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TITLE: Increasing Adherence to Follow-Up of Breast Abnormalities
in Low-Income Korean American Women: A Randomized
Controlled Trial

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13. ABSTRACT (Maximum 200 Words) The purpose of this study is to design an intervention to assist Korean American women who have been identified with a potential breast abnormality through the Breast Cancer Early Detection Program (BCEDEP) and who have missed their first follow-up appointment (at risk women). Intervention activities will include reminder phone calls or home visits by a trained peer counselor to explain the importance of follow-up procedures, emotional support, help with transportation to follow-up appointments, translations, organizing care for children or grandchildren during medical appointments, and other assistance to overcome barriers to follow-up identified during the initial phase of the study. We will collect extensive process measures including number and type of intervention activities requested and delivered in order to estimate the feasibility for institutionalizing intervention activities. We will conduct chart reviews and a follow-up survey to evaluate the effectiveness of the intervention in increasing adherence to follow-up procedures. Human Subject approval for exploratory interviews with patients and providers was obtained from UCLA on 3/19/2003. Human Subject approval from the DOD is pending.				
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Introduction:

The purpose of this study is to design an intervention to assist Korean American women who have been identified with a potential breast abnormality through the Breast Cancer Early Detection Program (BCEDP) and who have missed their first follow-up appointment(at risk women). Intervention activities will include reminder phone calls or home visits by a trained peer counselor to explain the importance of follow-up procedures, emotional support, help with transportation to follow-up appointments, translations, organizing care for children or grandchildren during medical appointments, and other assistance to overcome barriers to follow-up identified during the initial phase of the study. We will collect extensive process measures including number and type of intervention activities requested and delivered in order to estimate the feasibility for institutionalizing intervention activities. We will conduct chart reviews and a follow-up survey to evaluate the effectiveness of the intervention in increasing adherence to follow-up procedures.

Body:

Recommendation for funding was received December 10, 2002. On January 10, 2003, the protocol for phase I of the study (exploratory semi-structured interviews with 20 Korean American women and 5 health care providers) was submitted to the UCLA IRB committee. An approval was received 3/11/2003. Dr. Maxwell submitted a detailed research proposal and the UCLA IRB approval to the DOD on 3/19/2003. Funding for this study was released 9/1/2003. The protocol received an initial review by DOD personnel which was sent to Dr. Maxwell on 5/17/2004. At this time, Dr. Maxwell is in the process of responding to the remaining concerns. No activities involving human subjects have been initiated.

The following activities listed in the Statement of Work have been completed:

Task 1:

As part of the exploratory phase of the study, we had planned to review 30 charts in order to learn more about women who do and do not undergo diagnostic follow-up procedures in a timely manner. We are planning to drop this plan for two reasons: (1) The DOD Human Subject expert questioned the value of the chart review, given the limited information that is found in the charts. (2) We have found in two recently conducted studies with KA women that involved chart reviews that chart information is indeed very limited and does generally not provide much information on why women may or may not comply with follow-up recommendations after an abnormal mammogram. Therefore, after discussing this issue within our research group and with KHEIR collaborators, we decided to drop the chart reviews in phase I of the study. We will submit this change to the original Statement of Work to the Grants Officer.

We developed discussion guides for telephone interviews with health care providers and with Korean women for the exploratory phase of the study (Phase I). These discussion guides have been attached.

Key Research Accomplishments:

We do not have to report any key research accomplishments since we are still awaiting DOD Human Subject approval.

Reportable Outcomes:

N/A

Conclusions:

N/A

References:

N/A

Appendices:

1. Original Statement of Work
2. Interview Guide for Health Care Providers (Phase I: Intervention Development)
3. Interview Guide for KA women (Phase I: Intervention Development)

Statement of Work

Task 1: Setup and Formative Research (Months 01-06)

- a. Develop chart review forms; develop discussion guides for semi-structured interviews (English and Korean, using standard translation procedures including back translations)
- b. Identify women who received a referral for follow-up procedures in the past 12 months from BCEDP logs. Conduct chart reviews (N=30) and telephone interviews (N=20) with these women (Angela Jo, Kim Young)
- c. Identify 5 health care professionals through participating sites and conduct semi-structured interviews (Maxwell, Jo, Young)
- d. Draft intervention components (strategies, scripts, materials) and assessment forms (intervention activity logs, needs assessment questions) - all materials in English and Korean language
- e. Hire and train 3 mature, English-Korean bilingual Korean American peer counselors
- f. Establish procedures to identify women who missed follow-up appointments on a daily basis
- g. Pretest intervention in 6-10 KA women, revise and finalize
- h. Establish randomization procedure

Task 2: Enroll subjects into randomized trial (Months 07-30)

- a. Identify eligible subjects (N=253 during the 2 year recruitment), randomize into the study and administer verbal informed consent to intervention subjects (choice of English or Korean).

Task 3: Conduct Intervention (Months 07-33)

1. Conduct telephone needs assessment and counseling for each newly enrolled intervention subject (N=86). Contact each intervention subject at least once every other week until completion of diagnostic follow-up/treatment. Offer intervention components as appropriate. Document all contacts, responses to needs assessment questions, intervention requests and activities.
1. Conduct alternative protocol for intervention subjects who cannot be reached by telephone.
2. After completion of the follow-up survey, provide intervention to women in the control group who did not complete follow-up procedures.

Task 4: Data Collection (Months 3-40)

- a. Collect and compile log sheets from contacts with intervention subjects (process measures) into a data base (months 7-35)
- b. Develop (draft, translate, back translate, pretest, revise) follow-up survey based on the Adherence Model (months 3-12)

- c. Hire and train interviewer(s) to conduct follow-up survey (months 12-13)
- d. Conduct post-intervention survey with all subjects (N=160) 6 months after referral for diagnostic follow-up. Administer verbal consent prior to conducting survey to subjects in the control group (months 13-40)
- e. Conduct chart reviews for all subjects (N=160) 6 months after referral for diagnostic follow-up (months 13-40)

Task 5: Data Management and Analysis (Months 1-42)

- a. Transcribe and translate into English audiotapes from semi-structured interviews.
- b. Analyze qualitative and quantitative data from Task 1.
For qualitative data analysis, summarize transcripts from semi-structured interviews, including key points and notable quotes (in English and Korean language) using standard procedures (Krueger 1994); compare and consolidate summaries prepared independently by two Korean speaking investigators (Drs. Jo and Kim); sort findings by the domains of the Adherence Model.
For quantitative analysis, tabulate findings from semi-structured interviews, including specific needs expressed, services requested and barriers and concerns voiced about follow-up procedures. Tabulate findings from chart reviews by adherence status.
- c. Set up data entry programs and enter information from intervention log sheets, needs assessments, intervention requests and activities (process measures)
- d. Set up data entry program and enter information from 6 month follow-up survey
- e. Set up data entry program and enter information from chart reviews
- f. Data management and cleaning will be ongoing
- g. Data analysis, preparation of annual reports and manuscripts.

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Interview Guide for Health Care Providers (Phase I: Intervention Development)

Interviewer: _____

MD ID: _____

Date: _____

OBJECTIVES

1. Determine the provider's standard office procedures or protocols on follow-up diagnostic procedures for breast abnormalities
2. Determine patients' adherence to follow-up diagnostic procedures from the provider's perspective
3. Identify predictors of adherence to follow-up diagnostic procedures among KA women with breast abnormalities
4. Identify barriers to adherence to follow-up diagnostic procedures among KA women with breast abnormalities
5. Identify culturally and linguistically sensitive methods of interventions to increase rate of adherence among KAs
6. Determine how specifically can the peer counselors help the KA women adhere to the follow-up breast diagnostics

Remind subject that s/he is free to decline to answer specific questions or to end the interview at any time without any negative consequences.

Questions

I would first like to ask you about Standard Office Procedures

1. What happens in your office when you identify a KA woman with a breast abnormality on a mammogram or in a clinical breast exam?
2. How are results and the need for follow-up communicated to her?
3. Who are the personnel responsible?
4. What is the time frame involved?
5. What strategies are used?
6. What reactions have you observed among KA women when they learn that they have a potential breast abnormality and require a follow-up procedure?

Now let me ask you about your opinion regarding adherence to follow-up procedures among KA women

1. Perceived current adherence rate
2. Perception of why the adherence rate is where it is (i.e. high or low)

Barriers to Adherence

What prevents KA Women from following-up?

Listen and prompt for:

A. Physician factors

1. Lack of time
2. Lack of adequate understanding on the protocols
3. Don't think it's important
4. Too complicated
5. Others

B. Administrative factors

1. No incentives
2. Inadequate financial support
3. No time
4. Inadequate or inefficient system
5. Others

C. Health care and structural factors

D. Other Factors

Predictors of Adherence

What would help KAs to get recommended follow-up procedures in a timely manner?

Listen and prompt for:

E. Physician factors

1. Having more administrative time
2. Having more knowledge on the follow-up protocols
3. Having more administrative assistance (i.e. more personnel)
4. Others

F. Administrative factors

1. Having adequate financial support
2. Developing a more efficient system
 - a. Probe what would make the system more efficient

3. **Having extra personnel**
 - a. **Probe role description**
4. **Others**

G. Structural factors

H. Other Factors

Intervention methods

1. What are some ways to encourage KA women to adhere to follow-up diagnostics?
Listen and prompt for:
 - A. **Having a peer counselor**
 - B. **Having someone who could translate**
 - C. **Giving reminders (probe what kind of reminders)**
 - D. **Others**

Peer Counselor

1. What are some ways that a peer counselor could help KA women with adherence to follow-up?
Listen and prompt for:
 - E. **Providing transportation**
 - F. **Providing translation**
 - G. **Providing answers to some of the questions that women may have**
 - H. **Providing psychosocial support**
 - I. **Others**

This completes our interview. Thank you very much for your time. Do you have any questions for me? [Answer any questions] Thanks again. Good bye.

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Interview Guide for KA women (Phase I: Intervention Development)

Interviewer: _____

Case ID: _____

Date: _____

OBJECTIVES

1. Assess what happened from the time of their initial clinic visit for breast cancer screening
2. Identify predictors of adherence
3. Identify barriers to adherence
4. Identify culturally and linguistically sensitive methods of interventions to increase rate of adherence among KA women
5. Determine how specifically the peer counselors might help the KA women adhere to the follow-up breast diagnostics

Remind subject that she is free to decline to answer specific questions or to end the interview at any time without any negative consequences.

Questions:

1. First, I would like to talk to you about the time when you had a mammogram at KHEIR.
 - A. What happened at the clinic when you went on _____ date?
 - B. Do you know the result of your breast screening exam?
Mammogram?
Clinical Breast Exam?
 - C. Was is normal or abnormal?
If abnormal, what was abnormal (i.e. CBE or Mammogram)?
How did you find out that your test/exam was abnormal?
Did you understand?
Were your questions answered?
 - D. After your initial visit, did you receive any phone calls or written messages from the clinic?
How many times did they contact you?
What did she/he/they say?

When the doctor said [repeat patient's words],
what did that mean to you?

2. Did you follow-up with what was recommended?

If yes, what helped you to follow up with what was recommended?

Listen and prompt for:

- Having received clear information from the doctor
- Having friend/family support
- Knowing that finding cancer early could mean cure
- Knew someone who had gone through the procedure
- Others

If no, what prevented you from following up with what was recommended?

Listen and prompt for:

- Not receiving clear information from the doctor
- Transportation issues
- Time/work interference
- Not knowing where the facility is
- Not knowing the language
- No one to baby-sit my kids
- Physically incapable
- Psychologic issues – too depressed or too anxious
- Fear of getting the cancer diagnosis (explore the kinds of fear)
- Worried about
 - The cost of the test
 - The cost of the possible surgeries and treatments
 - Having to upset or worry the family members
 - Not agreeing with the results or what the doctor told you (why?)
 - Wanted to get a second opinion
 - Wanted to try alternative/OM/acupuncture/herbal medicine first
 - Others

1. Intervention Methods

Now, let's think about what would help KA women like you to complete recommended follow-up procedures in a timely manner?

Listen and prompt for:

- Having a peer counselor
- Having someone who could translate
- Giving reminders (probe what kind of reminders)
- Others

If we were to train a KA woman to help you to complete recommended follow-up procedures, what kind of help should she provide to women like you?

Listen and prompt for:

Providing transportation

Providing translation

Providing answers to some of the questions that women may have

Providing psychosocial support

Others

IF WOMAN DID NOT COMPLETE DIAGNOSTIC FOLLOW-UP PROCEDURES,
ENCOURAGE HER TO DO SO.

This completes our interview. Thank you very much for your time. Do you have any questions for me? [Answer any questions] Thanks again. Good bye.