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

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13. Abstract *(Maximum 200 words) (abstract should contain no proprietary or confidential information)*

Breast cancer represents a serious health concern for women, across the disease spectrum. First despite advances in technology used for intensive disease surveillance and innovative preventive options, interest in and utilization of these technologies is less than optimal, especially among low-income, African-American women and first-degree relatives. Second, among women who have completed cancer treatment, psychological after-effects that can have a negative impact on adjustment and adherence to screening practices are prevalent. Finally, for those cancer patients whose disease has metastasized, clinically relevant psychosocial adjustment problems need to be recognized and managed. It is for these reasons that research leading to improvements in quality of life throughout the disease spectrum is necessary. The Behavioral Center for Excellence, through the coordination of four projects, seeks to understand and evaluate psychosocial approaches for promoting psychological and physical adaptation to cancer risk, treatment and survival. Each project systematically assesses and addresses barriers to, and facilitators of, adjustment and adherence and evaluates interventions designed for this cause. With support from four core facilities, the BCE has assembled a multi-disciplinary research team to conduct an interrelated set of studies that are theoretically-guided, thematically convergent, and synergistic in the impact on the behavioral aspects of breast cancer.

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

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10/31/02

Psychosocial and Behavioral Medicine Program
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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:

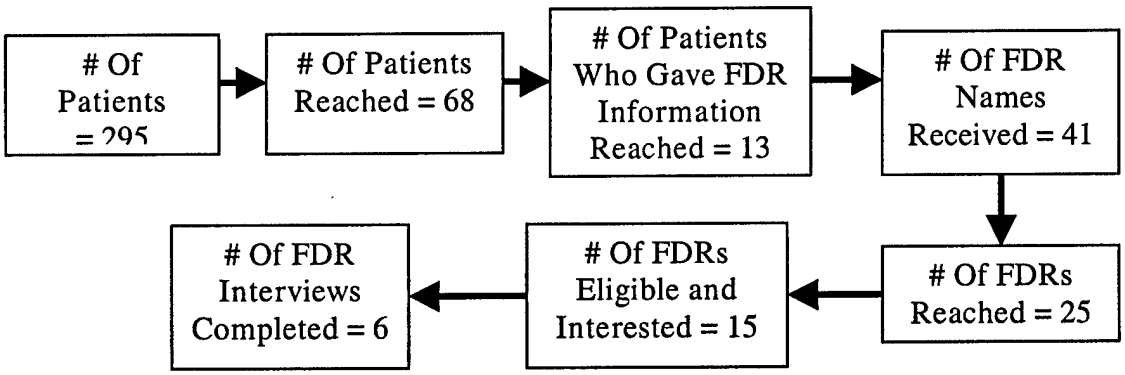
a. Submit Protocol to Institutional Review Boards	(Month 7)
b. Establish Recruitment Procedures/Staff Training for Phase 2	(Month 8)

c. Recruit Participants, Conduct Longitudinal Study (Months 9-30)

To date, we have completed one of the three focus groups that we planned to conduct for Phase 1. As part of this focus group, we have completed 6 interviews with the target population. As such, we are approximately 7 months behind the schedule outlined in our Statement of Work (i.e., we continue to seek recruitment of participants in the focus groups – subtask b, under Task 1).

There are several reasons that account for the revised schedule. First, since this project involves the recruitment of study participants from outside of Fox Chase Cancer Center, we had an additional Institutional Review Board (IRB) from which to seek approval before initiating participant recruitment. In addition, we had not figured the amount of time needed for securing DoD IRB review into our calculations. Thus, rather than taking the allotted 1 month for IRB approval of the protocol, at least 4 months were needed before we could initiate participant recruitment. Second, our projected accrual of the target population has been slower than expected because it has been a challenge to reach African American breast cancer patients. Our initial recruitment strategy involved receipt of a patient list, including phone numbers, from our physician-collaborators at Temple University Hospital. A Research Assistant (RA) would then attempt to contact these patients to seek contact information about the patients' first-degree relatives (FDRs). Once FDR contact information was gathered, the RA would attempt to contact the FDR to assess eligibility and interest in the study. Below, in Figure 1, we summarize our efforts to date using this recruitment approach.

Figure 1: Summary of Recruitment Efforts



Based on these data, we were only able to reach about one-quarter of the patients because of incorrect telephone numbers, changed telephone numbers that were not listed, or because the telephone calls were never answered, even after upwards of 20 attempts. Thus, we amended the study to allow trained Health Educators and RAs to attend clinic where new patients were receiving care. The goal was to reach a greater proportion of patients by providing all African American patients a study brochure and making study personnel available each day to collect FDR information. Unfortunately, since this amendment was approved, there has not been a significant change in recruitment. Our sense is that patients remain wary of providing FDR information to the Fox Chase Cancer Center personnel for reasons of mistrust or skepticism, since they are not well-integrated into the Temple team.

Overall, we believe that our recruitment difficulties stem from an inability to gain access to the FDR information. Therefore, we are working with the clinic to devise new methods to overcome this barrier. To address this concern, we are presently preparing an additional amendment to our recruitment methods. This modification would involve having the Temple University Hospital physician provide a letter to the patient informing her of the project and explaining to her the rationale for speaking with study representatives about their FDR information. We have meetings scheduled with the Clinic Director and physicians on October 11th, 2002 to discuss this change, and we are optimistic that greater involvement and explanation from the physician will increase the yield of FDR names from the patients. In turn, we expect a greater yield of FDR names to result in improved recruitment of FDRs, along with a resumption to our original projected timeline depicted in the Statement of Work.

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.
- Continuing to collect focus group data.
- Met with the Communications Core to develop focus group materials and protocol.
- Met with Informatics Core to discuss Project data issues.
- Trained staff at Temple University Hospital.
- Developed extensive patient recruitment procedures.
- In the process of devising new recruitment procedures that will integrate Temple University Hospital Physicians into the recruitment process by having them introduce the study to their patients and thereby facilitate the understanding of the study.
- Collecting data on feasibility issues.

REPORTABLE OUTCOMES

Aside from our recruitment activity, summarized in Figure 1, we do not have additional reportable outcomes at this point. Since we expect to continue to recruit at least 10-15 additional FDRs for the focus groups, we have not begun to analyze the focus group data yet, and have no reportable outcomes to provide for Phase 1 at this point. We have not begun Phase 2 of the study, since the methodology for Phase 2 depends on the findings from Phase 1 of the study. Below is a list of presentations and publications that are related to Project 1 activities.

- Presentations:

  Fleisher, L., Schnoll, R., Miller, S., McKeown-Conn, N., Brower, L. Annual Meeting of the American Society of Preventive Oncology. Poster on: Women's self-reported knowledge about cancer risks, risk assessment programs and genetic testing: Preliminary findings. New York, N.Y., March, 2001.

  Fleisher, L., Miller, S.M., McKeown-Conn, N., Brower, L., Schnoll, R., Babb, J. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Increasing Knowledge of Cancer Risk and Cancer Programs. Orlando, FL, September, 2002.

  Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Invited Keynote Plenary Speaker on: Behavioral contributions to breast cancer prevention and control. Part of Plenary Session on Breast Cancer Prevention. Orlando, FL, September, 2002.

  Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Poster presentation: Tailored communication to enhance adaptation across the breast cancer spectrum. Orlando, FL, September, 2002.

- Publications:

  Miller, S.M., Fang, C.Y., Diefenbach, M.A., & Bales, C. (2001). Tailoring psychosocial interventions to the individual's health information processing style: The influence of monitoring versus blunting in cancer risk and disease. In A. Baum & B. Andersen (Eds.), Psychosocial interventions in cancer. Washington D.C.: American Psychological Association.

  Miller, S.M., Sherman, K., Buzaglo, J., & Rodoletz, M. (2001) Monitoring-Blunting behavioral signatures in coping with health threats: The example of cancer. Psicologia della Salute, 3, 37-48.

  Miller, S.M. (in press). Applications of the Monitoring Process Model. Applied Psychology: An International Review.

  Miller, S.M. & Sherman, K.S. (in press). Cancer screening. In N. Anderson (Ed.) The Encyclopedia of Health and Behavior. CA: Sage Publications.

  Sherman, K.S., Miller, S.M., Sheinfeld-Gorin, S. (in press) Psychosocial determinants of participation in breast cancer risk counseling programs and screening regimens among African American women. NY: Susan G. Komen Foundation and African American National Advisory Committee.

Miller, S.M., Bowen, D., & Croyle, R. (Eds.) Handbook of psychosocial approaches to cancer prevention. Washington, D.C.: American Psychological Association, in preparation.

Miller, S.M. McDaniel, S., Rolland, J., & Feetham, S. (Eds.) Individuals, families, and the new genetics. New York: Norton Publications, in preparation.

CONCLUSION

Overall, we have successfully completed focus group interviews with 6 study participants, which provides the basis of a rich data set. However, we are about 6-7 months behind schedule for Project 1, largely due to unanticipated delays from seeking additional regulatory approvals from the recruitment site and from the DoD, and from practical difficulties reaching the patient population from whom we are trying to recruit FDRs. At this point, the regulatory process is complete and we have gained a better understanding of the possible reasons why recruitment has been slower than anticipated. Further, we have taken steps to increase the rate of successful contact of patients (e.g., sending research personnel to the clinics) and are working to modify recruitment procedures to achieve a greater yield of FDR names (e.g., having Temple physicians provide a letter describing the study to patients at index visits and explaining the presence and function of study personnel). We expect that these modifications to our recruitment procedures will allow us to achieve our recruitment goals with this uniquely challenging, and understudied, population.

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Miller, S.M., Fang, C.Y., Manne, S.L., Engstrom, P.E., Daly, M.B. (1999). Decision making about prophylactic oophorectomy among at-risk women: Psychological influences and implications. Gynecologic Oncology, 75, 406-412.

Miller, S.M., Shoda, Y., & Hurley, K. (1996). Applying cognitive-social theory to health-productive behavior: Breast self-examination in cancer screening. Psychological Bulletin, 119, 70-94.

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

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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 will identify at-risk relatives at each site, and permission will be sought to contact them by phone for participation in the study. Study participants will be 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 will be 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 will be 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

FCCC IRB and DOD approval of final protocol and recruitment tools was received during this period. The focus during the past year has been on establishing procedures for

recruitment of participants and capture of data, as well as the establishment of the tailored message library. One FCCC Network Hospital (Reading Hospital) received IRB approval and three others (Community Medical Center, Polyclinic Hospital and Paoli Memorial Hospital) are in the process of obtaining IRB approval to conduct the study at their institutions. The following is a description of the research accomplishments associated with each Task as outlined in the approved Statement of Work.

During Year 1, we anticipated accomplishing Task 1, the study start-up phase, during the first six months. We subdivided this task into the following sub-tasks:

a.	Communications core to create tailored, personalized messages for experimental intervention	(months 1-6)
b.	Finalization of survey instruments	(months 1-3)
c.	Finalization of recruitment strategies	(months 1-3)
d.	Training of study personnel	(months 4-6)

The study staff and Communications Core developed a satisfaction survey that was administered to 55 current Family Risk Assessment Program (FRAP) participants to assess their reasons for participating in the program. Facilitators and barriers to participating in FRAP were collected. These qualitative data are being used to frame the development of the tailored messages to be used for the experimental intervention. The study team and Communications Core have met on a regular basis to facilitate the development of the message library.

Additionally, the study team has met with the statistician to establish the randomization scheme. A cluster randomization will be used such that multiple members of the same family will be randomized to either the experimental or control group.

The baseline and 12 month follow up survey instruments were pilot tested to ensure usability when collecting complex information over the telephone. The DOD and FCCC IRB approved these instruments. Study staff has met with the Informatics Core on a regular basis to facilitate programming requirements enabling participant data capture and project timeline management.

Recruitment strategies were finalized and corresponding recruitment tools were developed and approved by the DOD and FCCC IRB. These tools include: 1) a flyer to be distributed to breast cancer patients during clinic visits to describe the study, and 2) a participant brochure which describes the study and can be placed in the patient waiting areas. Additionally, an amendment to the protocol was approved by the DOD and FCCC IRB to allow for first-degree relatives (FDRs) of breast cancer patients to contact the program directly (as opposed to being referred by their relative). This is likely to occur in the event the FDR reads the brochure while accompanying their relative during treatment or follow up visits and contacts the program directly.

The Project Manager has worked with the Research Assistant to train her on the use of the FCCC Health Information Management System to access patient records. This

process is utilized to identify breast cancer patients whom we will approach during their clinic visits at FCCC. Additionally, the Project Manager met with the study staff at four of the participating FCCC Network hospitals to review study procedures and discuss the need to modify them at the individual sites. Site-specific recruiting strategies have been planned and the Project Manager assisted each of the sites in preparing submission to their respective IRBs. Plans for training the health educators who will be administering the intervention began. Consultation with the Cancer Information Service management occurred in order to assess the training tools used by their health educators, which may be of value when training staff for this study.

To date, the DoD and FCCC IRB have approved all amendments. Additionally, four FCCC Network Hospitals sites prepared submissions to their respective IRBs and one has received approval. Finally, an abstract was submitted to and accepted by the American Public Health Association for poster presentation at their annual meeting in November, 2002 (see Appendix C).

During Year 1 we also anticipated initiating Task 2, Conducting a Prospective, Randomized Trial. This task was also subdivided into sub-tasks that will be completed over a number of months:

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)

Plans for identification of FDRs have been established. Current breast cancer patients will be approached during their clinic/physician visits at all regulatory approved sites in order to describe the study and obtain their permission to contact their relatives. Informed consent will be obtained through completion of the Patient Informed Consent form. Study staff will work with Breast Evaluation Clinic staff at FCCC (and site staff at their respective facilities) to identify patients at the appropriate time during their treatment (i.e. 6-12 months following diagnosis). Additionally, participant brochures will be placed at various places within FCCC and at the Network sites to generate interest among eligible FDRs who may be accompanying their mother/sister during an appointment.

The pre-call letter to FDRs has been finalized and approved by the DOD and FCCC IRB. The processes associated with generating and mailing the letters has been established between study staff and the Informatics Core. The letter has been programmed by the Informatics Core and will be generated for eligible FDRs identified by study staff. The

study staff will facilitate mailing of the pre-call letter with two copies of the Relative Informed Consent form. A project management/timeline contact log will be generated by data management that will flag the date which study staff can begin to contact the FDR if they have not previously called to opt out of the study within the time specified in the letter. Study staff will contact the potential participant to discuss the study and review the Relative Informed Consent form. If FDRs agree to participate in the study, they will be asked to sign and return one copy of the consent form. They will also be asked the best day and time to contact them so that the baseline interview can be conducted once the signed consent form is received at FCCC.

The baseline instrument has been pilot tested and programmed to enable capture of data during the initial participant telephone interview. Specific questions from the instrument have been identified to guide the tailoring of messages for the individuals in the experimental group. This instrument will be administered over the telephone once signed Relative Informed Consent forms are received at FCCC.

The Informatics Core staff has programmed the follow-up letter. Once the baseline interview has been conducted and data are entered into the database, the Informatics Core will generate the follow up letter and provide it to the study staff. The monetary reimbursement will be enclosed and the letter mailed to each participant.

Delivery of sessions has not yet begun. This is due to longer than expected approval of the baseline instrument by the DOD. The instrument is critical to development of the message library and the study staff felt it was appropriate to wait for approval before moving too far ahead with message development. However, preliminary steps have been taken to develop the tailored message library with the Communications Core. Tailoring variables have been thoroughly discussed and the study team has defined how each variable will be dichotomized (e.g. high vs. intermediate risk). Individuals randomized to the experimental group will have messages tailored first to their attention style (high vs. low monitor), then to the individual variables (e.g. calculated risk-high vs. intermediate risk; screening behaviors-complier vs. non-complier). The control group will receive a general health message that has been used in previous studies with the same subject population. The counseling session will conclude with a description of the FRAP program and instructions on how to become enrolled. Within a week of the counseling phone call each experimental group participant will receive a copy of tailored print materials designed by the Communications Core which reinforce the messages delivered by phone, and an invitation to attend the FRAP Program for more in depth education and personal counseling about their risk for breast cancer. Tailored follow up print materials are being developed in tandem with the tailored messages. The control group participants will receive a packet of NCI designated information and an invitation to attend the FRAP Program for more in depth education and personal counseling about their risk for breast cancer.

Plans have been established to monitor telephone intervention session for quality control. However, since sessions have not yet begun, no quality control tests have been performed.

The tailored follow up print materials for use with the experimental group are being developed by the Communications Core in tandem with the development of the tailored message library. Existing NCI designated materials (e.g. "*What You Need to Know about Breast Cancer,*" "*The Facts about Breast Cancer and Mammograms,*" and "*Action Guide for Healthy Eating,*") will be mailed to control group participants. Participants in both groups will receive an invitation to attend the FRAP Program for more in depth education and personal counseling about their risk for breast cancer.

As noted above, the Informatics Core has completed the programming required to enter the baseline interview data. Additionally, a tracking system has been established in order to facilitate efficient management of the study. This system will be used to track each study event as completed and will enable the study team to identify reasons for participant's declining/terminating.

Task 3, to conduct data analyses on all data collected and to present/publish findings is not applicable to the Year 1 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)

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.
- Developed and administered participant satisfaction questionnaire (N=55) to current Family Risk Assessment Program participants to guide development of tailored message library.
- Ongoing work with Communications Core toward developing tailored messages.
- Established recruiting procedures for identifying eligible breast cancer patients and their first-degree relatives.
- Met with FCCC Network site staff (N=4) to coordinate study approval and start up activities at each site.
- Finalized data collection instruments and facilitated programming by Data Management Core staff.

REPORTABLE OUTCOMES

- Presentations

An abstract was submitted to and accepted by the American Public Health Association to be presented at a poster session at the annual meeting in November, 2002. The poster will focus on the process of developing the tailored communication messages.

Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Poster presentation: Tailored communication to enhance adaptation across the breast cancer spectrum. Orlando, FL, September, 2002.

- Publications:

Daly, M., Barsevick, A., Miller, S.M., Rogatko, A., Buckman, R., Costalas, J., Montgomery, S., & Binger, R. (2001). Communicating genetic test results to the family: A six-step skills-building strategy. Family and Community Health, 24, 13-26.

CONCLUSION

Study start up and message library development activities have progressed in the past year. The development of tailored messages has been a more complicated process than originally anticipated. Additionally, final DOD approval of the protocol took longer than expected. As a result, recruitment has not yet begun. The study staff has felt that it is more appropriate to wait until the final message library is in place so that we do not recruit participants without the next step of the study firmly in place. However, we have begun to identify breast cancer patients and establish an internal queue of women who will be at the appropriate time from diagnosis (e.g. 6-12 months) at such time we begin recruiting. Approval at the Network sites is driven by the fact that their IRBs do not meet as regularly as the IRB at FCCC. However, we plan to begin recruiting at FCCC first so that all logistical issues can be worked out before recruiting begins at the Network sites. We anticipate that the sites will have received IRB and subsequent DOD approval so that they can begin recruiting soon after recruitment commences at FCCC.

REFERENCES

None

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

Dr. Suzanne M. Miller, Ph.D., Principal Investigator
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Fox Chase Cancer Center

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, four focus groups will be conducted during Phase I of the study (months 1-6). Eight to ten women (N=40) from the target population (early stage, primary breast cancer patients) will participate in the focus groups. The goal of the focus groups is to facilitate the development and refinement of the CAP intervention and the measures. The first two focus groups will be 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 will be asked to discuss their perceived risk, expectancies and beliefs, values and goals, emotions, and coping strategies regarding their transition into 'survivorship'. Specific areas to be targeted include their cognitive-affective responses to cancer recurrence, cessation of treatment, sexuality, body image, and personal relationships. This information will be used to further refine the intervention and measures. The final two focus groups will be designed to evaluate the intervention and the battery of measures, for their applicability and feasibility. Focus group participants will review, and make suggestions about, both the

proposed intervention and battery of measures. All focus groups will be conducted by the Communications Core and focus group data will also be analyzed by the Core.

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 stratified according to treatment type (chemotherapy vs. radiation vs. both); patients in each of the three strata will be randomized into either the intervention or control condition. All consenting participants will receive the intervention or control session during their first post-adjuvant treatment follow-up medical visit. A booster session will be given two-week post-counseling intervention. All participants will be assessed via mail at three, 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 are 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)

Phase I implementation is currently underway. Four months were necessary to obtain final DoD IRB approval for Phase I of this study. Recruitment strategies were finalized in consult with the Communications Core in September 2002. Presently, we are in the process of recruiting patients for participation in Focus Groups scheduled for the end of October and the beginning of November.

Members of our team have met with physicians and nurses in the radiology oncology and medical oncology departments to discuss recruitment issues and have obtained consent

from them to contact their patients. This includes Dr. Michael M. Millenson, MD, Dr. Lori J. Goldstein, MD, Dr. Marcia C. Boraas, MD, Dr. Michael Torosian, MD, Dr. Penny Anderson, MD, Dr. Gary Freedman, MD, Dr. Mary Cianfrocca, DO, Dr. Mary Daly, MD, and Dr. Nicos Nicolaou.

Our team organized a "walk through" of the Breast Evaluation Clinic (BEC) for the health educator and research assistant by Social Services. The goals of this meeting were to: 1) establish the most optimal method for identifying women at the end of treatment; 2) identify and coordinate with the BEC Fellows; 3) become familiarized with BEC staff and daily function to develop an effective system to approach patients and introduce them to the study; 4) compare the established practices of Social Services and the BEC with our proposed methodology to integrate their approaches in the study protocols. In addition, a meeting was organized with the chairman of FCCC's IRB to discuss the development of effective communications during an introductory session for incoming breast cancer patients at the Breast Evaluation Clinic. We will be providing patients with an overview of breast-related behavioral research projects, which should facilitate recruitment into Project 3 for Phase 2.

A meeting was organized with Project 3 staff and the members of the Social Work department. We secured their cooperation in identifying focus group participants for Phase I and discussed preliminary strategies for efficient recruitment for Phase 2. In addition, we probed them for their insight and experience with respect to psychosocial issues that arise during re-entry for primary breast cancer patients to inform us about appropriate topics to be raised during Phase I focus groups.

Melanie Glenn, MPH, is serving as the Project Manager for Project 3 as part of her BCE pre-doctoral fellowship under the mentorship of Drs. Miller and Buzaglo and has completed training in patient recruitment, bioethics, and project management. With respect to patient recruitment, the Project Manager has been attending regular meetings with Colleen Boyd, MSW, the FCCC Social Worker specifically dedicated to the breast cancer clinic. Through these regular meetings, Ms. Glenn has obtained valuable input regarding the identification of eligible participants. Additionally, the Project Manager has been trained on the use of the FCCC Health Information Management System to access patient records. This process is utilized to identify breast cancer patients for recruitment into Phase I focus groups. Ms. Glenn has recently completed the electronic certification course in bioethics in compliance with FCCC's IRB.

Project meetings have been held on a regular basis with the Communications Core to discuss the initial design and format of Phase 1 focus groups as well as to devise the questions to be addressed. Subsequent meetings were held to make necessary revisions and to discuss availability of members of the Communications Core for conducting the focus groups. Discussions focused primarily on considerations related to focus group content. Because we intend to use the focus groups to guide the refinement and implementation of our CAP intervention in Phase II, particular attention will be given to participants' preferences to the timing of the delivery of the counseling intervention (i.e., in the last week of adjuvant therapy or at their first follow-up appointment). Also, since

recent citations have discussed the importance of assessing positive outcomes associated with cancer diagnosis and treatment (e.g., Cordova, Cunningham, Carlson, & Andrykowski, 2001), questions targeted to perceived benefits (e.g., meaning) will be included. Further, we discussed the necessity of recruiting patients up to one-year after termination of adjuvant treatment in order to avoid overlooking any concerns that may arise during the first year of re-entry. Finally, with the dissemination of NCI's recently released and updated version of the *Facing Forward* pamphlet for survivors, the research team decided that it was important to assess participants' awareness of, and response to, this printed material, since this publication has been promoted by NCI as standard-of-care for cancer patients at the end of treatment. Presently, the focus group format and Phase 1 questions are completed and scheduling is set to begin.

Preliminary discussions have begun among Project 3 staff to address anticipated issues related to Phase II assessment and interventions. Generated from Co-Investigator Dr. Joanne Buzaglo's attendance at the conference entitled "Cancer Survivorship: Resilience Across the Lifespan" jointly sponsored by the NCI and ACS in Washington, D.C. in June 2002, we are considering amending our assessment protocol to address the positive outcomes (i.e., post-traumatic growth) associated with the experience of a recent breast cancer diagnosis and treatment (e.g., Cordova et al., 2001). Moreover, we are reviewing the opportunity to evaluate the usability, readability, satisfaction and relevance of NCI's *Facing Forward* as an adjunct aim to Phase II since patients will be receiving this written material at the end of treatment as standard-of-care. To date, there has been no systematic assessment of the utility and impact of *Facing Forward.* Considerations include the development of enhanced print material to be incorporated into the Phase II study protocol. Any proposed study changes would be addressed in anticipated amendments to the DoD IRB as well as FCCC's IRB.

Task 2, which was to be initiated during year 1 and continued into year 3, involves conducting a randomized trial (N=300) comparing the Cognitive-Affective Processing (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 Education (GHE) 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 Laboratory Core (Months 7-30)

Our team has attended consultation meetings with the Informatics Core to initiate the database edifice. 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, which does not apply to this annual report, involves conducting data analyses on all data collected and presenting/publishing findings.

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)

We are currently delayed in our schedule because we did not consider the time needed for securing DoD IRB review; thus, instead of being able to recruit participants for the first round of focus groups in month 1, as had been anticipated, four months were necessary to gain final DoD IRB approval for Phase I of this study. We are currently in the process of recruiting patients for participation in focus groups scheduled for the end of October and the beginning of November, putting the study 4 months behind schedule.

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.
- Members of our team have met with physicians and nurses in the radiology oncology and medical oncology departments to discuss recruitment issues and have obtained written consent from the physicians to contact their patients.
- Our team was oriented to the Breast Evaluation Clinic (BEC) by Social Services to facilitate study recruitment.
- Melanie Glenn, MPH, has assumed the Project Manager position as of September 2002 and has received training in managing the various aspects of Project 3 (e.g., Health Information Management System, bioethics certification, patient recruitment protocol).
- Eligible participants to be recruited have been identified through the Fox Chase Cancer Center's electronic patient database. At this point, approximately 25 eligible participants have been identified for recruitment into the first round of focus groups.
- The establishment of regular project meetings with the Communications Core to discuss the initial design and format of Phase I focus groups. The focus group format and Phase 1 questions are completed and scheduling is set to begin.
- Preliminary data collection procedures have been established with the Informatics Core to initiate the database edifice.

REPORTABLE OUTCOMES

Potential participants are in the process of being contacted for recruitment into the first round of focus groups. As a result, we are in the early stages of data collection and have no major findings to report thus far. Below is a list of presentations and publications that are related to Project 3 activities.

- Presentations:

  Fleisher, L., Schnoll, R., Miller, S., McKeown-Conn, N., Brower, L. Annual Meeting of the American Society of Preventive Oncology. Poster on: Women's self-reported knowledge about cancer risks, risk assessment programs and genetic testing: Preliminary findings. New York, N.Y., March, 2001.

  Fleisher, L., Miller, S.M., McKeown-Conn, N., Brower, L., Schnoll, R., Babb, J. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Increasing Knowledge of Cancer Risk and Cancer Programs. Orlando, FL, September, 2002.

  Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Invited Keynote Plenary Speaker on: Behavioral contributions to breast cancer prevention and control. Part of Plenary Session on Breast Cancer Prevention. Orlando, FL, September, 2002.

  Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Poster presentation: Tailored communication to enhance adaptation across the breast cancer spectrum. Orlando, FL, September, 2002.

- Publications:

  Daly, M., Barsevick, A., Miller, S.M., Rogatko, A., Buckman, R., Costalas, J., Montgomery, S., & Binger, R. (2001). Communicating genetic test results to the family: A six-step skills-building strategy. Family and Community Health, 24, 13-26.

  Miller, S.M., Fang, C.Y., Diefenbach, M.A., & Bales, C. (2001). Tailoring psychosocial interventions to the individual's health information processing style: The influence of monitoring versus blunting in cancer risk and disease. In A. Baum & B. Andersen (Eds.), Psychosocial interventions in cancer. Washington D.C.: American Psychological Association.

Miller, S.M., Sherman, K., Buzaglo, J., & Rodoletz, M. (2001) Monitoring-Blunting behavioral signatures in coping with health threats: The example of cancer. Psicologia della Salute, 3, 37-48.

Miller, S.M. (in press). Applications of the Monitoring Process Model. Applied Psychology: An International Review.

Miller, S.M., Bowen, D., & Croyle, R. (Eds.) Handbook of psychosocial approaches to cancer prevention. Guilford Press, in preparation.

Miller, S.M. & Sherman, K.S. (in press). Cancer screening. In N. Anderson (Ed.) The Encyclopedia of Health and Behavior. CA: Sage Publications.

Miller, S.M., Bowen, D., & Croyle, R. (Eds.) Handbook of psychosocial approaches to cancer prevention. Washington, D.C.: American Psychological Association, in preparation.

Miller, S.M. McDaniel, S., Rolland, J., & Feetham, S. (Eds.) Individuals, families, and the new genetics. New York: Norton Publications, in preparation.

CONCLUSION

Concerted efforts are being made to begin conducting focus groups by the end of October/beginning of November 2002, which will help to bring the project back on schedule. For example, project staff is accessing HIMS, Fox Chase Cancer Center's electronic patient database, on a regular basis in order to identify eligible women for recruitment into first and second round focus groups. The project staff has also been working in collaboration with the Communications Core and will begin scheduling focus groups once a working number of eligible participants have been recruited. A standard protocol for patient recruitment has also been developed. In addition, the Informatics Core is working in collaboration with the project staff and preliminary plans have been made with this facility for methods of data collection and analysis. As these processes are underway, we anticipate no further major obstacles in conducting focus groups or in the analysis of the first set of data collected and expect no major delays in the progress of this project.

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

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Dr. Robert Schnoll, Ph.D., Co-Investigator

10/31/02

Psychosocial and Behavioral Medicine Program
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INTRODUCTION

Excluding skin cancers, breast cancer is the most common cancer among American women. Recent advances in early detection and treatment have resulted in higher cure rates for breast cancer. Unfortunately, however, approximately 6% of breast cancer patients continue to develop metastatic disease. For the majority of women diagnosed with metastatic disease, 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), The Cooper Health System Division of Hemotalogy/Oncology and Temple University Hospital. 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, currently with three study conditions: 1) Communication and Support intervention, 2) Supportive counseling intervention and 3) Control (standard of care). Patients are assigned to one of these three 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. Patients will be randomly assigned to therapists.

Consenting participants are stratified into groups having low or high baseline psychological distress and patients in each of the two strata are randomized to the intervention conditions

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)

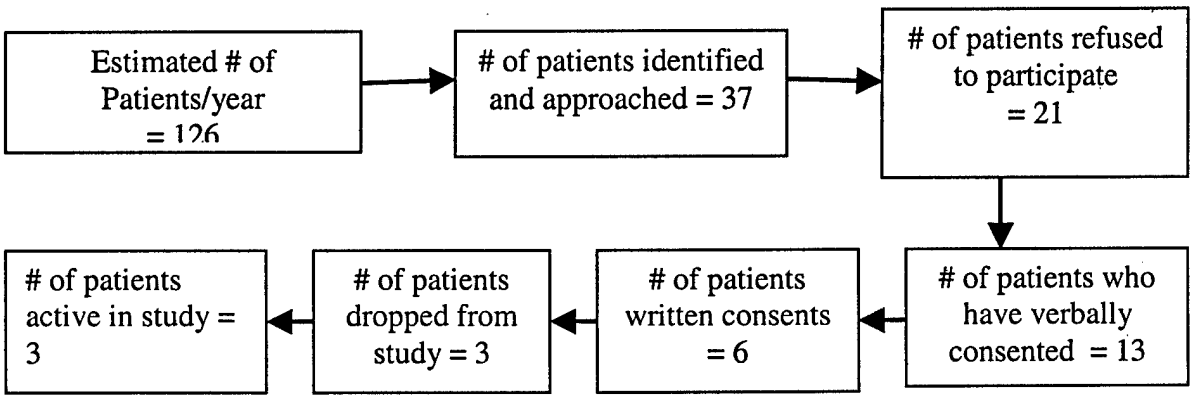
Based upon previous experience, Project 4 staff determined that focus groups would prove redundant to earlier work and experience conducted with this patient population. Therefore, in place of the focus groups (Task 1a, 1b and 1c) staff regularly met with the study interventionists in order to develop 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. Frequent therapist supervision (2d) has not been necessary thus far, as the slow recruitment has allowed the interventionists to give and receive feedback, with the PI and Project Manager, after each intervention session has been conducted. The PI and Project Manager have met several times, at irregular intervals, with the interventionists throughout the year. It is anticipated that, as recruitment rises, more formal, regularly scheduled supervision will be held with the interventionists. 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. Thus far, it has been unnecessary to conduct any follow-up assessments or treatment integrity checks (2f, 2g), as no individual has completed the six-session intervention. We anticipate that the enrolled individuals receiving an intervention will be completing it in a few weeks. Intervention sessions are audio taped for treatment integrity-tracking purposes.

Sluggish recruitment has been a significant issue in the first active year of the Project 4. Although this is a multi-site study, recruitment was not initiated at the Cooper Health or Temple University Hospital locations until July 2002. We believe that low recruitment figures 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.

Figure 1: Summary of Recruitment Efforts



We have attempted to address both issues through a variety of methods. The Project 4 staff has recently met with FCCC oncologists, nursing, and social work personnel to familiarize them with the study. To increase the overall number of eligible individuals we have initiated measures to add an additional site (Bryn Mawr Hospital) to the study. A further site is being explored, should the need continue. Additionally, a protocol amendment that removes the limitation of an eligible patient having to be within 4 months of diagnosis is in preparation for submission to the DoD.

Several changes to the protocol have been undertaken in order to reduce the refusal rate of approached eligible patients. Changes approved by the DoD and currently undergoing FCCC IRB review include financial reimbursement, of up to $225.00, to participants and the removal of some study assessment instruments to shorten the length of time necessary to complete each assessment. The length of surveys has been identified as a factor in a patient's decision whether or not to participate.

Finally, in order to increase the power of the data collected from individuals actually enrolled in Project 4, the Control arm of the study will be removed, pending FCCC IRB approval. Thus, all enrolled patients will receive one of the two study interventions. We believe that these protocol changes will effectively boost study enrollment to the originally anticipated number.

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 interventionist.
- 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.

- Presentations

  Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Poster presentation: Tailored communication to enhance adaptation across the breast cancer spectrum. Orlando, FL, September, 2002.

CONCLUSION

Data analysis will not begin for some time. Thus, no conclusions can be drawn at this time.

REFERENCES

None

DOD Progress Report
Leadership Core

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10/31/02

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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 CAP 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 Year 1 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) to develop, refine, and evaluate the overarching, unifying conceptual framework.

Task 1. To convene advisory committee and scientific meetings.

First, an External Advisory Committee has been chosen to provide consultation for the BCE senior staff. The committee will meet every 12-18 months, initially to review the planned research program and then to review program progress and to provide advice and consultation on the outcome, interpretation, and direction of the research program. Members of the Advisory Committee include Caryn Lerman, Ph.D., Professor, Department of Psychiatry, Associate Director, Cancer Control and Population Science, Abramson Cancer Center at the University of Pennsylvania; Chanita Hughes, Ph.D., Assistant Professor, Department of Psychiatry, University of Pennsylvania; Howard Leventhal, Ph.D., Center for Research on Health and Behavior, Rutgers University. The Committee will meet in the next 3-6 months.

Second, Dr. Miller, Director of the BCE, spearheaded the organization of the Behavioral Oncology Interest Group at the American Society for Preventive Oncology (ASPO). The first annual Behavioral Oncology Interest Group sponsored a Study Group Breakfast on March 13, 2001. The following researchers gave talks: Robert C. Croyle, Ph.D., chaired the symposium on Translating Basic Science into the Public Domain: The Role of Social & Behavioral Sciences in Cancer Prevention & Control; Caroline Gotay, Ph.D. presented

"Clincial Research Connections in Cancer Prevention & Control; Peter Salovey, Ph.D. presented "Communication to Promote Decision Making and Behavior in Cancer Prevention & Control; Dana Bovberg, PhD presented Psychoneuroimmunolgy in Cancer Prevention & Control; Dr. Croyle, concluded the symposium with future directions and plans for the Behavioral Oncology Interest Group. The second annual Behavioral Oncology Interest Group meeting took place at the ASPO conference in Bethesda, MD, March 10-12, 2002. Dr. Miller and other members of the BCE Leadership Core organized four round table sessions in which medical oncologists and behavioral scientists discussed the following key topics relevant to breast cancer prevention and control: 1) Behavioral Approaches to Genetic Risk Assessment and Testing; 2) Evidence for/against Biological Mechanisms of Psychosocial Effects on Cancer; 3) The Role of Risk Perceptions in Cancer Screening Adherence; 4) What has Targeting/Tailoring of Health Communications Contributed to Cancer Prevention and Control Research? These sessions were recorded and followed by an integrative breakfast session held at the end of the ASPO conference. The results from these meetings will be published in *Cancer Epidemiology, Biomarkers, and Prevention* and will focus on the standard for state-of-the-science behavioral research in behavioral oncology.

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:

- Scott Leischow, Ph.D., National Cancer Institute, spoke on "The Scope and Priorities of Tobacco Research Within NCI" on October 9, 2001.
- Sarah Bass, Ph.D., Fox Chase Cancer Center, spoke on "Relationships between Internet Use, Patient Task Behavior and Self-Efficacy in Newly Diagnosed Cancer Patients Who Call the Cancer Information Service" on November 6, 2001.
- Deborah McGuire, Ph.D., University of Pennsylvania, spoke on "Biobehavioral Interventions in Supportive Care: Oral Mucositis and Pain" on December 4, 2001.
- Jamie Ostroff, Ph.D., Memorial Sloan-Kettering, spoke on "Teachable Moments for Smoking Cessation in Health Care Settings" on January 22, 2002.
- Julie Backer, Ph.D., MPH, Albert Einstein Ethics and Health Policy Institute, "Balance or Bias on Breast Cancer Internet Web Sites?" on February 26, 2002.
- Dana Bovbjerg, Ph.D., Ruttenburg Cancer Center, Mt. Sinai School of Medicine, spoke on "Familial Breast Cancer Risk: A Psychobiological Perspective" on April 30, 2002.
- Chanita Hughes, Ph.D., University of Pennsylvania, spoke on "Managing Family Concerns and Medical Decision Making following Genetic Testing for Inherited Breast Cancer Risk" on October 15, 2002.

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

The Leadership Core has established 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:

- Discussions have been organized to enhance cooperative efforts to identify eligible participants across studies drawing from the same recruitment source. BCE members have provided assistance in modifying the focus groups and changing the recruitment strategy for Project 1 in order to facilitate the acquisition of sufficient participation. Further, recruitment strategies have been considered to accommodate potential overlap in the recruitment process for Projects 2 and 3. It has been established that the Informatics Core will flag prospective participants who meet eligibility critieria for both Projects 2 and 3. The Leadership Core has also instituted an introductory presentation for the patients of the Breast Evaluation Clinic that provides an overview of the BCE to potential participants during their initial visit.

- Focus has been placed on the theoretical applications of the C-SHIP model in the development of tailored communications. Progress has been made on refining the theory in an effort to assist projects in the development of effective communications. For example, vital input from staff from different projects and the Leadership Core have helped to refine the protocol and assessment tools for Project 2. In particular, extensive theoretically driven and evidence-based discussions have focused on the ways in which to tailor messages such that the interventions will vary according to the type and amount of information as well as level of family risk for breast cancer.

Task 3. To implement the Training Program.

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

Members of the Leadership Core for the BCE selected three FCCC faculty members to serve on a BCE Fellowship Search Committee. This committee was charged with 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 was comprised of Dr. Robert Schnoll, Dr. Mary Daly, and Dr. Eric Ross, who met on 3 occasions to devise fellowship announcements and candidate review criteria. A brochure that described aspects of the fellowship was devised. This brochure was distributed widely to local and regional universities and colleges and was disseminated on listserve websites, including ones operated by the American Society of Preventive Oncology, The Society of Behavioral Medicine, and the American Psychological Association. The following review criteria were 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. Six applications were received; 4 applicants indicated that they had accepted positions elsewhere prior to visiting FCCC for a formal interview. Two applicants were interviewed thus far, Steven Forish, Ph.D. and Elizabeth Petit deMange, Ph.D.; one was considered ineligible for the fellowship; the second was considered eligible and an offer was made. Unfortunately, the candidate decided to pursue another offer elsewhere.

Kerry Sherman, Ph.D., who will officially begin in the next few months, will fill one post-doctoral position. Dr. Sherman comes from University of Macquarie, Sydney, Australia with a special interest in developing behavioral protocols to enhance adaptation to breast cancer survivorship and to reduce psychological and medical sequalae associated with breast cancer treatment (e.g., lymphedema).

In addition, Melanie Glenn, MPH, who was identified through the Summer Internship Program, has recently joined the BCE Training Program as a pre-doctoral candidate. She brings with her a wealth of background in the recruitment, and the development, of health communications targeted to, underserved populations. As part of her graduate work, she was involved with promoting HIV/AIDS education and awareness to rural high-risk populations. She has a strong interest in applying her public health background to the development of tailored communications to enhance breast cancer prevention and control. She is currently involved in recruiting breast cancer survivors to participate in focus groups for the BCE Project 3 under the mentorship of Drs. Miller and Buzaglo.

The Summer Internship Program was established 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. Five interns joined us in the summer of 2002: Joel Gotkin, a senior in the Math, Science, and Engineering Program at Suncoast High School, Palm Beach County, Florida; Rachel Freedman, a Psychological and Social Sciences major at Pennsylvania State University Abington Campus, PA; Yvonne Pierpont, a Comprehensive Science major at Villanova University, PA; Tara Filmeyer, an MS candidate in Psychology at Saint Joseph's University, PA; and, Melanie Glenn, an MPH candidate at East Stroudsburg University, PA.

Dr. Buzaglo, Co-PI for BCE Project 3 directly supervised Joel Gotkin, Rachel Freedman, Yvonne Pierpont, Tara Filmeyer, and Melanie Glenn in their research activities, including development of multi-site participant recruitment strategies, data entry, development of a qualitative coding system for focus group data analysis, background literature search on breast cancer behavioral research, research design and methodology, manuscript and presentation preparation, and participation in team meetings. Each intern was required to

complete a web-based bioethics course and was provided with required readings highlighting the theoretical framework that guides our research.

Task 4. To develop, refine, and evaluate the overarching, unifying conceptual framework.

Guided by the C-SHIP framework, members of the Leadership Core have applied to the theory a comprehensive analysis to breast cancer risk. This work was spotlighted at the Era of Hope Breast Cancer Research Conference in Orlando, Florida in September, 2002. Dr. Suzanne Miller was an Invited Keynote Plenary Speaker on: Cutting edges of behavioral research in the prevention of breast cancer. In this talk, Dr. Miller highlighted the state-of-the-science with respect to breast cancer prevention and control with emphasis on the theoretical underpinnings and empirical approach to the design, development, implementation, and assessment of tailored health communications across the breast cancer spectrum. The leadership framework is also being developed and extended to the other cancer models, including prostate, ovarian, lung, head and neck, colorectal, and cervical.

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 biobehavioral 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 establishment of an External Advisory Committee.
- The establishment of monthly BCE meetings.
- The following steps have been implemented to support the BCE training program:
    - The creation of the BCE Training Program Committee that has overseen the development and implementation of promotional strategies to enhance recruitment of qualified candidates for the pre- and post-doctoral fellowships.
    - Kerry Sherman, Ph.D., who will officially begin in November 2002, will fill one post-doctoral position. Interviews are currently being conducted to fill the remaining post-doctoral position within the Training Program.

- Melanie Glenn, MPH, has recently joined the BCE Training Program as a pre-doctoral candidate. She is currently involved in recruiting breast cancer survivors to participate in focus groups for the BCE Project #3.

- The establishment of the Summer Internship Program to provide 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 development of the Behavioral Oncology Interest Group at the American Society for Preventive Oncology (ASPO).

- Preparation 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.

REPORTABLE OUTCOMES

At this time, the Leadership Core is providing 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. Further, the Core is actively engaged in implementing a Training Program.

- Presentations:

  Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Invited Keynote Plenary Speaker on: Behavioral contributions to breast cancer prevention and control. Part of Plenary Session on Breast Cancer Prevention. Orlando, FL, September, 2002.

  Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Poster presentation: Tailored communication to enhance adaptation across the breast cancer spectrum. Orlando, FL, September, 2002.

  Miller, S.M. Conference on A Decade of ELSI Research (sponsored by the National Institutes of Health). Paper on: Coping style correlates of participation in genetic testing for inherited breast and ovarian cancer risk. Bethesda, MD, January, 2001.

Miller, S.M. Conference on the Human Genome Odyssey: The Science, Business, Law and Ethics of Engineering Human Life (Sponsored by the University of Akron and the Northeastern Ohio Universities College of Medicine). Paper on: Monitoring coping style and genetic risk. Akron, OH, April, 2001.

Fleisher, L., Schnoll, R., Miller, S., McKeown-Conn, N., & Brower, L. Annual Meeting of the American Society of Preventive Oncology. Poster on: Women's self-reported knowledge about cancer risks, risk assessment programs and genetic testing: Preliminary findings. New York, N.Y., March, 2001.

Miller, S.M. Annual Meeting of the Society of Behavioral Medicine. Organizer and Chairperson of Symposium on: Building bridges from cognitive-social theory to tailored health communications. Seattle, WA, March, 2001.

Miller, S.M. Annual Meeting of the Society of Behavioral Medicine. Paper on: Monitoring coping style in cancer risk: Cognitive and social determinants of adjustment and adherence. Part of Symposium of Building Bridges from Cognitive-Social Theory to Tailored Health Communications. Seattle, WA, March, 2001.

Miller, S.M. Conference on Enhancing Outcomes in Women's Health: Translating Psychosocial and Behavioral Research into Primary Care, Community Interventions and Health Policy. (Sponsored by the American Psychological Association). Speaker on: Decision making and prophylactic oophorectomy. Part of Symposium on Decision Making and Genetics. Washington, D.C., October, 2001.

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Hurley, K.E., Miller, S.M., Costalas, J.W., & Daly, M.B. (2001). Anxiety/uncertainty reduction as a motivation for interest in prophylactic oophorectomy in women with a family history of ovarian cancer. Journal of Women's Health and Gender-Based Medicine, 10, 189-199.

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Fang, C.F., Miller, S.M., Daly, M., & Hurley, K. (2002). The influence of attentional style and risk perceptions on intentions to undergo prophylactic oophorectomy among FDRs. Psychology and Health, 17, 365-376.

Miller, S.M., Knowles, J., Schnoll, R.A., & Buzaglo, J. (2002). A cognitive-affective analysis of cancer behavior in the elderly: Are you as healthy as you feel? K. W. Schaie, H. Leventhal, & S. L. Willis (Eds.), Effective Health Behavior in Older Adults. (pp. 65-103) New York: Springer Publishing Co.

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Hurley, K., Miller, S.M., Gillespie, D., & Daly, M. The Price of Vigilance: Monitoring and beliefs about the efficacy of cancer prevention among women at familial risk for ovarian cancer.

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CONCLUSION

Members of the BCE have successfully assisted all research teams accomplish their tasks during this first year. Our efforts have 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
Informatics Core

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

10/31/02

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.

BODY

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. (Months 1-47)

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. (Months 3-48)

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

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.

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

- Core personnel are designing and developing comprehensive information management systems to meet the specific needs of projects II and IV. These customized relational database systems are being implemented using ORACLE database software. The database and management structure will facilitate efficient data capture and manipulation, as well as controll the exchange of information across the projects. All software is undergoing thorough testing before release to the user community.

- Client-server and web-enabled electronic data entry/retrieval and report generation software are being developed for Projects II and IV using the Oracle Developer/2000 suite of products.

- Data quality assurance procedures are being 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 are being developed.

- Software was developed to generate reports to 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.

REPORTABLE OUTCOMES

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. Project I is currently conducting focus groups to discuss issues related to breast cancer awareness and screening. Design, development, testing and deployment of the production database for phases 2 and 3 of the project will begin following the completion of the focus groups.

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 nearly 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 will contain cancer and vital status data on relatives of individuals recruited into the study. The software system will coordinate numerous tasks, including the scheduling of follow-up visits, and the distribution of mailed self-report questionnaires. This system is capable of generating multigenerational pedigrees from the union of family histories provided by two or more distinct study subjects in the same family. The family data will be easily updated from follow-up information to include deaths or new cancers reported for study

subjects, previously listed family members, as well as new births. All software developed, to-date, has undergone thorough testing. Username and password control are being used to ensure that investigators and research staff only have access to the information approved for their use.

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 has reviewed draft data collection instruments and project timelines. Project III is about to begin 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.

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 is currently under development. This system will maintain all of the information collected in this study. The software system will facilitate 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 developed data dictionaries based on the study requirements and the final data collection instruments. A case tool (PowerDesigner 6.1.0) has been 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 report as an html file for the data dictionary.

A system for the scheduling of follow-up visits and electronic screens displaying subjects due for follow-up was developed. All software developed, to-date, underwent thorough testing by demonstrating that each function is operational and performs according to specification. Username and password control are being used to ensure that investigators and research staff only have access to the information approved for their use.

- Presentations

Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Poster presentation: Tailored communication to enhance adaptation across the breast cancer spectrum. Orlando, FL, September, 2002.

CONCLUSION

This Core will serve 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 will be 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
Communications Core

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

10/31/02

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

INTRODUCTION

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

The Communications Core will fulfill two primary functions. The first, ***descriptive*** function consists of assessing information needs and culturally specific beliefs of the target populations that might interfere with cancer-relevant information processing and understanding. 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 will conduct in-depth assessments of the needs of the target populations through focus groups for each individual research project; analyze the information obtained through focus groups; and assist 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 will benefit and inform each of the projects as well as the entire Behavioral Center of Excellence.

These goals will be 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 will be in frequent contact to ensure that the objectives of the individual research projects will be achieved

BODY

In year 1 the Communications Core initiated the various tasks for each research project as specified in the Statement of Work and as listed below. The delay in IRB approval that affected all research projects, partially impacted the Communications Core. However, we used the additional time to prepare and consult with the investigators to be able to accomplish all tasks in a timely and efficient manner, once approval has been obtained. The specific tasks by research projects are:

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

Recruitment of forty First Degree Relatives (FDR's) of African American breast cancer patients receiving treatment at Temple University Hospital.	Month 1
Conduct three focus groups (N=30) with Project 1 study population to assess cultural specific beliefs about screening for breast cancer and genetic testing.	Months 2 – 3
Transcribe focus group audiotapes	Month 4
Perform content analysis on focus group transcriptions. Generate written reports documenting outcomes.	Month 5
Collaborate with personnel to discuss focus group outcomes.	Month 6:

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

Compilation of a library of possible personalized tailored messages to psychological (i.e., monitoring style) and clinical (.i.e. Gail score) variables.	Months 1-5
Development of a non-tailored interactive phone script for the General Health Information participants that adheres to current recommendations for breast cancer screening and counseling.	Month 5
Review the content and format of the tailored and non-tailored messages with project investigators.	Months 6-7

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

Recruit fifty women who are receiving treatment at Fox Chase Cancer Center (FCCC) for primary,	Months 1-2

early stage breast cancer to participate in focus groups.

Conduct two focus groups (N=20) to explore and assess the concerns expected by the study population for their transition into the post-treatment, re-entry phase of breast cancer. Transcribe focus group audiotapes and compile report based on findings. Refine the provisional intervention and measures for this study with project investigators.	Months 3-4
Conduct two focus groups (N=20) to test the modified intervention and battery of measures.	Month 5-6
Transcribe focus group audiotapes and compile report based on findings.	Month 7

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

Recruit fifteen women for focus groups. Participants can be either women with newly diagnosed breast cancer, or women who have been dealing with metastatic disease for over a year.	Months 1-2
Conduct the focus groups (N=10) to identify the main concerns and support needs of women with metastatic breast cancer.	Month 3
Transcribe focus group audiotapes and compile report based on findings.	Month 4
Collaborate with investigators to refine session materials.	Month 5

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.
- In anticipation as her role of focus group leader, Ms. Barabin-Burton attended an advanced training workshop for conducting focus groups. This 2-day training seminar, "Conducting Professional Focus Group Research" was held on Oct 3-5, 2002 in Rhode Island. The seminar addressed topics such as developing an effective focus group guide, how to most effectively elicit responses from focus group members, and how to change group dynamics. In addition, members of the Communications Core have started to augment the library of the Behavioral

Research Facility with articles from the communications literature. 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.** Accomplishments for project 1 have not progressed as anticipated as detailed in the attached report for project 1. The researchers faced unexpected difficulties recruiting first-degree relatives into focus groups. Members of the Communications Core attended regular meetings with the research team, developing the focus group guide and discussing recruitment methods. To date, focus group interviews with six participants have been conducted. The Communications Core also assisted in the development of specific recruitment materials and adapted these materials to the changed recruitment plan.

- **Project II.** Members of the Communications Core and the research team developed a satisfaction survey that was administered to 55 current Family Risk Assessment Program (FRAP) participants to assess their reasons for participating in the program. Facilitators and barriers to participating in FRAP were collected. These qualitative data are being used to frame the development of the tailored messages to be used for the experimental intervention. In addition we referred to the intervention protocol of a DoD-funded study that used tailored messages within the Cancer Information Service (CIS) as a template for the message library.

  Frequent meetings between the research team, the members of the Communications Core and the Informatics Core have resulted in agreement about the number of messages to be generated and the variables used for tailoring. The main tailoring variable is a person's information-seeking tendency (low or high monitors). High monitors have been found to require voluminous and detailed information, but subsequently react with increased distress when receiving such information. Low monitors, on the other hand, are satisfied with less detailed information, but also are less compliant with recommended health protective behaviors. Members of the Communications Core in collaboration with the research team of project II have developed messages that contain pertinent information about family history of breast cancer and screening recommendations. Each one of these messages has been adapted to the needs of high and low monitors. Message development has been a multi-step process involving the writing of several drafts that are checked for factual accuracy and ease of use by the research team. We are currently in the process of "fine-tuning" and pilot-testing these messages with members of the Cancer Information Service. Once they have been finalized they will be turned over to the Informatics Core, whose members will insert the messages into the appropriate tailoring software program.

- **Project III.** Members of the Communications Core have regularly met with members of the research team to develop the focus group guide, discuss recruitment methods and go over logistical aspects of conducting the focus

groups. Twenty-five women have been identified for the first focus group, which is scheduled for the end of October, 2002.

- **Project IV.** Between submission of the BCE and funding, the research team of project four has acquired considerable experience with the target research population (i.e., women with metastatic breast cancer). The research team decided that focus groups would not be necessary. During meetings, members of the Communications Core have assisted the research team in refining intervention and session materials.

REPORTABLE OUTCOMES

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

- Presentations

  Fleisher, L., Miller, S.M., McKeown-Conn, N., Brower, L., Schnoll, R., Babb, J. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Increasing Knowledge of Cancer Risk and Cancer Programs. Orlando, FL, September, 2002.

  Miller, S.M. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Poster presentation: Tailored communication to enhance adaptation across the breast cancer spectrum. Orlando, FL, September, 2002.

CONCLUSION

Members of the Communications Core have successfully assisted all research teams accomplish their tasks during this first year. Our efforts have focused on building a tailoring message library, preparing for focus groups including the development of focus group guides, discussing recruitment strategies, and refining recruitment and intervention materials. In addition, we have begun to add to the BRCF library by identifying and including key health communication research articles. Finally, the outreach coordinator and focus group leader has received additional training to be more effective in performing focus groups.

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None

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

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10/31/02

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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 (FRAP) 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.

The specific aims of the Laboratory 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 350 *BRCA1* and/or *BRCA2* mutation carriers 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 based 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

- Attend and participate in monthly Center meetings.
- 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.

REPORTABLE OUTCOMES

*=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.

1.a. Abstracts (selected, 2002)

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1.b. Presentation

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CONCLUSION

The work that we have preformed during the first year 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. 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.

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None

APPENDICES

None