DGIM Project Summary

**Name of Project:** Breast Cancer Risk Reduction in Primary Care Clinics: A Bilingual Intervention for Women and Physicians

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

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**Research question(s):**

We propose to conduct formative research, leading to the development and pretest of a tablet-PC based breast cancer risk education (BCRE) intervention 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 BCRE intervention group will indicate high rates of satisfaction with the format and content of the intervention.

2. **Impact:** Women participating in the BCRE 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-PC based BCRE intervention. This will be completed by:

a) Reviewing existing web-based breast cancer risk assessment tools
b) Conducting patient semi-structured interviews with patients identified from the General Internal Medicine (GIM) outpatient practices at UCSF with 28 patients from seven ethnic/language groups (white, African American, Chinese-speaking Chinese, English-speaking Chinese, English-speaking Asian, Spanish-speaking Latino, and English-speaking Latino)
c) Organizing expert physician panels that evaluate the content of the tablet-PC based BCRE intervention
d) Developing BCRE module and control prototypes
e) Pre-testing the BCRE tablet-PC prototype among 28 patients at the GIM outpatient practices from the same seven ethnic/language groups.

**Aim 2** will consist of a randomized controlled trial of the intervention and will be submitted for review once the tools have been developed.

**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 BCRE 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 40-75
• Self-identify as African American, White, Latina, or Asian
• Speak English, Spanish, or Chinese
• 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)

Patients for the semi-structured interviews (Aim 1.b) and the pre-testing (Aim 1.e) will be recruited from patient electronic appointment records provided by the GIM outpatient practices. We will contact the GIM physicians of 120 potentially eligible patients by mail to obtain approval for participation. Physicians will be provided with a copy of the patient information sheet to give to patients who request more information regarding the study. Approximately two weeks later, we will send eligible women invitation letters and opt-out postcards. Two weeks after the mailing, a researcher will call all patients who have not declined participation, determine their eligibility, and for those who agree, schedule an interview at a time and place convenient for the participant.

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 in-person interviews. Patients may experience minimal stress and loss of privacy during the patient semi-structured interviews, and pre-test interviews. The patient semi-structured interviews will consist of general questions about the presentation of risk information, knowledge of risk reduction options, and information they would like to receive. Patients will also be asked to evaluate existing risk education tools. Questions during the pre-test interviews will be asked to assess the design and comprehension of the patient feedback report. However, all efforts will be made to maintain patient confidentiality. Given the content of these interviews and the intervention, 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 who pre-test existing and pilot risk calculators 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)

Patient Semi-structured interviews: May 2010 – August 2010
Patient Clinical Pre-test: December 2010 – March 2011

Funding source

California Breast Cancer Research Program & Susan G. Komen Foundation

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

April 6, 2010