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Award Number: DAMD17-01-1-0238

TITLE: Tailored Communication to Enhance Adaptation Across the Breast Cancer Spectrum

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REPORT DATE: October 2005

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

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1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
01-10-2005	Annual	1 Oct 04 – 30 Sep 05

4. TITLE AND SUBTITLE
Tailored Communication to Enhance Adaptation Across the Breast Cancer Spectrum

5a. CONTRACT NUMBER

5b. GRANT NUMBER
DAMD17-01-1-0238

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Fox Chase Cancer Center
Philadelphia, PA 19111

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES
Original contains color plates: All DTIC reproductions will be in black and white.

14. ABSTRACT

Abstract is attached at following page.

15. SUBJECT TERMS
Tailored Cancer Communication

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	103	19b. TELEPHONE NUMBER *(include area code)*

ABSTRACT

The Behavioral Center of Excellence (BCE) in Breast Cancer was established to provide a comprehensive, multi-disciplinary approach for studying the process of, and methods for facilitating, successful adaptation in the context of breast cancer risk, treatment, and recovery. The four ongoing studies are derived from and integrated by a unifying theoretical framework, and are supported by four core facilities (i.e., Administrative, Communication, Genetic Testing and Bioinformatics Core). The four projects are: 1) development of an intervention to promote utilization of breast cancer risk assessment programs and adherence to screening recommendations among underserved African-American women; 2) use of a "teachable moment" and tailored communication materials to promote utilization of risk assessment and adherence to screening among daughters of diagnosed breast cancer patients; 3) the promotion of psychological and physical adaptation among breast cancer patients at the completion of active treatment(i.e., during the re-entry phase); 4) promotion of psychological adaptation among metastatic breast cancer patients. The overarching goal is to develop theoretically guided, tailored, and transportable breast cancer communications to enhance screening adherence, decision-making, and quality of life across the spectrum of disease (i.e., from risk through treatment to survivorship).

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DOD Progress Report, Project I
Understanding Breast Cancer Risk Assessment and Screening Behaviors Among the Underserved

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October, 2005

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INTRODUCTION

Breast cancer represents a serious health issue for African American women. Higher morbidity and mortality rates in this population may be due, in part, to lower uptake of breast cancer risk assessment and genetic counseling programs, as well as lower adherence to breast cancer screening recommendations (Miller & Champion, 1997). Yet, little information currently exists with respect to the psychosocial factors that facilitate participation in, and adherence to, available breast cancer risk assessment and screening programs. Further, there are no established intervention protocols to address the needs of this population. Guided by the research team's Cognitive-Social Health Information-Processing (C-SHIP) model, the overarching goal of Project 1 is to identify and assess barriers and facilitators to participation in breast cancer risk assessment and to adherence to breast cancer screening recommendations among African American women (Miller, 1995; Miller, 1996; Miller, Shoda, & Hurley, 1996; Miller, Fang, et al., 1999). These data will be used to develop and pilot test an intervention program to boost enrollment in breast cancer risk assessment programs and increase adherence to breast cancer screening guidelines among African American women.

The specific aims for Project 1 are as follows:

Aim 1: To develop a psychosocial assessment instrument, tailored to low-income African American FDRs of breast cancer patients, which assesses key psychosocial predictors of breast cancer surveillance behaviors (*Phase 1*).

Aim 2: To evaluate the psychometric nature of this questionnaire and to identify key longitudinal predictors (e.g., fatalism, attentional style) of participation in breast cancer risk assessment and of adherence to breast cancer screening recommendations (*Phase 2*).

Aim 3: To examine the feasibility and short-term impact of a cognitive-social intervention that is designed from Phase 1 and 2 data (*Phase 3*). Feasibility variables include number of recruitment calls needed, recruitment and attrition rates, level of satisfaction with the intervention, and degree to which women would recommend the program to others. Impact variables will include intention to pursue breast cancer risk assessment programs and adherence to breast cancer screening guidelines.

In Phase 1, we will conduct focus groups with African American FDRs of breast cancer patients (N = 30) to develop a psychosocial assessment of barriers and facilitators of participation in risk assessment programs and adherence to screening guidelines. We expect that low monitoring as well as a pattern characterized by low levels of knowledge about genetic risk and assessment programs, inaccurate risk perceptions, high fatalistic beliefs, low pros and high cons about risk assessment, and extremely high levels of emotional distress will emerge as important correlates of program interest and screening adherence. Phase 2 will be a longitudinal study with African American FDRs of breast cancer patients (N = 100) to evaluate the psychometric nature of this instrument and to identify prospective psychosocial predictors of intention/readiness to pursue breast cancer risk assessment and screening adherence. We hypothesize that high monitoring, as well as greater knowledge, higher risk perceptions, lower fatalism, higher pros and lower cons, and moderate levels of emotional distress will predict greater readiness to pursue risk assessment

and higher levels of screening adherence. In Phase 3, we will examine the feasibility and impact of an intervention for African American FDRs of breast cancer patients (N = 30) on interest in breast cancer risk assessment and screening adherence. We hypothesize that 75% of FDRs approached will agree to participate and that there will be a 20% attrition rate. Further, FDRs receiving this intervention will demonstrate greater interest in risk assessment program, as well as greater screening adherence.

Study findings will have applicability to enhancing current cancer prevention and control initiatives with underserved populations. This study will: 1) provide a theory-guided instrument for identifying women less likely to pursue risk assessment and adhere with screening guidelines; 2) identify a feasible, evidence-based approach to motivating breast cancer screening and participation in risk assessment programs among traditionally underserved women; and 3) provide information concerning the need for the simultaneous targeting and tailoring of interventions to promote decision-making about breast cancer assessment and adherence to surveillance behaviors. Overall, this study will provide important data for implementing breast cancer health-promotion interventions among underserved women on a broader scale.

BODY

During Year 1, we anticipated accomplishing Task 1 and initiating Task 2, as outlined in our Statement of Work. Task 1 involved refining a psychosocial familial risk questionnaire, tailored to low-income African American FDRs of breast cancer patients, that assesses key psychosocial correlates of interest in breast cancer risk assessment programs and adherence to breast cancer screening guidelines (*Phase 1*). We subdivided this task into the following sub-tasks:

a. Submit Protocol to Institutional Review Boards	(Month 1)
b. Recruit Focus Group Participants for Phase 1	(Months 2-3)
c. Conduct Focus Groups	(Month 4)
d. Analyze Focus Group Data	(Month 5)
e. Develop Assessment Instrument for Phase 2	(Month 6)

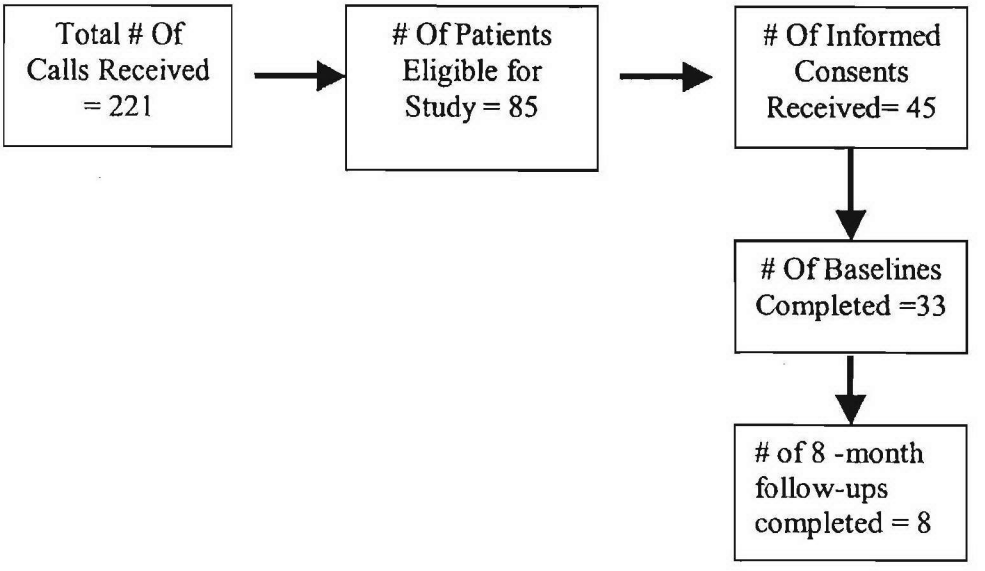
Task 2 involved evaluating the psychometric nature of the psychosocial familial risk questionnaire and identifying key longitudinal predictors of participation in breast cancer risk assessment and of adherence to breast cancer screening recommendations among female African American FDRs of breast cancer patients (N = 100; *Phase 2*). We subdivided this task into the following sub-tasks:

a. Submit Protocol to Institutional Review Boards	(Month 7)
b. Establish Recruitment Procedures/Staff Training for Phase 2	(Month 8)
c. Recruit Participants, Conduct Longitudinal Study	(Months 9-30)

To date, we have completed *Phase 1* of the overall project (i.e., Task 1, a-e). We have also submitted the protocol for *Phase 2* to the FCCC IRB for review and received approval (i.e., task 2, a) and began *Phase 2* data collection in the spring of 2004. Currently, recruitment efforts are being achieved by radio and newspaper ads that reach predominately African American women. The goal now is to continue subject recruitment and participation for Task 2.

Below, in Figure 1, we summarize our recruitment efforts for phase 2 of this project.

Figure 1: Summary of Recruitment Efforts (phase 2)



We have accrued 45 participants to date. Participants (only those who completed the baseline included) characteristics include:

Average age = 42
Median age = 42

Education
High School = 7
Some College = 16
Bachelor's Degree = 3
Graduate Degree = 7

We are in the process of devising a number of innovative recruitment strategies. The first approach is to recruit at IRB-approved local community churches serving predominantly African-American populations that Temple University Hospital serves. We have had success in utilizing faith-based sites as a channel to recruit participants in related studies. Second, we plan to submit an amendment to the IRB to recruit study participants through African-American sororities at Temple University (e.g., Delta Sigma Theta, Zeta Phi Zeta). Lastly, we have initiated contact with the local leader of the National Black Leadership Initiative on Cancer (NBLIC). The NBLIC is a 13-year-old outreach-based organization which had worked with at least 35 community-based organizations, including churches, schools, primary care medical practices, and civic organizations. Chapter volunteers have participated in a wide range of cancer awareness and prevention activities, conducted seminars, and served on committees for program planning and network development. Our aim is to partner with the NBLIC to reach

potential study participants and to provide relevant, culturally sensitive information with regard to breast cancer risk options to their constituents.

We have conducted focus groups with African American First-Degree Relatives (FDRs) of breast cancer patients (N = 27). Data from these focus groups have been used to develop a psychosocial assessment of barriers and facilitators of participation in risk assessment programs and adherence to screening guidelines. Further, guided by the Cognitive-Social Health Information Processing (C-SHIP) model, we are applying a qualitative approach to explore patterns of cognitive-affective profiles of African-American and their attitudes and beliefs about breast cancer risk and the options available to them. These qualitative data have been transcribed and will be scored and analyzed to delineate and describe the individual's risk-related responses, in terms of their patterns of: risk perceptions, outcome efficacy of risk assessment procedures, risk-related distress, values related to the uptake of prevention and screening behaviors, and self-regulatory strategies to cope with the challenges associated with hereditary risk. These qualitative data will be used to enrich our understanding of the quantitative dataset by specifying more clearly the content of at-risk individuals' concerns. This is a unique data set in that it combines qualitative and quantitative approaches to the understanding and analysis of how minority women process complex information related to hereditary risk to breast and ovarian cancer, and the decisions and behaviors that ensue over time.

KEY RESEARCH ACCOMPLISHMENTS OF PHASE TWO

- Attend and participate in monthly Center meetings.
- Recruited 45 participants in the study, out of which 33 completed baseline assessment and 8 completed the study (8-month follow-up)
- The Leadership Core applied for and received DOD approval for a no-cost one-year extension.

REPORTABLE OUTCOMES

None

CONCLUSION

Overall, we have successfully completed Phase 1 of this project, namely the focus group interviews with 27 participants. Phase 2 recruitment of this project has shown promise with radio and newspaper ads placed and interest in the study seems favorable. We expect that we will achieve our recruitment goals with this uniquely challenging, and understudied population and successfully complete the study through additional recruitment efforts.

REFERENCES

None

DOD Progress Report, Project II
A Teachable Moment within the Family: From Concept to Community

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October, 2005

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INTRODUCTION

Despite advances in cancer detection and treatment, breast cancer remains the most common cancer among women and accounts for a staggering number of lives lost per year. Knowledge about both the genetic and environmental causes of breast cancer is being translated into tailored screening protocols, chemoprevention approaches, and diet and lifestyle modifications, targeted to women at highest risk. First-degree relatives (FDRs) of breast cancer patients comprise a particularly appropriate group among whom to concentrate efforts to maximize risk reduction and early detection. Although a family history of breast cancer is a well-known risk factor, studies have shown that many women are unsure of their risk status and are often unaware of the cancer prevention strategies that may be appropriate for them. The diagnosis of breast cancer in a close relative may provide the ideal opportunity, a "teachable moment," to reach at-risk family members to address their needs and concerns and make available risk assessment and counseling programs. The goals of the proposed study are to test a health communication message personalized to a set of demographic, clinical and psychosocial factors and timed to capitalize on the heightened awareness of breast cancer risk attendant to the recent diagnosis in an FDR. The project represents a partnership between a comprehensive cancer center (FCCC) and a series of community hospitals (FCCC Network affiliated sites) in an effort to enhance dissemination of state-of-the-art cancer prevention and control strategies to the community setting. Affected patients identify at-risk relatives at each site, and permission is sought to contact them by phone for participation in the study. Study participants are randomized to either a personalized message keyed to age, risk level, family history, screening behaviors and attention style, or to a general, non-personalized health message. Surveys are administered to adult daughters and sisters at two time points -- baseline and 12 months later -- in order to capture both newly formed intentions to seek cancer risk information and counseling, adopt lifestyle changes, and/or initiate appropriate surveillance regimens, and the actual action upon these intentions. The C-SHIP model of cognitive-affective processing of health threats is used as the theoretical framework for this study.

Aim 1: To develop and evaluate a theory-driven message tailored to a set of relevant variables including monitoring attentional style to enhance participation in FCCC's Family Risk Assessment Program (FRAP). The hypotheses are that patients exposed to this tailored message will be more likely to 1) seek risk assessment and counseling through FRAP, and 2) adopt risk-reducing behaviors than those patients who receive a non-tailored risk message.

Aim 2: To examine the moderating effects of individual differences in educational level, relationship to the patient, and level of anxiety and cancer-related distress.

BODY

The focus in the project during the past year has been continued recruitment of participants at FCCC and VirtuaHealth, ongoing capture of data, as well as some interim data analysis.

The study staff at FCCC continued work with the coordinator at one active Network hospital, VirtuaHealth, to explore viable recruitment strategies. Discussions with additional FCCC Network and affiliated hospitals continue (Geisinger Medical Center, ChristianaCare Health System) and the sites are at various stages of assessing interest in conducting the study at their institutions. Reading and Paoli continue the annual review process at their sites. However, due to staffing constraints neither site has recruited any participants. This is a result of limited staff ability at the sites to identify breast cancer patients in the local medical practices. It is unlikely that these sites will become active before recruiting for the study is closed.

During Year 4, with Task 1-subtasks a and b completed, we continued with the following sub-tasks:

c. Finalization of recruitment strategies
d. Training of study personnel

Sub-task c.-Finalization of recruitment strategies, is an ongoing, dynamic process as we continue to explore viable strategies at both FCCC and the network sites. We have continued to display study brochures and flyers at various locations throughout FCCC and in physicians' offices in the Virtua community. Additionally, study staff has participated in various community events to recruit participants. Brochures are displayed and staff members are available to answer questions about the study. The Project Coordinator continues working with the network sites to try and establish viable recruiting strategies in the face of very limited human resources at the sites.

Sub-task d.-One of the two Health Educators conducting the telephone counseling sessions left FCCC and was replaced this year. The new Health Educator has extensive experience working in the Cancer Information Service and is well suited for this study (i.e. providing information by telephone). She was trained by the Project Coordinator and spent time observing the other Health Educator on the team. The Project Coordinator meets with the study team on an ongoing basis to identify problems, develop support tools and streamline the scheduling and implementation of the counseling sessions. The list of frequently asked questions (FAQs) and answers continues to be updated with input from the counselors evolving during their sessions with study participants.

We continued working on Task 2, Conducting a prospective, randomized trial. This task was subdivided into sub-tasks that are being completed on an ongoing basis.

a.	Identification of FDRs	(months 7-30)
b.	Mailing of pre-call letter	(months 7-30)
c.	Baseline telephone interview	(months 7-30)
d.	Follow-up letter	(months 7-30)
e.	Delivery of experimental and control sessions	(months 8-31)
f.	Quality control tests performed on a randomized sample of sessions	(months 8-31)
g.	Follow up print materials mailed to participants	(months 8-31)

h. Informatics Core to complete data entry and management (months 7-44)
i. Conduct 12-month follow up phone call (months 20-44)

We continued with identification of breast cancer patients through use of the new Clinical Information System at FCCC. The staff has found the best ways to utilize this system to identify breast cancer patients and assess whether they met the time from diagnosis criteria. IRB approved study brochures are being distributed to all new breast cancer patients coming to FCCC for their initial visit. Brochures are also placed around the center in high traffic areas, as well as displayed at various patient education events on campus. As described above, study staff also began participating in a recruiting table that is set up during the hours of the Breast Evaluation Clinic to display information about the project and answer questions for patients being seen in the clinic that day. With the migration of clinic space at FCCC to off-campus buildings, the study staff has met with the registration staff at these locations to introduce the study and identify the best ways to recruit patients at these locations. Once the patients are identified, the study staff has continued contacting them to set up a time to meet when they are scheduled to be at FCCC for a routine appointment. Once we briefly introduce the study to the patient over the phone and assess preliminary interest and eligibility, a time and place to meet in person is arranged. A member of the study staff then meets with the patient, explains the study, obtains informed consent and assists the patient in completing the Relative Information form (RIF) to identify their eligible FDRs **(subtask a)**. In a few cases this year, FDRs have contacted the study staff directly as a result of obtaining a brochure while accompanying their relative to a clinic appointment. This minimizes the need to recruit the patient and complete the RIF, streamlining the process of recruiting the FDR directly.

Once the RIF is completed, precall letters are then mailed to the FDR **(subtask b)** along with the Relative Informed Consent and HIPAA forms to introduce the study. If the FDR does not call to decline participation within a specified timeframe, the Informatics Core generates a contact log. This log flags the date for a member of the study staff to follow up on the precall letter with a phone call to assess the FDRs interest in participating in the study. Once we assess eligibility and the FDR has agreed to participate, the study staff obtains informed consent from the participant and asks her to sign and return the informed consent and HIPAA authorization forms.

Another phone call is scheduled for the baseline telephone interview **(subtask c)** at which time the baseline HHQ is completed over the telephone. The survey takes between 20-45 minutes to complete. The variability in time is mostly due to the size of the family and the accompanying family history information being collected. This call only takes place once the signed forms are received back by the study staff. A photocopy of the signed consent and HIPAA forms are then sent to the FDR for their records. Another call is scheduled within a few weeks of the baseline interview for the delivery of the counseling session.

Once the interview is completed, a follow up letter **(subtask d)** is generated by the Informatics Core and provided to the study staff. This letter confirms the date and time for the upcoming telephone counseling session and is sent along with a small monetary reimbursement to the participant thanking her for her time and interest in participating. The baseline HHQs are entered into the database and the participant is randomized to either the experimental or control groups. A tailored script is generated for each woman in the experimental group based on several variables captured during the baseline telephone interview. An algorithm was developed with the Informatics Core to create the script for each participant in the tailored group. These variables include attention style, family history/risk level and compliance with breast cancer screening. This process is discussed further in the Informatics and Communications Core sections of this report. Sample scripts are included as appendices. For women in the control group, a general health information script is generated covering such topics as diet, dietary supplements and exercise. The Project Coordinator reviews each script to ensure that the tailoring algorithm is correctly applied to the script and that the text is personalized for the specific participant.

The experimental and control counseling sessions **(subtask e)** are completed by two Health Educators trained to administer the intervention. The sessions take from 10-30 minutes and conclude with a description of the local Family Risk Assessment Program with contact information on how to enroll. Participants are given an opportunity to ask questions throughout the session and are given additional resources (e.g. NCI website, Cancer Information Service) by the counselor as appropriate to the individual situation.

A subset of six of these sessions was audiotaped with permission from the participant and the Project Coordinator reviewed these tapes to assess quality control of sessions **(subtask f)**. Sessions are being delivered appropriately and the format of the scripts encourages interaction between the participant and the counselor. The counselor notes participants' comments throughout the session and completes an evaluation form at the end of each session. The Project Coordinator reviews all evaluation forms and addresses any problems or questions that arose during the session.

Follow up print materials (i.e. fact sheets) are then mailed to participants **(subtask g)** within two weeks after the completion of the counseling sessions. These materials were developed with the Communications Core to correspond to the tailoring variables utilized in the tailored intervention group. Additionally, a fact sheet was created to reinforce information disseminated to control group participants. Samples of these materials are included as appendices to this report. Also included in this mailing is a brochure and invitation to enroll in FRAP for more in-depth counseling and education about their risk for developing breast cancer.

The Informatics Core staff enters and manages the data **(subtask h)** on an ongoing basis. Study staff continues to meet with the Informatics Core on a regular basis to ensure that participant data are being captured and project timelines are being met. Several project management reports were developed to assist the Project Coordinator with tracking

progress of the study. Each study event is recorded through use of a checklist and data entry process on an ongoing basis. Data from the baseline and follow up HHQs are entered into the database by Informatics Core staff. The study staff enters study checklists which capture each study event as every participant completes it. Additionally, appointments for telephone sessions are scheduled and managed utilizing an MS Outlook calendar.

The 12-month follow up Health History Questionnaire has been in use throughout the past year. We began administering the survey over the telephone in March, 2004 **(subtask i)** as participants reached the 12 month mark after their counseling session. The Informatics Core generates a call log after a participant has been in the study for 11 months, and study staff begins to contact participants to complete the follow up interview in the ensuing weeks. The follow up HHQ takes approximately 30 minutes to complete over the telephone. Once this interview is completed, the participant has completed the study.

Task 3, to conduct data analyses on all data collected and to present/publish findings is not applicable to the Year 4 Report. However, the subtasks are as follows:

a.	Statistical analyses of data obtained	(months 40-46)
b.	Publicize study findings	(months 43-48)
c.	Prepare final report for granting agency	(months 46-48)

We have done some preliminary data analysis (**subtask a**) in preparation for various presentations (e.g. Era of Hope meeting) throughout the year. This includes descriptive statistics to characterize the study population which can be found in the Reportable Outcomes section below.

KEY RESEARCH ACCOMPLISHMENTS

- Obtained informed consent on 38 new subjects, completed telephone counseling sessions with 39 subjects and completed 12-month follow up interviews on 46 participants during the past year.

We have accrued 135 participants, 126 of whom have been randomized (70 tailored intervention group, 56 control group). Of these participants, 84 have completed the 12-month follow up and thus, the study.
Participant characteristics include:
Age: 41 (median) (range 25-77)
Race: 115 White; 8 African American; 2 Asian, 1 unknown
Education level: 2 -8 to 11 yrs
27- High school or GED
3-Vocational or Technical school
43-Some College
33-Bachelor

12-Graduate
6-Doctoral

Participation in Family Risk Assessment Program: 1 tailored intervention group participant and 3 control group participants

- Attended and participate in monthly Center meetings.
- 12-month follow up Health History Questionnaires were administered to 46 subjects, completing their participation in the study
- Explored new recruiting procedures for identifying eligible breast cancer patients and their first-degree relatives.
- Ongoing communication with FCCC Network site staff (N=5) to coordinate study approval and start up activities at each site.

REPORTABLE OUTCOMES
- none

CONCLUSION

Subject recruitment continued at FCCC during the past year. We have continued to identify and refine recruitment procedures at both FCCC and network sites. We have established a consistent internal queue of women based on the appropriate time from diagnosis (e.g. 6-12 months) providing us with a steady flow of potential subjects to approach for participation in the study. We have identified the most effective recruitment strategies at FCCC and are using these as a model with the sites. We will continue to work with the network sites to identify additional opportunities for recruiting participants locally. Improved recruitment is anticipated in the coming year, with strong support of the study at the newest site gaining approval, and by incorporating creative recruitment strategies in the community.

REFERENCES
None

APPENDICES (with electronic document name and description)
Sample scripts:
Teachable Moment Intervention Scripts

- LMHRNC=low monitor, high risk family history, non-compliant with screening (Appendix #1)
- HMIRC=high monitor, intermediate risk family history, compliant with screening (Appendix #2)

Teachable Moment Control Script

- CTRL=control group

Print materials:
Family History/Risk Factors Fact Sheets:

- famriskHH=high monitor/high risk (Appendix #3)
- famriskHI=high monitor/intermediate risk (Appendix #4)
- famriskLH=low monitor/high risk (Appendix #5)
- famriskLI=low monitor/intermediate risk (Appendix #6)

Personal Risk Profile

- w-Tam=reference to tamoxifen where appropriate based on Gail model (Appendix #7)
- w-out Tam=no reference to tamoxifen based on Gail model (Appendix #8)

Screening Recommendations Fact Sheets:

- screenHCstartmammo= high monitor/compliant-start screening (used for women under age 40 who have not yet begun screening mammography) (Appendix #9)
- screenHCcontinuemammo=high monitor/compliant-continue screening (used to reinforce continued compliance w/mammography) (Appendix #10)
- screenHN=high monitor/non-compliant (Appendix #11)
- screenLCstartmammo=low monitor/complaint-start screening (same as H/C-S above) (Appendix #12)
- screenLCcontinuemammo=low monitor/compliant-continue screening (same as H/C-C above) (Appendix #13)
- screenLN=low monitor/non-compliant (Appendix #14)

Control Group Fact Sheet:

- Fact sheet exercise

DOD Progress Report, Project III
Facilitating Re-entry Following Treatment for Primary Breast Cancer

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October, 2005

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INTRODUCTION

As screening and surveillance for breast cancer has increased and treatment improved, the number of survivors of primary breast cancer has increased substantially (ACS, 2000; Pandey et al., 2000). The 5-year relative survival rate for localized breast cancer has increased from 72% in the 1940s to 96% today (ACS, 2000). Further, 71% of women diagnosed with breast cancer survive 10 years, and 57% survive 15 years (ACS, 2000). As the number of cancer survivors has increased, so too has the concern for the psychosocial adaptation of cancer survivors (e.g., Andersen, 1994; Ganz et al., 1996; Ganz et al., 1998; Gotay & Muraoka, 1998; Kornblith, 1998; Kurtz, Wyatt, & Kurtz, 1995; Schag et al., 1993; Wyatt & Friedman, 1996; Weitzner et al., 1997). However, little research has focused on easing the transition of individuals with early stage breast cancer from active treatment to follow-up care, referred to as the re-entry phase; even less research has focused on how individual differences moderate the process of adjustment to the challenges of survivorship (see Andersen, 1994; Helgeson et al., 2000). Guided by the Cognitive-Social Health Information Processing model (Miller, Shoda, et al. 1996; Miller, Mischel, et al. 1996), the primary objective of the proposed study is to develop and evaluate a tailored Cognitive-Affective Processing (CAP) intervention to facilitate psychosocial adjustment at re-entry following adjuvant treatment for primary breast cancer (Miller, 1995; Miller, 1996; Miller, Shoda, & Hurley, 1996; Miller, Fang, et al., 1999).

The specific aims for Project 1 are as follows:

Aim 1: To develop and evaluate a theory-based, individually tailored Cognitive-Affective Processing (CAP) intervention to facilitate re-entry following adjuvant treatment for primary breast cancer.

Aim 2: To examine the moderating effects of individual differences in attentional style (i.e., high vs. low monitoring) on the impact of the proposed intervention.

To reach the primary objective of the proposed study, three focus groups were conducted during Phase I of the study (months 1-6). Eighteen women from the target population (early stage, primary breast cancer patients) participated in the focus groups. The goal of the focus groups was to facilitate the development and refinement of the CAP intervention and the measures. The first two focus groups were designed to explore and assess the challenges confronted by the study population during the transition from being an active patient in treatment to a breast cancer survivor, i.e., the 're-entry' phase. Specifically, focus group participants were asked to discuss their perceived risk, expectancies and beliefs, values and goals, emotions, and coping strategies regarding their transition into 'survivorship'. Specific areas targeted included their cognitive-affective responses to cancer recurrence, cessation of treatment, sexuality, body image, and personal relationships. This information was used to further refine the intervention and measures. The final focus group was designed to obtain final suggestions for the improvement of the intervention and the battery of measures.

During Phase II, women (N=300) who have been diagnosed with Stage 0, I, or II breast cancer and are being treated at Fox Chase Cancer Center (FCCC) will be contacted for participation. Potential participants will be identified through the scheduling office at the Breast Cancer Evaluation Clinic at FCCC and will be recruited near the completion of their adjuvant treatment. After they have been given a description of the study, participants who meet eligibility criteria and wish to participate will be asked to sign a consent form. Consenting participants will be randomized into either the intervention or control condition. All consenting participants will receive the intervention or control session during a post-adjuvant treatment follow-up medical visit. A booster session will be given two-weeks post-counseling intervention. All participants will be assessed via mail at one, six and twelve months post-intervention. The health educator will contact the participant by phone to collect follow-up data in the event that participants do not return the questionnaires within 2 weeks.

BODY

During Year 1, the plan was to complete Task 1 and initiate Task 2, as outlined in our Statement of Work. Task 1 involves coordinating with the Communications Core in the testing and subsequent refinement of the cognitive-affective intervention designed to facilitate "re-entry" into the post-treatment phase of breast cancer for early stage breast cancer patients. This was to be accomplished through the use of focus groups to test both the intervention and the measures, with the Communications Core leading the process. The specific aims of Task 1 were to:

a. Recruit Focus Group Participants for Phase I	(Month 1-2)
b. Conduct Focus Groups	(Months 2-3)
c. Analyze Focus Group Data	(Month 3-4)
d. Refine Interventions/Measures	(Month 4-5)
e. Conduct Focus Groups to Evaluate Refined Interventions/Measures	(Month 5)
f. Establish Recruitment Procedures/Staff Training	(Months 5-6)

The responses from the three focus groups, in addition to comments and suggestions made by an external review committee, were used to refine the barriers intervention. While the intervention continues to addresses the cognitive-affective mediating units of participants, there is now a more refined assessment of the primary concerns and issues of breasts cancer survivors as well as the barriers to re-entry, which will be thoroughly addressed in the intervention session, with particular attention given to focus group participants' preferences for the timing of the delivery of the counseling intervention and the method by which the intervention will be delivered. Specifically, the intervention is delivered soon after the completion of adjuvant treatment with follow-up assessments conducted at the one-, six-, and twelve-month time points. The intervention draws heavily from the NCI publication, Facing Forward, and is consistent with its philosophy of taking an active role in recovery in combination with accepting changes that are beyond the patient's control. Further, the intervention provides strategies for coping with

barriers to the re-entry phase of recovery and participants receive additional resources for dealing with their concerns. Revisions to the originally approved protocol were approved by the FCCC IRB in May 2004

Because the information obtained from three focus groups was adequate to modify the barriers intervention, an amendment was submitted to conduct a pilot study (N=20) in place of the fourth focus group. This modification was also approved in May 2004. The recruitment for the pilot study was initiated during the past year in order to provide an evaluation of both the initial assessment and the revised intervention in terms of their thoroughness, applicability and feasibility. To enhance accrual rates for the study, recommendations were obtained from FCCC specialists (i.e., physicians, nurses, technicians) working with women with breast cancer towards the end of their treatment, in order to find more efficient ways to reach potential participants for the study. Based on the input received, the following amendments to the study protocol were submitted to the FCCC IRB/RRC and DOD IRB:

a. Amendment #5: Change to eligibility criteria

In an effort to enhance recruitment, we proposed to expand the study eligibility criteria to include women up to three months following their last adjuvant treatment appointment rather than 3-4 weeks post-treatment. The differences in the amount of time since completing treatment among participants will be taken into account in data analysis. Submitted to FCCC IRB/RRC on March 30th, 2005, and received approval on April 5th, 2005. Submitted to the DOD on April 7th, 2005. Approval from the DOD is still pending.

b. Amendment regarding recruitment materials

In an effort to facilitate recruitment of participants two recruitment materials were created: a brochure and a physician card. The brochure, to be displayed in the Radiation Treatment, Chemotherapy and Outpatient Clinic at FCCC, targets potential participants and contains study's description and contact information. The physician card targets medical staff working with patients with breast cancer and contains eligibility criteria, study description and contact information. Amendment was submitted to FCCC IRB/RRC on May 31st, 2005, and was approved on May 26th, 2005. Amendment was submitted to the DOD on June 28th, 2005. Approval from the DOD was received on September, 28th, 2005.

c. Amendment #7: Measure instruments: replacement and additions to the set of study measures

One study measurement "Health Protective Behaviors" will be replaced by "Behavioral Action Taken", a study specific measure designed to assess the extent to which patients engage in the actions recommended by "Facing Forward" book – a publication designed especially for breast cancer survivors by the National Cancer Institute. This author-constructed measure consists of five sections, each reflecting a chapter covered in Facing Forward, designed to assess the adoption of specific actions recommended in Facing Forward (i.e., using a follow-up guide to keep track of appointments, developing a plan to fight fatigue, using a pain diary to track pain levels). Patients are simply asked to report "Yes or No" with regard to engaging in each of the recommended actions. This measure will be

administered at baseline and at all three follow-ups. The rationale for proposing the replacement of "Health Protective Behaviors" measure with "Behavioral Action Taken" measure is that: 1) The "Behavioral Action Taken" measure targets health protective behaviors that participants in both control and experimental group have been informed about through the Facing Forward publication; 2) The "Behavioral Action Taken" measure has been design in such a way to assess engagement in health protective behavior before and after the intervention. Another minor change proposed regards "Cancer-Related Benefits" Scale. We omitted to list it in Table III, on page 17-18: Provisional Measures and Times of Administration. This measure is now included in Table III, and it is described in the body of the proposal. Amendment was submitted to FCCC IRB/RRC on August 9th, 2005 and approval was received on September 29, 2005. An amendment was submitted to the DOD on October 5th, 2005. Approval from the DOD is pending.

d. Amendment # 8: Delivery of the intervention over the phone
Given the high patient refusal rate to participate in this study has been often justified by lack of time to come for an in-person counseling session, this amendment proposed to offer participants in the study the option to chose between an in-person counseling session or an over-the-phone counseling session. The counseling intervention can be appropriately delivered over-the-phone, since is an educational counseling session designed to be easily transportable. Amendment was submitted to FCCC IRB/RRC on August 9th, 2005 and approval was received on September 29, 2005. An amendment was submitted to the DOD on October 5th, 2005. Approval from the DOD is pending.

e. Amendment #9: Extending eligibility criteria
Given the difficulty of reaching patients once they have finished adjuvant therapy, this amendment proposes to modify study eligibility criteria as to be able to recruit breast cancer patients while undergoing adjuvant therapy and/or within one year of their end of treatment. Amendment submitted to FCCC IRB/RRC on August 9th, 2005 with approval received on September 29, 2005. An amendment was submitted to the DOD on October 5th, 2005. Approval from the DOD is pending.

Task 2, which was to be initiated during year 1 and continued into year 3, involves conducting the revised randomized trial (N=300) comparing the Cognitive-Affective Preparation (CAP) protocol designed to address the barriers to "re-entry" into the post-treatment phase of breast cancer for early stage breast cancer patients. The CAP intervention will be compared with a General Health Information (GHI) control to equate for time and attention. The specific aspects of Task 2 are to:

a. Recruit Participants, Randomize to Treatments, Test Interventions (Months 7-30)
b. Participants Eligible for Genetic Testing will be Referred to the Genetic Susceptibility Testing (Months 7-30)

Laboratory Core

Task 2 will begin upon completion of the pilot study. Once 20 pilot participants have completed the baseline assessment and the intervention, we will begin recruitment for Task 2. Given the challenge of recruiting participants for the pilot study, as of September 2005, several strategies to enhance recruitment have been developed as outlined above. Implementation of these strategies is delayed due to the complex IRB approval process from both FCCC and the DOD.

Our team attended several consultation meetings with the Informatics Core to initiate the database edifice, and to adjust it in accordance with modifications to the protocol. Over the past year the Informatics Core designed and developed Project 3's (baseline) application. The next steps will be to initiate the follow-up database and data entry interface(s) plus analytic views. Preliminary data collection procedures were discussed as well as the facility's role in handling these data. Further arrangements will be made as the study progresses.

Task 3, involves conducting data analyses on all data collected and presenting/publishing findings. However, due to delays in the revision and approval of the intervention, this task has not been initiated. To allot for the extra time that will be needed to complete task 3, we requested a no-cost extension to continue this study in 2006 so that this request may be processed 30 days before the scheduled completion of the study.

a. In collaboration with the Informatics Core Statistical Analyses of Data Obtained (Months 31-42)
b. Publicize Study Findings (Months 43-48)
c. Prepare Final Report for Granting Agency (Months 43-48)

KEY RESEARCH ACCOMPLISHMENTS

- Continue to attend and participate in monthly Center meetings
- Initiated the pilot study: 259 potential participants referred to study, of which 205 ineligible; 42 of the patients referred to study met the eligibility criteria, out of which 16 denied participation, 26 consented to participate (3 completed the pilot intervention).
- Conducted meetings with FCCC Outpatient Clinic, Breast Cancer Clinic, and Ambulatory Care - Infusion Room staff (physicians, nurses, technicians) in order to get their input and support for increasing participation in the study.
- Developed recruitment materials (i.e. physician cards, brochures) in order to better reach potential participants.

- Submitted revisions to the FCCC IRB regarding use of recruitment materials, and extension of eligibility criteria in order to increase study accrual. Submitted the FCCC IRB approved revisions to the DOD and Approval is pending.

- Revised the study measures based on the preliminary information from the pilot study. "Behavioral Action Taken" will replace the "Health Protective Behaviors" measure upon FCCC and DOD IRB approval. This is a study specific measure designed to assess the extent to which patients engage in the actions recommended by "Facing Forward" book – a publication designed especially for breast cancer survivors by the National Cancer Institute.

- Submitted a new HIPPA authorization form using a new template developed by the FCCC IRB to DOD for approval.

- Data collection procedures have been established with the Informatics Core to initiate the database edifice with further plans to be developed and adjust as necessary.

- Applied and received DOD approval for a no-cost one-year extension.

REPORTABLE OUTCOMES

-none

CONCLUSION

Upon FCCC and DOD approval of all protocol revisions, we will start using new study recruitment strategies. Full implementation of Phase II will begin after we have collected baseline information, and conducted the study interventions for 20 participants. As these processes are underway, we anticipate no further major obstacles, given the one-year extension and the new recruitment strategies in the further progress of this project.

REFERENCES

None

DOD Progress Report, Project IV
Communication Skills Versus a Supportive Therapy Intervention for Women with Metastatic Breast Cancer

Dr. Sharon Manne, Ph.D., Principal Investigator
Dr. Robert Schnoll, Ph.D., Co-Investigator
Dr. Karthik Devarajan, Ph.D., Statistician

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

October 2005

INTRODUCTION

Excluding skin cancers, breast cancer is the most common cancer diagnosed in American women. Recent advances in early detection and treatment have resulted in higher cure rates for breast cancer. Unfortunately, approximately 6% of breast cancer patients develop metastatic disease (stage IV). For the majority of women diagnosed with metastatic breast cancer, median survival is approximately 18 to 24 months with systemic chemotherapy. The overall five-year survival rate for women with stage IV breast cancer is 21.3%. Thus, although a cure is not achieved for most patients, treatment improvements have made it possible for women to survive for relatively long periods of time with stable disease. Consequently, symptom relief and improvement in quality of life are critical therapeutic goals for this population.

The specific aims for Project 4 are as follows:

Aim 1: To compare the effectiveness of a communication and support skills intervention versus a supportive therapy intervention on the quality of life of women with metastatic breast cancer.

Aim 2: To explore the effects of individual differences (e.g., ambivalence over emotional expression), treatment expectancies, social support and coping on the impact of the interventions.

This is a multi-site study, with prospective subjects being identified at the Fox Chase Cancer Center (FCCC), Cooper Health System Division of Hemotalogy/Oncology, Temple Cancer Center, and Bryn Mawr Hospital (BMH) of the Main Line Health System. On-site physicians regularly provide the research assistant with a list of eligible patients who have given permission to be contacted for this study. Eligible participants are mailed a letter describing the study. Patients are approached and contacted in person by the Research Study Assistant during a clinic appointment, and the study is described in more detail. If the participant is interested in participating, informed consent will be obtained at that time. After obtaining written informed consent, the pre-intervention assessment packet is administered.

The study design is a randomized clinical trial with two study conditions: 1) Communication and Support Skills intervention, 2) Supportive counseling intervention. Patients are assigned to one of these conditions after the initial packet has been completed. The intervention programs are administered in an individual format with six in-person sessions and one telephone follow-up. Assignment is stratified into groups having low or high baseline psychological distress as determined by the Beck Depression Inventory.

The goal of this study is to determine whether an intervention targeted to women with breast cancer can impact their psychological distress. We have utilized a structured, CBT-oriented intervention that teaches effective communication and support skills because this type of intervention will assist patients in obtaining support from their existing support networks (rather than from other patients). Prior studies have suggested that deficits in

support from partners and a lack of open engagement with partners are particularly problematic for female, late stage patients and among metastatic breast cancer patients. We have selected supportive psychotherapy as a comparison condition because this intervention will not provide skills, but will provide emotional support. In addition, this condition will provide a control for the non-specific effects of therapy (therapeutic bond, treatment expectancies, time and attention spent on the patient). We will examine the role of these non-specific factors in treatment outcome. We also will assess adherence to treatment protocol and treatment discrimination, which have been ignored in prior research. By focusing an individual difference variable (lack of support) that has been shown to predict a beneficial outcome for interventions, we may be more likely to elicit a response to treatment that has not been consistently found in prior studies of metastatic breast cancer patients.

BODY

Below are the specific tasks to be accomplished, as originally outlined in the Statement of Work, in the context of this Project 4. In addition, we have provided estimates of the amount of time it will take to complete these tasks.

Task 1 (Months 1-5):

To refine the intervention manual for the support skills intervention and train psychotherapists in administration of both interventions.

a. Recruit Focus Group Participants	(Months 1-2)
b. Conduct Focus Groups	(Month 3)
c. Analyze Focus Group Data	(Month 4)
d. Train therapists in both conditions	(Month 5)
e. Prepare study questionnaires, recruitment materials, materials for therapists	(Month 5)

Task 2 (Months 6-47).

a. Recruit participants	(Months 6-42)
b. Administer study questionnaires	(Months 6-42)
c. Conduct intervention sessions	(Months 4-43)
d. Regular therapist supervision meetings	(Months 4-43)
e. Enter study data	(Months 4-47)
f. Conduct follow-up assessments	(Months 4-47)
g. Treatment integrity checks	(Months 4-47)

Based upon previous experience, Project 4 staff determined that focus groups would prove redundant to earlier work and experience conducted with this patient population. Therefore, in place of the focus groups (Task 1a, 1b and 1c) staff regularly met with the study interventionists in order to develop and tailor the intervention material. The training of project therapists (1d) was completed as scheduled. Though questionnaires and

therapist materials were completed as scheduled (1e), there was some delay and in the production of recruitment materials due to nature of the multi-site IRB approval process. Materials have included posters, letters (signature stamped by prospective participant's oncologists), pamphlets, and stickers to be attached to eligible patients medical charts. Currently all recruitment materials have been approved.

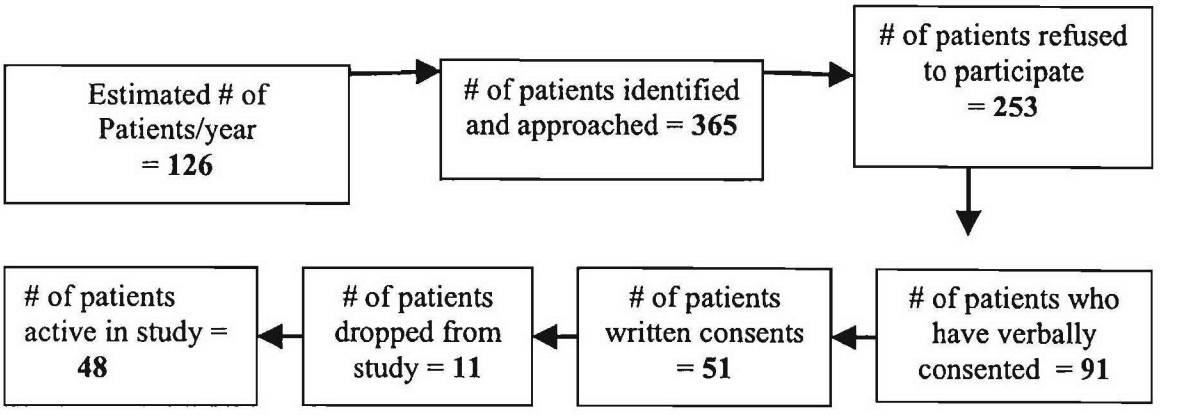
Though recruitment (2a) has begun, there was approximately a 4-month delay in start-up due to multiple protocol amendments, and their respective DoD and multi-site IRB approval requirements. Study questionnaires and conducting of intervention sessions (2b, 2c) commenced after the start-up delays, and has kept pace with recruitment. The PI and Project Manager have begun regular therapist supervision (2d) with the interventionists throughout the year. Data entry (2e) has been done concurrently with recruitment and intervention sessions. Project 4 staff has worked closely with the Informatics Core in order to develop data entry protocols, computerized data entry form screens, and a system which allows Project 4 staff to be automatically notified when different questionnaire elements are due to be sent to patients. Follow-up assessments and treatment integrity checks (2f, 2g) are being conducted on a regular basis. Intervention sessions are audio taped for treatment integrity-tracking purposes.

Sluggish recruitment continues to be a significant issue in the fourth active year of the Project 4. Identification and recruitment figures continue to be lower than originally anticipated. Low recruitment figures continue to stem from two primary causes; 1) we have identified fewer eligible individuals than previously estimated, and 2) we have experienced a higher refusal rate than anticipated. Below, in Figure 1, we summarize our recruitment efforts to date. Our sample size at this point is 48. 27 women have been assigned to the Communication and Support skills condition and 21 women have been assigned to the supportive condition. Of the 27 women assigned to the Communication and Support skills condition, seventeen have completed all six sessions and five have dropped out of study. Of the 21 assigned to the Supportive counseling condition, fifteen women have completed all 6 sessions and six have dropped out. Thirty-three of our 48 participants have completed the first follow up and twenty-four have completed the second follow up survey. Participant characteristics include:

- 48 breast cancer patients enrolled to date
    - 27 in Communication and Support Skills Counseling
    - 21 in Supportive Counseling
- Primarily Caucasian
    - 88% Caucasian, 8% African American, 2% Hispanic, 2% Multi-racial
- Average age: 58.39, range = 36 - 81
- Primarily well-educated
    - 0 - 4 years of school - 2%
    - 5 - 8 years of school - 2%
    - Finished high school - 37%
    - 1 - 3 years of college - 21%
    - Bachelors' Degree - 4%

- Trade of Business School - 10%
- Some Graduate School - 10%
- Graduate Degree - 14%

Figure 1: Summary of Recruitment Efforts through 9-2003



In terms of other study tasks, all session audiotapes are being coded for integrity by Dorothy Weber, our quality analyst. All study data has been entered to date, and supervision of study therapists has been both ongoing via feedback from Sandra Corbett to each therapist as well as accomplished by in person supervision meetings every 3-4 months.

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.
- Actively recruiting patients, both at FCCC and satellite sites.
- Actively administering the experimental interventions.
- Further development and tailoring of the interventions.
- Trained the interventionists.
- Further development of the recruitment procedures.
- Finalization of study assessment instruments.
- Utilized Informatics Core to develop and maintain data collection and management procedures.

REPORTABLE OUTCOMES

Aside from our recruitment activity, summarized in Figure 1, we do not have additional reportable outcomes at this point.

CONCLUSION

Task 1 study elements have been completed. Task 2 elements, including recruitment, intervention, treatment integrity and supervision, and data collection and entry are well underway. In the last three years we have made significant efforts to boost enrollment by adding a number of local hospitals to our study as well as by increasing awareness of our project among the oncologists treating patients at Fox Chase Cancer Center. This effort has addressed some of the enrollment problem but because we are dealing with a very ill population it is likely unrealistic to expect a high enrollment. We have made efforts to reduce study burden by reducing questionnaire length and adding subject incentives, to reduce refusal rates. We estimate that preliminary data analysis will begin sometime in the next reporting year (10/2005-10/2006). Thus, no analytical conclusions can be drawn at this time.

REFERENCES

None

DOD Progress Report
Leadership Core

Dr. Suzanne M. Miller, Ph.D.
Principal Investigator
Core Director

October 2005

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Under the direction of the Leadership Core, the development of the Behavioral Center of Excellence in Breast Cancer (BCE) has been guided by a unifying cognitive-affective processing (CAP) approach to breast cancer prevention and control that has informed the specific hypotheses of each project and has dictated the relevant interventions and assessments, and that provides a multidisciplinary linkage across projects. The senior leadership and administrative support core component is designed to ensure scientific collaboration, guidance, and integration across the research projects and to promote the efficient administration of all the components of the BCE grant. Through collaboration between the principal staff on the main projects and other cores, the Leadership Core is able to broaden past and ongoing research by pursuing a closely coordinated research program to modify attitudes, behavior patterns, and lifestyles in ways that will ultimately reduce breast cancer incidence, morbidity and mortality effectively, thus directly addressing the mission for consequential behavioral research in breast cancer.

The specific aims of the Leadership Core are as follows:

Aim 1: To provide oversight, and management of, all aspects of the BCE to maximize the efficiency of its integrative, inter-coordinated organizational structure.

The Leadership Core for the BCE is intended to be a resource to the Center as a whole, as well as to function as the administrative resource for each of the individual projects.

Aim 2: To continue to develop, refine, and evaluate the overarching, unifying conceptual framework.

In order to continually refine the guiding theory of research within the BCE, the Leadership Core will integrate data across projects to more comprehensively address the dynamics of the interactions between construals and the other cognitions and affects that they prime and activate within the processing system, as the individual interprets, transforms, and acts on diverse types of cancer risk information (Miller & Diefenbach, 1998).

Aim 3: To oversee and enhance the centralized quality control mechanism for designing, refining, and evaluating the theoretically derived assessments and interventions.

The Leadership Core will function to ensure that the project investigators create and tailor the Cognitive-Affective Preparatory interventions to target the entire pattern of intervening cognitive and affective dynamics that underlie effective modulation of distress and long-term adherence to breast cancer prevention-control behaviors.

Aim 4: To develop actuarial predictive indices of cognitive-affective processing types.

With oversight from the Leadership Core, a goal of the BCE is to clarify and harness Person x Situation interactions emphasized by the C-SHIP model. This requires a shift from global to specific, contextualized analysis and assessments.

Aim 5: To oversee and guide the planning, development, and implementation of new BCE projects.

By building on the strong network of projects already proposed, the vision of the BCE is to develop further studies that are relevant to the CAP agenda and that interact synergistically with the ongoing work.

Aim 6: To administer the Training Program.

The Leadership Core will oversee the implementation of the pre- and post- doctoral training program through the identification of qualified candidates with ambitions to pursue careers in behavioral medicine and the development of communications to enhance cancer prevention and control.

BODY

According to our Statement of Work the plan during Years 2 through 3 was to accomplish the following tasks: 1) to convene Advisory Committee and scientific meetings; 2) to oversee implementation of core functions and to oversee initiation of projects and cores; 3) to implement the Training Program and, 4) implement meta-analysis and thematic integration of findings

Task 1. To convene the advisory committee and scientific meetings.

First, the External Advisory Committee, which was chosen to provide consultation for the BCE senior staff, held its first meeting in December 2002 at FCCC. Dr. Howard Leventhal, Board of Governors Professor of Health Psychology, and Director of the Institute of Health, Policy and Aging Research at Rutgers University provided expert consultation in the theoretical application of cognitive-social principles to the assessment and development of the study interventions. Dr. Chanita Hughes, Assistant Professor in Psychology at the University of Pennsylvania provided expert consultation in cultural sensitivity with respect to intervention development and minority recruitment. The Committee is scheduled to re-convene in April 2006.

Second, Dr. Miller, Director of the BCE, leveraged the Behavioral Center of Excellence to spearhead the organization of several nationals groups. This includes leading the Behavioral Oncology Interest Group at the American Society for Preventive Oncology. At the second annual Behavioral Oncology Interest Group sponsored a Study Group Breakfast in March 2003. Dr. Miller, a member of the Steering Committee for ASPO, again chaired the ASPO Behavioral Special Interest Group Breakfast Presentation entitled "Models for Decision Making in Cancer Prevention." Dr. Deborah Bowen, Full

Member, Cancer Prevention Research Program at Fred Hutchinson Cancer Research Center, presented "Electronic decision making tools for prostate cancer screening in community settings." Dr. Michael Diefenbach, Assistant Professor, Mount Sinai School of Medicine, presented "Electronic decision making tools for early stage prostate cancer screening in community settings." Currently, Dr. Miller, a Member of the Steering Committee, is co-chairing the 2006 Annual Meeting of ASPO in Bethesda MD with a Pre-conference Day on Numeracy, entitled: "What Numbers Could Be: The Role of Numeracy in Understanding and Communicating Cancer Risk and Management Information". This meeting will consist of talks followed by roundtable discussions facilitated by behavioral scientists to focus on advances at the intersection of behavioral science and oncology, and to allow interchange and discussion of behavioral science issues as they relate to cancer prevention. Dr. Miller was also a leading organizer of 2005 Society of Behavioral Medicine Pre-conference Day Roundtable Sessions on Decision Making in Cancer. The Annals of Behavioral Medicine is dedicating an entire issue based on this Decision Making in the Cancer Context Pre-Conference Day with Dr. Miller as a guest editor. In addition, Dr. Miller is co-chair for the 2006 Annual Society of Behavioral Medicine Meeting entitled "Across the Lifespan", and serves on the steering committee for the Cancer Special Interest Group.

Third, Dr. Suzanne Miller and other members of the BCE team presented on all four BCE projects at the fourth Era of Hope DOD Breast Cancer Research Program's Meeting in Philadelphia in June 2005. Dr. Miller spoke on "Treating More than the Tumor" at the Behavioral Centers of Excellence Session. Dr. Linda Fleisher presented on "Genetics, Counseling, and Disease Control" at the Hereditary Breast Cancer Session. Two posters were also presented at the Behavioral Sciences and Decision Making Section: 1) Tailored Communication to Enhance Adaptation Across the Breast cancer Spectrum" and " Educating Women about Risk Counseling/Genetic Testing Makes a Difference in Intended Use of Services, Especially Among Those at High Risk: Results of a Randomized Trial of Callers to the Cancer Information Services". In addition, Dr. Miller co-chaired the Session: "People and Populations" that addressed a broad range of issues related to breast cancer including obesity, wait for diagnosis, mammography usage, delays and refusals in treatment, adult daughter caregivers, and impact of culture on screening across vulnerable populations including African Americans, Asian, other minorities, and elderly women.

Third, the Leadership Core has established the Behavioral Medicine Speakers Series at Fox Chase Cancer Center. The following speakers were invited to present their most current data to the Division of Population Sciences:

- Dr. Michael Green, Milton S. Hersey Medical Center, spoke on "Informed decision-Making and Genetic Testing for BRCA1/2" on December 14th, 2004.
- Dr. Mary Daly, Fox Chase Cancer Center, spoke on "Benign Breast Disease: a New Frontier", on January 25, 2005.
- Dr. Hayley Thompson, Mt. Sinai Medical School, spoke on "Medical Mistrust and Health Behaviors Among African Americans and Latinos in Harlem, NYC" on March 8th, 2005.

- Dr. Andrea Barsevick, Fox Chase Cancer Center, spoke on "Symptom Management for Black Breast Cancer Survivors" on May 3rd, 2005.
- Dr. Carolyn Fang, Fox Chase Cancer Center, spoke on "Perceived Control and Copying with Ovarian Cancer Risk" on May 19th, 2005.
- Dr. Mary Ropka, Fox Chase Cancer Center, spoke on "A Systematic Review of Decisions about Breast Cancer Genetic Testing: Will the real Up-take Rate Please Stand Up?" on May 24th, 2005.
- Dr. Paul B. Jacobsen, Moffitt Cancer Center, Tampa, Florida, spoke on "For Better or Worse: Patient Perspectives on Surviving Cancer" on July 19th, 2005.
- Dr. Ramona Swaby, Fox Chase Cancer Center, spoke on "Metastatic Breast Cancer" on August 23rd, 2005.
- Neal Meropol, Ph.D., Fox Chase Cancer Center, spoke on "Why don't more patients take part in clinical trials? It's all about signal transduction?" on September 13th, 2005.
- Dr. Pamela Shapiro, Abramson Cancer Center of the University of Pennsylvania, spoke on "Perspectives of Cancer Related Cognitive Difficulties...*But I can't find my way home*"" on October 18th, 2005

Fifth, in September 2004, investigators within the FCCC Community Clinical Oncology Program (CCOP) Research Base convened to discuss the expansion of hospital-based research into the community. Through the simulation of research efforts into the community, the FCCC CCOP Research Base will provide cancer patients, their families, and high-risk individuals access to new prevention and control studies closer to home. At this meeting, CCOP investigators discussed the community implementation of an intervention for breast cancer survivors using the NCI publication Facing Forward. In 2005 a grant proposal entitled "Efficacy and Feasibility of a Psychosocial Intervention within the CCOP Context: Evaluation of the Facing Forward Guide to Facilitate Life after Active Cancer Treatment" was approved by FCCC IRB/RRC and was submitted to NCI.

Finally, Dr. Miller recently became a member of the Board of Directors of the New Jersey Health Care Quality Institute and has recently been appointed as a member of the National Quality Forum's *Quality of Cancer Care Measures* project where she serves on the Symptom Management/End of Life Care Technical Panel. In addition to symptom management and end-of-life care, this project focuses on colorectal and breast cancer diagnosis and treatment. The Technical Panel is charged with conducting an initial assessment to evaluate candidate performance measures for their validity, which must occur before the Project's Steering Committee will consider recommending the measure to the National Quality Forum for endorsement. A one-day organizational meeting was held September, 2004, followed by a two-day measures assessment meeting on September, 2005.

Task 2. To oversee implementation of core functions and to oversee initiation of projects and cores.

The Leadership Core continues to hold monthly BCE meetings. Principal Investigators, Co-Investigators, Project Managers of the various BCE projects and Core staff attend these meetings that provide an opportunity for investigators to exchange ideas and provide input across studies. Agenda items include: 1) Updates from each project and core; 2) Training Program status; 3) DOD reporting requirements and IRB documentation; 4) Standardization of assessment tools across studies to maximize opportunities for meta-analysis; and 5) Cooperative strategies to enhance recruitment across studies. Meetings minutes are kept to record the current status of each study. Specifically:

- Recruitment for Phase 2 of project 1 began. Ads have been sent to local Philadelphia radio stations and newspapers for 2-week time slots for two separate time periods. Two hundred twenty one calls were received, but only 85 callers met the eligibility criteria, and out of these 45 consented to participate in the study. Alternative recruitment strategies will be employed to accrue the desired sample, and preliminary data analysis will be conducted. An amendment had been submitted and approved by FCCC IRB to exclude the criteria pertaining to one's income.
- Recruitment for Project 2 is still in progress. 12-month follow-up interviews were completed for 46 participants during the past year. has been finalized with input from the Core, especially on health behavior questions (e.g., alcohol use). New recruitment strategies have been refined at both FCCC and network sites.
- Recruitment for the pilot study portion of the study has been underway in 2004 and 2005. Due to low study accrual rates, several amendments (e.g., use of recruitment materials such as physician card, brochure, modification in eligibility criteria and delivery of intervention) to the protocol have been submitted to FCCC IRB and to DOD. Recruitment for the pilot study portion has been completed and recruitment for Task 2 of the study is scheduled to begin upon approval from the FCCC and DOD IRB.
- Recruitment for Project 4 is still in progress. Identification and recruitment figures continue to be lower than originally anticipated. The staff continues to recruit all eligible patients and collect first and second follow-up surveys. The sample size to this point is 48, with 27 women assigned to the Communication and Support skills condition and 21 women assigned to the supportive condition. Thirty two women in both conditions completed all six sessions.
- Monthly BCE meetings were instrumental in the revision of the intervention protocol for Project 1, 3.

Task 3. To implement the Training Program.

The following has been implemented to support the BCE Training Program:

Three FCCC faculty members serve on a BCE Fellowship Search Committee who were selected by members of the Leadership Core. This committee holds the responsibility of

disseminating an announcement about pre- and post-doctoral fellowship opportunities, developing an evaluation procedure, arranging for candidate interviews, and selecting candidates. The committee is comprised of Dr. Suzanne Miller, Dr. Joanne Buzaglo, and Dr. Mary Daly who meet to devise fellowship announcements and candidate review criteria. The following review criteria are used to evaluate potential candidates: Ability in Written Communication, Familiarity with Behavioral Oncology in General, Familiarity with Breast Cancer in Particular (Behavioral and Medical issues), General Research Experience, Apparent General Research Proficiency, Commitment to Research Career in Behavioral Oncology/Cancer Prevention and Control, Quality and Relevance of Academic Training, Enthusiasm for Fellowship, Convergence Between BCE Projects and Applicant's Experience, Convergence Between BCE Projects and Applicant's Career Goals.

Pagona Roussi, Ph.D., returned to the Psychosocial and Behavioral Medicine Program in September/October 2004 and September 2005. Dr. Roussi has been serving as a consultant to Dr. Miller and members of the research team on several ongoing grants. Dr. Roussi comes from Aristotle University of Thessaloniki, Thessaloniki, Greece offering expertise in stress and coping with major life events, with a special interest in serious illnesses. Dr. Roussi has a Ph.D. in Chemistry earned at Imperial College, London University, London, England in 1977. Since earning her Ph.D. in Clinical Psychology at Temple University, Philadelphia, Pennsylvania in 1995 Dr. Roussi has taught in the Department of Philosophy and Social Studies at the University of Crete, Crete, Greece as a Visiting Assistant Professor as well as in the Department of Psychology at Aristotle University of Thessaloniki, Thessaloniki, Greece. She has several publications, both independently and in collaboration with Dr. Miller and other Investigators. Her responsibilities at FCCC include analyzing data, writing manuscripts, and providing consultation and assistance with the designing of new interventions. Specifically, she has been involved in the development of the intervention protocol for Project 3 and for data-analytic plans.

Mary Ropka, Ph.D., R.N., F.A.A.N., joined the faculty at Fox Chase in May 2004 as an Associate Member in the Division of Population Science and has been involved in BCE as a mentee. She also holds adjunct appointments as Associate Professor in the Department of Health Evaluation Sciences at the University Of Virginia School Of Medicine and in the School of Nursing. Dr. Ropka is a clinical epidemiologist and oncology nurse who has a long-standing track record of interdisciplinary work and building new research programs and teams. She has experience with diverse study approaches, including multi-site clinical trials, survey research, observational designs, focus group studies and other qualitative approaches, and systematic reviews. Dr. Ropka's recent work, funded by a 5-year K07 Cancer Prevention (2001 – 2006), Control, and Population Sciences Career Development Award from NCI, is focused on decision support, behavioral cancer genetics, and cancer prevention and control in order to develop and test patient decision support interventions related to hereditary cancer risk. Dr. Miller is Co-Sponsor for her K07. In addition, Dr. Ropka is assisting Dr. Miller on the following: (1) developing the Signature Program proposal at Fox Chase focused on Health Decision Making; (2) the Behavioral Research Core Facility, of which Dr. Miller is the Director; (3) Dr. Ropka's K07 study, "Decision Making Needs and Family

Communication When Dealing With Hereditary Cancer Risk Decisions – A Qualitative Pilot Study", for which Dr. Miller is a co-investigator; (4) Dr. Ropka's June 2005 R21 application, "Facilitating Web-based Decision Support For Hereditary Cancer Risk"; (5) June 2005 CISRC grant application to NIH, of which Dr. Miller is PI of the Intervention Development and Measurement Core; (6) conducting a half-day pre-conference Cancer Special Interest Group session at the annual Society for Behavioral Medicine meeting in April 2005, "Decision Making in the Cancer Context – Translation from Basic Science Through Population Health", for which they are now co-editing a special issue of the *Annals of Behavioral Medicine.*

Catharine Wang, Ph.D. joined the Psychosocial and Behavioral Medicine Program in August 2005 as an Assistant Member in the Division of Population Science at FCCC and is involved as a mentee in the BCE. She has an extensive background in developing and evaluating tailored interactive multimedia and behavioral interventions. Prior to her appointment at FCCC, Dr. Wang was involved in several projects in collaboration with the Health Media Research Lab (now the Michigan Center for Health Communication Research) at the University of Michigan, led by Dr. Strecher. These projects included the development of an interactive CD-ROM program for BRCA1/2 education and counseling, and tailored health communication interventions to address multiple behavioral risk factors such as smoking cessation, physical activity and diet. In addition, Dr. Wang has a background in the area of decision research. She has collaborated with researchers at the University of Michigan to examine how various communication aids, such as graphic images or pictographs, may be used to improve the comprehension of risk communication and modify the influence of patient testimonials in treatment decision making. Dr. Miller is currently mentoring Dr. Wang in the application of theory to behavioral interventions and evaluation of public health programs related to breast cancer risk and survivorship.

Hong Nguyen, D.O., joined the Psychosocial and Behavioral Medicine Program as Senior Project Manager in June 2005 after completion of her medical school training at Philadelphia College of Osteopathic Medicine. Also a Health Policy Doctoral Candidate at the University of the Sciences in Philadelphia, she is being mentored by Dr. Suzanne Miller and Dr. Joanne Buzaglo within the BCE in research methodology and design, and behavioral oncology with an emphasis on healthcare disparities among racial/ethnic underserved minorities.

Melania Popa-Mabe, M.S.W., joined the Psychosocial and Behavioral Medicine Program in February 2005 as a Health Educator in February 2005, and in July 2005 assumed the role of Project Manager. She currently holds a Master Degree in Human Resources Management and is completing her Ph.D. in Social Welfare at School of Social Work and Social Research, Bryn Mawr College. Melania Popa-Mabe is being mentored by Dr. Suzanne Miller and Dr. Joanne Buzaglo within in the BCE in breast cancer research with an emphasis on survivorship and psychosocial correlates of cancer screening and prevention behavior among underserved populations.

Elizabeth Bernabeo, MPH, joined the Psychosocial and Behavioral Medicine Program in January 2004, and is involved as a mentee in the BCE. She currently holds a Master Degree in Public Health from Temple University and she is completing her Ph.D. in Social Welfare at School of Social Work and Social Research, Bryn Mawr College. Elizabeth Bernabeo is being mentored by Dr. Suzanne Miller and Dr. Joanne Buzaglo in decision-making process in cancer context, and psychosocial aspects of decision-making in the context of genetic testing. She is conducting her dissertation project: "Decision Making among High-Risk Women Undergoing Breast/Ovarian Genetic Testing" under the supervision and mentorship of Dr. Miller and Dr. Buzaglo.

Elizabetta Razzaboni, Ph.D., joined the Psychosocial and Behavioral Medicine Program in August 2004 and worked with the research team for eight weeks. She came to FCCC from the Department of Psychology at the University of Bologna, Bologna, Italy. She was actively involved in reviewing BCE focus group transcripts with a special focus on qualitative analysis. Drs. Miller and Buzaglo mentored her with respect to the application of cognitive-social theory to the development of assessment and behavioral intervention protocols for women at high risk for breast and ovarian cancer. Dr. Razzaboni is a member of an interdisciplinary oncology team in Bologna established to create a program for state-of-the-art care for women at familial risk for breast and ovarian cancer and is continuing to work collaboratively with BCE.

Catia Ghinelli, Ph.D., returned to the Psychosocial and Behavioral medicine Program in August-September 2005 as a mentee in the BCE. She originally came to FCCC from the Department of Psychology at the University of Bologna, Bologna, Italy in the summer of 2003 at which time she translated study protocols related to breast cancer survivorship and lymphedema. She continues to collect data on women diagnosed with early stage breast cancer and is actively involved in comparing cross-cultural datasets relevant to the BCE. Drs. Miller and Buzaglo provide ongoing guidance in the data collection and analysis.

Chana Gorodischer, CSW, Coordinator of the Eshkol Breast Health Center, Soroka University Medical Center, Ben Gurion University of the Negev, Israel. Ms. Gorodischer spent a two-week internship in August 2005 to study the cognitive-social model utilized to develop and assess the BCE behavioral protocols with a special focus on BCE 3, *Facilitating Re-entry Following Adjuvant Treatment for Primary Breast Cancer* as well as a related study entitled *Efficacy and Feasibility of a Psychosocial Intervention within the CCOP Context: Evaluation of the Facing Forward Guide to Facilitate Life after Active Cancer Treatment* (P.I. Dr. Suzanne M. Miller). Both of these ongoing funded projects will provide the foundation on which to build a research program that assesses the psychosocial needs of women who have undergone treatment for breast cancer as well as the development of innovative health communications and evaluation of the comprehensive psychosocial programs already in place at the Soroka Breast Health Center in Beer Sheva, Israel.

The Summer Internship Program continued to operate through Fall 2004. The Summer Internship program was established in 2002 to provide training opportunities to students

at the high school, undergraduate and graduate levels in the area of behavioral research within the context of breast cancer prevention and control to encourage future leaders in the field and to provide a source of candidates for the Training Program. Two interns joined us in the summer of 2004: Lovely Jacobs, a senior attending Samual S. Fels High School in Philadelphia, PA, joined FCCC in July 2004 as a participant in the Howard Hughes Student Scientist Program. She continued to work with the FCCC research team through summer 2005, and presented her research to other Howard Hughes student scientists in July 2005. Julie Michael joined FCCC in May 2004 as a senior at Villanova University in May 2004 to fulfill the requirements for her Bachelors degrees in Comprehensive Science (B.S.) and Psychology (B.A.) with a concentration in Ethics in Health Care. Upon completing her 15-week internship, she was offered, and accepted, and part-time position in the department. Each intern was required to complete a web-based bioethics course, was provided with required readings highlighting the theoretical framework that guides our research, and was responsible for conducting study-related literature searches using electronic databases such as PubMed and Ovid as well as retrieving journal articles electronically and from FCCC's on-campus library. Kate Barrett, currently a Senior at Brown University with a major in community health education, was instrumentally involved in conducting a qualitative analysis of transcripts of women who had undergone risk assessment and genetic testing at FCCC. Nina Howze, a Senior at East Stroudsburg University with a major in Public Health, was trained in recruitment for minority participants in BCE 1 and received mentorship in focus group implementation for minority populations.

Task 4. To implement meta-analysis and thematic integration of findings.

An extensive meta-analysis will be conducted, as planned in Task 4, upon the completion of data collection for the studies within the BCE.

The Leadership Core has contributed an extensive list of articles based on its literature search on breast cancer risk to the library of the Behavioral Research Core Facility (BRCF) at Fox Chase Cancer Center under the direction of Dr. Suzanne Miller. The BRCF provides the necessary infrastructure and resources to integrate basic and applied bio-behavioral and psychosocial research across the spectrum of cancer prevention and control research. Its mission and function are synergistic with that of the BCE. The BRCF library serves as an NCI- funded resource to investigators throughout the institution.

KEY RESEARCH ACCOMPLISHMENTS

- The continuation of monthly BCE meetings.
- The following steps have been implemented to support the BCE training program:
    - The continuing support of the BCE Training Program Committee that oversees the development and implementation of promotional strategies to

enhance recruitment of qualified candidates for the pre- and post-doctoral fellowships.

- Pagona Roussi, Ph.D., returned to the Behavioral Medicine Program as a consultant on the various projects within the BCE.

- Catia Ghinelli, Ph.D., joined the Behavioral Medicine Program in August 2005 as a visiting researcher providing consultation in cross-cultural data collection and quantitative data analysis for the projects within the BCE.

- Pamela J. Shapiro, Ph.D., is being interviewed to fill the remaining post-doctoral position within the Training Program. She currently holds a Postdoctoral Fellowship in the Department of Psychiatry and the Abramson Cancer Center of the University of Pennsylvania with research interests in health-related quality of life, the cognitive sequelae of cancer diagnosis and treatment, and issues of concern to women at risk for hereditary breast and ovarian cancers (HBOC).

- The establishment of a collaboration with the Eshkol Breast Health Center, Soroka University Medical Center, Ben Gurion University of the Negev, Israel to translate BCE protocols and develop innovative health communications and evaluation of the comprehensive psychosocial programs already in place at the Soroka Breast Health Center in Beer Sheva, Israel.

- The Summer Internship Program continued successfully for its third year in providing training opportunities to students at the high school, undergraduate and graduate level in the area of behavioral research within the context of breast cancer prevention and control to encourage future leaders in the field.

- The continuation of the Behavioral Oncology Interest Group at the American Society for Preventive Oncology (ASPO).

- Preparation and publication in 2006 of two volumes that will extend the theoretical model across the cancer continuum, including genetic risk, and provide an integrative synthesis of the behavioral medicine field. The titles of these volumes will be: "Individuals, families and the new era of genetics: Biopsychosocial perspectives" and "Handbook of behavioral science and cancer"

- Collaboration with Al Marcus, Ph.D., of the AMC Cancer Research Center, on a research consortium using the Cancer Information Service.

- The Leadership Core applied for and received DOD approval for a no-cost one-year extension.

REPORTABLE OUTCOMES

At this time, the Leadership Core continues to provide integrative oversight and management of all aspects of the BCE to maximize the efficiency of its inter-coordinated organizational structure. The Core continues to develop, refine, and evaluate the overarching, unifying conceptual framework in its efforts to oversee and enhance the centralized quality control mechanism for designing, refining, and evaluating the theoretically-derived assessments and interventions. The Core remains active in the ongoing maintenance of the Training Program.

- Presentations(for abstracts see Appendix #18):

  Miller, S.M. Invited Speaker, Presented as part of Invited Symposium on Educating Women about Risk Counseling/Genetic Testing Makes a Difference in Intended Use of Services, Especially among those at High-Risk: Results of a Randomized Trial Among Callers to the Cancer Information Service. The Department of Defense (DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005. (See PowerPoint Presentation in Appendix # 16)

  Miller, S.M. Invited Co-Chair, Invited Symposium on People and Populations. The Department of Defense(DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005.

  Miller, S.M. Invited Speaker on Tailored Communication to Enhance Adaptation across the Breast Cancer Spectrum. Presented as part of Invited Symposium on Behavioral Centers of Excellence: Treating More Than the Tumor. The Department of Defense (DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005. (See PowerPoint Presentation in Appendix #17)

- Publications (for abstracts see Appendix #18):

  Miller, S.M., Bowen, D. J., Campbell, M.K., Diefenbach, M.A., Gritz, E.R., Jacobsen, P.B., Stefanek, M., Fang, C.Y., Lazovich, D., Sherman, K.A., Wang, C. (2004). Current research promises and challenges in behavioral oncology: Report from the American Society of Preventive Oncology Annual Meeting. Cancer Epidemiology, Biomarkers and Prevention, 13, 171-180.

  Miller, S.M., Roussi, P., Daly, M.B., Buzaglo, J.S., Sherman, K.A., Godwin, A.K., Balshem, A., & Atchison, M.A. (2005). Enhanced counseling for women undergoing BRCA1/2 testing: Impact on subsequent decision making about risk prevention behaviors. Health Education and Behavior, Special Issue on Genetic Risk. (5), 654-67.

Miller, S.M., Fleisher, L., Roussi, P., Buzaglo, J.S., Schnoll, R.A., Slater, E., Rayser, & Popa-Mabe, M. (in press) Facilitating informed decision making about breast cancer risk and genetic counseling among women calling the NCI's Cancer Information Service. Journal of Health Communication, Special Issue on Health Communication.

CONCLUSION

Members of the BCE continue to successfully assist all research teams accomplish their tasks during its second year. Our efforts have remained focused on the development of the necessary infrastructure between project staff and the other core facilities in order to facilitate synergistic research efforts and integrative findings across the multiple projects.

REFERENCES

None

DOD Progress Report
Communications Core

Suzanne M. Miller, Ph.D., Principal Investigator
Michael A. Diefenbach, Ph.D., Core Director
Linda Fleisher, MPH, Co-Core Director

October 2005

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

The Communications Core has provided critical support and services for the research projects in the Behavioral Center of Excellence in Breast Cancer (BCE). The Communications Core builds on and extends the infrastructure, resources and expertise of the FCCC Behavioral Core to include state-of-the art communications theory and applications.

The Communications Core has two primary functions. The first, descriptive function consists of assessing information needs and culturally specific beliefs of populations targeted by the different Center projects. The second primary function of the Communications Core is to successfully translate this information into effective communication messages and strategies that meet the needs of the target population. To this end, the Communications Core conducts in-depth needs assessments of the target populations through focus groups for each individual research project; analyzes the information obtained; and assists in developing appropriate patient-tailored health communications.

Specifically, the aims of the Communications Core are:

Aim 1: To provide linkages to the FCCC Behavioral Core for assistance in evidence-based behavioral approaches and measures.

Aim 2: To expand the Behavioral Core resources to include communication theory and applications.

Aim 3: To facilitate the assessment of information needs of the target populations through focus groups.

Aim 4: To provide consultation in the development of interventions using behavioral, health education and communication principles and theories.

Aim 5: To provide formative evaluation services (e.g. implementation and analysis) to inform the development and pilot testing of interventions for specific populations.

By utilizing the Communications Core for all research projects an economy of scale is created with a synergistic impact that benefits and informs each of the projects as well as the entire Behavioral Center of Excellence.

These goals are achieved through a structured consultation and implementation process that includes an initial contact and needs assessment phase, a planning phase, and an implementation and follow-up phase. Throughout these phases, members of the Communications Core and members of the individual research projects have been in frequent contact to ensure that the objectives of the individual research projects are achieved.

BODY

In the first three years of the Center, the Communications Core worked closely with Invesigators to develop assessment approaches (e.g. focus groups) to gather critical information to addresss specific needs of the target audiences, integrate communication theory into the interventions and provide consultation for all projects. The Communications Core has also developed a Resource Repository of literature and resources on communications, tailoring, cultural implications and literacy.

In year 4, the Core has focused on the final phases of intervention development and strengthening linkages to the FCCC Behavioral Research Core. The Communications Core initiated the various tasks for each research project as specified in the Statement of Work as listed below. Here we describe an example from Project II highlighting the expertise and support provided from the Core, followed by a list specific tasks by research projects.

Core Exemplar – Project II

For Project II, tailored interventions were developed to enhance participation in risk assessment and adopt risk-reducing behaviors among first degree relatives of breast cancer patients. The tailored interverventions were generated through a tailoring engine developed in collaboration with the Communication and Informatics Core. The Communications Core developed a library of tailored breast cancer risk assessment messages to be matched to participant responses from the baseline phone interview. The tailored message addresses a number of variables, including: calculated breast cancer risk (the Gail Model), breast cancer family history pattern (sporadic, familial or putative hereditary), status of breast health behavior (mammography, diet, exercise) and attentional style (high or low monitor based on the Monitoring-Blunting Style Scale). An software program was developed with the Informatics Core to create algorithims to integrate the messages into the scripts for each participant in the tailored group. Two separate intervention scripts were generated for a) low monitors with a high risk family history and non-compliant with screening (see appendix #1) and b) high monitors with an intermediate risk family history and compliant with screening (see appendix #2). Additional tailored printed materials were developed regarding risk factors, personal risk profile and screening recommendations

- Risk Factors -- Risk Factors Fact Sheets were tailored to four different groups: 1) high monitor and high risk (see appendix # 3); 2) high monitor and intermediate risk (see appendix #4); 3) low monitor and high risk (see appendix #5); 4) low monitor and intermediate risk (see appendix #6)
- Personal Risk Profile -- Two printed materials were developed, one making reference to tamoxifen if appropriate based on the Gail model (see appendix #7) and the other with no reference to tamoxifen based on the Gail model.

- Screening Recommendations

Six Screening Recommendations Fact Sheets tailored to monitoring style, compliance with screening and age were developed for the following groups: 1) high monitors, under age 40 who have not yet begun screening mammography receive a message that recommend to start screening (see appendix #9); 2) high monitors who started screening receive a message that reinforce continued compliance with screening (see appendix #10); 3) high monitors that are not compliant with screening receive a message that recommend screening and emphasize that mammography is overdue (see appendix #11); 4) low monitors under age 40 who have not yet begun screening mammography receive a shorter message that recommend to start screening (see appendix # 12); 5) low monitors who started screening receive a shorter message that reinforce continued compliance with screening (see appendix # 13); 6) low monitors that are not compliant with screening receive a shorter message that recommend screening and emphasize that mammography is overdue (see appendix #14);

This tailoring engine, developed in collaboration with the Communication and Informatics Core, is the backbone to generate the tailored scripts and adjunct materials. The process and procedures to develop the tailoring engine were carefully designed and have been shared with Fox Chase Cancer Center's Behavioral Research Core Facility as described in Aim 1. This process has been used in other research projects that include tailored interventions. As shown in Appendix #15, this tailoring process have been adapted to an NCI grant focused on providing tailored telephone counseling for low income women to increase compliance with follow-up of abnormal pap smears.

Project I: Understanding Breast Cancer Risk Assessment and Screening Behavior Among the Underserved.

Reviewed and consulted on Phase II recruitment strategies – TV and Print	
Develop publication plan with research team	Month 10-12

Project II: Cancer-A teachable Moment Within the Family: From Concept to Community

Finalized tailored script for intervention	Month 1-3
Collaborated with research team and Informatics Core to finalize algorithms and tailoring system	Month 1-3
Review of scripts and print materials on periodic basis	Month 1-12
Develop publication plan with research team	Month 10-12

Project III: Facilitating Re-entry following Treatment for Primary Breast Cancer

Assisted in the development of analysis plan for focus groups	Month 1-4
Assisted in the development of the tailored Intervention	Month 4-5
Assisted in the establishment of the recruitment procedures	Month 6

Participated in Project Meetings	Month 6-12
Develop publication plan with research team	Month 10-12

Project IV: Impact of a Communication Skills versus a Supportive Therapy Intervention for Women with Metastatic Breast Cancer

Provided suggestions on additional recruitment strategies	Month 4-6

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.
- Members of the Communications Core have continued to augment the library of the Behavioral Research Facility with articles from the communications literature. Additional resources on cultural issues have been added. This resource is made available to all members of the BCE, as well as the wider community of researchers at FCCC. Further, project-specific accomplishments follow:
- **Project I.** In collaboration with project staff the Communications Core has completed focus groups analyses.
- **Project II.** The Core met a number of times with the research to review the final materials (tailored messages and counseling protocol) and continues to review tailored scripts and materials for quality control
- **Project III.** Members of the Communications Core have regularly met to develop an analysis plan for the focus group data.
- **Project IV.** The research team and members of the Communications Core have provided additional strategies to recruitment.

REPORTABLE OUTCOMES

Other than the key research accomplishments detailed above there are no reportable outcomes.

CONCLUSION

Members of the Communications Core have successfully assisted all research teams accomplish their tasks during their third year. Our efforts have focused on finalizing assessment and materials and analysis of focus group data to inform study procedures, protocols and materials. The Core has provided ongoing feedback at the monthly meetings and provided strategies for recruitment. We have also continued to add to the BRCF library by identifying and including key health communication research articles.

REFERENCES

None

DOD Progress Report
Informatics Core

Suzanne M. Miller, Ph.D., Principal Investigator
Eric Ross, Ph.D., Core Director

October 2005

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

The varied populations studied in this Behavioral Center of Excellence in Breast Cancer (BCE) and the complexity of the designs require development of study-specific computer based tools to provide critical project management and coordination, and for the collection, validation, storage, retrieval and analysis of data. The projects contained in this BCE include: Understanding Breast Cancer Risk Assessment and Screening Behavior Among the Underserved, Cancer-A Teachable Moment Within the Family: From Concept to Community, Facilitating Re-entry Following Treatment for Primary Breast Cancer, and Impact of a Communication Skills versus a Supportive Therapy Intervention for Women with Metastatic Breast Cancer.

The objective of this core is to facilitate the research conducted in this BCE by providing (1) a central repository for all of the data included in the research, (2) data entry and validation services and (3) report generation and standard statistical program services. To be included in this core data repository are: a) socio-demographic data on study populations, b) clinical information, c) family history, d) genetic testing data, e) psycho-social data, f) health history data, g) quality of life data, h) cancer screening data, and i) diet data. Data from approximately 1000 subjects collected in four research projects will ultimately be stored in this information system.

The specific aims of the core are:

Aim 1: To provide computer-based tools that facilitate the entry, storage, manipulation and retrieval of the large quantities of data generated in the proposed research.

Aim 2: To ensure the accuracy of the data maintained in the database by developing human and software based data consistency and quality control systems.

Aim 3: To provide high-quality data entry services.

Aim 4: To organize and maintain the database to maximize accessibility, while maintaining strict confidentiality.

Aim 5: To provide statistical computing support.

Below, we specify the tasks to be accomplished in the context of this project.

Task 1. Provide computer-based tools that facilitate the entry, storage, manipulation and retrieval of the large quantities of data generated in the proposed research.

a. In collaboration with the project investigators and research teams clearly define the specifications of the required information systems
b. Carefully design the needed database structures
c. Develop database systems
d. Design, and develop electronic data entry/retrieval systems

e. Test the electronic data entry/retrieval systems
f. Design and develop report and letter generation software
g. Test report and letter generation software
h. Review of applications by Project Investigators
i. Make modifications as needed. Put software into production
j. Support and enhance software system software as needed

Task 2. Ensure the accuracy of the data maintained in the database by developing human and software based data consistency and quality control systems. Provide data entry and data validation services. Provide statistical computing support.

a. In collaboration with the project investigators and research teams design, develop and test data quality assurance systems
b. Conduct data entry and data validation
c. Provide statistical programming services

BODY

The details of the information system developed for the three research projects are described below.

Project I: Understanding Breast Cancer Risk Assessment and Screening Behavior among the Underserved

The overall goal of Project I is to identify and assess barriers and facilitators to participation in breast cancer risk assessment and adherence to breast cancer screening recommendations among African American women.

Core staff collaborated with project investigators and staff to refine and finalize the data flow and telephone data collection instruments. Core staff used a case tool (PowerDesigner 6.1.0) to model the database, represent the physical organization of data in a graphic format, generate database creation and modification scripts, define referential integrity triggers and constraints, generate extended attributes, and generate a data dictionary. Core staff designed and developed a Computer Assisted Telephone Interview (CATI) system to meet the specific needs of this the study. The application calculates each participant's estimated risk of developing breast cancer through an interface with a FORTRAN implementation of Mitchell Gail's algorithm. A graphical user interface (GUI) system for displaying and scheduling follow-up phone interviews was developed and is currently being used by project staff.

Project II: Project II: Cancer – A Teachable Moment within the Family: From Concept to Community

The goal of this study is to test the effectiveness of a tailored intervention to increase participation rates in a FCCC high-risk breast cancer program (i.e.,

FRAP). A secondary aim is to explore the effect of the intervention on breast cancer screening practices.

Core staff collaborated with project investigators and research staff to refine and finalize the data flow and hardcopy data collection instruments. The relational database management system for this project is complete. This system will maintain all of the information collected in this study including: health history, clinical, epidemiologic, socio-demographic, and psychosocial data. In addition, this database contains cancer and vital status data on relatives of individuals recruited into the study. The software system coordinates numerous tasks, including the scheduling of follow-up visits, and the distribution of mailed self-report questionnaires. This system generates multigenerational pedigrees from the union of family histories provided by two or more distinct study subjects in the same family. The family data can be updated from follow-up information to include deaths or new cancers reported for study subjects, previously listed family members, as well as new births. The system randomizes participants to study arm based on strata defined by the participant's MBSS score, her family history (of cancer) and date of last mammogram. Tailored and control scripts are automatically generated at time of randomization using Oracle Reports. Core staff also developed: a ticker/reminder system to notify appropriate staff when a 12-month follow-up phone survey is due; report generation software to produce printed materials (dependant upon study arm assignment) and accompanying cover letters; and database views that are used by project staff to display information about study participation. All software has undergone thorough testing.

Project III: Facilitating Re-entry Following Treatment for Primary Breast Cancer

The primary objective of this study is to develop and evaluate a C-SHIP guided Cognitive-Affective Processing (CAP) intervention to facilitate psychosocial adjustment at re-entry, following adjuvant treatment for primary breast cancer. Core staff reviewed draft data collection instruments and project timelines. Project III is conducting focus groups to help refine the cognitive-affective intervention. Design, development, testing and deployment of the production database for the randomized trial will begin following the completion of the focus groups and finalization of the data collection instruments and study timelines.

Core staff collaborated with project investigators and research staff to refine and finalize the data flow and hardcopy data collection instruments for participant enrollment and the participant's baseline assessment. These are undergoing "final" testing by project staff. Core staff continue to collaborate on refinement of the participant follow-up data flow and data collection instruments.

Project IV: Impact of a Communication Skills versus a Supportive Therapy Intervention for Women with Metastatic Breast Cancer

The goal of this study is to compare a cognitive-behavioral intervention (with a communication and support training focus) to a supportive therapy intervention, on the quality of life of women with metastatic breast cancer. A secondary aim is to explore moderating effects of individual dispositional factors and mediating effects of support-related variables on the impact of the intervention strategies.

The relational database management system for this project has been completed. This system maintains all of the information collected in this study and facilitates many aspects of data collection and patient tracking. Core staff collaborated with project investigators and research staff to refine and finalize the data flow and hardcopy data collection instruments. Core staff prepared data dictionaries. PowerDesigner was used to model the database, represent the physical organization of data in a graphic format, generate database creation and modification scripts, define referential integrity triggers and constraints, and generate a data dictionary. A system for the scheduling of follow-up visits and electronic screens displaying subjects due for follow-up was also developed. All software has undergone thorough testing by demonstrating that each function is operational and performs according to specification. Views of the database have been created to facilitate analysis by investigators and study biostatisticians using SAS and SPSS.

KEY RESEARCH ACCOMPLISHMENTS

- Core staff attends and participates in monthly Center meetings.

- Core staff collaborated with project investigators and research staff to refine the data flow and hardcopy data collection instruments for all four projects. Core staff developed data dictionaries based on study requirements and data collection instruments.

- Core personnel have designed and developed comprehensive information management systems to meet the specific needs of projects I, II and IV and to address participant enrollment and baseline assessment for project III. These customized relational database systems have been implemented using a combination of tools including, Java/J2EE, Oracle Forms, Oracle Reports and Oracle database engine software. The database and management structure facilitate efficient data capture and manipulation, as well as control the exchange of information across the projects. All software has undergone thorough testing before release to the user community.

- Data quality assurance procedures have been implemented using software-based data entry checks as well as post-entry manual audits.

- Software for the scheduling of follow-up visits, and the distribution of mailed self-report questionnaires has been developed for Project II.

- Software was developed for all Projects to generate reports that allow tracking of study accrual and progress of individual study subjects.

- All FCCC computers used for storing the information were protected from inappropriate outside access by the FCCC firewall.

- Security measures for accessing data have been implemented. The first level controls access to the desktop computers and web-server. Fox Chase Cancer Center uses a Lightweight Directory Access protocol (LDAP) directory service, implementing a subset of the InteOrgperson/EduPerson V2.0 schema, to provide a robust, extensible, and well-controlled common authentication mechanism. The second level of username/password based security takes place at the database server and application interface level. Each user is assigned a unique Oracle username/password. Restrictions are applied to each user commensurate with their needs to access the data (roles) at the application level.

REPORTABLE OUTCOMES

- none

CONCLUSION

This Core serves as a resource for the Center of Excellence as a whole and will maintain a valuable source of data for current and future studies. By centralizing these services into an Informatics Core, we are better able to manage and coordinate the collection, storage, and distribution of a large amount of highly valuable data. Subject to informed consent, the information contained in the data repository will be available to all investigators in the Center of Excellence. By providing access to the data to all participants, sharing technical capabilities and ensuring the quality of the data, this core will not only facilitated achievement of the aims of the individual projects, but also make possible exploratory analyses beyond the stated aims of the projects.

REFERENCES

None

DOD Progress Report
Blood Collection and BRCA1 and BRCA2 Mutation Testing through the Genetic Susceptibility-Testing Laboratory Core

Dr. Suzanne M. Miller, Ph.D., Principal Investigator
Andrew K. Godwin, Ph.D., Core Director

October 2005

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

The strongest known epidemiological risk factor for breast cancer is a positive family history and studies of breast and ovarian cancer patients and their relatives consistently find statistical evidence for involvement of autosomal dominant genes. Therefore, the identification of specific genes has long been the focus of efforts to identify women at high risk. A promising approach for reducing the high incidence and mortality associated with breast cancer lies in the early detection of women at high risk. These women, once identified, can be targeted for more aggressive preventative programs and tailored interventions to help cope with their increased risk of developing cancer. As a result of the cloning of the two most prominent breast-ovarian cancer susceptibility genes, *BRCA1* and *BRCA2*, it is now possible to screen women from high-risk families for germ-line mutations. This Core was created to support Project 2, "Cancer-A Teachable Moment Within the Family; From Concept to Community" and Project 3, "Facilitating Re-entry following Treatment for Primary Breast Cancer". Project 2 proposes to test the efficacy of a health communication message personalized to a set of demographic, clinical, and psychosocial factors and timed to capitalize on the heightened awareness of breast cancer risk attributed to the recent diagnosis in a first-degree relative (FDR). The purpose of the health communication message is to encourage that these at-risk women participate in the Family Risk Assessment Program at FCCC or the Network Hospitals in order to receive personalized breast cancer risk information provided to the participants. *BRCA1* and *BRCA2* mutation analysis is offered to those who have familial patterns of breast cancer indicative of a possible involvement of a disease-associated germline mutation. Similarly, Project 3 proposes to provide tailored communications. However, the communications are provided to breast cancer patients actively undergoing treatment. The communications are designed to enhance adjustment, quality of life, and adherence to recommended follow-up regimens during survivorship. Participants are extended an offer to participate in FRAP to receive familial risk information. Eligible participants, based again on family history of breast cancer, are offered *BRCA1* and *BRCA2* mutation analysis.

Specifically, the aims of the Core are as follows:

Aim 1: To collect and bank blood samples from women with breast cancer or unaffected women with a family history of breast cancer as part of Projects 2 and 3.

Aim 2: To evaluate constitutive DNA from individuals participating in the Projects 2 and 3 for mutations in BRCA1 and BRCA2.

We have an extensive history of collecting and banking biospecimens from women at an increased risk for breast and/or ovarian cancer at the Fox Chase Cancer Center. During the past year we collected and processed blood samples from hundreds of FRAP participants and have screened for germline mutations in *BRCA1* and *BRCA2*. We have improved our methods to identify germline mutations as well as to assess the impact of these mutations on cancer risk. To date, we have identified more than **500** *BRCA1* and/or

BRCA2 mutation carriers (including **69** unique deleterious mutations) using our EMD approach. The personnel and methodology are in place to handle and screen the BCE samples as they are obtained. We attend the monthly BCE meetings to discuss recruitment and to up date the progress we have made in our genetic testing.

BODY

The strongest known epidemiologic risk factor for breast cancer is a positive family history and studies of breast and ovarian cancer patients and their relatives consistently find statistical evidence for involvement of autosomal dominant genes. Therefore, the identification of specific genes has long been the focus of efforts to identify women at high risk. A promising approach for reducing the high incidence and mortality associated with breast cancer lies in the early detection of women at high risk. These women, once identified, can be targeted for more aggressive preventative programs and tailored interventions to help cope with increased risk. As a result of the cloning of the two most prominent breast-ovarian cancer susceptibility genes, *BRCA1* and *BRCA2*, it is now possible to screen women from high-risk families for germ-line mutations. We developed this Core base on our previous experiences in effectively collecting thousands of blood samples from research participants with family histories of breast and/or ovarian cancer, and in screening for mutations in *BRCA1*, *BRCA2*, and other candidate breast cancer susceptibility genes. This Core supports Projects 2 and 3 (as well as the other Project in the BCE if the need arises), by providing a highly accurate and cost-effective means for testing eligible participants for mutations in the two most prominent breast cancer susceptibility genes, *BRCA1* and *BRCA2*.

KEY RESEARCH ACCOMPLISHMENTS

- Improved the ability to detect *BRCA1* and *BRCA2* mutations in genomic DNA.
- Reduced the cost of full *BRCA1* and *BRCA2* mutation analyses to a third of the cost of commercial testing without loss of sensitivity.
- Created *BRCA1* and *BRCA2* exon chips for detection of genomic rearrangements in these two genes.
- Included mutation detection technology for large deletions/insertions in *BRCA1*, an extension of PCR based mutation detection; included in our *BRCA1* and *BRCA2* full screen will be testing for the panel of 5 *BRCA1* deletions/insertions currently performed by the primary *BRCA1/BRCA2* clinical testing agent.
- Further reduced cost for *BRCA1* and *BRCA2* mutation analysis by enzyme mutation detection by performing our own DNA sequencing.

- Identified 56 novel polymorphisms common to ethnic populations; identified 5 novel frameshift mutaitons, 4 novel intronic variants, and 38 novel variants of uncertain significance in our ethnic populations.

- Developed a PCR based method to evaluate RNA for splicing changes in those specimens where intronic alterations have been identified.

REPORTABLE OUTCOMES

- Abstracts

*=supported by DAMD17-01-1-0238 ("Tailored Communications to Enhance Adaptation Across the breast Cancer Spectrum")
**=Demonstrates refinement and application of our methods to detect germline mutations in high-risk individuals.

- **Presentations**

*S.L. Neuhausen, H.T. Lynch, B.L. Weber, J.E. Garber, M.B. Daly, **A.K. Godwin**, T. Wagner, K. Nathanson, J. Farnham, S.A. Narod, T.R. Rebbeck. Modification of *BRCA1*- and *BRCA2*-Associated Breast and Ovarian Cancer Risk by *RAD51*. Proceedings of American Association of Cancer Research, 44:574, 2003.

- **Publications**

Wagner Costalas J, Itzen M, Malick J, Babb JS, Bove B, **Godwin A.K., Daly MB. Communication of *BRCA1* and *BRCA2* results to at-risk relatives: A cancer risk assessment program's experience. American Journal of Medical Genetics, 119C:11-18, 2003.

CONCLUSION

The work that we have preformed during the first four years of this application has served to improve our ability to detect mutations in the two prominent breast cancer susceptibility genes, *BRCA1* and *BRCA2*. We have published our mutation detection method and have shown that it is comparable if not superior to commercial methods at a significantly lower cost. We have also developed a method to detect large genomic rearrangements in *BRCA1* and *BRCA2* that elude detection when using PCR-based approaches to search for mutations. We are also developing in our testing regimen a PCR based method for detecting large insertions/deletions in *BRCA1*. Overall, we are in optimal position to appropriately analyze any and all BCE samples once they become available through Projects 2 and 3. Furthermore, we will be able to process more

samples than originally proposed due to our technical improvements and ability to automate the method.

REFERENCES

None

DOD Progress Report, October 2005
APPENDICES

Appendices referred to *in the DOD Progress Report Communications Core* & the *DOD Progress Report, Project II: A Teachable Moment within the Family: From Concept to Community*

Appendix #1 - Sample of tailored script for low monitors with a high risk family history and non-compliant with screening

Appendix #2 - Sample of tailored script for high monitors with an intermediate risk family history and compliant with screening

Appendix #3 – Sample of tailored printed materials: Risk Factors -- Risk Factors Fact Sheets for high monitors at high risk

Appendix #4 - Sample of tailored printed materials: Risk Factors -- Risk Factors Fact Sheets for high monitors at intermediate risk

Appendix #5 - Sample of tailored printed materials: Risk Factors -- Risk Factors Fact Sheets for low monitors at high risk

Appendix #6 - Sample of tailored printed materials: Risk Factors -- Risk Factors Fact Sheets for low monitors at intermediate risk

Appendix #7 - Sample of tailored printed materials: Personal Risk Profile -- making reference to tamoxifen if appropriate based on the Gail model

Appendix # 8 - Sample of tailored printed materials: Personal Risk Profile -- making no reference to tamoxifen based on the Gail model

Appendix # 9 - Sample of tailored printed materials: Screening Recommendation Fact Sheet for high monitors, under age 40 who have not yet begun screening mammography

Appendix # 10 - Sample of tailored printed materials: Screening Recommendation Fact Sheet for high monitors who started screening

Appendix # 11 - Sample of tailored printed materials: Screening Recommendation Fact Sheet for high monitors that are not compliant with screening

Appendix # 12 - Sample of tailored printed materials: Screening Recommendation Fact Sheet for low monitors under age 40 who have not yet begun screening mammography

Appendix # 13 - Sample of tailored printed materials: Screening Recommendation Fact Sheet for low monitors who started screening

Appendix # 14 - Sample of tailored printed materials: Screening Recommendation Fact Sheet for low monitors that are not compliant with screening

Appendix # 15 – Example of tailoring process and procedures

Appendices referred to *in the DOD Progress Report, Leadership Core*

Appendix # 16 – PowerPoint Presentation: Miller, S.M. Invited Speaker, Presented as part of Invited Symposium on Educating Women about Risk Counseling/Genetic Testing Makes a Difference in Intended Use of Services, Especially among those at High-Risk: Results of a Randomized Trial Among Callers to the Cancer Information Service. The Department of Defense (DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005.

Appendix # 17 - PowerPoint Presentation: Miller, S.M. Invited Speaker on Tailored Communication to Enhance Adaptation across the Breast Cancer Spectrum. Presented as part of Invited Symposium on Behavioral Centers of Excellence: Treating More Than the Tumor. The Department of Defense (DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005.

Appendix # 18 – Abstracts of Presentations and Publications related to the grant

TEACHABLE MOMENT INTERVENTION SCRIPT

Introduction

Hello, my name is _____, I'm calling from the Fox Chase Cancer Center. Is this_____ _____?

If yes:

A few weeks ago we spoke about a study we are offering to women who have a relative diagnosed with breast cancer. I'm following up on that call to see if I can share with you some of the information we have about breast cancer risks, and how that information might be important for you. I expect the call will take about 20-30 minutes. Do you have time to talk now?

If wrong person:

Is _____available?

If no:

Is there a better time I could call you?

Date:_____

Time:_____

Thank you. I'll call you back at the time you suggested and will look forward to talking to you.

If says "yes," has time to talk:

Great. We are learning a lot of new things about breast cancer and it's especially important for women like yourself, who have a relative diagnosed with breast cancer, to have access to that information because it could have an impact on your own health. I'd like to start with what we know about risk factors for breast cancer and then mention the most recent recommendations for breast cancer screening and prevention. Please feel free to stop me and ask questions as we are talking.

RISK FACTOR, FAMILY HISTORY SCRIPTS

LOW MONITOR , HIGH RISK

First I'd like to go over what determines a woman's risk for breast cancer. There are several different factors that influence a woman's risk for developing breast cancer. One is age. Breast cancer is more common in older women than in younger women. Another risk factor is family history. In families like yours, where there is already someone diagnosed with breast cancer, other women in the family have a higher than average risk. Having a relative with ovarian cancer can also increase a woman's risk, not only for ovarian cancer, but also for breast cancer. Also, if a relative in your family had breast cancer at a very early age, for instance before age 40, that also increases the risk for other family members. In your case, looking at your family history:

In addition to your mother, ____, it looks like you have 3 additional relative(s) with a history of breast cancer (with none of them before the age of 40).

We would call the pattern of breast cancer in your family "possibly hereditary," meaning the number of cancers suggest that these cancers may be related to the inheritance of one or more genes that can greatly increase the risk of getting breast or ovarian cancer. Further evaluation of your family history pattern and your other factors by a trained genetic risk counselor in the Family Risk Assessment Program may help to clarify this.

Do you have any questions about the pattern of cancers in your family?

_____

_____

_____

A lot of the other risk factors have to do with female hormones, both the internal hormones your own body makes, and any hormones you are exposed to in medications and possibly foods. Interestingly, having your first baby when you are young, say under 20 is protective, but never having children or having them after age 35 increases your risk. The number of breast biopsies you've had, particularly if they showed certain pre-cancerous features, can increase your risk.

Do you have any questions about any of these risk factors?

_____

_____

_____

There is actually a mathematical model that tries to put all these risks together in one number which tells you, based on the risk factors you have, both your five-year risk and your lifetime risk of getting breast cancer. It's called the **Gail Model,** and it's named after the statistician who developed it. In addition to your family history, the following risk factors used in the Gail model may increase your risk for developing breast cancer:

Older age (over 50)
Early first menstrual period (before age 12)
Late first full term pregnancy (after age 35) or never had a pregnancy
Number of previous breast biopies and results of those biopsies

You indicated on the survey we completed over the phone with you that, in addition to your family history, your risk factors include:

- Early first menstrual period (before age 12)
- Number of previous breast biopsies and results of those biopsies

Of course the Gail model is not perfect and there are still a lot of things we don't know about breast cancer and its causes. We will be sending you some follow up materials in the mail and will include the printout of your scores from this model. As I mentioned above, a trained cancer risk counselor in the Family Risk Assessment Program can help sort out all of this information with you.

Screening Recommendation Scripts

LOW MONITOR, NON-COMPLIANT

Next, I'd like to go over with you the current recommendations for screening and prevention of breast cancer. The goal of screening is to find cancers when they are at an early, and more curable stage. There are three different ways to detect early stage breast cancer. We generally urge women to examine their own breasts for unusual lumps or skin changes on a monthly basis, starting in their 20's. A clinical breast exam is given by a health care professional, usually once or twice a year during a routine gynecologic exam or physical exam. A physician or nurse exams the breasts for lumps and any other changes. The American Cancer Society recommends that all women begin annual mammography starting at age 40. No one of these screening tests is sufficient by itself. All three, breast self-exam, clinical breast exam and mammography are necessary to do the best job of finding a breast cancer at an early stage. Women with a family history of breast cancer may need to start screening at an earlier age. This is something you could discuss with your doctor or with a cancer risk counselor.

I see that you indicated in the survey we completed over the phone with you that:

- *You are examining your breasts on a regular basis.*

and that's great. However ...

- *You haven't had a clinical breast exam in the past year? Is it because you don't have a regular primary care doctor?*

  (Probe for other reasons)_____

  If you remind your doctor about your family history of breast cancer, he/she will probably want to do a clinical breast exam at least once a year.
  Or
  A cancer risk counseling program would be able to refer you to a health care professional who would do regular breast self-exams.

- *You haven't had a screening mammogram in the past year. Have you had trouble getting it scheduled?*

  (Probe for other reasons)_____

  You should discuss this with your physician or a cancer risk counselor to determine the best screening schedule for you.

For women over age 35:

Another option for women at increased risk for breast cancer is taking the drug Tamoxifen, which is approved for prevention in women with certain risk factors. Have you heard of Tamoxifen?_____ Tamoxifen has been shown to reduce the risk of breast cancer by 50%. You may want to discuss this option with your doctor.

Do you have any questions you would like to ask me?

_____

_____

_____

_____

The Family Risk Assessment Program at Fox Chase Cancer Center, Philadelphia, PA (800-325-4145) was established to provide to women like yourself additional information about breast cancer risk factors, and an individualized risk estimate based on your personal risk factors. A trained genetic counselor can also discuss the options for having a blood test for the BRCA1/2 genes if it seems appropriate. If you decide you would like to participate, you will also be given recommendations for screening and prevention which match your own risk pattern. We will be sending you information about the program in the mail, and a number to call if you are interested.

Thank you once again for your time. You will be receiving some additional materials in the mail that has more information on the topics we have discussed. You can also call the Cancer Information Service number, 1-800-4-CANCER and talk to a trained information specialist.

TEACHABLE MOMENT INTERVENTION SCRIPT

Introduction

Hello, my name is _____, I'm calling from the Fox Chase Cancer Center. Is this _____ _____?

If yes:

A few weeks ago we spoke about a study we are offering to women who have a relative diagnosed with breast cancer. I'm following up on that call to see if I can share with you some of the information we have about breast cancer risks, and how that information might be important for you. I expect the call will take about 20-30 minutes. Do you have time to talk now?

If wrong person:

Is _____available?

If no:

Is there a better time I could call you?

Date:_____

Time:_____

Thank you. I'll call you back at the time you suggested and will look forward to talking to you.

If says "yes," has time to talk:

Great. We are learning a lot of new things about breast cancer and it's especially important for women like yourself, who have a relative diagnosed with breast cancer, to have access to that information because it could have an impact on your own health. I'd like to start with what we know about risk factors for breast cancer and then mention the most recent recommendations for breast cancer screening and prevention. Please feel free to stop me and ask questions as we are talking.

RISK FACTOR, FAMILY HISTORY SCRIPTS

HIGH MONITOR , INTERMEDIATE RISK

First I'd like to go over what determines a woman's risk for breast cancer. There are several different factors that influence a woman's risk for developing breast cancer. One is age. Breast cancer is more common in older women than in younger women. It seems that most tissues, as they age, become more prone to genetic damage that can lead to cancer. So the longer a woman lives, the more likely she is to have a cell or cells in the breast tissue develop changes leading to cancer. Another risk factor is family history. In families like yours, where there is already someone diagnosed with breast cancer, other women in the family have a higher than average risk. In some cases, this may be explained by several women in the same family sharing common exposures or lifestyle factors. There is also the possibility that there is a genetic mutation being passed down through the family that greatly increases the risk of breast cancer. Two genes, BRCA1 and BRCA2 have been found to be associated with breast and ovarian cancer when they are inherited in a damaged or mutated form. So if a parent carries one of these damaged genes, they have a 50% chance of passing it down to each of their children. Fortunately damaged genes like this are not common, but if a family does have one of these genes there are certain clues in the family history:

If the breast cancers are occurring at very young ages, for instance less than 40;
If a woman gets breast cancer in both breasts;
If there is also ovarian cancer in the family;
Or if a man in the family gets breast cancer;

Each of these things increases the possibility that the cancers may be linked to a BRCA1 or BRCA2 mutation. In your case, looking at your family history:

In addition to your mother,____ , it looks like you have 1 additional relative(s) with a history of breast cancer (with none of them before the age of 40).

We would call the pattern of breast cancer in your family "familial" meaning the cancer(s) are not likely to be due to BRCA1 or BRCA2 mutations, but may be due to other genetic predispositions, or may be related to a combination of other risk factors. A more thorough evaluation of your risk factors and family history by a trained counselor may help to clarify this more.

Do you have any questions about the pattern of cancers in your family?

A lot of the other risk factors have to do with female hormones, both the internal hormones your own body makes, and any hormones you are exposed to in medications and possibly foods. Scientists think there is a link between estrogen and risk for breast cancer. So the more estrogen you are exposed to in your lifetime, the higher is your risk for breast cancer. This possibility was recently strengthened by a study that found that women who used hormone replacement therapy (which included both estrogen and progesterone) for menopause had a somewhat increased chance of developing breast cancer.

Having your first baby when you are young, say under 20, is protective. But never having children or having them after age 35 increases your risk. A pregnancy when you are young helps the cells in the breast become fully mature and therefore less likely to suffer genetic damage. If you never get pregnant, the cells remain somewhat immature and more vulnerable. If your first pregnancy is after age 35, apparently the cells have already sustained some genetic damage (just from aging) and are more susceptible to the influence of the hormones related to the pregnancy.

The number of breast biopsies you've had, particularly if they showed certain pre-cancerous features, can increase your risk. We don't think it's the biopsy itself that affects your risk, but rather the changes found in the tissue that led to the biopsy in the first place.

Do you have any questions about any of these risk factors?

_____

_____

_____

There is actually a mathematical model that tries to put all these risks together in one number which tells you, based on the risk factors you have, both your five-year risk and your lifetime risk of getting breast cancer. It's called the **Gail Model,** and it's named after the statistician who developed it. In addition to your family history, the following risk factors used in the Gail model may increase your risk for developing breast cancer:

Older age (over 50) since the risk of developing breast cancer increases with age and the great majority of breast cancer cases occur in women older than age 50.

Early first menstrual period (before age 12) may slightly increase your breast cancer risk due to a longer lifetime exposure to the estrogen produced by your ovaries.

Late first full term pregnancy (after age 35) or never had a pregnancy. The breast tissue of women whose 1st pregnancy is after age 35, or who've never had a pregnancy appears to be more susceptible to hormone changes and other exposures that can lead to cancer. Early pregnancy, on the other hand, appears to provide some protection against these pre-cancerous changes.

Number of previous breast biopies and results of those biopsies. The risk of breast cancer increases if the biopsies showed a change in breast tissue known as atypical hyperplasia. Your risk increases because of whatever breast changes prompted the biopsies. Biopsies themselves do not cause cancer.

You indicated on the survey we completed over the phone with you that you don't have any of these risk factors.

Of course the Gail model is not perfect and there are still a lot of things we don't know about breast cancer and its causes. We will be sending you some follow up materials in the mail and will include the printout of your scores from this model. As I mentioned above, a trained cancer risk counselor in the Family Risk Assessment Program can help sort out all of this information with you.

Screening Recommendation Scripts

HIGH MONITOR, COMPLIANT

Next, I'd like to go over with you the current recommendations for screening and prevention of breast cancer. The goal of screening is to find cancers when they are at an early, and more curable stage. The earlier a cancer is found and removed, the lower the risk of it spreading to other parts of the body. There are three different ways to detect early stage breast cancer. We generally urge women to examine their own breasts for unusual lumps or skin changes on a monthly basis, starting in their 20's. Once you get used to what your breast tissue feels like, you may be able to detect an area that feels different than the usual tissue or is new. You can also see subtle changes in the skin of the breast like dimpling or redness that might indicate a breast tumor. A clinical breast exam is given by a health care professional, usually once or twice a year during a routine gynecologic exam or physical exam. A physician or nurse exams the breasts for abnormal lumps and any other changes in the shape of the breast or the appearance of the skin. The American Cancer Society recommends that all women begin annual mammography starting at age 40. Mammograms can detect lumps that are less than the size of a pea. They can also detect areas of abnormal calcium deposits, even before any lump can be seen. No one of these screening tests is sufficient by itself. All three, breast self-exam, clinical breast exam and mammography are necessary to do the best job of finding a breast cancer at an early stage. Women with a family history of breast cancer may need to start screening with annual mammograms at an earlier age. This is something you could discuss with your doctor or with a cancer risk counselor.

I see that you indicated in the survey we completed over the phone with you that:

- *You have had a clinical breast exam in the past three years.*

and that's great. However ...

- *You are not examining your breasts on a regular basis. Is it because you aren't sure what you're feeling?*

  (Probe for other reasons)_____

  It's helpful to have a health care professional teach you a reliable way to exam your breasts so you can get used to the way normal breast tissue feels, and what to look for in the skin. We can do this in the FRAP clinic.

Do you have any questions you would like to ask me?

_____

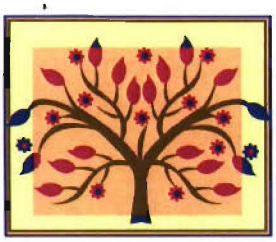
_____

_____

_____

The Family Risk Assessment Program at Fox Chase Cancer Center, Philadelphia, PA (800-325-4145) was established to provide to women like yourself additional information about breast cancer risk factors, and an individualized risk estimate based on your personal risk factors. A trained genetic counselor can also discuss the options for having a blood test for the BRCA1/2 genes if it seems appropriate. If you decide you would like to participate, you will also be given recommendations for screening and prevention which match your own risk pattern. We will be sending you information about the program in the mail, and a number to call if you are interested.

Thank you once again for your time. You will be receiving some additional materials in the mail that has more information on the topics we have discussed. You can also call the Cancer Information Service number, 1-800-4-CANCER and talk to a trained information specialist.



Family History/Risk Factors Fact Sheet

There are several different factors that influence a woman's risk for developing breast cancer. One is age. Breast cancer is more common in older women than in younger women. It seems that most tissues, as they age, become more prone to genetic damage that can lead to cancer. So the longer a woman lives, the more likely she is to have a cell or cells in the breast tissue which can develop changes leading to cancer.

Another risk factor is family history. In families like yours, where there are multiple people diagnosed with breast cancer, other women in the family have a higher than average risk. In some cases, this may be explained by several women in the same family sharing common exposures or lifestyle factors. There is also the possibility that there is a genetic mutation being passed down through the family that greatly increases the risk of breast cancer.

Two genes, *BRCA1* and *BRCA2* have been found to be associated with breast and ovarian cancer when they are inherited in a damaged or mutated form. So if a parent carries one of these damaged genes, they have a 50% chance of passing it down to each of their children. Fortunately damaged genes like this are not common, but if a family does have one of these genes there are certain clues in the family history:

* If the breast cancers are occurring at very young ages, for instance less than 40;
* If there are multiple cases of breast cancer in one side of the family;
* If a woman gets breast cancer in both breasts;
* If there is also ovarian cancer in the family;
* Or if a man in the family gets breast cancer;

A lot of the other risk factors have to do with female hormones, both the internal hormones your own body makes, and any hormones you are exposed to in medications and possibly foods. Scientists think there is a link between estrogen and risk for breast cancer. So the more estrogen you are exposed to in your lifetime, the higher your risk for breast cancer. This possibility was recently strengthened by a study that found that women who used hormone replacement therapy (which included both estrogen and progesterone) for menopause had a somewhat increased chance of developing breast cancer.

Having your first baby when you are young, say under 20, is protective. But never having children or having them after age 35 increases your risk. A pregnancy when you are young helps the cells in the breast become fully mature and therefore less likely to suffer genetic damage. If you never get pregnant, the cells remain somewhat immature and more vulnerable. If your first pregnancy is after age 35, apparently the cells have already sustained some genetic damage (from aging) and are more susceptible to the influence of the hormones related to the pregnancy.

The number of breast biopsies you've had, particularly if they showed certain pre-cancerous features, can increase your risk. We don't think it's the biopsy itself that affects your risk, but rather the changes found in the tissue that led to the biopsy in the first place.

Please see the attached sheet for your personal risk profile.

The Family Risk Assessment Program (FRAP) at Fox Chase Cancer Center and its Network of community hospitals was established to provide women like yourself additional information about breast cancer risk factors and an individualized risk estimate based on your personal risk factors. A trained genetic counselor can also discuss the options for having a blood test for the *BRCA1/2* genes if it seems appropriate. If you decide you would like to participate, you will also be given recommendations for screening and prevention which match your own risk pattern. Please refer to the enclosed brochure or the contact information in the attached cover letter for the program in your area.

Family History/Risk Factors Fact Sheet

There are several different factors that influence a woman's risk for developing breast cancer. One is age. Breast cancer is more common in older women than in younger women. It seems that most tissues, as they age, become more prone to genetic damage that can lead to cancer. So the longer a woman lives, the more likely she is to have a cell or cells in the breast tissue which can develop changes leading to cancer.

Another risk factor is family history. In families like yours, where there is already someone diagnosed with breast cancer, other women in the family have a higher than average risk. In some cases, this may be explained by several women in the same family sharing common exposures or lifestyle factors. There is also the possibility that there is a gene being passed down through the family that greatly increases the risk of breast cancer.

Two genes, *BRCA1* and *BRCA2* have been found to be associated with breast and ovarian cancer when they are inherited in a damaged or mutated form. So if a parent carries one of these damaged genes, they have a 50% chance of passing it down to each of their children. Fortunately damaged genes like this are not common, but if a family does have one of these genes there are certain clues in the family history:

* If the breast cancers are occurring at very young ages, for instance less than 40;
* If a woman gets breast cancer in both breasts;
* If there is also ovarian cancer in the family;
* Or if a man in the family gets breast cancer;

A lot of the other risk factors have to do with female hormones, both the internal hormones your own body makes, and any hormones you are exposed to in medications and possibly foods. Scientists think there is a link between estrogen and risk for breast cancer. So the more estrogen you are exposed to in your lifetime, the higher your risk for breast cancer. This possibility was recently strengthened by a study that found that women who used hormone replacement therapy (which included both estrogen and progesterone) for menopause had a somewhat increased chance of developing breast cancer.

Having your first baby when you are young, say under 20, is protective. But never having children or having them after age 35 increases your risk. A pregnancy when you are young helps the cells in the breast become fully mature and therefore less likely to suffer genetic damage. If you never get pregnant, the cells remain somewhat immature and more vulnerable. If your first pregnancy is after age 35, apparently the cells have already sustained some genetic damage (just from aging) and are more susceptible to the influence of the hormones related to the pregnancy.

The number of breast biopsies you've had, particularly if they showed certain pre-cancerous features, can increase your risk. We don't think it's the biopsy itself that affects your risk, but rather the changes found in the tissue that led to the biopsy in the first place.

Please see the attached sheet for your personal risk profile.

The Family Risk Assessment Program (FRAP) at Fox Chase Cancer Center and its Network of community hospitals was established to provide women like yourself additional information about breast cancer risk factors and an individualized risk estimate based on your personal risk factors. A trained genetic counselor can also discuss the options for having a blood test for the *BRCA1/2* genes if it seems appropriate. If you decide you would like to participate, you will also be given recommendations for screening and prevention which match your own risk pattern. Please refer to the enclosed brochure or the contact information in the attached cover letter for the program in your area.

Family History/Risk Factors Fact Sheet

There are several different factors that influence a woman's risk for developing breast cancer:

1. Older age. Breast cancer is more common in older women than in younger women.

2. Family history. In families like yours, where there are multiple people diagnosed with breast cancer, other women in the family have a higher than average risk.

3. Genes. Two genes, *BRCA1* and *BRCA2* have been found to be associated with breast and ovarian cancer when they are inherited in a damaged or mutated form. Fortunately damaged genes like this are not common, but we can tell from certain clues in the family history if a family may have one of the mutations:

* Breast cancer occurs at very young ages, for instance less than 40;
* Multiple cases of breast cancer in the family;
* Breast cancer in both breasts;
* Ovarian cancer in the family;
* A man in the family with breast cancer;

4. Female Hormones. Scientists think there is a link between the hormones your body makes or hormones you are exposed to through food or medications (including estrogen and progesterone), and breast cancer. One such medication could be hormone replacement therapy for menopause.

5. Age at first pregnancy. Never having children or having them after age 35 increases your risk for breast cancer, but having your first baby when you are young, say under 20, is protective.

6. Breast biopsies. The number of breast biopsies you've had, particularly if they showed certain pre-cancerous features, can increase your risk. We don't think it's the biopsy itself that affects your risk, but rather the changes found in the tissue that led to the biopsy in the first place.

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PERSONAL RISK PROFILE for

_____

As we discussed during the telephone counseling session, the Gail model tries to put your risk factors together to give you five-year and lifetime risk estimates for developing breast cancer. Based on the information you provided to us, your personal risk factors for breast cancer include:

☐ **age 50 or over**

☐ **young age (before age 12) when your periods started**

☐ **not having children**

or

☐ **having your first child after age 35**

☐ **having _____ first-degree relative(s) with breast cancer**

☐ **having _____ breast biopsies**

Considered together, based on the Gail model, we calculate your risk as follows:

5-year risk

Based on the data provided your estimated risk for invasive breast cancer over the next 5 years is _____%, compared over the same period to that of _____% for a woman of your age with average risk factors.

This also means that your estimated risk for NOT getting invasive breast cancer over the next 5 years is _____%.

Your 5 year risk is sufficient to consider discussing with your doctor the use of tamoxifen to help prevent breast cancer. Tamoxifen has been shown to reduce the risk of getting breast cancer in women at high risk by 50%.

Lifetime risk

Your lifetime risk (to age 90) for invasive breast cancer is _____%. A woman of your age with average risk factors would have an estimated risk of invasive breast cancer of _____%. This also means that your estimated risk for NOT getting invasive breast cancer in your lifetime is_____%.

PERSONAL RISK PROFILE for

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Screening Recommendations Fact Sheet

Current recommendations for screening and prevention of breast cancer work toward the goal of finding cancers when they are at an early, and more curable stage. The earlier a cancer is found and removed, the lower the risk of it spreading to other parts of the body. Therefore, it is very important for you to continue a regimen of breast cancer screenings.

There are three different ways to detect early stage breast cancer. We generally urge women to examine their own breasts for unusual lumps or skin changes on a monthly basis, starting in their 20's. Once you get used to what your breast tissue feels like, you may be able to detect an area that feels different than the usual tissue. You can also see subtle changes in the skin of the breast like dimpling or redness that should be brought to the attention of a health care provider.

A clinical breast exam is given by a health care professional, usually once or twice a year during a routine gynecologic exam or physical exam. A physician or nurse examines the breasts for abnormal lumps and any other changes in the shape of the breast or the appearance of the skin.

The American Cancer Society recommends that all women begin annual mammography starting at age 40. Women with a family history of breast cancer may need to start screening with annual mammograms at an earlier age. This is something you could discuss with your doctor or with a cancer risk counselor. Mammograms can detect lumps that are less than the size of a pea. They can also detect areas of abnormal calcium deposits, even before any lump can be seen.

No one of these screening tests is sufficient by itself. All three, breast self-exam, clinical breast exam and mammography combined can find breast cancer at an early stage.

Another option for women at increased risk for breast cancer is taking the drug Tamoxifen, approved for prevention in women with certain risk factors. Tamoxifen blocks estrogen from entering the glandular cells in the breast, and therefore can protect those cells from estrogen stimulation. Tamoxifen has now been shown to reduce the risk of getting breast cancer in women with a high risk by 50 percent.

Based on your age and your family history, we would recommend starting annual mammograms at age _____.

The Family Risk Assessment Program (FRAP) at Fox Chase Cancer Center and its Network of community hospitals was established to provide women like yourself additional information about breast cancer risk factors and an individualized risk estimate based on your personal risk factors. A trained genetic counselor can also discuss the options for having a blood test for the *BRCA 1/2* genes if it seems appropriate. If you decide you would like to participate, you will also be given recommendations for screening and prevention which match your own risk pattern. Please refer to the enclosed brochure or the contact information in the attached cover letter for the program in your area.

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Based on your age and family history, we would recommend you continue with annual mammograms as you are already doing.

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H/N

Screening Recommendations Fact Sheet

Screening for breast cancer is recommended because it may find cancers when they are at an early, and more curable stage. That's why it is important to continue a routine of exams and mammograms.

There are three different ways to detect early stage breast cancer:

1. Breast Self Exam (BSE) Women should examine their breasts on a monthly basis for changes in the breast tissue such as unusual lumps or dimpling of the skin.

2. Clinical Breast Exam This exam is given by a health care professional, usually once or twice a year during a routine gynecologic exam or physical exam. A physician or nurse examines the breasts for abnormal lumps and any other changes in the shape of the breast or the appearance of the skin.

3. Mammograms The American Cancer Society recommends that all women begin annual mammography starting at age 40. Women with a family history of breast cancer may need to start annual mammograms at an earlier age.

No one of these screening tests is sufficient by itself. All three, breast self-exam, clinical breast exam and mammography combined can find a breast cancer at an early stage.

Another option for women at increased risk for breast cancer is taking the drug Tamoxifen. Tamoxifen has been shown to reduce the risk of getting breast cancer in high risk women by half.

Based on your age and your family history, we would recommend starting annual mammograms at age_____.

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L/N

The Tailoring Process

Application to Facilitating Follow-up Adherence to Abnormal Pap Smears

Step	Description	Formative Evaluation	Operationalization for Project
Analyzing the Health Problem	Identify and describe the health outcome? Identify and describe the factors that may be influential, such as beliefs, values, motivation, norms and lifestyle. Determine the proposed outcome for the tailoring messages	• N/A due to existing research specifically related to this underserved population	• Follow-up to abnormal pap smears among underserved populations is low • Barriers for this specific underserved population that have been identified through previous research are: lack of understanding about purpose of colpooscopy; cancer worry; practical barriers, e.g., forgetting appointment (JNCI, 1997). • C-SHIP model provides a psychological framework to address individual barriers **Outcomes:** • Enhanced short-term and long-term adherence to follow-up procedures and appointments and psychosocial adjustment to cervical risk
Developing a Program Framework	Outline all parts of the tailored communication, including number and timeframe of assessments and feedback, key messages, and approaches. This is the Blueprint" for the entire production and delivery of tailored communication		Given the application of this intervention within a public health gynecological clinic, the tailoring assessment will be collected once on all participants, including those receiving Standard Care. For those women assigned to one of the 2 intervention arms, the assessment will be followed by one of 2 tailored communications delivered by different modalities. • Telephone Barriers Assessment delivered approximately 2 weeks pre-colposcopy • Delivery of Tailored Communications Pre-Appointment -Telephone Counseling delivered immediately post-barrier assessment (1X) -Mail-Home Print Materials sent within 48

			hours post-barriers assessment (1X) • Key messages will address primary based on the telephone barriers assessment
Developing Tailoring Assessments	Identify and modify assessment modules which will provide the data for the tailoring algorithm and messages Use of validated items is critical, but it is also important to determine the appropriateness and relevancy of the assessment to the target population	• All components of the barriers assessment will be evaluated for readability, modified accordingly, and retested until 6-8th grade reading level is achieved • In-depth interviews with the target population will be conducted to assess cultural appropriateness, ease of completion, and understandability (6-10 people)	The assessment is based on previous research in this community to address barriers to follow-up. It will be adapted and edited to ensure cultural appropriateness, ease of completion and understandability.
Designing Feedback	This is the plan of the technical and design elements of the feedback. It is the template for the feedback including physical characteristics of the messages (e.g. format, number of pages, color, tone), handling of location and size of messages, use of preprinted elements and textual and graphics characteristics	For Telephone Counseling • Conduct internal testing of the protocol for flow and ease of delivery For Print-Based Materials • Develop and review sample of layout	• The tailored telephone counseling protocol will be designed for a computer screen so that the interviewer can read it while speaking to the participant • The tailored mail-home print materials will be designed to fit onto a fold-out, four-color pamphlet. Use of preprinted textual and graphic elements will be used to enhance interest targeted to minority audience
Writing Tailored Messages	Content creation addressing approach, tone and information for each message Development of message library and all possible responses	• Identify 3 reviewers (medical provider, health educator, & communication expert) • Reviewers will evaluate the telephone and print messages for consistency, quality and tone • Conduct message testing via focus groups among target population to address cultural appropriateness and tone	• Modify and streamline already existing messages developed for the original telephone counseling protocol (JNCI, 1997) • For each barrier, a corresponding telephone and print message will be developed

Creating Tailored Algorithims	Create logic statements and decision rules This step allows for the formal linking of messages and assessment questions and is a layout that will be used for automating the algorithm	• Develop sample telephone protocols and print layouts for internal review to evaluate flow, ease and appeal	• Develop written flow chart addressing each of the barriers with corresponding text • To facilitate placement and layout of standard and tailored messages, barriers will be categorized into 3 broad areas: - risk-related knowledge - cancer worry - practical barriers
Automating the Tailoring Process	This includes both the system design (e.g. converting algorithm into program logic) and writing the computer program Translate algorithm into a computerized system to automate process	• Beta-test computer-generated sample materials with reviewers for format, readability, and quality. • Usability testing with potential users provides the last step in pretesting for readability, ease and acceptability (e.g., central intercept interviews)	• Collaborate with data management to develop tailoring software
Implementing the Program	Develop systems and processes to ensure cleaning, storing and collecting data, and integration of quality control systems in the production process The nature of tailoring with its dependency on data must have ongoing quality control in both data management and production (timeliness, production process)	• N/A	Research Assistant will review 50% of the telephone and print communications in the first month for quality control; thereafter, a 20% random sample of the tailored communications will be reviewed • Monitoring of telephone contact via audiotape. Delivery of messages will be checked for internal consistency, tone, and flow • Print material will be reviewed for accuracy, flow, and delivery,
Evaluating the Program	Develop and implement evaluation measures, including process, impact and outcome It is important to assess the target audiences reactions and satisfaction with the format and approach, as well as testing the impact of the messages on beliefs, attitudes and behaviors		Evaluation of the comparative efficacy of Tailored Telephone Counseling and Mail-Home Print Materials through the assessment of study outcome measures • Short- and long-term adherence to medical management of CIN and HPV-related conditions • Cognitive-affective adjustment to cervical risk • Cost-effectiveness

Adapted from Krueter, Farrell, Olevitch, Brennan, 2000.

Improving Appropriate Use of Risk Counseling & Genetic Testing Service Among Women Calling the Cancer Information Service

Research funded by DAMD17-98-1-8306

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Fox Chase Cancer Center
Philadelphia, PA

Background

- **Growing Interest**
  Scientific discoveries in human genetics and media attention has led to a growing interest in genetic risk and genetic testing (Miki et al., 1994; Wooster et al., 1995; Pavelic & Gall-Troselj, 2001; Mullan et al., 2001)
- **Limited Resources**
  There is a limited number of trained providers and services to educate women about this complex issue

Background

- **Inconsistency Between Interest and Appropriateness**
  Studies show women are interested in genetic testing (40 – 93% in primary care practice), yet they may not seek information on the relevancy for them personally

  Studies show that approximately 80% of women with family histories of breast or ovarian are highly interested in testing, yet other studies show only about 50% actually opt to be tested.

Theoretical Approach
Cognitive-Social Health Information Processing (C-SHIP) Model

- Premise of the C-SHIP Model is that individuals respond more adaptively when provided with information in a systematic way helping them prepare for their cognitive and affective response to risk-related feedback
- Individual differences in how people attend to information plays a role in how they respond to risk feedback. High Monitors generally scan for information - Low Monitors distract from threatening information

Overview of Study

This DOD-funded, 3 year, randomized study tested the feasibility and effectiveness of a theory based educational intervention provided by the National Cancer Institute's Atlantic Region Cancer Information Service (CIS) to increase a woman's knowledge of:

- the determinants of a genetic predisposition to breast or ovarian cancer
- personal family history and other risk factors
- the benefits and drawbacks of genetic testing
- the process of risk assessment/genetic testing

Study Design

Phase 1, Year 1- Formative Evaluation	Phase 2, Years 2 & 3 - Study Implementation and Analysis
▪ Structured interviews with women entering the Family Risk Assessment Program at Fox Chase Cancer Center (FRAP) ▪ Structured interviews and Focus Groups with genetic counseling professionals in PA and NJ ▪ Professional Advisory Committee ▪ Development of CIS training curriculum ▪ Design and Development of a Computer-Assisted Telephone Interview System	Call into the CIS - 1-800-4-CANCER ↓ Recruitment ↙ ↘ Enhanced Intervention Standard Intervention ↘ ↙ 2 week follow-up ↓ 2 month follow-up ↓ 6 month follow-up

Delivery of the Intervention: The Cancer Information Service (CIS)

The Atlantic Region CIS, housed at Fox Chase Cancer Center and serving NJ, PA and DE, was the pilot site for this study. Part of a network of regional offices serving the entire US, Puerto Rico and the US Virgin Islands, the National Cancer Institute's CIS provides the latest, most accurate cancer information through its Information Service (1-800-4-CANCER, cancer.gov), Partnership Program and Research Initiative.

Comparison of Interventions

- Standard
  - General Information
  - Assessment of Baseline Variables
  - Cancer Risks Concerns Survey
  - Breast/Ovarian Cancer Knowledge Scale
  - Review of General Risks
  - Cancer Patterns
- Enhanced - includes all of the standard elements plus,
  - Hallmarks of Inherited Disease
  - Family Cancer History
  - Challenges in Interpreting Family History Information
  - Process and Services
  - Pros and Cons of risk assessment/genetic testing

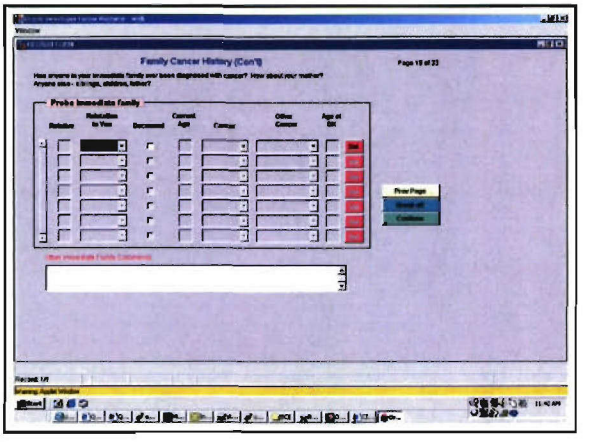
Staff offered a summary of information and referrals to risk assessment programs to all participants. All participants received National Cancer Institute materials as a follow-up to the initial call.

The Intervention

Derived from the Cognitive-Social Health Information Processing (C-SHIP) model*, the intervention targets key psychosocial variables found to be associated with adherence to cancer - health protective behaviors. They include:

- accurate risk perceptions
- accurate knowledge considering the specific health threat
- self-efficacy and control beliefs and expectations
- appropriate affective responses
- adaptive self-regulatory/coping skills

* Miller, Suzanne M., et. al., 1996



Study Accrual

	Baseline		1 week follow-up		1 month follow-up [1]		6 month follow-up [2]	
	N	%	N	%	N	%	N	%
Number eligible	492		279		279		199	
Number consented	322	(65)	--	--	--	--	--	--
Number dropped out	43	(13)						
Number not reached/declined	--	--	76	(27)	80	(29)	24	(12)
Number completed	279	(87)	203	(73)	199	(71)	175	(88)

1 Subjects that could not be reached at 2 weeks were maintained in the study and were eligible for 2 month follow-up.
2 Those who were not able to be reached at either 2 week or 2 month were not included in the 6 month follow-up interview.

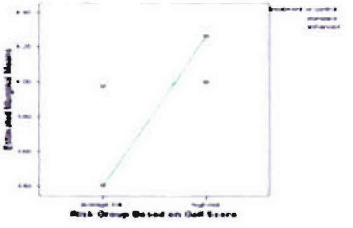
Description of Sample

Variable	Frequency or Mean	Percentage or Standard Deviation
Age	46.32 years	12.28 years
Education		
Some High School	10	4%
High School Grad	65	25.5%
Some College	69	27%
College Grad	69	27%
Post-graduate	42	16.5%
Race/Ethnicity		
Asian	2	1%
African American	14	5%
Hispanic	3	1%
Native American	6	2%
Caucasian	227	89%
Other	6	2%
Reason for Calling CIS		
For breast cancer risk information	208	79%
For ovarian cancer risk information	32	12%
For both breast and ovarian cancer risk information	34	12%
Cancer Diagnosis		
Yes	64	25%
No	213	77%
Past Use of Risk Assessment Services		
Yes	34	12%
No	242	88%

Knowledge and Attitudes - Baseline Assessment

Item	Correct Response	
	N	(%)
Many women get breast cancer without known risk factors	270	(91)
1 in 8 women will develop breast cancer in their lifetime	251	(85)
Women over 50 are more likely to get breast cancer than younger women	209	(71)
A woman without BRCA 1 & 2 still can get breast or ovarian cancer	196	(66)
Early detection means a greater chance of surviving breast cancer	290	(98)
Women over 40 should have mammograms at least every two years	222	(75)
A woman whose mother was diagnosed at age 69 is considered to be at high risk	78	(26)
A woman can inherit breast cancer gene mutations from her father	165	(56)
Most women who develop breast cancer do not have a family history of the disease	168	(57)
Ovarian and breast cancer in the same family can be a sign of hereditary cancer	250	(85)
Testing for breast cancer gene mutations will tell a woman if she has breast cancer	171	(58)
Men cannot inherit breast cancer gene mutations	248	(84)
If there are other types of cancer in the family, my risk is higher than average	199	(67)
The process of risk assessment and genetic testing is simple, involving only a physical examination and blood test	65	(22)
One of the advantages of risk assessment is by finding out your risk it can help you make decisions about risk reduction options, such as surgery and medications	278	(94)
There is no real disadvantage to pursuing risk assessment and genetic testing	162	(55)
A woman who develops breast cancer at an early age is more likely to have an inherited breast cancer	159	(54)

Means of Intention to Pursue Genetic Testing at 6 months after call to the CIS



Mod.501, Pwt.08, p<.05

Monitoring and Perceived Risk of Breast Cancer Women at Average Risk

	Perceived Risk			
	Baseline		Six month follow-up	
	M	SD	M	SD
Low Monitors	3.84	1.03	3.48	0.87
High Monitors	3.67	1.03	3.91	1.98
Total	3.73	1.03	3.76	0.96

Satisfaction with the CIS

	Satisfaction*					
	Baseline		Two Week follow-up		Six month follow-up	
Intervention Type	M	SD	M	SD	M	SD
Standard Group	4.63	0.68	4.51	0.75	4.51	0.64
Enhanced Group	4.63	0.57	4.37	0.84	4.38	0.86
Total	4.64	0.62	4.44	0.79	4.44	0.77
Monitoring Style						
Low Monitors	4.57	0.69	4.35	0.88	4.39	0.81
High Monitors	4.66	0.58	4.46	0.73	4.47	0.77
Total	4.61	0.64	4.40	0.83	4.43	0.79

*Assessed on a five point scale, 1 being not at all, 5 being very much.

Conclusions

This study evaluated a novel, theory-based approach to help guide women in making informed decisions. The findings indicate that:

- The intervention had a significant impact on intention to obtain genetic testing across risk groups at the six month follow-up ($p<.05$). The enhanced intervention diminished intention among women at average risk, but increased intention among women at high risk.
- Overall knowledge at baseline was fairly high. However, only 25% of the respondents understood that older age at diagnosis was not a determinant of inherited risk or that the process of genetic testing was much more complex than a simple blood test. There were no significant impacts on overall knowledge score between intervention or risk groups.
- High monitors of average risk, general knowledge increased more than for low monitors ($p<.05$)
- High monitors of average risk experienced an increase in risk perceptions for breast cancer compared to low monitors ($p<.05$)

Implications

- The enhanced intervention may lead to a fuller processing of the implications of, and consequences associated with, genetic testing especially among high risk women
- The enhanced intervention decreased the intention to pursue genetic counseling among average risk women decreasing use of inappropriate and limited resources
- The CIS and other information services can play a vital role in addressing the gaps in educational resources and provide interventions to help women understand their own risk and facilitate informed decision making
- High monitors exhibit a signature information processing style and future communications and educational interventions that match attentional styles may be more effective

Tailored Communication to Enhance Adaptation Across the Breast Cancer Spectrum

FOX CHASE CANCER CENTER

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Research funded by DAMD 17-01-1-0238

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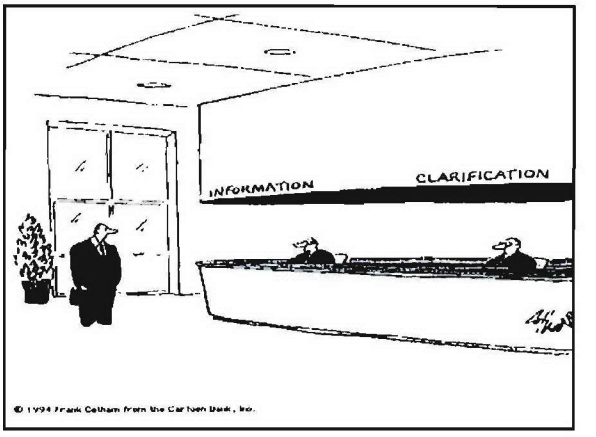
Betsy Bove

The Behavioral Center of Excellence (BCE) in Breast Cancer

- Provides a comprehensive, multi-disciplinary approach for studying the process of, and methods for facilitating successful adaptation to breast cancer risk, treatment, and recovery.
- Four ongoing studies are derived from and integrated by a unifying theoretical framework, and are supported by four core facilities (i.e., Administrative, Communication, Genetic Testing and Bioinformatics Core).
- The overarching goal is to develop theoretically guided, tailored, and transportable breast cancer communications to enhance screening adherence, decision-making, and quality of life across the spectrum of disease (i.e., from risk through treatment to survivorship).



Behavioral Center of Excellence

- Guided by the Cognitive-Social Health Information Processing (C-SHIP) model and supported by four core facilities, four studies focus on different health challenges:
  - screening adherence
  - risk assessment decision making
  - and adjustment to disease
  - metastasis

Cognitive-Social Health Information Processing (C-SHIP) Model

- The C-SHIP model provides a unifying framework that specifies the principles for developing and evaluating tailored breast cancer communication strategies
- Individuals are characterized by distinctive processing patterns in how they:
  - Encode cancer risk-related information
  - React to cancer threats cognitively, emotionally, and behaviorally

Cognitions and Affects Involved in Health Information Processing

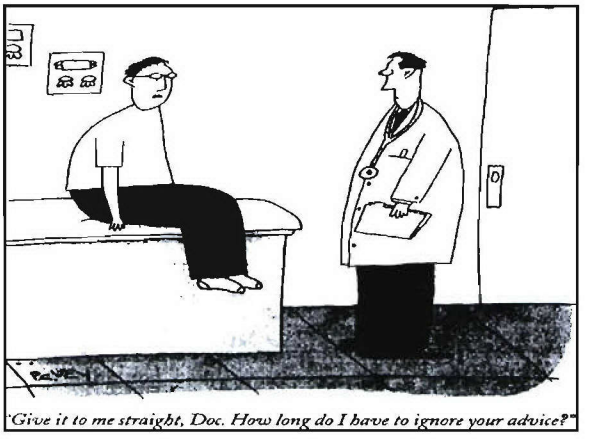
- Health-Relevant Encodings (e.g., risk perceptions)
- Expectancies and Beliefs (e.g., utility of screening)
- Affects/Emotions (e.g., risk-related distress)
- Health-Relevant Values and Goals (e.g., childbearing)
- Self-Regulatory Strategies (e.g., anxiety management)

Note: Adapted from Miller et al., *Gynecologic Oncology*, 1999

Attentional Style

- **Monitoring**
  The extent to which the individual attends to, scans for, and amplifies information about cancer threats
- **Blunting**
  The extent to which the individual ignores, distracts from, and minimizes information about cancer threats

Note: Miller, *Cancer*, 1995



"Give it to me straight, Doc. How long do I have to ignore your advice?"

"No, no, that's not a sin, either. My goodness, you must have worried yourself to death."

Project 1: Understanding Breast Cancer Risk Assessment and Screening Behavior among the Underserved
(P.I., Suzanne M. Miller, Ph.D.)

- **Aim 1**: To develop a *psychosocial familial risk questionnaire* tailored to low-income African American FDRs of breast cancer patients (Phase 1)
- **Aim 2**: To evaluate the *psychometric nature* of the familial risk questionnaire and identify key longitudinal predictors of interest in breast cancer risk assessment and of adherence to breast cancer screening guidelines (Phase 2)
- **Aim 3**: To examine the feasibility and preliminary impact of a *C-SHIP-guided intervention* designed to promote interest in breast cancer risk assessment and screening using the data obtained in Phases 1 and 2 (Phase 3)

Project 1 – Breast Cancer Risk Assessment and Screening Behavior

Phase 1
- Conducted 7 focus groups (N=27) with African American FDRs of breast cancer patients to develop the *Barriers and Facilitators of Interest (BFI) in Breast Cancer Risk Assessment and Screening Practices* questionnaire

Phase 2
- Recruiting FDRs of breast cancer patients for the longitudinal study (N=100) to evaluate the psychometric nature of the questionnaire and to identify psychosocial predictors of intention/readiness to pursue breast cancer risk assessment and screening adherence

Phase 3
- Based on Phase 1 and 2 data, we will develop an intervention to facilitate risk assessment and screening adherence

Project 2: A Teachable Moment within the Family: From Concept to Community (P.I., Mary Daly, M.D.)

❖ **Aim 1:** Test whether a telephone counseling tailored to psychological (i.e., attentional style), clinical (i.e.,family history of breast cancer), and behavior (i.e., adherence to screening) factors increase interest of relatives of breast cancer patients in risk assessment and counseling

❖ **Aim 2:** Assess the adoption of risk-reduction behaviors (i.e., participation in risk-assessment and counselling, adherence to appropriate management recommendations) in the 12 months following the intervention

Project 2 – A Teachable Moment within the Family

Phase I

- **Approach** newly diagnosed (6-12 months) breast cancer patients at FCCC and in community hospital settings. Contact eligible FDRs and obtain consent to participate in the study.

To date 125 participants accrued (N=360)

Phase II

- **Baseline Assessment** of family history, personal medical history, reproductive history, psychosocial measures
- **Randomized** to tailored message intervention vs. general health message intervention

To date 115 participants accrued

Phase III

- **Telephone Counseling Intervention** (tailored vs. general, delivered within a month following baseline assessment)
- **Follow-up** (12months) to assess adoption of risk reducing behaviors

To date, 66 participants completed the study

Project 3: Facilitating Re-entry Following Treatment for Primary Breast Cancer (P.I., Suzanne M. Miller, Ph.D.)

❖ **Aim 1**: To evaluate a theory-based, tailored Cognitive-Affective Preparation intervention to facilitate re-entry following adjuvant treatment for primary breast cancer. The intervention prepares the individual for the challenges that arise during re-entry by realistically anticipating the cognitive-emotional reactions to re-entry in the context of a brief, structured one-on-one barriers counseling session

❖ **Aim 2:** To examine the moderating effects of attentional style (i.e. monitoring vs. blunting) on the effectiveness of the intervention

Project 3 – Facilitating Re-entry Following Treatment

Phase 1

Conducted **3 Focus Groups** with early stage primary breast cancer patients (N=18)

- ❖ Assess survivors' attitudes and beliefs about re-entry
- ❖ Evaluate and refine intervention

Phase 2

Randomized control trial (N=300)

Participants at the end of adjuvant treatment for early stage disease (0-2) are randomized to:

- ❖ Cognitive-Affective Processing intervention
- ❖ General Health Information intervention

Project 4: Communication Skills vs. Supportive Therapy Intervention for Women with Metastatic Breast Cancer (P.I., Sharon Manne, Ph.D.)

❖ **Aim 1:** To compare the effectiveness of a communication and support skills intervention versus a supportive therapy intervention on the quality of life of women with metastatic breast cancer

❖ **Aim 2:** To explore the effects of individual differences (e.g., ambivalence over emotional expression, treatment expectancies, social support and coping) on the impact of the interventions

Project 4 – Communication Skills vs. Supportive Therapy for Women with Metastatic Breast Cancer

❖ **Randomized control trial**

Participants - women with metastatic breast cancer - are randomized to:

1) Communication & Support Skills Counseling

To date 25 patients enrolled

OR

2) Supportive Counseling (Control)

To date 19 patients enrolled

Randomization stratified upon High/low Beck Depression Inventory Scale (BDI)

Prevalence of Baseline Distress on the BDI		
No or minimal depression	Score less than 10	36%
Mild to moderate depression	Score 10 to 18	51%
Moderate to severe depression	Score 19 to 29	7%
Severe depression	Score 30 to 63	7%

Communications Core

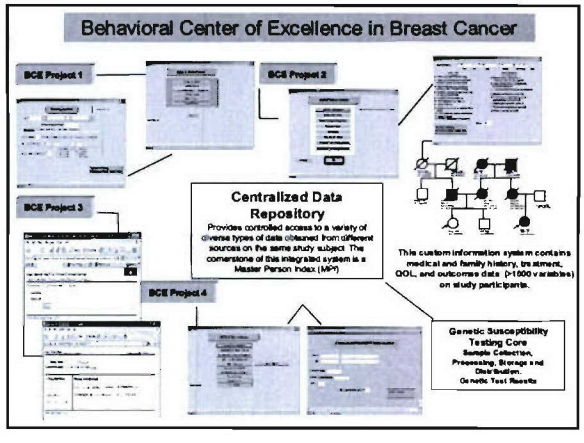
- **Aim 1**: Provide linkages to the BCE major projects for assistance in evidence-based behavioral approaches and measures
- **Aim 2**: Expand the BCE resources to address communication theory and application
- **Aim 3**: Facilitate the assessment of information needs of target populations
- **Aim 4**: Provide consultation in the development of interventions, using behavioral, health education and communication principles and theories
- **Aim 5**: Provide formative evaluation services to inform the development and pilot testing of interventions for specific populations

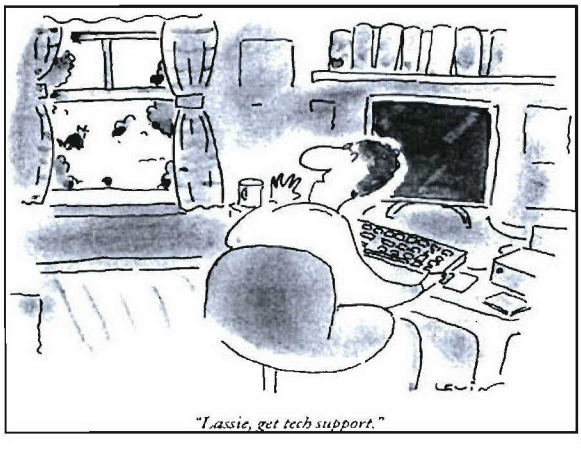
Communication Core: Development of a Tailored Interactive Intervention

- Identified key tailoring variables guided by C-SHIP theory (e.g., patient's perceived risk)
- Fostered collaboration with regional CIS program in development of telephone-based protocols and training
- Developed message library to tailor relevant information to patient's monitoring attentional style
- Refined message library to a 7th grade reading level and made contents "conversational" to allow for participant comments

The Informatics Core

- **Aim 1**: To provide computer-based tools that facilitate the entry, storage, manipulation and retrieval of large quantities of data
- **Aim 2**: To ensure the accuracy of the data maintained in the database by developing human and software based data consistency and quality control systems
- **Aim 3**: To provide high-quality data entry services
- **Aim 4**: To organize and maintain the database to maximize accessibility, while maintaining strict confidentiality
- **Aim 5**: To provide statistical computing support

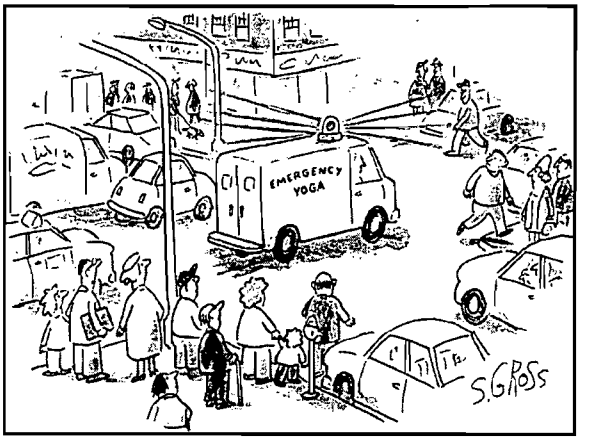




"Lassie, get tech support."

Implications

- The development of feasible, effective, and transportable health communications that can be widely disseminated and easily implemented
- Meta-analytic examination of data accrued across divergent breast cancer contexts and across different ethnic populations



Abstracts of Presentations and Publications Related to the Grant

Presentations:

Miller, S.M. Invited Speaker, Presented as part of Invited Symposium on Educating Women about Risk Counseling/Genetic Testing Makes a Difference in Intended Use of Services, Especially among those at High-Risk: Results of a Randomized Trial Among Callers to the Cancer Information Service. The Department of Defense (DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005.

ABSTRACT: Few services exist to help women make informed decisions about whether or not they are appropriate candidates for genetic risk assessment programs. The National Cancer Institute's Cancer Information Service (CIS) is an existing informational resource that is available to the public and can be utilized to meet this growing need through the toll-free 1-800-4 CANCER information service. It was hypothesized that a theory driven approach (Cognitive-Social Health Information Processing or C-SHIP) would improve the appropriate identification of risk and the utilization of high-risk counseling/genetic testing services. The randomization trial focused on women over 18 who called the Atlantic Region CIS for information on breast cancer genetics and risk (N=279) over a two-year period (1999-2001). After providing an informed consent after usual service, callers were randomized to two groups. The first group received the standard CIS intervention, which focuses on basic information on genetics and cancer risks, as well as referral to approved high-risk programs. The second group received an enhanced C-SHIP-guided intervention, which is designed to increase callers' understanding of: 1) the kinds of information that are required to determine inherited risk; 2) their own personal family history of cancer; and 3) the benefits and limitations of genetic testing. The analyses indicated a number of key findings. For women at high risk who received the enhanced intervention, there was a significant increase in preparation ($p<.05$) and intention ($p<.05$) to pursue genetic testing/risk assessment at 6 months, compared to high-risk women in the standard intervention. Conversely, women at average risk in the enhanced intervention exhibited a decrease in preparation to pursue genetic testing/risk assessment at 6-months, compared to average risk women in the stand interventions ($p<.05$). In addition, the enhanced intervention decreased the intention to pursue genetic counseling among average risk women, decreasing use of inappropriate and limited resources ($p<.05$). These findings suggest that the enhanced intervention may lead to a fuller processing of the implications of, and consequences associated with, genetic testing especially among high risk women. Thus, our theory based approach may be useful in helping patients bridge the gap between the growing public awareness of genetic risk, and the translation to improved cognitive and emotional processing of risk information.

Miller, S.M. Invited Speaker on Tailored Communication to Enhance Adaptation across the Breast Cancer Spectrum. Presented as part of Invited Symposium on Behavioral Centers of Excellence: Treating More Than the Tumor. The Department of Defense (DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005.

ABSTRACT: The overarching goal of the Behavioral Center of Excellence in Breast Cancer is to study the process of, and theory-and evidence-based interventions for facilitating, successful adaptation for breast cancer risk, disease, and survivorship. The studies are all derived from, and integrated by, a unifying theoretical framework – the Cognitive-Social Health Information Processing (C-SHIP) model – which specifies the principles for developing and evaluating tailored breast cancer communication strategies to enhance decision making, improve quality of life, and adjustment, and promote adherence, across the breast cancer spectrum. Specifically, the four projects are: 1) development of an intervention to promote utilization of breast cancer risk assessment programs and adherence to screening recommendations among underserved African-American women; 2) use of a "teachable moment" and tailored communication materials to promote utilization of risk assessment and adherence to screening among daughters of diagnosed breast cancer patients; 3) the promotion of psychological and physical adaptation among breast cancer patients at the completion of active treatment(i.e., during the re-entry phase); 4) promotion of psychological adaptation among metastatic breast cancer patients. The studies are supported by the four core facilities that provide an integrative infrastructure for this research and supportive resources, including: 1) administrative oversight and mentoring of trainees; 2) development of tailored communications; 3) genetic testing; and 4) bioinformatics. Developmental phases for each project have been completed and the second phases have been implemented. Specifically, regarding Project 1, qualitative data collected during Phase 1 has been analyzed and specific themes concerning breast cancer screening and genetic testing were identified. These findings were used to reshape the assessment instrument to be used for Phase 2, which is examining the quantitative predictive value of this assessment tool. Regarding Project 2, data are being collected to evaluate the impact of risk feedback tailored to monitoring attentional style. The protocol for Project 3 has been revised to address the primary concerns and issues of breast cancer survivors, based on Phase I findings. In Phase II, the intervention ill provide tailored strategies for assessing and addressing the individual's personal cognitive-emotional and action barriers to re-entry. Finally, with respect to Project 4, efforts continue to recruit advanced breast cancer patients into a communication and support skills intervention and to collect first and second follow-up surveys. Overall, the results will inform the design of feasible, effective, and transportable behavioral communications that can widely be disseminated and easily implemented, thereby having the potential to significantly impact the morbidity and mortality rates attributable to breast cancer, as well as reducing the psychosocial sequelae of the breast cancer experience. Ultimately, the studies will allow for the meta-analytic examination of data accrued across divergent breast cancer contexts and across different ethnic populations.
Original work supported by the U.S. Army Medical Research and Material Command under DAMD17-01-1-0238 and current work supported by U.S. Department of Defense.

Publications:

Miller, S.M., Bowen, D. J., Campbell, M.K., Diefenbach, M.A., Gritz, E.R., Jacobsen, P.B., Stefanek, M., Fang, C.Y., Lazovich, D., Sherman, K.A., Wang, C. (2004). Current research promises and challenges in behavioral oncology: Report from the American Society of Preventive Oncology Annual Meeting. Cancer Epidemiology, Biomarkers and Prevention, 13, 171-180.

ABSTRACT: The Behavioral Oncology Interest Group of the American Society of Preventive Oncology held a Roundtable session on March 10, 2002, at the American Society of Preventive Oncology annual meeting in Bethesda, Maryland, to discuss the current state-of-the-science in behavioral approaches to cancer prevention and control and to delineate priorities for additional research. Four key areas were considered: (a) behavioral approaches to cancer genetic risk assessment and testing; (b) biological mechanisms of psychosocial effects on cancer; (c) the role of risk perceptions in cancer screening adherence; and (d) the impact of tailored and targeted interventions on cancer prevention and control research. The evidence reviewed indicates that behavioral approaches have made significant contributions to cancer prevention and control research. At the same time, there is a need to more closely link future investigations to the underlying base of behavioral science principles and paradigms that guide them. To successfully bridge the gap between the availability of effective new cancer prevention and control technologies and the participants they are meant to serve will require the development of more integrative conceptual models, the incorporation of more rigorous methodological designs, and more precise identification of the individual and group characteristics of the groups under study.

Miller, S.M., Roussi, P., Daly, M.B., Buzaglo, J.S., Sherman, K.A., Godwin, A.K., Balshem, A., & Atchison, M.A. (2005). Enhanced counseling for women undergoing BRCA1/2 testing: Impact on subsequent decision making about risk prevention behaviors. Health Education and Behavior, Special Issue on Genetic Risk. (5), 654-67.

ABSTRACT: The authors evaluated the impact of an enhanced counseling intervention, designed to promote well-informed decision making for follow-up risk reduction options for ovarian cancer, among high-risk women undergoing BRCA1/2 testing (N = 77). Following standard genetic counseling, participants received either an enhanced counseling session-designed to help participants anticipate their reactions to possible test outcomes and plan for postresult consequences-or a general health information control session. One week after disclosure of test results, women in the enhanced counseling group experienced a greater reduction in avoidant ideation, suggesting more complete processing of risk feedback. At the 6-monthfollow-up, intervention respondents reported seeking out more information about prophylactic oophorectomy and were more likely to have actually undergone preventive surgery. The results indicate that the use of enhanced counseling can play an important role in decision making about risk reduction behaviors following BRCA1/2 testing.

Miller, S.M., Fleisher, L., Roussi, P., Buzaglo, J.S., Schnoll, R.A., Slater, E., Rayser, & Popa-Mabe, M. (in press) Facilitating informed decision making about breast cancer risk and genetic counseling among women calling the NCI's Cancer Information Service. Journal of Health Communication, Special Issue on Health Communication.

ABSTRACT: Despite increased interest among the public in breast cancer genetic risk and genetic testing, there are limited services to help women make informed decisions about genetic testing. This study, conducted with female callers (N=279) to the NCI's Atlantic Region Cancer Information Service (CIS), developed and evaluated a theory-based, educational intervention designed to increase callers' understanding of: a) the kinds of information required to determine inherited risk; b) their own personal family history of cancer; and c) the benefits and limitations of genetic testing. Callers requesting information about breast/ovarian cancer risk, risk assessment services, and genetic testing were randomized to either: 1) standard care or 2) the educational intervention. Results show that the enhanced intervention reduced intention to obtain genetic testing among women at average risk and increased intention among high risk women at 6 months. In addition, high monitors, who typically attend to and seek information, demonstrated greater increases in knowledge and perceived risk over the six-month interval, than low monitors, who typically distract from information. These findings suggest that theoretically designed interventions can be effective in helping women understand their cancer risk and appropriate risk assessment options and can be successfully implemented within a service program, like the CIS.