Performing Breast Cancer Risk Assessments in a Community Setting

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This article describes the implementation of a risk assessment program for women having screening mammography at a community center. The program used the National Cancer Institute’s Breast Cancer Risk Assessment Tool to raise awareness in high-risk women. An evidence-based process is essential when implementing changes in clinical practice to overcome challenges and barriers.

Evidence-based practice (EBP) integrates clinical expertise and best available evidence to provide quality health care (Newhouse, Dearholt, Poe, Pugh, & White, 2005). Successfully translating evidence into practice can occur through the use of an organizational and collaborative framework (LoBiondo-Wood & Haber, 2006). This project aimed to implement a program using the National Cancer Institute’s (NCI’s) Breast Cancer Risk Assessment Tool (BCRAT), also known as the modified Gail model (Gail et al., 1989), for women having screening mammograms at a community breast center affiliated with a not-for-profit hospital system. This project addressed recommendations from the American Cancer Society (ACS, 2009) and the U.S. Preventive Services Task Force (2009) on breast cancer screening for women at high risk (20% or higher lifetime risk) through the addition of screening breast magnetic resonance imaging (MRI) scans. In addition, the project capitalized on Murphy et al.’s (2008) work indicating that the population of women receiving screening mammography requires greater awareness of breast cancer risk factors.

Synthesis of Evidence

Breast cancer is the most frequently diagnosed malignancy among women in the United States (Edwards, Maradique, Seibert, Saunders-Goldson, & Humphreys, 2009; Mahoney, Bevers, Linos, & Willett, 2008). Women have an estimated 12% lifetime risk of developing breast cancer (Fletcher, 2009; Mahoney et al., 2008). Gender and age are identified as the two major elements that quantify risk for breast cancer. Although other factors associated with personal and family history have been shown to increase a woman’s risk for breast cancer (Edwards et al., 2009; Mahoney et al., 2008), the majority of breast cancers are sporadic (Katapodi & Aouizerat, 2005). In addition, women are not aware of all breast cancer risk factors (Katapodi & Aouizerat, 2005).

Schwartz et al. (2008) defined a risk factor as any variable that increases an affected individual’s risk of breast cancer. Risk factors have been classified as major and minor (Schwartz et al., 2008). Major risk factors increase relative risk by at least double, whereas minor risk factors increase a relative risk by less than double (Joy, Penhoet, & Petitti, 2005; Schwartz et al., 2008). Major risk factors include BRCA mutation, family history of breast cancer in a first-degree relative younger than age 60, receiving mantle radiation before age 30, personal history of high-risk lesions, personal history of breast or ovarian cancer, and breast density (Boyd et al., 2007; Edwards et al., 2009; Joy et al., 2005; Mahoney et al., 2008; McKian et al., 2009; Palomares, Machia, Lehman, Daling, & McTiernan, 2006; Schwartz et al., 2008; Travis et al., 2005). Minor risk factors include age at first birth, early menarche, late menopause, breast cancer in second- or third-degree relatives, obesity, history of hormone-replacement therapy, and alcohol intake (Gail et al., 1989; Joy et al., 2005; Schwartz et al., 2008).

Interest in stratifying women into risk categories in the screening population and providing appropriate interventions for risk reduction and surveillance is increasing (Amir et al., 2003; Bondy, Vogel, Halabi, & Lustbader, 1992; Brown, 2005; Decarli et al., 2006; Edwards et al., 2009; Fletcher, 2009; Gail et al., 1989; Hollingsworth & Stough, 2008; Jones et al., 2005). Risk assessment prediction tools are designed to estimate a woman’s risk for breast cancer based on multiple coexisting risk factors. The original Gail model was developed using data from women who were actively undergoing annual screening mammography as part of the Breast Cancer Detection and Demonstration Project (Gail et al., 1989). The model has been validated and evaluated...
by several groups (Barlow et al., 2006; Bondy et al., 1992; Bondy, Lustbader, Halabi, Ross, & Vogel, 1994; Costantino et al., 1999; Spiegelman, Colditz, Hunter, & Hertzmark, 1994; Tice et al., 2008).

The BCRAT is available on the NCI Web site and provides a five-year and lifetime (up to age 90) estimate of empirical risk for breast cancer (NCI, 2008; Schwartz et al., 2008). The BCRAT model includes the following elements: current age, age at menarche, previous number of breast biopsies including the presence of atypical ductal hyperplasia, age at first live birth, family history of breast cancer in first-degree relatives, and race or ethnicity (Edwards et al., 2009; NCI, 2008).

The strengths and limitations of the model have been well documented. The model performs well at the population level, with calibration scores reported as 0.93 (Decarli et al., 2006) and 1.03 (Costantino et al., 1999). Calibration scores close to 1 indicate favorable performance of a model to predict the observed rate of cancer in a group (Fletcher, 2009). A systematic review by Cummings et al. (2009) confirmed the Gail model was well calibrated, as did the Agency for Healthcare Research and Quality’s 2009 evidence report. The model does not perform as well at the individual level, with c statistics reported ranging from 0.47 (Pankratz et al., 2008) to 0.63 (Barlow et al., 2006). Concordance statistics of 0.5 are equivalent to a 50% chance where perfect discrimination scores equal 1 (Fletcher, 2009). Therefore, the model performs better at the population level.

The BCRAT model should not be used in women with a personal history of breast cancer, lobular carcinoma in situ, or ductal carcinoma in situ. In addition, the model is limited because it does not include paternal family history and age of onset of breast cancer among family members (Edwards et al., 2009; NCI, 2008).

Attempts to improve the current model have centered on adding mammographic density (Boyd et al., 2007; Palomares et al., 2006; Tice et al., 2008), nipple aspirate fluid (Tice et al., 2005), and lobular regression (McKian et al., 2009) to the risk factors. In addition, studies are ongoing to gather more data and increase the accuracy of the tool for women in minority populations (NCI, 2011).

Despite its limitations, the BCRAT model has been used in screening mammography programs as an objective method to identify women at increased risk for breast cancer and to implement risk-reduction strategies including increased surveillance. Gail et al. (1989) said,

"Increasing public awareness of breast cancer risk factors, such as having a relative with breast cancer, has created a demand for informed counseling of patients at elevated risk. A woman's decision to embark on a program of intensive surveillance with mammography, or even to undergo prophylactic mastectomy, depends on her awareness of the medical options, on personal preferences, and, very importantly, on an individual estimate of her developing breast cancer in a defined period. Such an estimate is also useful for designing prevention trials in high-risk subsets of the population and in targeting screening and prevention efforts (p. 1879)."

No single model can address all elements in breast cancer risk assessment. However, the BCRAT, along with family history, can be used as an efficient and systematic initial step in combining screening for breast cancer risk with mammography in the screening population (Brown, 2005; Cummings et al., 2009; Hollingsworth et al., 2004; Tice et al., 2008).

Management options to consider for women at a moderate to high risk for breast cancer include continuing to receive regular annual mammography, use of MRI in addition to annual mammography, chemoprevention, genetic testing, and prophylactic surgery (Brown, 2005; Hollingsworth & Stough, 2008). ACS guidelines recommend that women with a lifetime risk higher than 20% for breast cancer should receive an MRI and mammography every year (ACS, 2009). Women at a moderate lifetime risk of 15%–20% should discuss the benefits and limitations of adding annual MRI. The U.S. Preventive Services Task Force (2009) reported that the use of MRI in high-risk women without cancer has a sensitivity of 71%–100% and a specificity of 81%–97%. A systematic review by Warner et al. (2008) concluded that screening with both mammography and MRI may exclude cancerous lesions more effectively than mammography alone for women at high risk for breast cancer. In addition, Graubard, Freedman, and Gail (2010) estimated that almost 900,000 women in the United States would be eligible for high-risk screening with MRI if the BCRAT was used to assess risk. Given the evidence, the implementation of this quality improvement project was identified as a priority by the authors’ community-based breast center.

**Team Formation**

Successful strategic plans have common purposes and objectives (Knox, Sigby, & Irving, 1997). A SWOT (strengths, weaknesses, opportunities, and threats) analysis was used to assist with implementation of the strategic plan (see Figure 1). Once the SWOT aspects were identified, a plan for implementation could be developed (Crow et al., 2008).

Based on the SWOT analysis, the authors developed a strategic plan to implement the program. First, a multidisciplinary patient-centered work group was initiated with the goal of improving coordination of care along the breast health continuum based on the needs and perspective of the patients and all customers, external and internal (Greiner & Knebel, 2003). The working group reviewed the evidence and approved a strategic plan for implementation of the program.

A project timeline was presented to the work group during the initial meeting. The work group included representatives from the following disciplines: nursing, navigation, administration, medical oncology, radiation oncology, surgery, radiology, gynecology and primary care, mammography, revenue management, medical staff services, and the board of directors. Critical to this process was the identification of a facilitator with effective communication skills to deliver the information and motivate team members for successful implementation of the project.

Members of the work group approved the strategy for implementing the screening risk assessment model. In addition, the work group was charged with finding a measure for project evaluation.

**Project Implementation**

The multidisciplinary team met three times over a period of 10 weeks to review the evidence on breast cancer risk assessment and to approve a plan for implementation of the project. A continuing
A comprehensive risk assessment program was provided for the mammography technologists and radiologists at various times prior to implementation of the BCRAT. The CME objectives were to review breast cancer risk factors, improve the understanding of statistical measurements of risk, and review national guidelines on the use of screening MRI. Forty-two mammography technologists and one radiologist attended the CME program. Evaluations ranged from very good to excellent. As a result, the BCRAT was implemented in four mammography facilities on November 1, 2010.

Program Evaluation and Clinical Implications

Nineteen MRI scans were performed during the first month following implementation of the BCRAT, compared to 10 scans performed during the same time frame one year prior. None of the breast MRIs were a direct result of the screening risk assessments that began in November 2010. However, three women who received scans had the risk assessment done on the day of the MRI. Ongoing evaluation of the risk assessment program at the six-month period (November 1, 2010, through May 31, 2011) identified 395 women receiving a lifetime risk assessment score higher than 20%.

A comprehensive risk assessment program includes a process for identifying patients from the screening mammography population (C.M. Teems, personal communication, July 5, 2010). The program presents an opportunity for community-based breast centers to provide an initial screening risk assessment by using the BCRAT, raising awareness of risk factors and including high-risk screening through the addition of MRI. Use of an EBP process is essential when implementing changes in clinical practice to overcome challenges and barriers (Newhouse et al., 2005). In addition, evidence-based care delivery assists with the achievement of best practices and encourages accountability (LoBiondo-Wood & Haber, 2006; Newhouse et al., 2005). Ongoing evaluation of the risk assessment program will provide further evidence of improved screening for women at high risk for sporadic breast cancer.

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References


