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Daniel W. Nixon, M.D., Editor-in-Chief
Preventive Medicine
525 B Street, Suite 1900
San Diego, CA 92101-4495

Dear Dr. Nixon:

As corresponding author, I would like to submit the enclosed manuscript, entitled "The Value of Breast Cancer Risk Assessment and Education in a Community Breast Clinic", for consideration for publication in your journal *Preventive Medicine*. The authors would like to submit this manuscript as an original research article. All authors have read and approved this manuscript.

The study upon which this manuscript is based received institutional review board approval, and signed informed consent was obtained from each participant in this study. Sources of funding for this study are acknowledged within the manuscript. This project was, for the most part, initiated, completed, and analyzed by the investigators.

All required materials (as per the online "Guide for Authors") have been included with this letter and submitted by e-mail (to pm@elsevier.com) as instructed. Please notify me immediately if any deficiencies are noted. Thank you for your consideration of this manuscript.

Sincerely,

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Title Page

Title: The Value of Breast Cancer Risk Assessment and Education in a Community Breast Clinic

Running Title: Breast Cancer Risk Assessment

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Condensed Abstract

Individualized breast cancer risk assessments provided through the community breast care center affect women's risk perception and their understanding of and emotions toward new options in screening, chemoprevention, and inherited risk. But truly impacting women's health care actions in these areas may require greater involvement of the primary care physician.

Abstract

BACKGROUND. Several models are available to estimate an individual's risk of developing breast cancer, based on her specific risk factors. Beyond management of breast cancer screening, these estimates also aid patients in evaluating the options of breast cancer chemoprevention and genetic risk assessment. We determined risk levels present in a typical breast clinic population and assessed the benefit of adding individualized breast cancer risk assessment (RA) and education to the standard breast screening strategy.

METHODS. A total of 1238 women accepted an individualized RA offered at routine mammography at our community breast care center. We recorded actions taken and knowledge about breast cancer prevention and risk perception changed as a result of individuals receiving this information with their standard breast screening.

RESULTS. We classified 26.8% of participants as being at increased risk for breast cancer. As measured by direct survey of participants, the RAs seemed to have significant impact on participants' understanding, psychosocial responses, and risk perception. As measured by participants' actions based on the RAs, there instead appeared to be little impact from this risk information. Very few participants pursued the options of chemoprevention or genetic testing as a result of the RAs.

CONCLUSIONS. Although risk information provided through the community breast clinic may effect knowledge, attitudes, and emotions concerning breast cancer screening, truly impacting women's actions regarding screening, chemoprevention, and genetic risk may require the direct involvement of primary care physicians.

Key words

breast cancer, risk assessment, risk perception, Gail model, chemoprevention, tamoxifen, hereditary breast and ovarian cancer, *BRCA1/BRCA2*, genetic testing, family history

INTRODUCTION

The strategy for breast cancer screening widely accepted in the U.S. comprises the triad of regular mammography, clinical breast exams and breast self-exams, as included in guidelines of several major organizations.[1,2] Since this triad's establishment into clinical practice, a tool for estimating breast cancer risk—the Gail model—has been developed.[3] Additional advances have been made in risk assessment (RA) for women with strong family histories of breast cancer. As a result, several models can now estimate an individual's risk of developing breast cancer, based on her specific risk factors. For a review of these models, see Euhus.[4]

In addition to early screening, women at high risk of developing breast cancer now have the option of chemoprevention. In 1998, the National Surgical Adjuvant Breast and Bowel Project's Breast Cancer Prevention Trial (NSABP P-1) reported that women with a 5-year Gail risk greater than 1.6% who used tamoxifen had a reduced incidence of breast cancer (by 49% overall) compared to controls.[5] With FDA approval, tamoxifen became an option for reducing breast cancer risk. Although studies have tried to define subgroups that will most benefit from tamoxifen prevention,[6] few have directly gauged interest in the actual use of chemoprevention in an at-risk clinical population.[7] Likewise, few studies have determined levels of breast cancer risk within a general population. Assessing acceptance (among patients and providers) of tamoxifen—the first available agent for cancer chemoprevention—may provide direction for the development and distribution of new chemopreventive agents.

In this study we sought to determine whether individualized breast cancer RA and education has benefit when added to the early detection triad and provided through the community breast care center. Many studies have shown that women's perception of their breast cancer risk often does not correspond to their

actual risk. A more accurate presentation of risk may aid in screening compliance and in better knowledge of options available for managing and reducing breast cancer risk.

METHODS

Participants

Individualized breast cancer RAs were offered to women upon registration for breast imaging at the Center for Breast Care at the Orange County Regional Cancer Center, from Jan. 2000 through July 2001. Consent information and the intake survey were presented to subjects by the Center's front desk staff. Women previously diagnosed with invasive breast cancer, or ductal or lobular carcinoma in situ, were excluded. The study received institutional review board approval, and signed informed consent was obtained from each participant.

A total of 1238 women chose to participate. Each completed the intake survey, providing information on risk factors for a Gail model assessment and on extended family history to ascertain inherited cancer risk. No record was kept of how many were offered RA or declined participation. Not every woman who registered for imaging during this period was directly offered the survey (although program information was displayed in the waiting room).

Procedures

Upon receiving each participant's survey, the study coordinator determined the Gail model risk and evaluated the family history for hereditary cancer risk. The intake survey contained questions about the number and ages at diagnosis of all first-degree relatives with breast cancer, any relatives diagnosed with breast and/or ovarian cancer, and any relatives diagnosed with multiple breast cancers. This information was used to determine "Extended Familial Risk" (EFR) for hereditary breast cancer, based on the criteria of the American College of Medical Genetics[8] (Table 1). The risk of women without EFR was based primarily on the Gail model estimate. The risk of women with EFR was based on a combination of the risk estimates of Claus et al.,[9] Couch et al.,[10] Myriad Genetics Laboratories,[11–13] and BRCAPRO,[14] as appropriate. The CancerGene software program[14] was utilized for these latter RA models. For each woman who had

received imaging at study intake, the study coordinator and a study physician evaluated the imaging report prior to contact about the RA result. If biopsy was recommended based on this imaging, we held the RA until the biopsy results could be incorporated into the assessment.

Based on the appropriate combination of risk estimates, each participant was categorized as: NIR (Not at Increased Risk), IR (at Increased Risk, Gail 5-year risk >1.6%), and/or EFR (as defined in Table 1). The IR and EFR categories were not exclusive.

Women categorized as NIR were notified by mail of their RA results, and the referring physician received a summary. These written results contained the participant's Gail scores stated in several ways (percentage risk and "n out of 100" risk), comparison to the average (for her age/race), explanation of the risk factors used for the estimate, and information on the importance of continued breast screening, regardless of the RA result. A follow-up survey containing questions similar to those in the intake survey was included. These questions elicited psychosocial responses to the RA, what had been gained from participating, and subsequent risk perception.

Participants categorized as IR or EFR were invited to set up an appointment for in-person discussion of their results. This invitation was made by telephone and/or by mail. Those who did not respond were contacted at least twice by telephone and/or written notification. For those who still failed to respond, the referring physician received a letter summarizing the patient's results and was encouraged to refer the patient for in-person consultation.

The study coordinator (SDK), a cancer genetic counselor and geneticist (but not a physician), provided all consultations. In some instances, an oncologist (LP) participated in the consultation. Consultations lasted from 45–90 minutes. Consultations were tailored to each woman's history but included these elements: description of the risk factors upon which the RA was based, clarification of family cancer history, discussion of the woman's specific risks (phrased in several different ways and compared to average values), and discussion of options for screening and risk reduction suggested by her risk. The latter

included discussion of: age- and risk-appropriate screening (mammography, clinical breast exam, and breast self-exam), considerations of the risks and benefits of tamoxifen chemoprevention, the availability of the STAR chemoprevention trial (Study of Tamoxifen and Raloxifene, see Wolmark and Dunn[15]), and lifestyle modifications of possible benefit.

Consultations for women with EFR were similar to the above, with emphasis shifted from Gail risk to family history risk as appropriate. With sufficient risk of an inherited susceptibility, more time was spent discussing information concerning *BRCA* mutations/testing and the specific indication of risk from the family history. All of the information covered in a *BRCA* "pre-testing" genetic session was not included, but an explanation of and referral to a full cancer genetic consultation was offered. (Our cancer genetics program provides counseling without charge and assists clients in obtaining insurance authorization or investigating other sources to cover testing costs.)

Each participant and her physician received follow-up letters summarizing the IR/EFR consultation. The participant's letter included a follow-up survey, similar to the intake survey. These were mailed 1–2 weeks following the consultation. A second survey was sent 2–9 months after the consultation to determine actions taken based on the RA. This survey covered: initiating physician contact specifically about breast cancer risk, making changes in health care based on the RA, and discussing risk information with family or friends.

Data Analysis

Independent and dependent variables were compared in two-way frequency tables. Independence between rows and columns of each table were determined with the Pearson chi-square test. When a cell value was 5 or less, a two-tailed Fisher's exact test was used. A p value of less than 0.05 was accepted as significant.

RESULTS

Characteristics of the Study Sample

The mean age of participants was 50 (range: 21–83 years; Table 2). Most participants were white (84.4%), with some of Hispanic (7.4%) or Asian (5.3%) ethnicity. Of total participants, 71.9% had no elevated risk (NIR) by either the Gail model or extended assessment of family history. Of those with elevated risk, 224 (18.1% of total participants) were categorized as IR and 175 (14.1%) were categorized as EFR (Table 2). One hundred eight participants (8.7%) were categorized as EFR but had a 5-year Gail risk <1.7% and would not have been assigned an elevated risk if the family history had been limited to that considered by the Gail model.

Assessment Process Completion

Of all participants, 26.8% were categorized as IR or EFR. Of those classified IR, 44 were judged not to be good candidates for tamoxifen risk-reduction, based on their age and 5-year risk near or below their age-average risk. These judgments were based on the benefit/risk indices discussed in Gail, et al.[6] These women were all over 60 and most had 5-year risks below 2.5%. These individuals and their physicians were notified by mail of their risk and of the option of tamoxifen therapy, with the explanation that its risk may outweigh the benefits, given their age and risk level.

Excluding those above, the remainder of the 332 women classified as IR and/or EFR were invited to set up an appointment to discuss their RA. One hundred eleven (33.4%) of these responded to the invitation and completed a full consultation (Table 3). Seventeen women formally withdrew from the study or were excluded by a diagnosis of breast cancer or other health management concern. The majority of at-risk women (180, 54.2%) never responded to the invitation to receive the RA results, even after several notifications. Because these were non-responses, we could not determine why these women chose not to receive their results, even though initially consenting to and providing intake information necessary for assessment.

Impact on Those at Increased Risk

At-risk participants who had received their results were contacted some time after the consultation to determine changes made based on the information received. These follow-up contacts were made 2–9 months after consultation. Many (30/63, 47.6%) failed to provide this follow-up information. Of those responding (34 total), two (5.9%) had specifically contacted their physicians to discuss the RA and five (14.7%) stated that their physicians had specifically contacted them for this purpose. Only one of these had specifically arranged an appointment to go over the RA information. Eleven women (32.4%) discussed the assessment during a regular appointment. Eighteen women had not discussed it with their physician or had not seen their physician since the assessment. Six of these planned to discuss the assessment with their physician at a future appointment while two did not plan such a discussion.

Nine of the 34 who responded (26.5%) had made changes in health practices, health care, or lifestyle based on the RA. One subject started taking tamoxifen for risk reduction following the RA. Three subjects stopped using hormone replacement therapy (HRT), switching to raloxifene. Another made changes in HRT dose. Two subjects were still considering entering the STAR trial or starting raloxifene at the time of follow-up. Two subjects made diet or lifestyle changes following the RA.

Contraindications to tamoxifen became evident for several at-risk women during the consultation. Five revealed personal or strong family histories of stroke or blood clots. Two, being satisfied with HRT, did not wish to disrupt it. Another was satisfied taking raloxifene. Two women considered their risk to be insufficient to consider tamoxifen; another stated a preference for natural, non-drug approaches. One woman was seriously considering the option of prophylactic mastectomy and was less inclined to consider tamoxifen at the time.

A total of 59 women with EFR for inherited breast cancer completed a RA consultation. Ten did not meet EFR criteria upon clarifying the family history. For 27, the family's risk of carrying a BRCA mutation was below 10%. These were counseled using general guidelines that indicate doubtful benefit of genetic testing at this risk level.[16] Three women were not personally at significant risk of a *BRCA* mutation but had other

family members who were. These women were given information on *BRCA* counseling/testing and were encouraged to discuss this risk with appropriate relatives.

The risk of carrying a BRCA mutation exceeded 10% for 17 subjects. In addition to risk information, these received: a) information concerning genetic counseling and testing, and b) a referral to return for more extensive pre-test counseling for *BRCA* mutation testing. Two subjects had insignificant *BRCA* mutation risk but family histories suggesting hereditary nonpolyposis colorectal cancer and were counseled accordingly. Among those with possible hereditary cancer susceptibility, 13 took no further action (through our program) following the RA consultation. Six took limited follow-up actions beyond the initial consultation but fell short of initiating full pre-test counseling. No subjects initiated the full pre-test counseling process following the RA consultation and none completed *BRCA* testing (of which we are aware).

Information Impact

Participants were surveyed before and after receiving their RA results concerning the information anticipated and received. Nearly all of those responding felt that they received a better understanding of breast cancer risk factors (96.8%), which was not significantly different from the proportion that anticipated receiving a better understanding (97.4%). Most respondents (95.6%) indicated that they received information regarding their future breast health care, but this was slightly (significantly) less than those who had anticipated such information (98.6%). Regarding whether the assessment had given "an opportunity to expand my knowledge regarding breast cancer, including current treatment options and benefits," considerably more anticipated receiving this information (96.6%) than actually received it (82.5%). The latter figure is actually surprisingly high, considering that cancer treatment information was not included with any of the standard sets of information provided.

Psychosocial Effects

At intake, participants were asked about emotional and psychological responses (such as anxiety or relief) that they anticipated experiencing from the RA. Their actual responses were surveyed after completion of

the assessment (Table 4). Among all participants, most indicated that they felt more confident (93.8%), less anxious (76.9%), and relieved (80.6%) concerning their breast health following the RA. Each of these measures was greater than the respective number who had anticipated feeling increased confidence (87.6%), reduced anxiety (56.4%), and relief (65.1%); each difference was statistically significant. Among those at increased risk who had a RA consultation, most also felt more confident (90.2%), less anxious (63.0%), and relieved (61.5%) following the RA. In contrast to all participants, these values were not significantly different from the numbers who anticipated these feelings prior to the RA (confident = 92.7%, less anxious = 63.0%, relieved = 65.4%). Few participants anticipated feeling depressed (5.5%) by the assessment and significantly fewer reported actually feeling depressed after participating (0.9%, 2 participants). No participant at increased risk reported feeling depressed following the assessment consultation; one participant had anticipated this feeling. Among all participants, the percentage reporting a heightened sense of empowerment after the assessment (72.5%) was not significantly different from the percentage anticipating this feeling (74.3%). More participants anticipated feeling like a more active participant in their health care (97.8%) than actually reported feeling this following the assessment (92.6%), but this difference was not statistically significant among those at increased risk. When asked whether RA should be included as part of regular clinical breast exams and mammography, 94.6% of those not at increased risk agreed, as did 89.6% of those at increased risk.

Effect on Risk Perception

Participants were asked at intake and again following RA whether they felt that their breast cancer risk was: (1) higher than that of an average woman of their age, (2) about the same as average, or (3) lower than average, or whether (4) they had not thought about their risk in this way. Of the women who answered this question at both times, the majority (55.5%, 228/411) had a different response following RA than at intake. Most (120/411, 29.2% of the total) had downgraded their perception from a higher to a lower level of risk. Much less (30/411, 7.3% of the total) upgraded their risk perception from a lower to a higher level.

To determine how closely post-assessment risk perception corresponded to the assessment risks, the risk status of those within each perception category was evaluated. Of those perceiving their risk as greater than

average, 92.9% (26/28) had Gail risks that were both (5-year and lifetime) greater than average and only 3.8% (1/28) had Gail risks that were both less than average. Of those perceiving their risk as lower than average, 82.5% (170/206) had Gail risks that were both less than average and 7.3% (15/206) had Gail risks that were both greater than average. (We made no attempt to determine how much deviation from average could still be considered "average." Any value 0.1% or more above average was considered "greater than average;" any value 0.1% or more below average was considered "less than average.")

Changing women's perception of their risk would be a laudable result of RA, but only if the changes reflected reality. Participants may have downgraded their risk perception based on receiving a favorable mammogram, independent of their RA results. To determine the validity of risk perception changes, we evaluated the Gail risk status of those who had changed their perception following the assessment. Of those who had upgraded their risk perception from "about average" to "higher than average," all (11/11) had at least one Gail risk that was greater than average. Of those upgrading their risk perception from "lower than average" to "average," 23.4% (4/17) had Gail risks that were both greater than average and 52.9% (9/17) had Gail risks that were both less than average. (No risk perception changed from "lower than average" to "higher than average.")

Of those downgrading their risk perception from "average" to "lower than average," 94.2% (81/86) had at least one Gail risk that was less than average and 4.7% (4/86) had Gail risks that were both greater than average. Of those downgrading from "higher than average" to "average" or "lower than average," 71.0% (22/31) had at least one Gail risk that was less than or equal to average and 29.0% (9/31) had Gail risks that were both greater than average.

DISCUSSION

Few studies have documented the levels of Gail risk or the profile of breast cancer risk factors within a general clinic population. Some studies have examined these features in high-risk or other specialized populations, including women with a family history of breast cancer,[17,18] women attending a high-risk breast clinic,[7] indigent women attending a public hospital gynecology clinic,[19] and women (pre-diagnosis)

with early-onset breast cancer.[20] In 1994, Spiegelman et al. assessed risks in a large population of women in the course of validating the original Gail model.[21] Those data were not published in a form that is directly comparable to our own. Our study has documented the Gail risk estimates and risk factors among 1238 patients visiting our general, suburban community Center for Breast Care. Overall, 18.1% of women who enrolled in our study had a 5-year Gail risk greater than 1.6%, 3.6% had a risk greater than 3.0%, and only 0.6% had a risk exceeding 5.0%. As women were not randomly enrolled and the entire population was not sampled, these numbers probably are not representative of the general population. Instead, this represents a potential level of at-risk women within a typical clinical population who may be interested in or benefit from a RA program. Self-selective enrollment may have presented bias toward those with elevated breast cancer risk. The proportion of participants with a family history of breast cancer (14.0% with a first degree relative affected, 38.9% reporting any family history of breast cancer) may reflect such a bias. This exceeds most estimates of the presence of family history of breast cancer in the general population. Helmes et al., working with a similarly self-selected (although younger) population, noted that 15% had at least one relative with breast cancer.[22] A study by Mouchawar et al. showed bias for those with a family history among their subjects.[23] Although 15% of women in their total database (of 240,000 women) reported at least a first-degree relative with breast cancer, 61% of the women responding to their survey (310) had a first-degree relative with breast cancer. Other studies determining the prevalence of breast cancer family history among populations of women unaffected by cancer have reported values ranging from 4.8% to 7.3%.[21,24–26]

Among participants at increased risk, 29.9% had a family history indicating a potential risk of a *BRCA* mutation. Overall, 8.7% (108 participants) had a Gail risk less than 1.7% but had a family history suggesting risk for a *BRCA* mutation warranting further evaluation. Nineteen of these had sufficient risk to warrant discussion of genetic testing options, at a level where testing may provide benefit. This increased risk would not have been identified under strict application of the Gail model risk factors. This illustrates the importance for providers to recognize the known limitation of the Gail model to include the risk from a potential *BRCA* mutation. Some family histories strongly indicative of such a risk (particularly those containing ovarian cancer or containing breast cancer in the paternal lineage) can be completely missed by

the Gail model. Even those recognized as having increased risk by the Gail model may not receive consideration of all aspects of their risk (e.g., their increased risk for ovarian cancer or the potential benefit for genetic testing to refine their risk) if a potential *BRCA* mutation risk is not also recognized.

We wished to determine the value of adding RA to the standard screening triad of mammography, clinical exam and self-exam. This value can be assessed using several different criteria. For all women at increased risk who enrolled in the study, one measure of program ineffectiveness could be the large percentage of women who chose not to complete the RA. Of the 332 women at increased risk, only one third (111) chose to receive their results. Over half (180) did not respond to repeated attempts to set up the RA consultation. Given the nature of this "non-response," we could not determine why these individuals failed to respond. The invitation to schedule the consultation did not indicate an elevated risk. Therefore, whether fear or other emotions concerning the risk value itself contributed to noncompliance is uncertain. Whatever the preconceptions of the risk consultation might have been, the nature and extent of the lack of response indicates that many enrollees did not value the information enough to complete the assessment. Some disinclination to the RA may have been due to the novelty of this service to standard medical practice and uncertainty about what the RA entailed or could offer (although this was described in the consent information).

Among at-risk participants completing the consultation, one measure of program effectiveness is the number of women changing health behaviors based on the RA. Like the previous criterion, the impact of the program as judged by this measure is disappointing. Of those who provided this information, only a small minority (5.9%) specifically contacted their physician or were contacted by their physician (14.7%) about the assessment. Even after a reasonable period, only a third of these women had discussed the RA in a regular appointment with their physician. Very few women made medical changes based on the RA: one participant started using preventive tamoxifen and four others made changes to their HRT. This is a small percentage of those who responded to the follow-up survey (5/34 = 14.7%) and even less of those who had an increased Gail risk (5/224 = 2.2%) or who completed the assessment consultation (5/84 = 9.5%).

The complicated decision to use tamoxifen to reduce breast cancer risk must carefully consider individual preferences and medical history;[6] therefore, it is difficult to determine the number of participants "expected" to have initiated tamoxifen therapy. Regardless of this consideration, one out of 84 women with a Gail risk greater than 1.6% is probably less than even the most conservative estimates. Independent of the education effort used, resistance to tamoxifen use may come from the side effects of the agent itself, as suggested by others[7,27] and by the levels of attrition in the three major tamoxifen chemoprevention trials.[5,28,29] Even with extensive education about risk and options suggested by this risk, given the general reluctance towards chemoprevention, this education may have limited value if not originating from one's own physician. This limitation is compounded by the fact that initiating tamoxifen therapy requires consideration of and coordination with elements of women's past, present, and future health management. Such consideration lies most appropriately with the primary physician. Port et al.[7] found that two patients out of 43 elected to use preventive tamoxifen after a presentation from that study's physician. They noted that the education sessions did not seem to influence patients' decisions. The authors speculated that motivation towards and the decision about chemoprevention is greatly influenced by the patient-physician interaction. Kinney et al.[30] found that the primary care physician played an important role on their patient's decision to enroll in the Breast Cancer Prevention Trial. The physician's role may be particularly relevant in chemoprevention, as a patient must be motivated not against a concrete symptom but by a more nebulous "risk," while the side effects of the preventive agent may be much more salient to the patient.

Similar consideration of requisite patient- or physician-generated motivation may be a factor when hereditary risk is indicated, although the numbers behind this observation are much lower. Although 17 participants were suitable for full pre-test counseling for *BRCA* predisposition, none took advantage of a no-cost genetics consultation. We are unaware of studies examining the effect of differing levels of baseline knowledge of hereditary breast cancer at the time of referral on the decision to actually pursue genetic counseling/testing. (Many studies have measured an effect on *interest* in genetic testing, but not on actual utilization of these services. Helmes et al.[22] recruited women into a study that included the possibility of genetic counseling and testing. They found that women with either greater awareness of or interest in genetic testing were statistically more likely to participate.) Such studies could prove valuable to

understanding public acceptance of genetic tests, particularly as their clinical availability is predicted to increase greatly in the future.

If participation of the primary provider is necessary to motivate patients to action, our results suggest that this may be a larger obstacle than direct patient education. A total of 188 community physicians had patients who participated in the study. Each physician received written summary of his/her patient's assessment. Detailed information packets were included for physicians whose patients had increased risk: 71 contained information on the P-1 trial and preventive use of tamoxifen; 42 contained general information on *BRCA* testing. Despite the number of packets sent, less than five physicians contacted the program with questions about their patient's assessment or with requests for additional information. For the patients (numbering 180) who were at increased risk and who did not respond to invitations to receive their results, their physicians were notified of the results and encouraged to refer the patient to the consultation. Only very few patients re-contacted the study as the result of such a referral, suggesting that these results were perhaps not communicated to the patients. Whether direct physician education/involvement is a better approach for exposing patients to options to manage cancer risk remains to be addressed by future studies.

The self-report of participants on pre- and post-assessment surveys was another way to evaluate program effectiveness. This was the primary means to measure the impact on women who were not at increased risk. More positive results were seen using this criterion. Over 95% of participants reported having a better understanding of risk factors and better information regarding future breast health care as a result of the assessment. Over 85% indicated that they had received information useful to family members, friends and coworkers. As a result of the RA, vast majorities of participants felt more confident and like more active participants in their health care. Large majorities of women felt less anxious and relieved from the risk information, and most experienced a heightened sense of empowerment. Of all participants, fewer than ten felt more anxious or depressed after the RA. Over 90% of all participants agreed that the assessment should be included as part of regular clinical breast exams and mammography.

The other large impact of the program was on risk perception. As did previous studies, we found that most women initially overestimated their risk for developing breast cancer.[7,23,31–35] The RAs seemed to successfully adjust participants' perceptions to be more concordant with their Gail risk. Over half changed their risk estimate following the assessment. Comparing individuals' Gail risk to their final perceived risk, and the direction of change in perceived risk, revealed that most participants had adjusted their risk perception appropriately. This suggests that the risk perception change was not an artifact of a general downgrading of risk based on having just received a negative mammogram, independent of the assessment or actual level of risk. This analysis has some limitations. First, it assumes that participants accepted their Gail risk as an accurate measure of their risk. This analysis does not take into account women who may have noted their Gail risk from the assessment but who disagreed with it, basing their perceptions instead on other factors. Second, the analysis does not include individual perceptions of how wide is the spread of values that may still be considered "average." We arbitrarily defined a 0.1% change from average as being "greater than" or "less than" average. Some subjects may perceive, for example, a 0.5% increase as still within the range of "average."

Collectively, previous studies have not reached a definitive conclusion on the effect of congruent risk perception on mammogram intention (and, more rarely, actual screening behavior). Most of these studies have examined high-risk populations of women; few have included general risk populations. Literature reviews found that most interventions designed to produce a more congruent risk perception were successful.[36,37] Data on the effect of this congruence on screening intention or behavior were much more variable. Several studies found that risk education provided congruent risk perceptions and positive emotional benefit and led to no less motivation to receive screening. The one study that had actually measured screening behavior found that, among less-educated study participants, risk counseling led to reduced mammography use.[38] Aside from the accuracy of risk perception, Curry et al. found that women who were contacted with information discussing their personal risk were more likely to get a mammogram than were women whose risk was only discussed in general terms.[39] A number of studies by Lerman and colleagues have generally shown that women with increased worry following mammography tended to report a greater intention for mammogram compliance, while those expressing relief were less likely to

return for screening.[32,40,41] (Exceptions occurred for some women with excess anxiety, which could have a deleterious effect on screening compliance.) More recent studies have found that directed information about breast cancer risk can increase screening intention and compliance. Lipkus et al. found that risk feedback did not affect, or increased, women's intentions to get screened.[33] Royak-Schaler et al. found that pointed discussion of family history and personal risk promoted compliance with screening goals, even though accurate knowledge of specific risk factors was not necessary for this compliance.[42]

The interactions of risk perception, worry, and anxiety with screening compliance are complex and may be confounded by these and other factors,[33,36,37] including existing screening behaviors and beliefs. It is likely that these interactions are specific and different for those at high, moderate, and low risk. Most studies have concentrated on those at high risk, with less attention to those of moderate- and low-risk. Attention to screening compliance in these latter groups is important, as it is known that the models have their limitations and that much breast cancer does occur in women who are not identified as "high-risk". It is important not to dissuade these from screening efforts based on over-reliance on risk models.

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TABLE 1
Criteria for Classification of "Extended Familial Risk" (EFR)

Three or more first- or second-degree relatives diagnosed with breast cancer, regardless of age at diagnosis
Less than three affected relatives, but:

- Family member diagnosed with breast cancer at age 45 or younger, or
- One or more cases of ovarian cancer at any age, and one or more blood relatives diagnosed with breast cancer at any age, or
- Breast and ovarian primary cancers diagnosed in a family member, or
- Multiple primary or bilateral breast cancers in one family member, or
- Breast cancer in a male relative, or
- Ashkenazi Jewish background and one or more relatives diagnosed with breast cancer or ovarian cancer at any age, or
- Family member identified with detectable mutation

NOTE: These criteria were adapted from the American College of Medical Genetics,[8] "Clues which increase the likelihood that a cancer-susceptibility mutation is present in a family."

TABLE 2
Descriptive Data of Study Participants

	All Participants		NIR		IR (±EFR)	
	No.	%	No.	%	No.	%
Total	1238		890	71.9	224	18.1
No FH[a]	744	60.1	668	75.1	74	33.0
Any FH[b]	482	38.9	212	23.8	149	66.5
1° FH[c]	173	14.0	26	2.9	116	51.8
EFR	175	14.1			67	29.9
IR & EFR	67	5.4				
EFR only	108	8.7				
0 biopsies	985	79.6	760	85.4	121	54.0
≥1 biopsy	250	20.2	127	14.3	103	46.0
Age at intake						
Mean	50.05		48.62		57.75	
Range	21–83		23–82		40–83	
5-yr Gail Risk						
Mean	1.24%		0.96%		2.52%	
Range	0.0% – 7.6%		0.0% – 1.6%		1.7% – 7.6%	
Lifetime Gail Risk						
Mean	10.61%		9.49%		14.57%	
Range	2.0% – 41.2%		2.0% – 20.9%		3.5% – 41.2%	
5-yr Gail Risk						
<0.5%	82					
0.6% – 1.0%	452					
1.1% – 1.6%	423					
1.7% – 2.0%					87	
2.1% – 3.0%					92	
3.1% – 4.0%					28	
4.1% – 5.0%					10	
>5.0%					7	

IR: Increased Risk (Gail 5-yr risk >1.6%); EFR: Extended Familial Risk (meeting criteria of Table 1); NIR: Not at Increased Risk (Gail 5-yr risk <1.7%, no EFR).

[a] No FH: No family history of breast or ovarian cancer reported.

[b] Any FH: Any family history of breast cancer reported.

[c] 1° FH: First-degree relative diagnosed with breast cancer reported.

TABLE 3
Completion of "At Risk" Consultations

	Number	% Of "At Risk" Participants (n=332)[a]
Completed risk assessment consultations	111	33.4
IR only:	54	
IR & EFR:	30	
EFR only:	27	
Unlikely tamoxifen benefit[b]	44	13.3
No Response	180	54.2
IR +/- EFR	159	
IR only	51	
IR & EFR	34	
EFR only	74	
Unconfirmed information[c]	21	
Withdrawal from study	17	5.1
By participant	6	
From breast cancer diagnosis	6	
Other	5	

IR: Increased Risk (Gail 5-yr risk >1.6%); EFR: Extended Familial Risk (meeting criteria of Table 1); NIR: Not at Increased Risk (Gail 5-yr risk <1.7%, no EFR).

[a] All participants classified as IR and/or EFR

[b] For these participants, although IR, the risk of tamoxifen preventive therapy was likely to outweigh benefit, based on age and level of risk.

[c] Possible IR or EFR, but unable to confirm with participant: questionable family history or personal history (e.g., biopsy status) from survey response

TABLE 4
Emotional/Psychological Responses to Risk Assessment

	N[a]	Anticipated[b] (% Yes)	After RA[b] (% Yes)	P
All participants				
More confident	340	87.6	93.8	.005
More anxious	226	14.2	2.2	<.001
Less anxious	234	56.4	76.9	<.001
Relieved	252	65.1	80.6	<.001
Depressed	219	5.5	0.9	.007
A heightened sense of personal empowerment	269	74.3	72.5	.624
Like a more active participant in my future health care	325	97.8	92.6	.002
That this assessment should be included as part of regular screening	374		93.3	
NIR participants				
More confident	277	87.0	94.2	.004
More anxious	190	14.7	1.6	<.001
Less anxious	195	53.8	78.5	<.001
Relieved	209	64.1	83.3	<.001
Depressed	187	5.3	1.1	.019
A heightened sense of personal empowerment	223	72.6	71.3	.752
Like a more active participant in my future health care	265	97.7	91.7	.002
That this assessment should be included as part of regular screening	299		94.6	
IR &/or EFR participants completing RA consultation				
More confident	41	92.7	90.2	1.0
More anxious	22	13.6	4.5	.607
Less anxious	27	63.0	63.0	1.0
Relieved	26	65.4	61.5	1.0
Depressed	21	4.8	0	1.0
A heightened sense of personal empowerment	31	80.6	80.6	1.0
Like a more active participant in my future health care	41	97.6	95.1	1.0
That this assessment should be included as part of regular screening	48		89.6	

RA: Risk Assessment; IR: Increased Risk (Gail 5-yr risk >1.6%); EFR: Extended Familial Risk (meeting criteria of Table 1); NIR: Not at Increased Risk (Gail 5-yr risk <1.7%, no EFR).

[a] Includes only those respondents answering both the pre-RA and post-RA question.

[b] Percentage of respondents answering yes to the question "In regards to my personal breast health, upon completing this individual assessment I feel:" (or "…I anticipate that I may feel:")…