentation, three additional gynecologists stated they would use the model. Several gynecologists said they would use the Gail model "selectively." Reasons cited for not using the model were time constraints and discomfort in ordering Tamoxifen. Respondents also indicated continued interest in presentations and seminars on the subject of breast cancer risk screening and prevention.

Our next step was to develop an office-based patient questionnaire (page 42) designed in collaboration with a registered nurse and nurse practitioner from a local gynecology practice. Patients were asked to complete the ques*continued on page 38* The Breast Cancer Risk Assessment (BCRA) Tool is an interactive tool designed by scientists at the National Cancer Institute (NCI) and the National Surgical Adjuvant Breast and Bowel Project (NSABP) to estimate a woman's risk of developing invasive breast cancer. The tool has been updated for African-American women based on the Contraceptive and Reproductive Experiences (CARE) Study, and for Asian and Pacific Islander women in the United States based on the Asian American Breast Cancer Study (AABCS). Before using the tool, please note the following:

- The Breast Cancer Risk Assessment Tool was designed for use by health professionals. If you are not a health professional, you are encouraged to discuss the results and your personal risk of breast cancer with your doctor.
- ➤ The tool should not be used to calculate breast cancer risk for women who have already had a diagnosis of breast cancer, lobular carcinoma *in situ* (LCIS), or ductal carcinoma *in situ* (DCIS).
- The BCRA risk calculator may be updated periodically as new data or research becomes available.

- Although the tool has been used with success in clinics for women with strong family histories of breast cancer, more specific methods of estimating risk are appropriate for women known to have breast cancer-producing mutations in the *BRCA1* or *BRCA2* genes.
- Other factors may also affect risk and are not accounted for by the tool. These factors include previous radiation therapy to the chest for the treatment of Hodgkin lymphoma or women who have recently immigrated to the United States from certain regions of Asia where breast cancer risk is low. Further, the tool may not be appropriate for women living outside the United States. The tool's risk calculations assume that a woman is screened for breast cancer as in the general U.S. population. A woman who does not have mammograms will have somewhat lower chances of a diagnosis of breast cancer.
- For information to help your patients understand cancer risk visit: http://understandingrisk.cancer.gov. This interactive website will help your patients make informed decisions about how to lower their risk.



Risk Calculator

Here is a list of the questions that must be answered to calculate

risk. With the online tool, users can click a question number for a brief explanation, or read all explanations. Users then select their answers from drop-down menus.

1. Does the woman have a medical history of any breast cancer or of ductal carcinoma *in situ* (DCIS) or lobular carcinoma *in situ* (LCIS)?

- 2. What is the woman's age? (This tool only calculates risk for women 35 years of age or older.)
- 3. What was the woman's age at the time of her first menstrual period?
- 4. What was the woman's age at the time of her first live birth of a child?
- 5. How many of the woman's

first degree relatives (mother, sisters, daughters) have had breast cancer?

- 6. Has the woman ever had a breast biopsy?
 - a. How many breast biopsies (positive or negative) has the woman had?
 - b. Has the woman had at least one breast biopsy with atypical hyperplasia?
- 7. What is the woman's race and ethnicity?

tionnaire during their routine annual exam. The questionnaire was given to women between the ages 35 to 70 who also had a first-degree relative diagnosed with breast cancer. We selected these criteria based on data that suggest that the risk to benefit ratio of medical preventive treatment is less optimal in older women^{6,9} and that women without a family or personal history of breast disease are less apt to take medication to reduce cancer risk.^{7,10}

The patient questionnaire included all the standard questions on the Gail model risk assessment form. A registered nurse used a laptop to access NCI's online tool and calculate the patient's risk. The information was placed on the patient's chart for the physician or nurse practitioner to review as part of the physical exam. For patients with a high five-year risk (>1.6 percent), the physician or NP discussed preventive therapy with the patient. In some cases, a referral was made to a medical oncologist. In discussing preventive therapy, the physician provided relevant written information related to Tamoxifen and Raloxifene at the time of the patient visit. (Since the term chemoprevention could have negative connotations for a healthy female, physicians referred to these two medications as preventive therapies.)

Our Results

Between August 2009 and January 2010, we screened 1,570 women in one gynecology practice. Of these women, 158 (10 percent) were deemed to be high risk and were advised or referred for breast cancer risk reduction. Those women

What's in a Name?

The BCRA Tool is based on a statistical model known as the "Gail model," which is named after Dr. Mitchell Gail, Senior Investigator in the Biostatistics Branch of NCI's Division of Cancer Epidemiology and Genetics. The model uses a woman's own personal medical history (number of previous breast biopsies and the presence of atypical hyperplasia in any previous breast biopsy specimen); her own reproductive history (age at the start of menstruation and age at the first live birth of a child); and the history of breast cancer among her first-degree relatives (mother, sisters, daughters) to estimate her risk of developing invasive breast cancer over specific periods of time.

determined to be at risk were also offered the opportunity to speak to a nurse practitioner about their results. At this meeting, patients could receive further education on their results and/or assistance in deciding whether to consult with a medical oncologist.

In the past year, another community gynecologist in private practice associated with our hospital has begun to include breast cancer risk screening in her patient's yearly physical exams. This practice similarly found that approximately 10 percent of the women screened were determined to be at high risk for breast cancer and were referred for possible medication and/or other risk reducing strategies.

At the time this article went to press, our team was unable to determine the percentage of women that will ultimately be placed on or accept preventive therapy; however, these data will be collected as part of an ongoing follow-up study. The clinicians in the gynecology practices reported anecdotally that this education—as well as information regarding lifestyle changes that contribute to prevention was well received by the majority of the patients.

Going Forward

The absolute benefit of breast cancer reduction with preventive therapy often surpasses the cardiac mortality benefit of drugs used to lower cholesterol and hypertension. Despite this robust data demonstrating that breast cancer reduction with preventive therapy is efficacious, the concept has not taken a firm hold in everyday practice.

Presently, trials are underway testing aromatase inhibitors (AIs) in reducing breast cancer risk. However, parallel to what has been the case with Tamoxifen and Raloxifene, the results may have little practical impact if women are not being routinely screened for risk.

Our team's collaborative effort clearly demonstrated that several of the barriers to routine screening of healthy women can be addressed, thereby potentially increasing awareness of and access to preventive therapies. Ultimately a screening and prevention program cannot succeed without the participation of primary care physicians. Our results demonstrated that while there is a lack of information at the primary care level, clinicians can be educated on breast cancer risk screening and prevention. In fact, we have found that an education program is indeed necessary to enable primary care providers to include this screening program as part of the general physical examination. We have also demonstrated that primary care practitioners can take the first step in screening, identifying, educating, and treating women with high breast cancer risk. Perhaps most importantly—our model is easily incorporated into gynecological practice, generating a significant number of highrisk patients that would have not otherwise been identified.

Why now? With the cost of healthcare escalating, the medical and nursing community must find ways to incorporate cost and life-saving measures into the care we provide. In addition to educating primary care physicians about breast cancer risk assessment, educating our patients is also critical. Educated and informed patients can advocate for themselves, which ultimately further reduces some of the costs associated with healthcare. In the end, our collaboration showed that it is possible to integrate cancer screening and education into daily practice with minimal disruption to patient flow.

While it is beyond the scope of this article to address all the barriers to widespread breast cancer risk assessment, collaboration between community hospitals, cancer centers, private gynecological practices, and primary care physicians does alleviate some barriers and makes prevention processes possible. After all—prevention of cancer is the ultimate goal.

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Huntington Hospital Questionnaire for Physicians

1. How would you best describe yourself:

Gynecologist

General Surgeon

Breast Cancer Surgeon

Plastic Surgeon

- Internist
- □ Family Practice

□ Other

2. As part of a female patient's routine follow-up Physical, is a breast exam performed?

- □ YES
- D NO

3. As part of the History/Physical for female patients, are risks for breast cancer assessed?

- □ YES
- D NO
- □ SOMETIMES

If you answered YES or SOMETIMES, what do you routinely use to assess breast cancer risk? Check all the apply.

- □ Age
- Oral contraceptive use
- □ Age at time of first birth of a child
- □ History of breast biopsy
- □ History of smoking
- □ Family history of breast cancer

- Menstrual history
- Parity
- History of pre-cancerous lesions of breast
- □ History of other cancers
- □ Alcohol intake
- □ Other (explain)_

4. Do you refer patients for routine or follow-up mammograms?

- □ YES
- D NO

5. Are you familiar with the Gail model to assess risk?

- ☐ Not familiar
- Somewhat familiar
- Very familiar

6. If familiar, do you use the Gail model to assess risk?

- All the time
- □ Sometimes

Do not use routinely

Refer patients elsewhere for risk assessment

7. Which of the following would you find useful?

- Educational series regarding breast cancer risk and use of the Gail model
- □ Incorporation of the Gail model tool as part of your History/Physical
- Gail model tool made available for patients at Huntington Hospital Women's Health Center
- □ Risk assessment of cancer by staff at screening sites
- None of the above
- Other (please explain)_

8. Are you aware of any medications that can reduce breast cancer recurrence?

- □ YES
- D NO

Huntington Hospital Questionnaire for Gynecologists

Did you find the recent presentation informative? Prior to the presentation were you aware of the Gail model risk tool? Prior to the presentation were you using the Gail model risk tool? Prior to the presentation were you aware of the <i>BRCA1/2</i> risk tool? ¹ Will you use the Gail model tool for what might be perceived as a high-risk	□ YES □ YES □ YES □ YES	□ NO □ NO □ NO □ NO
patient?	□ YES	D NO
Will you use the Gail model tool for all your patients?	□ YES	D NO
Will you use the BRCA1/2 risk tool for what might be perceived as a		
high-risk patient?1	YES	D NO
Will you use the BRCA1/2 risk tool for all your patients? ¹	YES	D NO
Are you familiar with raloxifene (Evista®) for osteopenia?	□ YES	D NO
Have you prescribed raloxifene (Evista) for osteopenia?	□ YES	D NO
Are you familiar with tamoxifen (Nolvadex®)?	YES	D NO
Have you prescribed tamoxifen (Nolvadex) for breast cancer prevention?	YES	D NO
Would you be comfortable prescribing Evista for breast cancer prevention?	□ YES	D NO
Would you be comfortable prescribing Nolvadex for breast cancer prevention?	□ YES	D NO

Please review the cases below and respond how you would approach the patient:

- 1. 45-year-old pre-menopause female, menarche at age 11, 2 children first born at 41; family history of breast cancer in mother; breast biopsy X 2 in the past, both benign.
 - a. Proceed with Gail assessment and, if high, refer to oncologist.
 - b. Proceed with Gail assessment and, if high, place on Nolvadex.
 - c. Refer to oncologist.
 - d. Risk assessment not needed.
- 2. 67-year-old female, menarche at age 12, 3 children first born at 39; family history of breast cancer in mother and sister; breast biopsy X 2 in the past, both benign.
 - a. Proceed with Gail assessment and, if high, place on Nolvadex.
 - b. Proceed with Gail assessment and, if high, place on Evista.
 - c. Refer to oncologist.
 - d. Risk assessment not needed.
- 3. What, if any, reservation would you have in applying risk models to some of your patients (circle all the apply).
 - a. I have no reservations.
 - b. I do not feel comfortable with the risk assessment (Gail) model.
 - c. I do not feel comfortable with the use of Evista as prevention in post-menopause women.
 - d. I do not feel comfortable with the use of Nolvadex as prevention in pre-menopause women.
 - e. I plan to use the Gail model selectively.
- 4. Would you be interested in attending an updated seminar on breast cancer prevention next year?
 - Yes

□ No

References

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WGM OB/GYN Breast Cancer Risk Assessment Tool Questionnaire

The Breast Cancer Risk Assessment Tool is an interactive tool designed by scientists at the National Cancer Institute (NCI) and the National Surgical Adjuvant Breast and Bowel Project (NSABP) to estimate a woman's risk of developing invasive breast cancer. Those who show a potential for breast cancer can be counseled and referred in regard to opportunities and strategies for prevention.

Please fill out the following questionnaire if you are between the ages of 35 and 70.

- IF NO for question 1, STOP HERE.
- IF YES for question 1, please answer the following:
- 2. Do you have a history of any breast cancer or of ductal carcinoma *in situ* (DCIS) or lobular carcinoma *in situ* (LCIS)?
 - □ YES
 - D NO

IF YES for question 2, STOP HERE.

IF NO for question 2, CONTINUE.

3. What is your present age? _____

4. What was your age at the time of your first menstrual period?

- 5. What was your age at the time of the birth of your first child?
- 6. How many of your first degree relatives (mother, sisters, daughters) have had breast cancer?
- 7. Have you ever had a breast biopsy?
 - □ YES
 - D NO

IF YES:

a. How many breast biopsies (positive or negative) have you had?

b. Have you had at least one biopsy with "atypical hyperplasia?"

- □ YES
- □ NO
- 8. What is your race and ethnicity?