Short Communication

Predictors of Participation in Genetic Research in a Primary Care Physician Network

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Abstract
This study evaluated the process of recruiting women from a primary care physician network into a study of genetic counseling for breast cancer. It also investigated predictors of women’s interest in participating in genetic counseling research. Women were recruited in three stages: (a) via an initial contact letter; (b) a telephone screening survey; and (c) a mailed baseline questionnaire. We performed a logistic regression with participation as the outcome. We sent 4690 initial contact letters and conducted 2081 telephone surveys to recruit 340 participants. Number of relatives with cancer, higher interest in taking a genetic test for breast cancer, and lower degree of worry about cancer were strong predictors for women’s participation. Recruitment data showed interest in a study on genetic counseling for breast cancer risk. However, interest decreased as study requirements increased. Participation in genetics-related studies is related to psychological differences that must be considered when generalizing findings.

Introduction
Genetic testing for breast cancer susceptibility, a new method of gaining information about one’s risk for breast cancer, is now available to the general public (1, 2). There are several somewhat inconsistent recommendations as to what the criteria for genetic testing referrals should be, making clinical decisions difficult (3).

Several studies have been published on uptake or potential uptake of genetic testing, mostly in high-risk or clinical samples (4–11). These studies indicate that psychological variables, such as perceived risk, were consistently important predictors of consideration of uptake. However, there may be bias in the recruitment of participants to studies of genetic counseling and testing (12), and these biases could affect outcomes.

A primary care network provides a useful setting for this research. Currently, genetic testing for cancer risk is offered through physician referral. Indeed, women who are interested in testing might contact their primary care physician to obtain a referral for genetic testing, rather than contacting a geneticist or oncologist (13). Recruiting for studies within a primary care physician network could help estimate the potential bias in studies of genetic education, genetic counseling, and genetic testing in this setting.

This paper has two goals. First, we described and evaluated the process of recruiting women from a primary care physician network into a study on genetic counseling for breast cancer risk. We presented participation and interest at three stages of the recruitment process. The second goal was to investigate predictors of women’s study participation. We investigated psychological factors that distinguished between women who participated or did not participate in a research project about genetic counseling for breast cancer risk.

Materials and Methods
Participants
Women were recruited through the largest network of primary care physicians in Washington state over a period of 11 months. The network maintains a computerized, financially based database of all of its 500,000 patients in the Seattle metropolitan area that captures information including age, sex, name, address, and phone number. The network is organized in six regions with more than 30 clinics. We selected two regions containing 10 clinics and received a list of all managed care patients who had a paid claim within the last year to get contact information that was the most up-to-date. We excluded women covered by Medicare or Medicaid because these agencies are likely to have different policies on genetic counseling and genetic testing compared with commercial health plans.

Study Procedures
For recruitment, we sent randomly selected women a letter briefly describing the study and offering the opportunity to participate in a study providing genetic counseling for breast cancer risk. The letter requested the woman’s permission to contact her by phone and provided a number to call to remove her name from the contact list. After 10 days, study staff called women who had not declined participation and asked them to complete a brief telephone survey consisting of eligibility criteria, demographic information, and questions on perceived risk, cancer worries, and intentions to obtain genetic testing. Women were eligible to continue in the study if they were between 18–64 years of age, had no personal history of breast or ovarian cancer, had not obtained genetic testing for cancer risk, lived within 60 miles of the Fred Hutchinson Cancer Research Center, and planned to live there for at least 1 year, had a phone, spoke English, were literate, were a patient in the network, and were covered by a commercial health plan. All participants were asked to participate in a randomized trial of genetic counseling for

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breast cancer risk in which they would receive genetic counseling for breast cancer risk and be informed of testing if they expressed interest and were appropriate candidates. Upon completion of the brief telephone survey we mailed all eligible and interested participants a 45-min, self-administered baseline questionnaire and a consent form. Women were asked to return the completed questionnaire and the signed consent form in a postage-paid envelope within 1 week. This study was approved by the investigational review boards of the Fred Hutchinson Cancer Research Center and of the Providence Medical Group.

Measures
The telephone screening survey included the following measures relevant for the present analyses. All variables were used as continuous variables in the regression analyses.

Background Data. We measured age in years. Number of relatives with cancer was measured by asking, “How many of your blood relatives, including distant relatives, have had cancer?” with the answer choices, “2 or more,” “1,” or “0.”

Perceived Risk. We modeled a question about perceived risk for breast cancer after Diefenbach et al. (14) Specifically, the question was, “What do you think your risk is for getting breast cancer someday?” Answer categories were “very low,” “low,” “medium,” “high,” and “very high.”

Perceived Carrier Status. We measured perceived chance of being a carrier with a single item: “In your opinion, what do you think the chances are that you have an altered breast cancer gene?” Answer choices were “no chance,” “small chance,” “medium chance,” “high chance,” and “definitely have an altered breast cancer gene.”

Awareness of Genetic Testing. We introduced genetic testing for breast cancer risk by giving the information that, “such testing can tell some women about their inherited risk to develop breast cancer in the future.” Awareness of this test was assessed by asking, “How much have you heard or read about genetic testing for breast cancer risk?” with response categories of “almost nothing,” “relatively little,” “a fair amount,” and “a lot.”

Interest in Genetic Testing. We measured interest in genetic testing with a single item: “Would you be interested in taking a genetic test for breast cancer risk?” with the answer choices, “definitely not,” “probably not,” “probably yes,” and “definitely yes.”

Cancer Worry. To assess cancer worry, we selected a widely used scale developed by Lerman et al. (15) This simple scale measures the frequency of worry about cancer in different settings. The four questions asked were as follows: (a) “During the past month, how often have you thought about your own chances of developing breast cancer?”; (b) “During the past month, how often have thoughts about your chances of getting breast cancer affected your ability to perform your daily activities?”; (c) “During the past month, how often have you thought about your own chances of developing other cancers?”; and (d) “During the past month, how often have thoughts about your chances of getting breast cancer affected your mood?” The answer choices ranged from 1 (“not at all or rarely”) to 4 (“a lot”). We calculated a sum score of the four items to obtain a scale score. The minimum score is 4 and the highest score possible is 16. Reliability for these items was α = .60 in this study.

Statistical Analyses
To meet the first aim of this paper, we reported the stage yield and cumulative yield at all recruitment stages. All percentages for the stage yield refer to the total number of approaches at the respective recruitment stage. We used algorithms defined by the American Association for Public Opinion Research (16) to calculate response rates. To meet the second aim, we performed a logistic regression (17). Our initial sample for the regression were women who expressed initial interest in participation at the telephone survey. The outcome for this regression was participation in the randomized study, defined as returning the final survey and agreeing to join the study. Excluded from the regression were women who did not meet the eligibility criteria for the study. We used age, number of relatives with cancer, perceived risk for breast cancer, perceived chance of having an altered breast cancer gene, awareness of genetic testing, interest in taking the test, and cancer worry as predictors and interest in participation as the outcome measure. We used SPSS backward stepwise regression and computed odds ratios and 95% confidence intervals.

Results
We mailed 4690 letters to potential participants. The post office returned 26.6% of these letters because they had invalid addresses. All letters that were returned with a better address within the area were remailed. We did not remail 14.8% of the letters (55.4% of all returned letters) because we did not have a better eligible address for them. Only 65 (1.4%) of the total number of participants who were sent letters expressed disinterest at this stage and called the study line to prevent a call from occurring. The remaining 3933 participants (83.9%) were contacted in the second stage of recruitment, the telephone screening survey.

We attempted to call a total of 3933 potential participants. We were not able to reach 33.9% of the potential participants, mostly because we did not have a working phone number for them. We were able to speak with 64.1% of all women at this second recruitment stage: 2.3% did not complete the survey because they did not speak enough English, 10.5% were disinterested at this stage, and 51.3% completed this survey. The response rate was 83.0%. Of the 2018 women who completed the survey, 349 (8.9%) were ineligible because they did not meet the study criteria, 485 (12.3%) were disinterested, and 265 (6.7%) were both ineligible and disinterested. At the end of the telephone screening stage, 919 women (23.4% of all attempted calls) were eligible and continued to the next stage of recruitment, the mailed baseline questionnaire.

We mailed a study invitation letter to all 919 potential study participants. Ten did not reach their destination because women had moved out of the area or for other reasons. Eleven surveys revealed information that made the women ineligible: four were disinterested at this stage and seven did not fit the eligibility criteria. The total number of women participating in the randomized trial on genetic counseling for breast cancer was 340, or 37.0%.

A brief description of the final study population (n = 340) shows that our sample was mainly white (85.1%), which matches the data from the 1990 census for King County (85.2% white). More than half (59.5%) of the women in our sample were married, and 84.8% were either full-time or part-time used. Study participants were more highly educated (65.5% graduated from college or graduate or professional school) compared with census data, where only 37.6% had a college or graduate degree. The mean age was 41.1 years. Fifteen percent had at least one relative with breast cancer.

The logistic regression was conducted on all invitees (n = 919) minus the 21 participants who were ineligible or not found after screening. The model investigated differences between women who did (n = 340) or did not (n = 558) participate in the
study. Interest in taking a genetic test had a significant odds ratio, as did awareness of genetic testing. The odds of participating were approximately 1.4 times more likely for every unit increase in interest in genetic testing. Similarly, the odds of participating were 1.2 times more likely with every unit increase in awareness of genetic testing. Number of relatives with cancer was a statistically significant predictor where the more relatives with breast cancer, the more interest there was in participating. One unit increase in the relative number produced an increase in the likelihood of participation of 1.4 times. Perceived carrier status, perceived risk, and age did not significantly influence the decision to participate in the study. Cancer worry had a significant negative relationship with the outcome, indicating that women who expressed more cancer worry were less likely to continue participation in the study. For every 1 unit decrease in cancer worry, participants were 1.1 times more likely to participate (Table 1).

**Discussion**

In concordance with other studies, (4–6) our data showed that initially many women were generally interested in a study on genetic counseling for breast cancer. However, the data also showed that the closer women got to committing to counseling and the more tasks participants had to complete, the more women decided not to participate in the study. Specifically, at the first recruitment stage, very few women called the study line to remove their name from the contact list, indicating that very few were opposed to being contacted for the study. Note that some women may not have read the letter or that they did not want to take the time to call the study line, despite any potential disinterest in the study. This was supported by outcome data for the telephone survey, in which 10.5% of the women were not willing to complete the screening survey once contacted. However, most women were willing to complete the survey and many of those were interested participating in the study. The pattern changed when we mailed the self-administered baseline survey. Only 37% returned the baseline survey, despite expressed interest in the study at the screening stage. Reasons for this fairly low cooperation rate could be the length of the survey (45 min), the detailed questions about family history of breast cancer, or personal questions.

The second goal of this paper was to investigate psychological factors predicting women’s participation in a study on genetic counseling for breast cancer.

Number of relatives with cancer, interest in taking a genetic test, and awareness of genetic testing were significant predictors. These variables indicate greater interest, awareness, or attention to relevant issues and represent potential bias in study participants compared with the general public. An interesting finding was that higher cancer worry scores meant less likelihood of participation in the study. Although the effect is small, this finding indicates that those women at greatest worry exclude themselves from studies, again representing possible bias.

There are some limitations to our study. We had no access to information about women who declined participation at the initial contact letter mailing or about women who were not willing to complete the screening survey. Our study sample only included women who were covered by a commercial health plan. We did not have data on women over 65 years of age, women who were covered by Medicaid, or women without health insurance.

Recruitment data from a study on genetic counseling for breast cancer risk might give us valuable information on women’s interest in and estimates of uptake of genetic testing. Women were approached and told about the possibility of being in a study that would provide genetic counseling and possibly testing. Data from this study indicates that initial interest is very high among in a sample of female patients of a primary care physician network, but actual participation in the study is much lower. We, therefore, hypothesize that actual uptake of genetic testing for breast cancer will be much lower than initial expressed interest, a finding supported by studies of the uptake of testing for Huntington’s disease.

**References**

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