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ABSTRACT

Even though mammography has been proven to be effective in reducing breast cancer mortality this simple screening measure is underutilized by women in the general population as well as by women who are at high-risk. The effect of a reminder telephone call intervention has not been studied in this high-risk population where the need for compliance is crucial. The hypothesis for this study is that a simple reminder telephone call will significantly increase mammography frequency in high-risk women compared to a control group. Currently, 428 women have consented to participate in the study. Interestingly, 332 (76%) reported obtaining annual mammograms already. Therefore, only subjects who were considered non-compliant (n=32) were randomized to the intervention or control group. Sixty-four (15%) of the women who responded declined participation. Reminder and follow-up telephone calls have been initiated on the 32 women randomized to the study. An interim analysis was not conducted due to the small number of women in each arm and varying months that mammograms were due. It is anticipated that the final year will provide adequate data to conduct an analysis on the effectiveness of a simple reminder telephone call on mammography compliance in this group of high risk women.

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Introduction

Women who are part of a hereditary breast ovarian cancer (HBOC) family are at an increased risk for developing breast cancer much earlier than the general population. In many families the breast cancers occur 10-20 years earlier than the general population. Therefore, women who have a first degree relative with breast cancer, but have not been affected with breast cancer themselves are recommended to follow intense screening recommendations starting at the age of twenty-five. These screening recommendations consist of monthly self-breast examination (SBE), bi-annual clinical breast exams (CBE), and annual mammography. Mammography has been proven to reduce breast cancer mortality and morbidity when followed as recommended. According to Shapiro et al (1974) breast cancer screening demonstrated a 30% mortality reduction among all intervention women, of whom 65% obtained a mammogram after being mailed recommendations and telephone follow-up. Even though mammography decreases mortality and morbidity, it is still be underutilized by women in the general population as well as by high-risk women. Rawl (2000) stated although initial mammography utilization rates for women over 50 in the general population are high, compliance with regular, repeat mammograms is quite low. "Evidence indicates that although first-degree relatives of breast cancer cases are at increased risk of developing the disease themselves, they may be underutilizing screening mammography" (Bastani, 1999). Findings of a recent study conducted by Tinley, et al (2003) has shown women who are part of a HBOC family with an identified BRCA1 or BRCA2 mutation are not following the recommendation of annual mammography. Eighty-eight percent of the women who tested positive for a known BRCA1 or BRCA2 mutation and received genetic counseling with result disclosure were found to be following annual mammography according to Tinley's findings. However, only 66% of women in these same families who had a first degree relative affected with breast or ovarian cancer, but did not know their genetic status were following annual mammography. Annual mammography compliance was still low in these high-risk women despite being educated about their high risk and provided with the recommendation to start annual mammography at age 25. Several intervention studies have been conducted to determine if simple strategies such as a reminder letter or reminder telephone call increase mammography rates. Bastani (1999) found that a reminder letter had an impact on women who had a first degree relative affected with breast cancer. However, Bastani found no effect among women less than 50 years of age and a fairly large effect (20% advantage) among women older than 50 years of age. Taplin, et al (2000) reported that women who received a reminder call were more likely to get mammograms (HR = 1.9; 95% CI = 1.6-2.4) than women who received reminder postcards. Taplin also compared the effect of a motivational call compared to a simple reminder call. It was determined a simple reminder call was just as effective as a more time-consuming motivational call. Mohler, (1995) found reminder telephone calls made by medical assistants were cost-effective and had a significant effect on promoting mammography compliance.

Body

Women who are part of a HBOC family and have a first-degree relative with breast or ovarian cancer are at a high risk for developing breast cancer. Therefore, it is vital these women adhere to the recommended screening measures, inclusive of annual mammography beginning at age twenty-five. A simple reminder telephone call from a receptionist may promote increased compliance in mammography among these women. The hypothesis for this study is that a simple reminder telephone call will increase mammography frequency in high risk women compared to a control group of high risk women who will not receive a reminder telephone call.

One-thousand and fifty-eight women were identified as being eligible for the study and were therefore invited to participate in this research study. Four-hundred and twenty-eight (40.5%) responded and 630 (59.5%) did not respond. Of the 428 women who responded, 332 (78%) reported that they were already compliant with annual mammography and had been for at least the past two years. Only 32 (7%) women who responded reported that they were not compliant with annual mammography. Therefore, these 32 women were randomized to either the intervention or control group. Demographic information on these 32 women is provided in Appendix 1. Sixty-four (15%) women declined participation in the study. Twenty-seven of these women who declined did not provide a specific reason, 15 had undergone a prophylactic bilateral mastectomy, 6 had developed breast cancer, and 6 did not have health insurance to cover the annual mammogram.

Reminder and follow-up telephone calls have been initiated on the 32 women randomized to the study. Since the actual number of women who have received a reminder telephone call and follow-up call (n=4) in the intervention group is small, a comparison analysis was not conducted at this time.

Key Research Accomplishments

Tasks as described in the approved statement of work are on target.

- Task 1: Development of Study Tracking, Months 1-2
 - a. A tracking system in Excel has been created to track all subjects who were invited to participate in the study.
 - b. All eligible subjects were identified from the Hereditary Cancer Institute database.
 - c. A separate excel spreadsheet was developed to track the randomized subjects as to their mammogram due month so that a schedule of reminder and follow-up telephone calls can be followed.
 - d. A consent form and Healthcare Insurance Portability and Accountability (HIPAA) form were developed according to institutional and federal regulations.
 - e. An invitation letter was developed which provided a brief description of the study.
 - f. Institutional Review Board (IRB) approval was obtained for the study, consent and HIPAA form.
 - g. Training of the research assistant was conducted so that reminder and follow-up telephone calls are conducted in a consistent and accurate manner.

- Task 2: Recruitment of Eligible Subjects, Months 2-5
 - a. All eligible were invited to participate and were mailed an invitation letter, our IRB approved consent form and HIPAA form along with the Pre-Intervention Assessment (PIA) questionnaire.
 - b. Follow-up letters were mailed to 778 individuals who did not respond to the initial invitation letter. When an adequate number of responses were received, it was noted that the majority of the women consenting to participate already reported themselves as being compliant with annual mammography for at least the past two years. Therefore, only non-compliant women were randomized to the study. Approval for this change in protocol change was obtained from the Department of Defense.

- c. Another Excel spreadsheet was developed to enter all of the PIA information on the subjects who responded to the invitation letter.
 - d. As mentioned in 2b, only women who stated that they were not compliant with annual mammography for at least the past two years (n=32) were randomized to either the intervention or control group.
 - e. A schedule was established in Excel as to when each subject randomized to the study would receive their reminder and/or follow-up telephone calls.
- Task 3: Conduct Scheduled Reminder and Follow-Up Calls, Months 5-22
 - a. Reminder telephone calls have been conducted as scheduled. To date, 4 women in the intervention group have received a reminder and follow-up telephone call, 2 have received only the reminder telephone call.
 - b. Follow-up telephone calls have been conducted as scheduled for women in the intervention and control groups. To date, 6 women in the control group have received a follow-up telephone call.
 - c. The PI has continually monitored the research assistant and data entry for the study. Both the research assistant and data entry person have come to the PI for questions and clarification throughout the study, which were addressed and resolved.
 - f. Annual report is written and submitted.

Reportable Outcomes

In addition, this research study design and current status have been presented at two conferences via a poster presentation:

- International Society of Nurses in Genetics Annual Conference held October 23-26, 2004 in Toronto, Canada.
- Era of Hope 2005, Department of Defense held June 8-June 11, 2005 in Philadelphia, PA.

Conclusion

So far this study has provided the PI with very valuable experience in conducting a randomized study and the details required to carry out the work. Through mentorship from Drs. Henry Lynch and Patrice Watson the PI has gained invaluable knowledge and experience. The final year of this study will provide the PI with the experience of conducting a statistical analysis on the data provided in the study thereby advancing her training for a career in clinical breast cancer research. In addition, it is hopeful that the simple intervention of a reminder telephone call will be determined to significantly increase mammography compliance in high-risk women who have reported themselves as being non-compliant. If the hypothesis is not supported, then additional intervention measures will need to be explored and researched in order to increase mammography compliance in these high risk women.

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Appendix 1: Demographics of Randomized Subjects (n=32)

Age (years)	43.6 (34-79)
Race (Caucasian)	100% (32/32)
Education Level (some college+)	84% (<high school graduate-postgraduate)
Have Health Insurance	94% (30/32)
Household Income (US\$)	35,001-50,000 (<25,000->75,000)