**DGIM Project Summary**

**Name of Project:**
*Redes en Acción*: National Patient Navigator Intervention Study

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

PI (Primary Contact): Eliseo J. Pérez-Stable, M.D., eliseops@medicine.ucsf.edu

Co-I: Anna Nápoles, Ph.D., anna.napoles-springer@ucsf.edu

**Research question(s):**
Does a “patient navigator” program that uses a trained community health worker to assist Latina patients in utilizing cancer care services:
1) Improve adherence to recommended clinical follow-up for an abnormal mammogram;
2) Reduce the time lag between an abnormal breast cancer screening result and confirmatory tests and initiation of treatment;
3) Improve patient satisfaction with the health care system experience

**Brief Background/Significance:**
Latinas face many barriers that contribute to non-adherence and/or delay in diagnosis and treatment after an abnormal or suspicious screening result. These barriers include reduced access to care; lack of insurance and social support; cost; mistrust; language issues; lack of transportation and child care; knowledge and health beliefs; competing health, family, and work responsibilities; psychological distress; cultural factors; poor physician-patient communication; and system inefficiencies. Often, due to a variety of reasons, patients will become frustrated or discouraged and chose to discontinue the breast care they need. And, even though, the majority of women lost to follow-up after an abnormal mammogram will eventually return to the system, they return with a more advanced stage of the disease.

Patient navigation is a model that has been used to reduce cancer-related health disparities among low-income, underserved minority women by reducing barriers, improving adherence, and timely diagnosis and treatment. Since the establishment of the first navigation program at Harlem Hospital, more than 200 cancer programs have implemented some form of patient navigation, with support from private foundations and local efforts. Unfortunately, there is a paucity of studies published in peer-reviewed journals documenting patient navigation effectiveness. Observational studies have reported improvement in screening rates, adherence, timeliness in follow-up, diagnosis and treatment, lower breast cancer stage at diagnosis, and higher patient satisfaction.

**Inclusion/exclusion criteria (list)**

**Inclusion criteria.**
- For baseline data chart review: through medical records audits, we will identify a total of 50 women meeting the same eligibility criteria for the intervention, who received their qualifying abnormal mammogram in the preceding year.
- For the intervention: 50 English and Spanish speaking female Latinas 18 years of age and older who received screening mammography at UCSF-Mt. Zion Center for Women's Imaging or San Mateo Medical Center/Mills-Peninsula Breast Health Services and receive mammography screening results specified as BIRADS 0, 3, 4 or 5, will be offered participation in the study. Ethnicity will be established by self-report for women in the intervention.
- For the key informant surveys: 1) health care facility administrative or clinical staff member; 2) familiar with the Patient Navigation intervention; 3) employed at the health care facility during the study period. We will survey approximately 6 key informants.
Exclusion criteria. Women who do not self-identify as Latina, are younger than age 18, and have mammography screening results classified as other than BIRADS 3, 4, or 5 will be excluded.

Method of contact/recruitment (be specific)

1. Recruitment of patients. After the Project Director identifies potentially eligible women through radiology records, the Patient Navigator (for SMCC site) or Project Director (for UCSF site) will work with a clinic nurse, radiology technician, or other health care professional to review patient mammography screening results to identify potentially eligible participants. When the health care professional conveys the results of the mammogram by telephone or in-person to the patient, she will inform the patient about the study. If the patient is interested in the study and in receiving patient navigation services to help resolve the abnormal mammogram, the health care professional will ask the patient’s permission to release her name and phone number to the PN. The patient will also receive a low-literacy, bilingual information sheet (Attachments 1A & 1B) about the study with the delivery of her mammogram results. Patients who are willing to participate will be referred to the PN. Patients who agree to participate will be scheduled for an initial visit with the PN either the same day that the patient agrees if the PN is on-site, or at a later time via a phone call from the PN. Patients who do not agree to participate will be administered the Refusal Survey by the PN or the clinic nurse.

2. Recruitment of key informants. Through her on-site visits and interaction with staff, the PN will identify administrative or clinical staff who are familiar with the PN program and would be able to provide feedback on the program. The Patient Navigator and Project Director will select jointly a convenience sample of 3 key informants from each site for a total of six interviews. Key informants will be identified and selected according to these three screening criteria to be administered verbally by the Project Director: 1) administrative or clinical employee of the intervention site; 2) has interacted with patients who have received services from the Patient Navigator or staff members who have worked directly with the Patient Navigator to coordinate navigation services; 3) self-assesses themselves as able to provide feedback on the utility of the patient navigation services. During an on-site visit, the Project Director will verbally explain the key informant portion of the study to the potential participant, ask if they would be willing to participate, and is so, provide them with the survey to be self-administered, the consent form, and a postage-paid, self-addressed envelope for the return of the survey.

Benefits/burden for participants (clearly identify potential for harm)

Patients in this study will receive free patient navigation services. These services may include but will not be limited to identifying action items with nurses to facilitate/expedite resolution of breast health problems, performing prospective data collection to facilitate resolution of these medical problem(s), and resolving non-medical delays in evaluation. Participants from this study will not receive monetary compensation for their participation in this study.

This study involves minimum risks to participants. Participants will be asked to complete a patient survey; however, patients may feel sad or worried when they are asked about their personal or family history of cancer and about their feelings toward breast cancer. Therefore, patients may experience emotional discomfort in answering questions.

The PN will be properly trained to detect and manage such emotional discomforts of the patient. The PN will also be properly trained to refer participants to pastoral, palliative and psychological services within the community.
Any benefits or burden to DGIM practitioners?

The patient navigator will provide patient follow-up on behalf of DGIM practitioners. There should be no additional burden to practitioners, other than providing assistance to the PN or Project Director in identification of potentially eligible patients and informing them of the study via a flyer. The total number of women to be recruited will be about 25 for SMCC and 25 for UCSF over the course of a year.

Timeline for recruitment (projected start and stop dates)


Funding source

National Cancer Institute

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

Two DGIM faculty members are conducting the study. Fellows are welcome to assist with data analysis and manuscript preparation.

Do you agree to notify us when recruitment is completed?

Yes.

Date form completed

March 19, 2009

Submitted by:

Eliseo J. Pérez-Stable, M.D.
Anna Nápoles, Ph.D.