

# Implementation in a Large Health System of a Program to Identify Women at High Risk for Breast Cancer

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## Abstract

**Purpose:** Patients at high risk for developing breast cancer can be identified using a validated predictive tool: the Gail model. Patients thus identified can undergo careful breast cancer screening and be considered for preventive measures, such as chemoprevention with tamoxifen or raloxifene. An organized health system can create a screening and high-risk intervention program for breast cancer and potentially save lives and resources. Multiple components of the health system must work together in a multidisciplinary manner to successfully implement such a program.

**Methods:** Aurora Health Care is a large health system in Wisconsin. In 2007, a medical center within Aurora initiated a program to identify patients at high risk for developing breast cancer and intervene with screening and prevention. The program used

the Gail model, which was administered to patients presenting for comprehensive physical examination at the women's center.

**Results:** During the first year, 5,718 Gail model scores were calculated, and 15.2% of patients were deemed high risk. Most were counseled by their primary care providers, and few underwent screening with magnetic resonance imaging, genetics consultation, or chemoprevention. Primary care providers expressed concerns regarding the accuracy of the Gail model, the additional time necessary for patient counseling, how few patients underwent chemoprevention, and perceived medicolegal risk. The program was altered to address these concerns.

**Conclusion:** Success of a breast cancer risk and intervention program in a large health system is more likely if concerns of participating disciplines are acknowledged and addressed.

## Introduction

During the recent and ongoing health care reform debate across the United States, many aspects of our health care system are being scrutinized. One area of reasonable consensus is that US health care providers can do more in the area of prevention of disease. It is clearly safer for patients, and more cost effective to society, to prevent a condition than to treat it after it appears. It seems intuitive that the greatest good statistically can be achieved when patients at high risk for a condition are targeted for prevention. In addition, when patients are informed that they are at high risk for a potentially life-threatening condition, their compliance with prevention measures may be greater.

Breast cancer is the most common form of cancer among women in the United States, affecting one in eight women who live to full life expectancy. As a result, numerous research efforts have been made with regard to prevention, screening, and identification of high-risk patients. This plethora of information may then enable the creation of an evidence-based screening and high-risk intervention program for breast cancer in an organized health system and potentially save lives and resources. Great challenges exist in the successful implementation of a high-risk breast cancer program, because primary care providers, breast care specialists, administrators, and support staff must work together in a multidisciplinary manner to achieve the common goal.

Aurora Health Care is the largest health care system in eastern Wisconsin, with 13 hospitals, 100 clinics, and 3,400 physician providers, including primary care providers and specialists. Aurora BayCare Medical Center (Green Bay, WI) is one of the hospitals and clinics within Aurora Health Care. In March 2007, Aurora BayCare initiated a program to identify

patients at high risk for breast cancer and offer appropriate screening and prevention in an organized fashion. This monograph recounts the process of the development and implementation of this program, along with the challenges and successes encountered along the way.

Titled the Ready, Set, GO GAIL! project, the program began as a collaborative effort between the Aurora BayCare Comprehensive Breast Care Center and Aurora BayCare Medical Center Women's Center. The former consists of a dedicated breast surgeon and breast care navigator, and the latter comprises 12 obstetricians/gynecologists and four nurse practitioners.

The program uses the Gail model to identify patients deemed high risk for breast cancer.<sup>1</sup> This model uses individual patient characteristics to determine a 5-year and lifetime percentage risk of breast cancer development in women age 35 to 70 years, along with a comparison with the age-matched female population at large. The Gail model was validated then used in the NSABP (National Surgical Adjuvant Breast and Bowel Project) P-1 study, which demonstrated that tamoxifen, an estrogen receptor modulator, can decrease the incidence of invasive and noninvasive breast cancer in high-risk women.<sup>2</sup> The Gail model is brief and easy to administer to patients, and an easy-to-use Web site from the National Cancer Institute enables determination of individual risk profiles.<sup>3</sup>

The NSABP STAR (Study of Tamoxifen and Raloxifene) P-2 trial further developed the evidence-based options for chemoprevention in women deemed high risk for breast cancer development.<sup>4</sup> Raloxifene, another estrogen receptor modulator, was as effective as tamoxifen in reducing the incidence of invasive breast cancer, and it was associated with lower

risk of the adverse effects seen most often in the postmenopausal population.

## Methods

A committee on high-risk breast cancer was developed at Aurora BayCare in 2006, consisting of the breast surgeon, administrators, and clinicians from the women's center as well as marketing personnel. Regular meetings led to development of the Ready, Set, GO GAIL! project. Before rolling out the project, a computer slide presentation was created and presented on three occasions by the breast surgeon to clinicians and staff of the women's center, with continuing medical education credit made available to the providers. Details of the logistics of the project were given, and emphasis was placed on the potential benefits from the prevention and early detection of breast cancer in high-risk patients. It was theorized that the more the practitioners were convinced of the value of the program, the better their compliance in participation would be. The Gail model was explained, along with a detailed discussion of the indications and contraindications for the use of chemoprevention in high-risk women. The women's center staff members were also educated by the breast surgeon on the rationale for the project as well as on the details of Gail score calculation and the method of score storage in Aurora electronic medical records. No additional staff members were hired for the program.

Great effort was made by the breast surgeon to make the women's center providers comfortable with counseling high-risk patients. A standard dictation template was created for them to use to make patient visits more efficient. The breast center surgeon created written guidelines for such consultations. Items covered included lifestyle prevention strategies; surveillance strategies with mammography, breast self-assessment, and clinical breast examination; indications for breast magnetic resonance imaging (MRI); family history triggers that would prompt genetics consultation for possible *BRCA* gene mutation testing; chemoprevention options with tamoxifen or raloxifene along with indications, contraindications, common adverse effects, and risks; and surgical risk-reduction options of mastectomy.

The Ready, Set, GO GAIL! project is intended for women age 35 to 70 years who present for comprehensive physical examination (CPE) at the women's center. If she has not done so within the past year, each woman completes a Gail model questionnaire before her examination. This can be accomplished in just a few minutes in the waiting area. When the patient is brought to the examination room, the staff member accesses the National Cancer Institute Gail model from a program downloaded onto a laptop computer. The patient's data are entered quickly, and a Gail score is calculated. This task of Gail score calculation has become a standard routine, performed while the staff member updates medication and allergy profiles in the electronic medical record. Results are printed and scanned into the record.

If a patient is deemed high risk (Gail Model prediction of  $\geq 1.7\%$  risk of breast cancer in 5 years or lifetime risk  $\geq 20\%$  or both), the staff member notifies the women's center provider

**Table 1.** Demographic Data Collected in Year 1 of Gail Model Project

Data	Results	
	No.	%
No. of Gail models administered	5,718	
Total No. of high-risk patients	868	15.2
5-year Gail risk score $\geq 1.7\%$ and lifetime Gail risk score $\geq 20\%$	123	
5-year Gail risk score $\geq 1.7\%$ only	707	
Lifetime Gail risk score $\geq 20\%$ only	38	
High-risk patients referred to breast center	128	14.7
High-risk patients completing consultation at breast center	60	6.4
High-risk patients receiving indicated screening mammogram within 1 year of CPE	696	80.2
High-risk patients receiving screening MRI	21	2.4
High-risk patients administered chemoprevention	17	2.0
High-risk patients seen by genetics counselor	10	1.2

Abbreviations: CPE, comprehensive physical examination; MRI, magnetic resonance imaging.

at the outset of the visit. The provider has the option of performing a high-risk consultation or referring the patient to the comprehensive breast care center for the consultation. Breast center staff are available to perform the consultation the same day.

## Results

During the first year, 5,718 Gail model scores were calculated, and 15.2% met criteria for high risk (Table 1). Of the high-risk consultations performed for these patients, 85% were performed by primary care providers; 15% of patients were referred to the breast center. Half of those referred to the breast center actually appeared for their visits.

Of those patients deemed high risk, 80% underwent screening mammogram within the following year after identification as high risk. Only 2.4% of the high-risk patients underwent MRI imaging, only 2.0% were administered chemoprevention, and only 1.2% underwent genetic consultation for consideration of *BRCA* gene mutation testing.

## Discussion

The primary care providers were, by and large, supportive of the program at its outset. Especially compelling were the data from the NSABP P-1 and P-2 studies. The former showed a 49% decrease in incidence of invasive breast cancer in high-risk patients administered tamoxifen.<sup>2</sup> The latter showed raloxifene is as effective as tamoxifen in reducing the risk of invasive breast cancer, with a lower incidence of some risks compared with tamoxifen.<sup>4</sup> With time, however, the providers expressed some reservations.

Some were concerned with the accuracy of the Gail model in identifying individual patients as high risk. Previous biopsy of nonproliferative conditions, for example, would often lead to a

high-risk score that seemed discordant with the belief that only proliferative conditions were associated with true increased risk of breast cancer. Some expressed dismay with the amount of time that unexpectedly was needed to counsel a newly determined high-risk patient at an office visit for which a routine CPE had originally been planned. Some noted how few patients decided to begin tamoxifen or raloxifene chemoprevention despite being counseled as to their high-risk status. This led them to question just how much benefit was being realized for the effort put forth. And some expressed concern of medicolegal liability potentially brought about by the project. Specifically, if a patient were deemed high risk by Gail model calculation, and there was incomplete documentation of a thorough high-risk consultation in the record, and the patient were to sustain a breast cancer event, might the provider or health care system be liable for not successfully providing risk counseling?

In September 2009, reevaluation of the program began in light of these provider concerns. Coincidentally, at the time of this reevaluation, other breast centers within Aurora Health Care expressed interest in creating high-risk programs for their regions. In fact, the Breast Care Quality Subcommittee of the Aurora Cancer Committee has gone forward with plans to roll out on a system-wide basis high-risk screening and consultation, which will be offered to all women of appropriate age presenting for CPEs with Aurora providers. A system-wide ad hoc committee of breast specialists has been developed to address the concerns of the primary care providers in the original Ready, Set GO GAIL! project. Proposals put forward to date include using the Gail model as a wide-net, easily calculated screening tool for high-risk patients, then using the Tyrer-Cuzick risk assessment model<sup>5</sup> to confirm high-risk status.

The Tyrer-Cuzick model<sup>5</sup> is another validated tool for measuring a woman's risk of developing breast cancer; it has been shown to be a more accurate predictor of risk than the Gail model.<sup>6</sup> It uses more patient profile data than the Gail model, including body mass index, hormone use history, and second- and third-degree family history. It also uses proliferative disease biopsy history as a risk factor rather than nonproliferative biopsy results (Table 2).

The ad hoc committee has also proposed use of the electronic medical record for automatic patient notification of high-risk status. Specifically, if a Gail score were calculated for a patient, and it met high-risk criteria, the system would automatically send a letter to the patient notifying her of her possible high-risk condition. The letter would introduce the breast center and give instructions to call for a consultation. This would allow for full documentation that patients were notified of their high-risk status. It would also enable the primary care provider to avoid an unexpected time-consuming consultation during a CPE, because the patient would receive the letter a few days after the CPE and could schedule an appropriate consultation at a later date.

The program did indeed seem to enhance compliance with breast cancer screening. Compared with 2005 national data showing that 67.4% of US women age 40 years and older had had a mammogram in the previous 2 years,<sup>7</sup> our high-risk

**Table 2.** Comparison of Factors Considered in Gail and Tyrer-Cuzick Risk Predictive Models

Gail Model	Tyrer-Cuzick Model
Patient age	Patient age
Age at menarche	Age at menarche
Age at first live birth	Age at first live birth
No. of first-degree relatives with breast cancer	First-, second-, or third-degree relatives with breast or ovarian cancer
No. of previous breast biopsies	
Breast biopsy with atypical hyperplasia	Breast biopsy with atypical hyperplasia
	Menopausal status
	Age at menopause
	Body mass index
	Hormone replacement therapy use history

women completed screening mammograms at an 80% rate the first year of the program. The program did not seem to lead to an unnecessary increase in resource utilization. The American Cancer Society has advocated the use of screening MRI in patients whose lifetime risk of breast cancer exceeds 20%.<sup>8</sup> Although 161 of our high-risk patients met this threshold in the first year and were counseled regarding MRI, only 21 (13%) proceeded to have the study. Of particular interest to us was the small percentage of women deemed high risk and candidates for chemoprevention who actually started such medication. The US Preventive Services Task Force 2002 Grade B recommendation for discussion of chemoprevention with high-risk patients has not translated into even nominal treatment levels among our patients.<sup>9</sup>

Prevention of and surveillance for breast cancer is clearly a rewarding effort for health care providers who care for adult women. The identification of women at high risk for this condition likely makes the prevention and surveillance statistically more efficient. A program using the Gail model to identify high-risk patients can be implemented in a large health system and applied when women present for annual visits. The program requires cooperation from several disciplines within the health system. Success seems more likely if the rationale for patient benefit is explained to all involved, if concerns of those involved are acknowledged and addressed, and if a modern electronic record system is used. Data generated from the program work well in the evaluation of resource use and effects, if any, on screening habits.

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#### Authors' Disclosures of Potential Conflicts of Interest

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