DGIM Project Summary

Name of Project: Breast Cancer Risk Reduction in Primary Care Clinics: A Bilingual Intervention for Women and Physicians & Breast Cancer Risk Reduction: A Patient-Doctor Intervention

Investigator(s). (Include phone numbers and email address, indicate PI and primary contact)

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Research question(s):

We propose to conduct a randomized controlled trial to evaluate the effectiveness of a tablet computer-based breast cancer risk education intervention (BreastCare) to: a) facilitate discussion of breast cancer risk reduction practices, b) improve patient-physician communication of breast cancer risk, and c) improve patient knowledge about her individual risk of developing breast cancer.

Specific hypotheses to be tested in future randomized controlled trials of the intervention are:

1. Patient acceptability: Women participating in the BreastCare intervention group will indicate high rates of satisfaction with the format and content of the intervention.

2. Impact: Women participating in the BreastCare intervention group will report greater participation in patient-physician discussion of breast cancer risk, have increased knowledge and understanding of risk reduction options, and have more up-to-date mammography screening as compared to those in the comparison condition.

To test the hypotheses, we have identified two specific aims.

Aim 1: To conduct formative research, leading to the development and pretest of the tablet computer-based BreastCare intervention. This Aim was completed.

Aim 2: Assess the effectiveness of the tablet BreastCare intervention by conducting a randomized controlled trial at GIM primary care clinics over a 12- to 14-month period.

   a) Every 4 weeks, randomize clinics to either the intervention or comparison condition.

   b) Conduct a baseline telephone survey among women in the intervention and comparison groups.

   c) Implement the BreastCare intervention among 460 women (Asian, Black, Latina, White), age 40 to 74.

   d) Implement the comparison condition among 460 women (Asian, Black, Latina, White), age 40 to 74.

   e) Conduct a follow-up telephone survey and electronic chart reviews among women
in the intervention and comparison groups.

f) Conduct a self-administered feedback survey among intervention physicians.
g) Among intervention and comparison groups, measure primary outcomes: breast cancer risk knowledge, accurate perception of risk, receipt of appropriate recommended risk reduction actions based on risk, and up-to-date screening.

Brief Background/Significance:

Despite the availability of well-established tools for risk assessment and expanding options for risk reduction, these are not optimally integrated into clinical practice or tailored to the needs of diverse populations. The proposed intervention has the capacity to reduce breast care incidence and mortality by facilitating the diffusion of knowledge and empowering women with personalized information about their risk and risk reduction options and facilitating discussion with their physicians. The BreastCare intervention will provide a time-efficient, systematic strategy to bring breast cancer risk reduction to the forefront of care.

Inclusion/exclusion criteria (list)

INCLUSION
• Women who visit the GIM practices at UCSF and SFGH during the study period
• Age 40-74
• Self-identify as African American, White, Latina, or Asian
• Speak and read English, Spanish, or Chinese/Cantonese
• Have no history of breast cancer or ductal carcinoma in situ

EXCLUSION
• Women whose physician object to their participation in the study

Method of contact/recruitment (be specific)

Potentially eligible GIM clinic patients who are scheduled for an appointment in three weeks will be mailed an introductory letter describing the study and providing multiple methods to opt-out (phone, email, postcard).

One week before their appointment, a research assistant will call the patient to ask if they would like to participate. If the patient agrees, she will complete a 15-minute baseline phone survey. Patients randomized to the intervention condition will be asked to come 15 minutes early to their appointment to complete a computerized breast cancer risk assessment. Patients randomized to the control condition will receive usual care.

At the appointment, intervention patients will meet with the research assistant, confirm their consent, and complete the 5-minute computer assessment. A paper report of the risk results will be given to the patient and a similar report will be put in her chart for her physician.

Within one week after the appointment, a research assistant will call the patient to complete a 15-minute follow-up phone survey.

At the end of the intervention we will email all participating physicians a 5-minute feedback survey.
Benefits/burden for participants (clearly identify potential for harm)

BURDEN
There are no physical risks to the participants in this study. The potential risks to all subjects are minimal as the research protocols involve only voluntary participation in telephone and computer surveys. Patients may experience minimal stress and loss of privacy during the surveys. The telephone and computer surveys will consist of general questions about the patient’s health, reproductive, and family history, as well as some demographic questions. However, all efforts will be made to maintain patient confidentiality. Given the content of these surveys, the risks to patients are minimal.

BENEFIT
Patients who participate in this study will receive personalized breast cancer risk assessment feedback and information. This feedback will also include important information and recommendations for breast cancer risk reduction. In addition, patients will have the opportunity to use the feedback to discuss their risk and their risk reduction options directly with their physicians.

Any benefits or burden to DGIM practitioners?

Patients in the intervention group may have an increased awareness of their personal breast cancer risk. This has the potential to affect the manner in which clinic visits are typically performed (e.g. increased breast cancer risk discussion). This could be viewed as a benefit and/or a burden to DGIM practitioners.

Timeline for recruitment (projected start and stop dates)

Recruitment: April 2011-April 2012

Funding source

California Breast Cancer Research Program & Susan G. Komen for the Cure

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular)

All of the Co-Investigators for this study are from DGIM. We will not actively advertise or recruit collaborators, but if there is interest, there can be the opportunity for residents or fellows to be involved in the interviews, qualitative analysis, and/or results dissemination.

Do you agree to notify us when recruitment is completed?

Yes

Date form completed
February 7, 2011
ATTACHMENTS:

Recruitment and Consent Materials:
1. Patient Recruitment Letter
2. Patient Opt Out Postcard
3. Patient Phone Consent
4. Physician Consent

Instruments and Patient Materials:
5. Patient Baseline Phone Survey
6. Patient Follow-up Phone Survey
7. BreastCare computer survey (ppt example)
8. Library of Messages for Patient Reports
9. Library of Messages for Physician Reports
10. Lower Your Risk_Patient Info Leaflet
11. Genetic Counseling_Patient Info Leaflet
12. Risk Factors_Patient Info Leaflet
13. Physician Online Feedback Questionnaire