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13. ABSTRACT *(Maximum 200*

The goal of our project "Increasing Access to Modern Multidisciplinary Breast Cancer Care" is to increase the utilization of currently available technologies for the screening, diagnosis, and treatment of breast carcinoma, particularly among the medically underserved. This goal is addressed through 2 projects providing education to health care consumers and providers, 3 projects which employ direct interventions to increase the utilization of available technologies and treatments, 2 projects addressing cost-effectiveness of new technologies, and a core facilities upgrade. Education projects include breast health education by peer educators in linguistically isolated minorities, and a small group educational course for nurses providing primary care to the underserved which employs patient surrogates. The direct interventions include a randomized trial of same day mammography to increase screening compliance, a randomized trial of a dietary education intervention in Hispanic women, and an evaluation of modern computer technology in a network breast cancer conference as a way to increase clinical trial accrual. The cost-effectiveness of stereotactic breast biopsy and outpatient bone marrow transplantation are evaluated. The specific aims and work to date for each of these projects are presented in this year 1 report.

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FOREWORD

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Monica Morrow MD 7/12/97

PI - Signature Date

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OVERVIEW OF PROJECTS

The goal of our grant "Increasing Access to Modern Multidisciplinary Cancer Care" is to increase the utilization of currently available screening techniques and breast cancer treatments, particularly in medically underserved populations. This goal is addressed in the eight component projects of the grant, which are grouped under the general themes of a core facility upgrade, education initiatives for health care providers and patients, direct interventions to increase the utilization of proven treatments, and evaluations of the cost-effectiveness of new technologies.

The component projects of the grant, the principal investigators, and the specific aims of each project are described below.

Core Facilities Upgrade

Project #1: Epidemiology Data Base

PI - Monica Morrow MD

The specific aims of this project are to identify and collect risk information on a group of 10,000 women without breast cancer during the period of the grant. In addition, the existing breast cancer data base will be expanded to include a few additional risk factor data points.

Education Initiatives for Health Care Providers and Patients

Project #2: Chicago Ethnic Community Breast Cancer Education and Screening: Woman to Woman Outreach

PI - Miriam Rodin MD, Ph.D

The objective of this project is to develop training programs in breast cancer screening modalities for health advocates and peer health educators for dissemination along peer health information pathways. This program will target linguistically isolated minorities

Project #3: Breast Education for Minority Providers

PI - Monica Morrow MD

The specific aims of this study are to develop a breast health curriculum for nurses which includes identification of risk factors, knowledge of normal anatomy and physiology, current techniques of breast cancer screening, diagnosis, and treatment, and community resources for the support of breast cancer patients. This project will educate minority care providers in breast health as defined by the curriculum, as well as in the techniques of clinical breast exam and breast self-examination instruction.

Direct Interventions to Increase Utilization of Services and Clinical Trials

Project #4: Increasing Adherence to Screening Mammography Recommendations

PI - Nancy Dolan MD

The objective of this project is to determine whether the combined use of targeted messages and same day mammography increases adherence among women who receive physician screening mammography recommendations. This will be studied in an academic general medicine practice, a private practice, a geriatric practice, and a public health clinic.

Project #5: Breast Cancer Risk Reduction in Hispanic Women

PI - Marian Fitzgibbon Ph.D.

The specific aims of this study are to conduct a prospective, randomized trial of an 8 month dietary intervention that is low in fat and high in fruits and vegetables in premenopausal Hispanic women. The frequency of breast self-examination and anxiety related to breast self-examination will also be measured. Serum carotenoids and total fatty acids will be used as intermediate biomarkers for the dietary intervention.

Project #6: Multidisciplinary Networked Breast Cancer Conference

PI - William Gradishar MD

The specific aim of this project is to make available the expertise of an academic multidisciplinary breast cancer management team to practitioners in hospitals in the Northwestern Health Care Network in order to optimize selection of local therapy, the use of adjuvant systemic therapy, and patient participation in clinical trials.

Cost-Effectiveness of New Technologies

Project #7: Cost-effectiveness of stereotactic biopsy versus excisional biopsy for women with abnormal mammograms

PI - Charles Bennett MD, Ph.D.

The goal of this project is to develop a model which will accurately generate cost-effectiveness estimates for stereotactic breast biopsy versus excisional biopsy. This model will be tested using mammographic lesions of varying degrees of suspicion and different modalities of local therapy. Costs will be determined to the completion of local therapy rather than to the diagnosis of carcinoma.

Project #8: Inpatient versus Outpatient High-Dose Therapy

PI - Jane Winter MD

The specific aims of this project are to compare the costs of inpatient versus outpatient high dose therapy and autologous stem cell reinfusion, and to measure quality of life for patients during each of these interventions. The cost analysis will include not only hospital and physician costs, but out of pocket costs to patients and caregivers in the outpatient intervention.

Project 1: Epidemiology Data Base

INTRODUCTION

The identification of women at increased risk for the development of breast cancer is an important goal for screening programs and prevention initiatives. Although multiple risk factors have been identified, the interaction between risk factors is poorly understood. In addition, information on risk has been derived for the entire population of women with invasive breast cancer. It is not clear whether all types of invasive carcinoma share common risk factors. The increasingly frequent identification of women at risk due to precursor histologies such as ductal carcinoma in situ, lobular carcinoma in situ, and atypical hyperplasia has raised important questions about interactions between these variables and other known breast cancer risk factors. The concordance, or lack thereof, of risk factors between women with invasive carcinoma and those with high risk histology also has the potential to offer important clues as to the natural history of these precursor lesions.

A detailed breast cancer data base is in place at the Lynn Sage Comprehensive Breast Center which includes information on risk factors, method of diagnosis, local and systemic therapy and outcomes for cancer patients treated at the Center. A total of 560 patients have been entered in this data base since its inception in July, 1995. The purpose of this project is to collect risk data on a cohort of 10,000 women without breast cancer for use as a control population in comparative studies of risk factors.

Work to Date

A. *Recruitment of a Data Manager*

Jennifer Clauson BS was hired as project data manager in January, 1997. She has prior experience with the recruitment and retention of volunteers for clinical research studies and appropriate computer skills. She has undergone extensive training in the breast cancer data base with quality assurance monitoring by Kathleen O'Connell MSW, data base manager.

B. *Development of Data Points*

The risk data which is currently collected for breast cancer patients was reviewed by participating members of the breast team and collaborators in the department of

epidemiology. Data points pertaining to alcohol and tobacco use, and diabetes were added to the standard risk questionnaire. After the data points were identified a questionnaire was formatted and pilot tested on 50 women undergoing screening mammograms for comprehension and convenience. Based on their responses, the questionnaire was revised to its final format, which is included as an appendix.

C. *Conversion to Scannable Format*

During the course of developing the questionnaire, it became apparent that manual data entry of this amount of information was probably not feasible, even for a full-time data manager. In addition, the amount of detail in the breast cancer data base makes manual entry of this data cumbersome even though patient numbers are smaller. Consultation was obtained with Kallista, Inc., the developers of our data base regarding switching to a scannable format. The decision was made to undertake this conversion with funds provided from other sources. Research on the available software and scanners was carried out, and the products potentially meeting our needs were identified. At present three software packages have been identified and are being tested with our data base. Purchase of the scanner is anticipated in the next two months.

D. *Accrual of Research Subjects*

The patient questionnaires were introduced into the breast center in March 1997. To date, 310 completed questionnaires have been received. This represents only one-third of our target volume for this time period. However, this low patient accrual is readily explainable by the procedural changes in our mammography center during this time period. Due to an increase in the volume of diagnostic (as opposed to screening) mammography, high case complexity, and an increase in the number of invasive radiology procedures, patients attempting to schedule screening mammograms were encountering waits of three months or longer. This was felt by the clinical leadership of the hospital to be unsatisfactory. The long term solution to this problem is an expansion of our mammography facility which is ongoing, with a scheduled completion date of September 1,1997. In the interim, patients undergoing screening mammography have been diverted to offsite locations or are having mammograms in the evening or on weekends. These studies are done by a rotating staff of technologists with varying levels of awareness and commitment to our clinical research studies. With the resumption of single site screening during daytime hours in September, we anticipate that we will be able to increase study recruitment to target levels.

Conclusions

During the past year we have hired a data manager, designed and tested our data questionnaire, and have initiated participant accrual to this study. In addition, upgrades to our

data base system have been undertaken to allow smooth processing of data during the course of the study. Insufficient time has elapsed for the generation of scientific data from this project.

Appendices

Patient Questionnaire

Project 2: Chicago Ethnic Community Breast Cancer Education and Screening Woman-to-Woman Outreach

Introduction

This project is a field test of a model of lay health worker outreach to increase breast cancer awareness and screening among immigrant and other ethnic minority women in Chicago. Considerable research by others among African-American and Hispanic women has shown they are under-screened and comparatively unaware of the benefits of screening. Less is known about beliefs and practices among the myriad of Asian and other cultural minority and immigrant women. The model of using natural helpers in communities to increase participation in preventive health is not novel. Lay health workers have been used in Third World countries and in inner city U.S. communities. This project involves the recruitment and training of a corps of lay educators in seven culturally or linguistically isolated communities in order to (1) increase adoption of mammography and breast self-exam (2) discover community and cultural factors which promote screening (3) evaluate the effectiveness lay health workers in different communities.

Scope

The project provides for the recruitment, training and supervision of lay breast health educators in seven minority/immigrant communities: Ethiopian (includes Eritrean, Somali), Indian subcontinent (includes at present principally Urdu and Gujarati language groups), Native American, Korean, Bosnian (Muslim), Chinese (Mandarin and Cantonese languages) and Filipino community mutual aid associations. Lay educators are trained in breast self examination using the technique described by Pennypacker (Mammotech, Inc.) and instructed in basic breast health facts and current screening guidelines. Each group of lay educators is supervised by a health advocate who is on staff of the ethnic mutual aid association. Lay educators keep logs of their outreach and are assigned approximate quotas for follow-up in return for small monthly stipends. The supervising

advocates assist women recruited by the lay health educators in obtaining mammograms at community facilities. Women educated by the lay health workers are invited to "post-testing" sessions to measure the effect of outreach, not only on seeking mammography, but on knowledge, attitudes and BSE technique in order to explain the effectiveness (or ineffectiveness) of lay education.

Measures were selected a priori, that is, published validated instruments designed to measure breast health attitudes and behavioral intentions were selected and translated into the target languages. Forward and backward translations were used to verify content and meaning. Supervisors monitor the number of requests for assistance with mammograms, however, given the lead time needed for compliance we also elected to measure "intervening" steps in adoption. Rakowski et al (1993) adapted the transtheoretical model of Prochaska et al (1983) and the decisional balance schematic of Velicer et al (1985) to measure impact on mammography. We adopted the 12-item decisional balance questionnaire and the 4-stage adoption model of mammography and BSE (Rakowski et al 1992). To measure impact on BSE we adopted our own shortened 15-item version of the 39-item Champion Health Belief Questionnaire (1984,1985). We adopted our own observational measure of BSE technique and accuracy (reported in siegel, Rodin 1996). A new instrument, a 15-item true-false "Breast Cancer Facts" was piloted.

Work to date

Subcontracts are effective with seven community mutual aid organizations. Each provides one 0.25 FTE staff to serve as project site co-ordinator (Health Advocate). Each Health Advocate is responsible to recruit, assist in training, and supervise a target of six lay health educators per group. To date, the instruments have been piloted with the lay educators with results reported below. After initial three trainings and several additional review trainings to improve knowledge and technique scores, there are currently 7 active health advocates and 35 of a target of 42 active lay educators. The lay educators have

made 195 initial teaching contacts and 58 follow-up teaching contacts as tabulated from returned log sheets from 5 organizations. Logs from 2 additional organizations have not been tabulated as of mid-April. Community women indicating a desire to obtain mammograms are being followed up by telephone by the health advocates to assist in making appointments at Chicago Board of Health (Lower West and Uptown) mammography services and at three community hospitals. Forty-six women (an incomplete count) have been scheduled for first mammograms as of April, 1997. We have conducted post-testing of trained community women in one community and are scheduling first round post-testing in the remainder.

Findings

It is too early in the project to determine the effectiveness of the intervention in motivating breast screening adherence among the "downstream" community target women. However, quantitative data have been obtained from pilot testing of instruments permitting comment on necessary refinements. In addition, project staff including the PI, project manager (V. Warren) and health advocates have gained considerable qualitative experience in matters affecting lay health worker training and supervision needs which will improve overall project performance in the coming years.

The reliabilities for five-point Likert-scaled instruments, HBQ 15-items and Decisional Balance Scale, were analyzed using the Kronbach's alpha procedure on the Stata statistical package.

Table 1
Health Belief Questionnaire 15 item (BSE)
Pre- and Post-Training Reliabilities: Seven Ethnic Groups

	Pre-training Alpha	Post-Training Alpha	
Indo-Pak	.79	.76	given in English
Filipino	.80	.81	English
Native Am	.80	.78	English
Chinese	.86	.90	Chinese trans
Ethio	.86	.94	Amharic trans
Bosnian	.78	.82	Bosnian trans
Korean	.78	.82	Korean trans

These results show fair reliability of this instrument for measuring attitudes towards BSE. However of interest, is that the items contributing the most to whole scale reliability were not stable between groups or between retakings. This may reflect small numbers in each group and an item analysis is in process. The alphas reported here are within the ranges reported for the whole scale in a prior study among Southeast Asian women. Reliability of this scale appears to be consistent although translated.

Table 2:

Whole Scale and Sub-scale Reliabilities of the Decisional Balance Scale for Seven Ethnic Groups

		Subscales	
	Whole Scale Alpha	Barriers Alpha	Benefits Alpha
Indo-Pak	.89	.97	.67
Filipino	.68	.78	.77
Native Am	.91	.81	.82
Chinese	.90	.93	.55
Ethio	.62	.26	.65
Bosnian	.33	.35	....
Korean	.92	.84	.87

The Decisional Balance Scale performed acceptably in three groups (Native American, Chinese and Korean), marginally in one (Indo-Pak) and unacceptably in three. With one exception, the barriers subscale performed more reliably than did the benefits subscale. This suggests that benefits as measured by this instrument do not tap the constructs motivating these women to seek preventive care. It was more successful in tapping the more concrete barriers to seeking care. We are conducting additional focus discussions with women in these communities to define more clearly what salient items should be included in a subsequent drafts.

We did examine the demographic characteristics of the lay educators themselves to identify patterns of response that may have been attributable to group differences in age, education, acculturation, and duration of U.S. residence. We found no clear pattern of association. However, the Bosnian women are the most recently arrived; and the Ethiopian women the least educated.

Table 3:

Lay Educator Demographics

	Mean Age Yrs.	Mean Yrs. Educ	Mean Yrs. In US
Indo-Pak	49	all college	14
Filipino	62	15	5
Native Am	48	all college	NA
Chinese	53	12	24
Ethic	34	5	5
Bosnian	45	14	2
Korean	51	all high school	9

Results

Any results at this time are necessarily preliminary. Qualitatively, the lay educators do stimulate interest in obtaining mammograms among the women they contact, as evidenced by the supervisors reports of requests for assistance. It is not possible at this time to calculate and "effectiveness ratio", nor are there sufficient numbers of logs to perform statistical analysis on stages of change, stages of adoption. We are concerned as well to explain the reasons for change or for non-adoption. Our preliminary data for instrument development suggests the present instruments require further refinement. Furthermore, we have not yet accumulated enough community subjects to determine how closely attitude measures and knowledge predict behavior and behavioral intent (Adoption). A number avenues need to be simultaneously pursued. Re-verification of translations of specific items is one avenue. The levels of literacy, duration of U.S. residence and cultural practices specific to each group have to be further evaluated. I have not reported the Knowledge Quiz precisely because translation problems appear to make the present tool unusable. Specifically, evaluation of negative statements and statements asking a judgement of a numeric value (such as age) appear problematic in several languages.

Problems

The management of such a complex project is indeed a challenge. We are continuously intrigued and challenged by the differences in language and culture. Each group requires a somewhat different management style. However, the principle problems have involved

the retention and motivation of essentially volunteer educators. In two groups, there has been a complete turnover of lay educators and supervisors, from which we have learned about desireable traits in lay health workers, including age (40 to 60), education (some high school, non-professional) and willingness to take direction from a younger woman. Women have been quite energetic in reaching out to their own networks, but less confident about teaching women with whom they are not well-acquainted. Health fairs and "breast parties" have offered a social setting for the lay educators be introduced to interested women. Realistically, we believe that on average a lay educator will be engaged for about a year, possibly two, and then will likely be replaced with another woman to reach her personal network. We are also having to deliver continuing education components for the program, since one song doth not an opera make. The on-going controversy about mammography for 40-49 year olds has been confusing for the health workers. Finally, community women are reluctant to come in for post-testing. Clearly, there is little benefit to them in taking time to fill out forms. We have structured inducements including an attractive "Certificate of Appreciation", solicited donations of gift certificates from large local grocery and drug chains, and held drawings for certificates among the women expressing interest in the program. I anticipate reaching sufficient numbers for adequate hypothesis testing as outlined in the original proposal.

Conclusions

Lay health educators appear to be effective in motivating women in ethnically iosolated communities to seek breasr cancer screening. The reasons for their effectiveness are not yet understood. Hypotheses will tested concerning the role of knowledge, attitude and belief in a variety of ethnic communities.

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Appendices

Health belief questionnaire

Mammography questionnaire

Sample test

Stages of adoption log

Stages of adoption questionnaire

Breast self exam observation scale

PROJECT #3: Breast Health Education for Minority Providers

Introduction

The purpose of this study is to improve the knowledge level of minority care providers regarding breast health and breast screening practices and to teach these providers the proper technique of breast examination. Studies have demonstrated that even among women with a regular source of medical care, 25% to 50% had not had a breast examination by a health care provider within the past year, and 50% to 75% of women over 50 had not had a mammogram.[1] Breast health screening was especially infrequent among women with less than a high school education or a household income below $15,000. Patient awareness of breast cancer risk and a recommendation by a health care provider to undergo screening mammography have been demonstrated to improve patient compliance.[2,3] For many women, nurses serve as a major contact point with the health care system. However, a minority of nurses regularly perform breast examinations, and 37% of 2,800 registered nurses reported knowledge deficits regarding breast cancer risk factors and signs and symptoms of breast cancer.[4] This information suggests that breast health education programs for nurses caring for medically underserved women have the potential to increase the utilization of breast cancer screening tests in this patient population.

Scope

The participants in this course are nurses employed by the Chicago Department of Health Clinics, The Erie Family Health Center, and the Winfield Moody Health Center. These sites together see approximately 440,000 underserved patients annually and have no funds for continuing medical education of nurses. The educational intervention is conducted in a small group format and includes a baseline assessment of knowledge using both a written test and a standardized patient. The intervention consists of small group lectures and "hands on" instruction in breast self examination (BSE) using models. A written post test and the performance of a breast history and physical examination on a standardized patient at the completion of the course are used to assess the immediate impact of the intervention on behavior. Participants will be recalled one year after completing the course to assess skills retention. A sample test is included in the appendix.

Work to Date

A. *Curriculum Development*

The nurse instructors in the program, Kay Pearson RN, MS, Cathy Bucci BS, RN and Susan Cox BS, RN met and developed an outline of the body of knowledge to be addressed in the didactic portion of the course during month 1 of the grant. During months 2 and 3, this outline was used to develop the course syllabus. Beth Fine MS, Coordinator of the Graduate Program on Genetic Counseling at Northwestern University Medical School and Kathleen O'Connell MSW, Oncology Social Worker for the breast program were recruited to provide syllabus material on genetic counseling and psychosocial needs of breast cancer patients, and to teach these portions of the course. The course syllabus defines the educational objectives of the course, includes an agenda for each session, and outlines of the material for each session. A glossary and a reference list are also included. A copy of the syllabus is included in the appendix. When syllabus development was complete, an application for continuing medical education credit for course participants was made through the Northwestern Memorial Hospital Department of Nursing. This was approved, and course participants receive 16.5 CME credits. At the same time, 2 standardized patients were recruited through the standardized patient office of Northwestern University Medical School. Cathy Bucci RN and Kay Pearson RN met with the standardized patients to review the goals of the course and the evaluation process prior to beginning the course. During month 4, nursing leaders at the participating institutions were contacted regarding course scheduling. In response to input from potential nurse participants, the format of the course was changed from eight two hour sessions to four sessions of four hours in length. Courses have been held in November, May and June. A total of 43 students registered for the courses which were limited to 12 participants per course, and 25 have completed the course, attending all four sessions. The July course is ongoing at this time with 9 participants.

B. *Demographics of Course Participants*

Self reported information on age, ethnicity, education, and work experience for the

initial 25 participants is provided in tabular form.

Age (years)	*n*
20-29	3(12%)
30-39	3(12%)
40-49	10(40%)
50-59	6(24%)
60-69	3(12%)
Ethnic Background	
African American	15(60%)
Asian	1(4%)
Caucasian	5(20%)
Hispanic	4(16%)
Highest Degree Attained	
LPN	4(16%)
RN	18(72%)
MS	3(12%)
Years of Experience	
<5	3(12%)
5-10	4(16%)
>10	18(72%)

C. *Results of Intervention*

Twenty-one (84%) of the participants entering the course stated that they taught breast

self examination as part of their clinical practice, and 20 (80%) reported that they recommended breast screening on the basis of the American Cancer Society guidelines. However, only 1 participant scored above the 90th percentile on the written pretest. The evaluation of breast examination technique by the standardized patients revealed a number of deficiencies. The most common of these were failure to palpate the supraclavicular nodes (82%), failure to support the arm while examining the axillary nodes (77%), and incomplete search of all breast tissue (64%). When the pre- and post-intervention results for the standardized patient exam were compared, 73% of students improved and 27% demonstrated no improvement as determined by the number of areas correctly examined. The written test scores are presented in tabular form.

Test Scores on Written Exam (% Correct)	*Pre-Test*	*Post-Test*
>90	*1*	*10*
75-90	*17*	*15*
50-74	*7*	-----
<50	-----	-----

Course participants were asked to rate the course on a 5 point scale for its utility in increasing their knowledge and relevance to their practice. All ratings were in the top two categories, and written comments were also favorable.

Conclusions

The preliminary results of this study indicate that this small group educational format is effective in improving participants knowledge of breast health and screening as well as their breast examination skills in the short term. Whether these skills are retained will be assessed one year after course completion with an additional written test and standardized patient examination. These results are particularly encouraging in light of the experience of the

course participants. The majority were senior nurses with more than ten years experience, who reported that patient education in breast health was a regular part of their clinical practice. The use of the standardized patient model identified significant deficits in breast examination skills in this experienced group of practitioners. The appropriateness of the curriculum has been affirmed by the improvement in participant performance on the post-tests and the positive evaluations from the students. These evaluations are being carefully reviewed as we undertake our first curriculum revision. The biggest problem to date in this project has been the high drop out rate of course registrants prior to the beginning of the course. This is improving as "word of mouth" demonstrates that this is a useful experience, and we are now confirming registration one week prior to each course start date.

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Appendices

(1) Sample Pre-Test

(2) Course Syllabus

Project 4: Increasing Adherence to Physician's Screening Mammography Recommendations: A Randomized Controlled Clinical Trial

Introduction

Research to date suggests that screening for breast cancer with mammography decreases breast cancer mortality in women age 50 years and older.[1-3] Major professional organizations, therefore, concur that women 50 years and older should have regular clinical breast exams and screening mammography.[4-5] Despite these recommendations surveys indicate that only a third of women 50 and older obtain annual mammography.[6-7] The reasons for lack of adherence involve complex factors related to women, physicians, and the health care system. While lack of physician referral is the most common reason women cite for not undergoing mammography,[6-12] among those that do receive a recommendation, only 40%-60% undergo screening.[13-15]

In a pilot study conducted in Northwestern Medical Faculty Foundation (NMFF) general medicine practice, we identified two separate steps in the process of adherence; 1) acceptance of the recommendation, and 2) completion of the intended test, each with it's own barriers. Women who refused the test were older and were more likely to think mammography was unnecessary. Women who agreed to the test but failed to adhere often cited reasons of inconvenience. We conducted a randomized clinical trial in the NMFF general medicine practice site to test an intervention aimed at the second step of the adherence process. Specifically we tested whether offering same day mammography increases adherence to screening recommendations among acceptors.

Work to date

From August 1 to December 31, 1996 we completed enrollment and data collection for the same day mammogram study taking place in the NMFF practice which had been going on since February 2, 1995. Nine hundred and twenty three women age 50 and older were enrolled in the study, 407 in the intervention group and 509 in the control

group. Of the 407 women in the intervention group, 104 (26%) received a same-day mammogram and reported overall satisfaction with the experience as 1.4 (SD +/- 1.0) out of a 5 point scale with 1 being highly satisfied. Three months after the recommendation was made, 58% of those in the intervention group had obtained the mammogram compared to 42% in the control ($p = < 0.001$), increasing to 61% and 49% respectively at six months ($p = < 0.001$). Three month adherence rates were higher in the intervention group compared to the control group for all subgroup analyses except for the subgroup of women who had had three or more mammograms within the past five years. In summary, same day mammography availability increased adherence rates and was associated with high levels of satisfaction.

The focus of the current study will test the generalizability of the above results to other practice settings. In addition we will be studying the effect of educational target messages in increasing acceptance of the recommendation in these settings as well.

The study population will consist of female patients age 50 - 79 presenting for appointments at one of three practice sites, each located in Chicago. To date, three clinical practice sites have agreed to participate in the study: 1) a geriatric practice with four physicians and a team of nurses, social workers, and other support services, 2) a private practice site with ten physicians, and 3) a public health clinic. Same day mammography screening is available to patients at each of these practice sites. Physicians, practice managers, and receptionists at each site have been oriented with regard to study logistics, patient enrollment, and data collection. Data collection strategies have been developed to meet the particular staffing needs of each site. At the geriatric and public health sites research assistants will collect data and administer questionnaires, and at the private practice site receptionists will administer questionnaires. A research assistant will oversee the data collection process at the private practice site.

Forms for data collection have been developed and refined; a physician enrollment

form (#1), patient consent form (#2), patient questionnaire (#3), and research protocol (#4) each attached in appendix. A research assistant has been trained in methods of chart review and computer reivew. These forms and methods have been sampled on a small group of 212 patients at the geriatric practice site. Of this sampling, 25 women were excluded because of breast cancer, 33 had mammograms within the past year, 5 have advanced medical problems which made it impossible for them to participate, 13 agreed to participate and completed the questionnaire, 34 declined to participate, 57 patients were cancelled/no show, and 45 patients were missed by the receptionist. Based on this sampling of patient records , a number of refinements have been made to the study protocol. In the geriatric practice site it was noted that with advanced age, health complications increase dramatically making the utility of mammography screening questionable. Therefore, an age limit of under 80 has been set as an additional criterion for enrollment in the study. This geriatric clinic has a very high rate of schedule changes and missed opportunities by the office receptionist. These factors have been taken into account in the data collection plan for this setting; 1) a research assistant will update schedules twice weekly, and 2) a research assistant will take over patient enrollment rather than the office receptionist. In addition, changes have been made to the consent form and patient questionnaire to make them easier for patients to read.

Of interest was the seemingly high refusal to participate rate among the geriatric patient population. Physicians in the center confirmed that, among this population of women, resistance to mammography is generally high. We believe that women may be refusing to participate because they think acceptance to participate will require them to get a mammogram. Based on this initial observation, the script which is used to recruit women to participate in the study is being modified. The revised script will focus on the issue of breast cancer rather than mammography as a screening device. It is our hope that we can enroll more of these women to tap into their reasons for resistance.

Finally, an individual plan for data collection has been developed to meet the unique

operational logistics of each site. We will continue to collect and analyze information on this sample and make any necessary refinements.

We anticipate that from July, 1997 - December, 1998 women from these three practice sites will be enrolled in the study. Study participants will be given a study information / consent form (appendix #2) and a breast cancer screening questionnaire (appendix #4), and a study enrollment form (appendix # 1) will be attached to each chart to serve as a prompt to physicians to recommend screening mammography to eligible women. At the time of check-out questionnaires will be collected. The research protocol sheet (appendix #4) will be followed to record if mammography was recommended, whether or not patients intend to obtain the mammogram, if so where, and if not why. Women in the control group will check out as usual. Women in the intervention group who refuse mammography (as assigned using a random numbers chart) will receive educational messages targeted to their stated reason for refusal. Women who accept the recommendation will be offered the opportunity to get the mammography directly after their visit. Research assistants will implement this protocol at the geriatric practice and at the public health clinic. At the private practice site, receptionists will implement the protocol and a research assistant will visit the site at least weekly to assist with any problems related to the study.

Conclusion

The results of our initial study demonstrate that the availability of same day mammography increases compliance with a physician recommendation to undergo mammographic screening. This phase of the project will test the generalizability of these results to other practice settings, as well as specific messages to improve screening compliance in both groups.

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Appendices

1. Physician Enrollment Form
2. Patient Consent Form
3. Patient Questionnaire
4. Research Protocol

Project 5: Mujeres Felices por Ser Saludables: Healthy Happy Women. A breast cancer risk reduction program for premenopausal Hispanic women.

Introduction

A. Rationale

The Breast Cancer Risk Reduction in Hispanic Women Program has been designed as a randomized intervention study to assess breast cancer risk reduction in a group of 300 premenopausal Hispanic women. There is a strong rationale to suggest that this age and ethnic group comprises an ideal subgroup for study of breast cancer risk reduction behavior.

In the United States, breast cancer is the most commonly diagnosed malignancy in women (Cancer Facts and Figures, 1993). However, incidence and mortality vary widely among different racial and ethnic groups (IARC, 1992). The overall incidence of breast cancer is higher among non-Hispanic white women (Eidson et al., 1994; Trapido et al., 1994), but recent data suggest that the incidence has risen more dramatically in Hispanic women (Eidson et al., 1994). A number of factors contribute to cancer onset, but changes in lifestyle, specifically dietary changes, could be one factor contributing to increased risk. Furthermore, despite the importance of early detection in breast cancer survival, studies show that the minimum recommendations for breast screening are not met in any racial or ethnic group in the US. However, for Hispanic women, the rates for screening are even lower than for white or African-American women (Fox & Stein, 1991; Vernon et al., 1991). National Health Objectives for the year 2000 include increasing screening behavior among Hispanic women.

Younger Hispanic women may be a particularly important group to study because the existing studies only targeted older women (e.g., Zapka et al., 1993). For older women, predictors of cancer screening include access to care, anxiety related to screening, and

socioeconomic factors. Language has been noted as a strong predictor in breast screening behavior (Stein, Fox & Murate, 191; Richardson et al., 1987). Presently, we do not know if the predictors of breast health are the same in a population of younger Hispanic women.

Overall, Hispanics are the fastest growing ethnic minority in the US. Between 1993 and the year 2000, there will be a 24.2% increase in the US Hispanic population and only a 3.3% increase in non-Hispanic whites (US Census, 1990). Unfortunately, a high percentage of both Mexican Americans and Puerto Ricans live in poverty, 38% and 25 %, respectively. Given that health problems occur disproportionately among those of lower socioeconomic and acculturation status, this places economically disadvantaged Hispanic Americans at increased risk. Therefore, prevention of the development of behaviors consistent with increased risk of breast cancer has considerable public health implications.

The aims of the study are:

1. To conduct an 8-month active intervention.
2. To measure adherence to a dietary intervention that promotes low fat and high fruit and vegetable consumption.
3. To measure potential changes in serum carotenoid and total fatty acid concentrations as a function of dietary changes.
4. To measure frequency of breast self-exam (BSE).
5. To measure anxiety related to BSE.
6. To measure communication with health care providers related to breast health.

B. Study Design.

Three hundred eligible women will be recruited and randomly assigned to a classroom group or a mail group. During the first 8 months (active intervention), the classroom group will receive 16 ongoing dietary and BSE intervention sessions in order to achieve adherence to a low fat/high fiber diet and increased behaviors related to breast health. Booster sessions will follow the active intervention during the one-year follow-up. Data collection will occur at baseline, 8 months, and 1 year follow-up.

Work to Date

A. Establish Agreement With the Erie Family Health Center

The Breast Cancer Risk Reduction in Hispanic Women project was originally designed to take place at the Chicago Nutrition Center in Chicago's West Town Neighborhood. The Chicago Nutrition Center is affiliated with and located only a few blocks from the Erie Family Health Center, a community health clinic which serves a largely Hispanic/Latina population. Based on recommendations by members of the Erie Family Health Center and the Director of the Chicago Nutrition Center we have established a collaborative agreement with members of the Health Center regarding rental of space on the third floor of the Health Center which will be designated for the project. This space will be used for recruitment, Health Center Visits (data collection), and intervention sessions. Currently, we are finalizing a subcontract to Erie Family Health Center which will allow us to provide financial compensation for the space and for personnel involved in the project.

In addition to the physical space, specific members of the Erie Family Health Center have contributed significantly to the preparation of this important community project. Ms. Erlinda Binghay is the Director of the Chicago Nutrition Center, and has played a central role in guiding our affiliation with the Health Center. In addition, she has worked closely with the Principal Investigator in the development of the curriculum. Ms. Eva Hernandez is the Community Outreach Coordinator for the Health Center, and she has helped guide the focus groups and identify community health advocates who will assist in data collection and child care.

B. Design of the Project

Over the last year considerable progress has been made towards finalizing the design and operation of this Breast Cancer Risk Reduction project. Some minor changes (see below) were made to the original timeline. Specifically, data collection will occur at

three Health Center Visits. The Health Center Visits will occur at baseline (pre-intervention), 8-months (post active-intervention), and 20-months. The one-year post-active intervention was reduced to eight months based on recommendations from our community affiliates regarding retention purposes. Specific details related to the study protocol are described fully in the Manual of Operations (see Appendix). This manual will be finalized in May, 1997.

TIMELINE

Preparation:
August 1996 - May 1997: Hire staff, formalize agreements with community organization, conduct focus groups, prepare manual of operations, prepare forms and questionnaires, train and certify all data collectors and interventionists.

Cohort I

May 1997 - June 1997	Recruit/Complete Baseline Health Center Visits
May 1997 - Jan 1998	Active Intervention
Jan 1998 - Feb 1998	Complete 8-month Health Center Visit
Jan 1998 - Jan 1999	Follow-up year (booster sessions)
Jan 1999 - Feb 1999	20-month follow-up Visit

Cohort II

Sept 1997 - Oct 1997	Recruit/Complete Baseline Health Center Visits
Sept 1997 - May 1998	Active Intervention
May 1998 - June 1998	Complete 8-month Health Center Visit
May 1998 - May 1999	Follow-up year (booster sessions)
May 1999 - June 1999	20-month follow-up Visit

Cohort III

March 1998 - April 1998	Recruit/Complete Baseline Health Center Visits
March 1998 - Nov 1998	Active Intervention
Nov 1998 - Dec 1998	Complete 8-month Health Center Visit
Nov 1998 - Nov 1999	Follow-up year (booster sessions)
Nov 1999 - Dec 1999	20-month follow-up Visit

C. Focus Groups

For behavior change strategies related to diet and breast health to be effective, collaborative effort between researchers and the target population must be established.

Although ethnic minorities and individuals of lower socioeconomic status have become a central focus of cancer risk reduction efforts, effective curriculums to address the needs of these populations are minimal (Jepson, Kessler, Portnoy, & Gibbs, 1991; Freeman, 1989). To fully engage individuals in health promotion, special attention must be directed to differences in culture and socioeconomic status. Because our aim is to reach low acculturated Hispanic women, we understood the need to develop an intervention that incorporates the ethnic foods and health beliefs of our target population, as well as the need to be sensitive to the literacy level and language preference of potential participants. To meet these needs and develop the most appropriate curriculum, we conducted four focus groups in which several open ended questions were asked. These questions allowed us to structure the discussion without undue rigidity.

Subjects

Names of women representing the target population were provided by Eva Hernandez of the Erie Family Health Center and invited to participate in the focus groups. We contacted about 15-20 of these Hispanic women, and 12 women participated in the focus groups. They were between the ages of 24 and 44 years. Eight of the women were Mexican and 4 were Puerto Rican. Six were married, 5 were single, and 1 was divorced. Two of the women were illiterate and had no formal schooling; one had only a first grade education; five had a 6th grade education; three were high school graduates; and one had some college. The majority of the women had studied in Mexico. The majority had been in the US more than 5 years and most were more comfortable speaking in Spanish. A $5 Jewel Food Coupon was given to each participant for attendance.

Procedure

A total of four focus group were conducted between November, 1996 and January 1997. These focus groups were held at the Health Center on Tuesdays between 4 and 8 PM. They were planned for one and one half hours but usually lasted longer. All

focus groups were either audio or video taped. The first three focus groups were led by Eva Hernandez (community liaison staff member at EFHC) and co-led by Margarita Hernandez and Georgina de la Torre (project staff). The last focus group was led by Margarita Hernnadez and co-led by Georgina de la Torre. The agenda and questions asked are described below.

Description of Focus Groups

Focus Group # 1

The aim of the first focus group was to assess needs of the participants for **content** of the curriculum.

1. Is cancer and breast cancer prevention an important health issue to you?
2. Would you want to participate in a project to learn more about breast cancer prevention that targets healthy eating and early detection methods?
3. Do you think diet affects your health?
4. Do you think that diet can affect you future health?
5. Why do you buy the foods you buy?
5. To what extent do you think your behavior affects your health?

Focus Group # 2

The second focus group began with the introduction of new participants and a summary of focus group # 1. The aim of the second focus group was twofold: 1) to assess **delivery** (time, number of meetings, presentation style, reading materials) of the intervention; and 2) to asssess **retention** strategies (what would keep individuals in a program).

1. Is the amount of time of each session and the number of sessions proposed reasonable?
2. What would an ideal intervention include? What types of techniques or presentation or style would you envision as being a super program?
3. Is two or three hours too long to spend for a health center visit?
4. Do you think your family would like your spending time in this type of program?
5. What do you think of the reading materials we have proposed?

Focus Group # 3

The third focus group began with the introduction of new participants and other staff who observed the focus group. The aim of this focus group was twofold: 1) to

determine **knowledge and interest** in discussing breast health; and 2) to **review recipes**.

1. Have you learned about BSE in the past?
2. What did you like about what you learned?
3. What would help you learn about BSE ?
4. Has a doctor or nurse ever helped you learn about BSE?
5. Did you notice any lumps in the breast model?
6. What do you think about using the model to help you learn about BSE?
7. How do you think other women would react to learning about BSE on a breast model?
8. What are some of your favorite recipes to cook for your family?
9. Do you use printed recipes?
10. Which of the recipes look hard and which ones look easy to prepare?

Focus Group # 4

The fourth focus group began with the introduction of new participants. The aim of this focus group was to **review potential reading materials and to assess comfort discussing breast health.**

1. What do you think about the food guides? Do you prefer a guide with names of foods and number of grams of fat and fiber so you can add up our daily total?
2. Would you prefer a guide in Spanish or English or both?
3. Would you be willing to use a fruit and vegetable scorecard?
4. Who would you talk to if you found a lump in your breast?
5. Would you talk to a doctor or nurse who was a man about breast cancer or ask questions about your breasts?
6. Would you be likely to have a mammogram and be able to talk about it?
7. Would you be likely to practice BSE and if so, what would be most helpful in trying to remember when to do BSE. Would a call from a friend or nurse be helpful?
8. What ideas do you have about how to remember to practice BSE?

Other general questions that were addressed during the Focus Group # 4.

1. How do you feel about homework assignments or quizzes?
2. How do you feel about using a calendar to keep track of things?
3. How would you feel about using a computer or interactive modules?

Summary of Results

Focus Group # 1

All women agreed that they were comfortable with the topic of breast health and voiced numerous opinions about the content they desired. However, their knowledge

and experience of BSE was very limited. When they thought about breast cancer, they often thought about breast removal and ultimately, death. Some women were not sure if age made a difference with BSE, mammography, or cancer. They were under the impression that not breast feeding could cause breast cancer because milk could accumulate in the breast.

Some women did not feel that diet affected health. Some felt that it did play a role, but did not know to what extent. Most felt that being overweight did affect your health. The reasons for buying certain foods was related to the likes of their family, cultural preferences, and economics. Economics seemed to play the most important role. They realized the there were healthy and unhealthy foods, but did not have a great deal of knowledge as to what was healthy. Many myths about good foods and bad foods that are common in the Mexican and Puerto Rican cultures were discussed. The participants agreed that preparation of foods can make them unhealthy and knew that adding fat and lard to food could be unhealthy. They wanted these types of things clarified in a program and were very eager to learn more about both cancer and breast health.

Overall, the interest and motivation about breast health and nutrition was high. All women agreed that their favorite teaching methods were a combination of approaches (e.g., videos, some minimal reading material, breast models, hearing from a breast cancer survivor). Most did not want reading materials that were detailed. They preferred English and Spanish on the same page.

Focus Group # 2

Most women said the best time for a class would be early evening, and agreed this depended on their families. Most thought the length of the classes should be about 90 minutes. The women felt that two to three hours would be appropriate for a health center visit, but felt their families may or may not be supportive depending on the time commitment. They stressed that their favorite presentation for the classes would be a mix of didactics, videos and "hands on" projects. The participants stressed that they did not want much reading material.

Focus Group # 3

Very few of the participants were knowledgeable about BSE. They had never been introduced to breast models and enjoyed the chance to practice on them and find lumps They thought that women would enjoy learning about BSE and how to be more assertive with health care providers.

Most women agreed that they liked ethnic cooking. They believed the foods they eat are healthy, but can become unhealthy due to methods of preparation. The participants all admitted to using too much added fat in their diet. They liked recipes

that had few words and were illustrated, and agreed that a great deal of writing would be boring and dissuade them from using the recipes. They would like to integrate more foods, but admitted that their children and husbands preferences would take precedence.

Focus Group # 4

Most of the women had heard about mammography but none had ever had a mammogram. Most participants felt they would be afraid to get one because of the pain involved. They liked the idea of a calendar to help them remember to do BSE.

The women were very animated about the nutrition materials. They liked information in both English and Spanish. They wanted more information about fat and calories. They also liked the fat guide.

D. Recruitment/Retention

Georgina de la Torre is bilingual and bi-cultural (Mexican-American), and was hired to coordinate all recruitment and retention efforts. The first step in the recruitment process was the development of a study logo/name which represents the project's goals as well as the spirit of the Hispanic/Latina community. Therefore, in October and November of 1996, a logo/name contest was advertised throughout the neighborhoods surrounding the Erie Family Health Center. For their entries, all 52 participants were given a water bottle (donated by the American Dietetic Association). The final design was chosen by staff consensus, and was created by Mario Espinosa. He received a $25.00 restaurant gift certificate for submitting the winning design: ***Mujeres Felices por Ser Soludables*** (Healthy Happy Women). Tony Baer, a local graphic artist, donated his time and expertise to format the logo for the computer. The logo/name has been used on all printed material including stationery, posters, and brochures (see Appendix).

To successfully recruit participants for this project, it is important to have support from communities and services which reach Hispanic/Latina women. Therefore, we have identified specific marketing and recruitment strategies. For marketing, the first press release was submitted by Northwestern University Public Relations in February, 1997 to major Chicago newspapers and radio stations, including the Spanish language

broadcast media, as well as local newspapers in the neighborhoods surrounding the Erie Family Health Center. In addition, project staff have attended a number of community health fairs (e.g., International Women's Day Health Fair, and 40-Fest) to promote the project. The regional chapter of Y-Me has also agreed to assist with disseminating project brochures.

In response to the initial press release, approximately 43 women called the recruitment hotline expressing interest in the study and wanting more information. An eligibility questionnaire was administered to these women over the phone (Appendix), and 29 women meet the eligibility criteria (i.e., between the ages of 20-40, no personal history of cancer except skin cancer, not currently pregnant or planning pregnancy in next two years, and not diabetic). Because we have not begun scheduling Health Center Visits, the recruitment coordinator has remained in contact with these women through the mail. A local Spanish television station (Channel 66 - Univision) also responded to the announcement and has agreed to support this important project.

Our primary recruitment efforts will focus on Hispanic/Latina women who utilize services at the Erie Family Health Center; Hispanics account for 83% percent of the populations who use their services. We requested a printed list of names and telephone numbers of all age eligible (i.e., 20-40 years) Hispanic/Latina women who have visited the Erie family Health Center during September 1995 - September 1996. This list contains more than 900 names of women, and we will begin contacting them by telephone in May 1997. Sequential recruitment efforts will target neighborhood stores, laundromats, park districts, and churches.

The recruitment/retention coordinator has outlined a number of retention strategies for assuring a participant's adherence, performance, and continued participation in the project. First, reminder phone calls will be made for all scheduled health center visits.

A phone chain will be established for women in the intervention group to remind each other to attend class. T-shirts were purchased which have the project logo/name on the front; these T-shirts will be given to every participant. In addition, we have solicited donations from local retail organizations (e.g., Garden Botanika).

E. Data Collection/Management

Over the last year, the forms and questionnaires were developed for data collection during the Health Center Visits (see Appendix). Based on information obtained from the focus groups, we expect many participants to prefer completing the Health Center Visits in Spanish. Therefore, Spanish and English versions of all forms and questionnaires were created as follows. First, an English version of a form/questionnaire was drafted, then it was translated into Spanish by the project coordinator and then back-translated into English by the assistant project coordinator or the recruitment/retention coordinator. The investigators reviewed the two English versions for any discrepancies that may have occurred during translation. The Spanish version of the appropriate form/questionnaire was then revised accordingly. We accessed three sources for the translation of hard-to-translate words (i.e., binge, no-stick spray). These sources include one mono-lingual Spanish dictionary (Grijalbo: Diccionario Practico de la Lengua Expañola. Ed. Bolado, AC. Ediciones Grijalbo, SA, 1988; Barcelona), one bilingual dictionary (Bantom New College Spanish and English Ditcionary. Ed. Williams, EB. Bantam Books, 1991; New York), as well as health-care and nutrition consultants affiliated with Erie Family Health Center.

All forms and questionnaires were piloted for general comprehensibility, length of time they took to complete, and flow of the questions among both English and Spanish speaking women from the targeted community. In general, most questionnaires were found to be understandable and flowed well. Specifically, for the breast health questionnaire (Form 107) we evaluated whether both English and Spanish speaking women could appropriately identify the rank order and the definition of the response choices. The questionnaire appears to be very effective in eliciting appropriate

responses. In addition, we modified the Kristal Eating Habits questionnaire to include an opening question (e.g., *Do you eat chicken*?), which allowed us to remove the response *does not apply*, which was very confusing to the participants.

For the collection of dietary data, four staff (including two nutritionists) were trained and certified to administer the 24 hour diet recall using NDS (Nutrition Coordinating Center, Minneapolis, MN). In May, all staff involved in the project will participate in an 8 hour training for interviewing skills.

During year one, the computer programmer and data manager developed the data entry screens in Access. In addition, methods were developed for generating labels for all forms and biologic samples.

F. Curriculum

Following the focus groups, we were able to incorporate much of the information into the development of the intervention. We have developed 16 sessions that address both nutrition and breast health. Our goal was to integrate nutrition and breast health to create a more cohesive intervention.

Each session is 90 minutes in length. There is an initial introduction that often includes an "icebreaker" task for the participants. This is followed by the session and a homework assignment. We have usually incorporated refreshments as part of the delivery of that session. The entire curriculum is included in the Appendix. Below please find a sample of one session.

Session 2.

20 minutes - Change can be positive icebreaker
30 minutes - Breast Facts, the Basics (Video, followed by short discussion)

15 minutes - Healthy eating and cancer introduction - presentation based on National Cancer Institute guidelines. Actual food will be included in the presentation for participants to try.
15 minutes - Enlisting family support in healthy eating
10 minutes -Homework assignment - Pantry "Check-up". Women choose a partner to discuss pantry check-up with during the week. A participant phone tree is set-up. Solicitation of volunteers to help with food shopping and preparation for the next session.

Home Activities	→	Outcomes Reinforced
Pantry Check up	→	Increase in intake of foods low in fat and high in fiber
Call your partner to discuss pantry check-up	→	Reinforce taking care of health and healthy eating.

Conclusions

This report outlines the progress to date on the Breast Cancer Risk Reduction Project, "Mujeres Felices por Ser Saludables." During the past year we have finalized the design and data collection procedures for our project. We also conducted focus groups to aid in our curriculum development. We are presently near to completing our 16-week integrated nutrition/breast health curriculum.

We have worked closely with staff members of the Erie Family Health Center to design a culturally sensitive and relevant program. We will continue to collaborate closely with them to augment our integration into the Westown Hispanic community.

We realize that recruiting and retaining participants for prevention trials is challenging. The difficulties are compounded when the setting is in a low-income minority community. We feel our work thus far has helped to lay very solid groundwork for a successful intervention.

Appendices

A. Manual of Operations

B. Summary of Focus Groups

C. Marketing/Recruitment Material

1. Stationery
2. Brochure
3. English and Spanish Posters

D. Data Collection Forms/Questionnaires

1. Procedures for Piloting Questionnaires
2. Greeting Consent Form
3. Status of Forms
4. Consent Forms
5. Eligibility Form
6. Blood Collection and Processing Form
7. Blood Collection and Processing Form - Quality Control
8. Anthropometric Form
9. Anthropometric Form - Quality Control
10. Breast Health Form
11. Diet Interview Form
12. Health Interview Form
13. Food Habits Questionnaire

E. Intervention Materials

Project 6: Multidisciplinary Networked Breast Cancer Conference

Introduction

The goals of the Multidisciplinary Breast Cancer Management Conference (MBCMC) are to optimize patient care by bringing a group of experts together that include surgical oncologists, medical oncologists, radiation therapists, pathologists, genetic counselors and other experts participating in the care of breast cancer patients. The MBCMC at Northwestern University has been a long standing conference that meets weekly to discuss the management of all new breast cancer patients evaluated at Northwestern Memorial Hospital. The conference is attended not only by the primary participants, but also by medical students, house staff, nursing and primary care physicians. The format of the conference involves the review of specific cases and related materials including mammograms and pathology. The treatment options are evaluated for each patient and consideration is given to available clinical trials that may be appropriate for a given patient. Northwestern Memorial Hospital, the primary teaching hospital of Northwestern University Medical School has developed the Northwestern Health Care Network. Other participating hospitals include Highland Park Hospital, Evanston Hospital, Swedish Covenant Hospital, Silver Cross Hospital, Northwest Community Hospital and Ingalls Hospital. Of the hospitals that make up the Network, only Northwestern Memorial and Evanston Hospital accrue significant numbers of patients to investigational clinical trials sponsored either by Northwestern, the Eastern Cooperative Oncology Group, pharmaceutical company-sponsored trials, or the National Surgical Adjuvant Breast Project.

The purpose of the Network Breast Cancer Conference (NBCC) is to permit physicians at remote locations (Network Hospitals) to participate in the

conference. Physicians at remote locations caring for breast cancer patients would potentially benefit from discussion of their patient at the MBCMC. The remote participant (Network Hospital) would be the presenter, providing information related to a particular patient to the group of specialists at Northwestern. In turn, the specialists at Northwestern would be able to provide a collective opinion regarding the optimal management for the patient, including discussion of clinical trials. In addition to discussing the case, available technology would allow for the visualization of quality images of both pathology and mammograms.

Work to Date

This project is being developed in conjunction with I.S. Grupe, Inc. (ISG). ISG is a small business located in Westmont, IL, that performs work in the areas of information creation, maintenance and dissemination. Under two consecutive contracts, ISG built and maintained the National Cancer Institute Cancerlit and PDQ databases. They are currently active in the fields of multimedia information retrieval, CD-ROM databases, and the design and development of Internet applications. Peter Schipma, the President of ISG, is the primary contact person involved with this project.

During the first four months of this project, staff members from ISG met with the principals who participate in the MBCMC at Northwestern. In addition, they attended the conference regularly during the first few months of funding. Their goal in doing so was to observe the interactions between experts at the MBCMC. More importantly, they familiarized themselves with the conference room and the technical requirements necessary to place equipment in the conference room for the purposes of linking the Conference to Network Hospitals (camera, light table for viewing mammograms, monitor and microscope for viewing pathology slides).

The principal investigator, William J. Gradishar, M.D., also contacted physicians caring for breast cancer patients at the Network Hospitals to make them aware of the development of this project. In the coming months, the plan is to visit each of the Network Hospitals to familiarize them with the details related to the technical setup of this project.

The technology infrastructure (hardware) upon which this project is predicated consists of three major components:

1. Personal computers with extensive processing power
2. ISDN telecommunication lines
3. Graphical user interface operating system with multi-user and multi-object support

The most recent activities related to this project focused on obtaining bids for the appropriate hardware and software necessary to proceed. Since this application was submitted, the cost of ISDN telecommunication lines has decreased significantly and provide more options for the development of this project. Bids were solicited from a number of different vendors for hardware necessary to support this project. The bids were evaluated and an order has been placed for equipment necessary to support all of the Network Hospitals. We anticipate that arrival of this equipment will be with the next week. The Network interconnection will be supported by Novell Netware. The basic conference support tools will be available in the Intel ProShare video communications package. ProShare provides the capabilities to deliver images, highlight lines of text, circle areas of interest on an x-ray (mammogram), present the voice and image of a speaker, etc. Operating under Windows and Netware, it provides full capability for all aspects of interactive conferencing. A list of the purchased equipment is included in the Appendix.

We anticipate that a prototype system will be in place by September, 1997. The prototype will be tested at Northwestern Memorial Hospital, and when it has been debugged, the other network hospitals will be added to the system one at a time. The next several months will be devoted to familiarizing off site participants with the equipment.

One of the objectives of this project is to determine whether this tool (NBCC) increases accrual of patients to clinical trials from Network hospitals. In addition, critically evaluating physician satisfaction will be important to determine whether or not experts at Northwestern feel they are able to convey important information to physicians at Network hospitals. Equally important will be the determination of whether physicians at Network hospital find this system useful to the care of their patients. Paul Yarnold, Ph.D., a faculty member in the Division of General Medicine and an expert on assessment of technology, has been recruited to help devise surveys/questionnaires to evaluate the efficacy of the project.

Conclusions

The most difficult part of this project has been to identify the ideal hardware and software necessary to support the NBCC. The technology has changed dramatically even since this application was submitted. In an effort to optimize the life span of both hardware and software that will be purchased for this project, critical analysis of the needs has been undertaken for the last six months. We anticipate physician satisfaction and accrual to clinical trials will be forthcoming.

Appendices

Purchased equipment

Project 7: Cost Effectiveness of Stereotactic Biopsy versus Excisional Biopsy for Women with Abnormal Mammograms

Introduction

Stereotactic breast biopsy has been advocated as an alternative to open surgical biopsy for the diagnosis of mammographically detected breast lesions. Between 75% and 90% of the abnormalities that are identified on screening mammograms are benign (1-7). Avoiding an open surgical procedure with its associated cost, morbidity, anxiety, and emotional concerns is a reasonable goal for women with benign lesions. Stereotactic biopsy is a reasonable substitute, but there is uncertainty about the accuracy of the procedure, its ability to completely characterize malignancies and allow for definitive surgical treatment, and the consequences of missing a diagnosis of early breast cancer (8). Although stereotactic biopsies are clearly less invasive and costly than excisional biopsy, it is not clear that the procedure is more cost-effective than excisional biopsy in the long run given the above mentioned concerns. To date, studies evaluating the cost-effectiveness of stereotactic breast biopsy have considered only the costs to diagnosis, rather than the cost to completion of local therapy. Since a diagnostic biopsy may serve as the definitive lumpectomy in many cases of carcinoma (9), the cost-effectiveness of stereotactic biopsy may vary with the degree of suspicion of the mammographic abnormality.

The purpose of this study is to evaluate the cost-effectiveness of stereotactic biopsy versus surgical excisional biopsy for non-palpable breast abnormalities, considering both the degree of suspicion of the lesion and the type of local therapy which is undertaken.

Work to Date

Decision Analysis Model

A decision analysis model was formulated to represent the flow of decisions and chance

events related to the consequences of an abnormal mammogram. These assumptions were utilized to develop a decision tree (figure 1) which will be used to perform the cost analysis. The model was developed in collaboration with co-investigators from radiology and surgery to accurately reflect clinical practice at our institution.

The four diagnoses of either surgical or core biopsy were determined to be invasive cancer, ductal carcinoma in situ (DCIS), benign (which includes radial scar, fibrocystic disease, fibroadenoma, focal fibrosis, usual ductal hyperplasia, atypical ductal hyperplasia, papilloma, sclerosing adenosis, lobular carcinoma in situ, atrophic tissue and apocrine metaplasia), and missed. Missed diagnoses will be classified as those DCIS or invasive cancer diagnoses identified following an initial benign diagnosis during the study.

Treatment possibilities for each of the diagnoses are the second tier of the tree. For invasive cancer they are mastectomy or lumpectomy (with or without lymph node dissection based on the size of the primary tumor). Patients receiving lumpectomy will have the tumor margins scored negative or positive. The lumpectomy is definitive when the margins are negative, or further re-excision or mastectomy is performed when the margins are determined to be positive. Patients with a diagnosis of DCIS undergo either a lumpectomy or mastectomy without lymph node removal, with disease status verified using this tissue. Patients with confirmed DCIS and negative margins require no further surgery. Those who are found to have invasive carcinoma after definitive excision may have axillary lymph node dissection, and re-excision should the margins be positive for cancer. The costs to the completion of surgical therapy will be calculated.

Patient Accrual

Patients included in this study were all patients seen at the Lynn Sage Breast Center beginning in September 1, 1996, for a core or surgical biopsy prescribed due to an abnormal mammogram. Patients with clinically evident breast abnormalities are

excluded. Data included in this report are for all patients with complete follow-up data receiving a biopsy between September 1, 1996 and January 31, 1997. Data are reported as procedures, not per patient, as some patients had multiple lesions with different outcomes. Total procedure performed were 175 surgical biopsies and 187 core biopsies, of which complete data were available for 161 surgical biopsies and 166 core biopsies.

As patients were seen in the radiology department, the physician performing the biopsy or wire localization recorded the "degree of suspicion" for a cancer diagnosis as 1 probably benign, 2 low, 3 intermediate, or 4 high. This information, as well as clinical data, information regarding follow-up diagnostic and surgical procedures, and pathologic results were tracked by the breast center nurses and entered into a database. Printed reports from this data base were entered into an Excel database and data comparing age, type of mammographic abnormality, degree of suspicion, and diagnosis were tabulated. Values for missed diagnoses will be determined in the future when adequate follow-up is available. Data comparing age, degree of suspicion of mammographic abnormality, and incidence of malignant lesions for patients undergoing core biopsy or surgical biopsy are shown in Table 1. Information on histologic findings is shown in Table 2 for core biopsy patients and Table 3 for surgical biopsy patients.

Values for the probability for each of the end states in the decision tree will be determined using the information from the clinical database once accrual has been completed. Five or six patients from each of the terminal points on the tree will be randomly selected and their billing data collected from the Northwestern Memorial Hospital finance department. This information, weighted by the probability of occurrence, will determine a cost for each procedure.

Conclusions

The initial patients entered into the study confirm that experienced mammographers can

identify lesions with a high probability of being benign or malignant with 90% accuracy. This finding will be confirmed with larger numbers of cases as the study progresses. However, these initial results indicate that selection of a biopsy approach based on the degree of suspicion of the mammographic abnormality would be clinically feasible if warranted on the basis of differences in cost effectiveness.

The initial sample also indicates that lesions felt to be highly suspicious for carcinoma are preferentially selected for surgical excision rather than core biopsy. This is a reflection of the practice patterns of the surgeons participating in the study. The use of core biopsy for highly suspicious lesions is increasing, and patient distribution in the next 6 month sample will be closely monitored. However, the initial rate of accrual to the study suggests that adequate numbers of patients in each category of lesion suspicion are being biopsied by core and open technique, and the final sample size will be large enough to provide meaningful data.

Figure 1

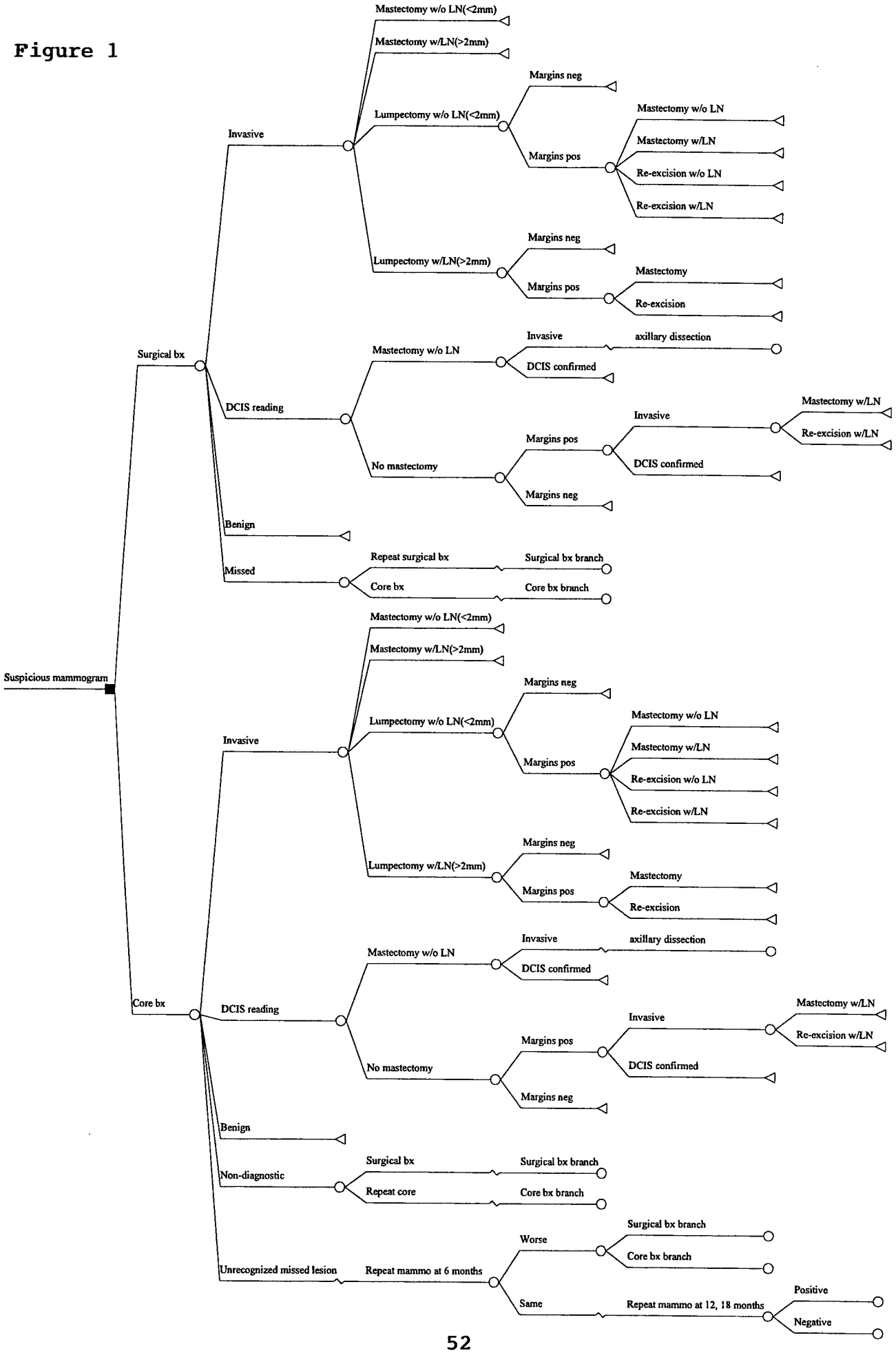
Suspicious mammogram
Surgical bx
Invasive
Mastectomy w/o LN(<2mm)
Mastectomy w/LN(>2mm)
Lumpectomy w/o LN(<2mm)
Margins neg
Margins pos
Mastectomy w/o LN
Mastectomy w/LN
Re-excision w/o LN
Re-excision w/LN
Lumpectomy w/LN(>2mm)
Margins neg
Margins pos
Mastectomy
Re-excision
DCIS reading
Mastectomy w/o LN
Invasive
axillary dissection
DCIS confirmed
No mastectomy
Margins pos
Invasive
Mastectomy w/LN
Re-excision w/LN
DCIS confirmed
Margins neg
Benign
Missed
Repeat surgical bx
Surgical bx branch
Core bx
Core bx branch
Core bx
Invasive
Mastectomy w/o LN(<2mm)
Mastectomy w/LN(>2mm)
Lumpectomy w/o LN(<2mm)
Margins neg
Margins pos
Mastectomy w/o LN
Mastectomy w/LN
Re-excision w/o LN
Re-excision w/LN
Lumpectomy w/LN(>2mm)
Margins neg
Margins pos
Mastectomy
Re-excision
DCIS reading
Mastectomy w/o LN
Invasive
axillary dissection
DCIS confirmed
No mastectomy
Margins pos
Invasive
Mastectomy w/LN
Re-excision w/LN
DCIS confirmed
Margins neg
Benign
Non-diagnostic
Surgical bx
Surgical bx branch
Repeat core
Core bx branch
Unrecognized missed lesion
Repeat mammo at 6 months
Worse
Surgical bx branch
Core bx branch
Same
Repeat mammo at 12, 18 months
Positive
Negative

TABLE 1

	Core Biopsy	Surgical Biopsy	
Procedures (#)	166	161	
Age (Mean +/- SD)	51 +/- 12	54 +/- 10	
Degree of Suspicion (%)			
Prob Benign	31.1	28.8	
Low	37.8	15.5	
Intermediate	19.3	21.1	
High	11.8	34.5	
Diagnosis (%)			
Benign	83.7	67.9	
DCIS	4.8	9.3	
Invasive	11.4	22.3	

TABLE 2

Core Biopsies (%)				
	Prob Benign	Low	Intermediate	High
Apocrine Metaplasia	0	0	4.3	0
Atrophic Tissue	2.5	4.3	2.2	6.7
Atypical Ductal Hyperplasia	2.5	2.2	6.5	3.3
Fat Necrosis	0	2.2	0	0
Fibroadenoma	46	45.6	15.2	0
Fibrocystic Disease	18	10.9	17.4	10
Focal Fibrosis	7.7	4.3	6.5	0
LCIS	0	4.3	0	0
Lobular Hyperplasia	5.1	2.2	2.2	0
Lymph Node	2.5	0	0	0
Papilloma	0	2.2	4.3	0
Radial Scar	0	2.2	2.2	0
Sclerosing Adenosis	2.5	4.3	0	0
Usual Ductal Hyperplasia	2.5	10.9	8.7	0
Total Benign	89.30%	95.60%	69.50%	20%
DCIS	2.5	2.2	13	10
Total DCIS	2.50%	2.20%	13%	10%
Primary Malignant	2.5	0	0	0
Infiltrating Ductal Ca	0	0	15.2	50
Infiltrating Lobular Ca	2.5	0	0	3.3
Infiltrating Medullary Ca	0	0	2.2	3.3
Infiltrating Tubular Ca	2.5	1	0	13.3
Total Malignant	7.50%	2.20%	17.40%	69.90%

TABLE 3

Surgical Biopsies (%)				
	Prob Benign	Low	Intermediate	High
Apocrine Metaplasia	0	8.3	4.4	0
Atrophic Tissue	0	4.2	0	0
Atypical Ductal Hyperplasia	7.1	4.2	4.4	7.1
Atypical Lobular Hyperplasia	2.4	0	0	0
Ductal Etasia	2.4	0	0	0
Fat Necrosis	0	0	0	0
Fibroadenoma	26.2	25	2.2	1.8
Fibrocystic Disease	28.6	37.5	37.8	10.7
Focal Fibrosis	9.5	0	4.4	1.8
LCIS	4.8	0	0	0
Lobular Hyperplasia	2.4	0	0	0
Lymph Node	0	0	0	0
Papilloma	0	4.2	6.7	3.6
Radial Scar	0	0	2.2	3.6
Sclerosing Adenosis	4.8	0	0	1.8
Usual Ductal Hyperplasia	2.4	4.2	4.4	0
Total Benign	90.60%	87.60%	66.50%	30.40%
DCIS	2.4	8.3	17.8	17.9
Total DCIS	2.40%	8.30%	17.80%	17.90%
Primary Malignant	0	0	0	0
Infiltrating Ductal Ca	3	4.2	13.3	39.3
Infiltrating Lobular Ca	0	0	0	1.8
Infiltrating Medullary Ca	0	0	0	0
Infiltrating Tubular Ca	0	0	2.2	10.7
Total Malignant	7.10%	4.20%	15.50%	51.80%

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PROJECT 8: INPATIENT VERSUS OUTPATIENT HIGH-DOSE THERAPY

Introduction

The cost of high dose therapy with stem cell rescue for the treatment of malignant disease has escalated over recent years, ranging from $50,000 to $103,000 (1), and the numbers of patients seeking such therapy nationally has grown exponentially. Increasing concern over growing health care expenditures and the high cost of new technology and pharmaceuticals has led to extraordinary scrutiny by payors and required that transplanters look at ways to reduce the overall cost of the procedure. Many factors contribute to the high cost of transplantation, including chemotherapy drugs, stem cell mobilization, blood products, supportive pharmaceuticals and care, and hospitalization. The intensive nursing care requirements have led to hospital room and board charges similar to those of intensive care units. (2) Although there is the perception that outpatient therapy is less expensive than inpatient treatment, this is not necessarily the case. In addition to the direct costs of home health visits, mobile medical equipment, emergency room treatment and additional staff training, substantial out-of-pocket and indirect costs may be incurred by the round the clock caregiver required for this procedure. A prospective economic analysis comparing matched individuals undergoing similar therapy as outpatients and inpatients is warranted. Another argument used to justify outpatient transplant over the traditional inpatient stay is the perception the outpatient therapy results in a superior quality of life (QOL) for patients, but this has not been studied.

The purpose of this project is to determine if the cost of high dose chemotherapy, with or without radiotherapy, with autologous peripheral blood

progenitor cell reinfusion for the treatment of breast cancer and the hematologic malignancies is reduced through the use of intensive outpatient support without causing a decrease in the quality of life. Quality of life assessment and comparison of inpatient and outpatient quality of life will be analyzed both descriptively and quantitatively. A comparison of the costs of inpatient versus outpatient high dose therapy with autologous stem cell reinfusion will be made.

Work to Date

Developmental and Administrative Accomplishments

After a thorough search for the optimal candidate, a research nurse was hired to begin work November, 1996. Educational materials for the patients who would be transplanted as outpatients and their caregivers were developed(Appendix). Procedures were developed for such activities as transporting patients and caregivers to the hospital each day, admitting patients as inpatients when the need arose, acquiring outpatient medications for patients, and obtaining and providing various needed medical services on an outpatient basis.

The original facility chosen for the outpatient apartment was abandoned because of concerns raised by the Infectious Disease group about the air handling system and the extensive renovation that would have been needed to prepare this facility for transplant patients. Thus, an alternate residence was selected, evaluated by the Infectious Disease service, and the required remodeling performed. Redecorating and minor renovations were completed just in time for admission of the first patient.

Quality of Life

Prior to enrollment of the first patient, we conducted a pilot study to test the feasibility of the QOL instrument administration. Feedback from the pilot study

was used to revise the QOL administration procedures. Also, we developed and tested a measure to evaluate the confidence of caregivers to assume the responsibilities of patient monitoring and care during outpatient transplant. Additional Quality of Life instruments were added to the protocol. Also, instruments were added to include an evaluation of the caregiver's perception of the patient's quality of life and of his or her own involvement in the patient's care. A consent form for the caregiver was developed.

A description of these scales is attached as an Appendix. After piloting the instruments with the first two patients, it was determined that a change in the schedule for administration of the instruments was warranted. The schedule now calls for a pretransplant assessment (baseline), weekly assessments during the transplant process, and a final assessment one month after discharge.

An SPSS data base has been established for collecting the Quality of Life data. The quality of life questionnaires have been administered to all six of the patients enrolled to date and the data is being entered into the data base which will be analyzed using the SPSS software program.

Cost Comparison

Cost data will be collected and analyzed using three data sources. The primary source of data for both inpatients and outpatients will be itemized patient bills. Samples have been reviewed and it was determined that all of the inpatient charges are included in two billing sources , the hospital bill and the Faculty Foundation bill (physician charges). Complete outpatient billing information can be obtained from these two sources plus the itemized bills from Northwestern Home Health. Contacts have been established at each of these agencies and cooperation has been assured. Secondly, a case report from has been developed (Appendix) to collect important clinical variables and provide key

dates and procedural information for cross referencing with patient billing data. Thirdly, for the outpatient arm only, a cost diary was developed based on similar instruments used in EORTC trials and through discussions with colleagues at Johns Hopkins University conducting similar studies. This diary was designed to capture direct out-of-pocket costs in the form of a daily log and indirect costs incurred by the caregiver by recording information on work hours lost, skilled tasks performed, and extra expenses incurred by the family due to absence. (Appendix) Billing data will be collected and formatted in a spreadsheet format and analyses (median costs, tests of significance and regression analyses) will be performed using SAS.

Patient Accrual

The research nurse has been actively involved in recruitment of patients for this study. At the weekly Bone Marrow Transplant Team meeting, each patient is discussed as a possible candidate for outpatient bone marrow transplant. Once the patient has been identified by the team as a potential candidate for outpatient transplant, the research nurse discusses the possibility of transplant as an outpatient with the patient. If the patient is interested, the nurse then works with the patient to find a suitable caregiver from family and friends. The patient and caregiver(s) attend a meeting with the Bone Marrow Transplant Team psychiatric staff members to evaluate and plan for emotional support. The research nurse then teaches the patient and caregiver the skills they will need to undergo outpatient transplant.

During this time, the Northwestern Memorial Hospital Managed Care Department ascertains whether the insurance company will agree to pay for the outpatient transplant. This has required one on one negotiations with the insurance companies. The research nurse has been involved in educating insurance companies about the outpatient process. Securing coverage for the apartment

costs has been difficult and this too has required involvement by the nurse.
To date, approximately 25 patients have been screened for outpatient transplant. Two patients who were potential outpatient candidates had progressive disease and did not proceed to transplant. Eight patients have declined to participate for various reasons. The others have either undergone transplant as outpatients or are currently in the process of completing the full evaluation.

As of May 5, 1997, a total of six individuals have been enrolled on study - three as inpatients and three as outpatients. Two of the outpatients have completed therapy and all three of the inpatients have completed therapy. The third outpatient is currently undergoing transplant. To date all seven participants have been women. The disease sites for the outpatients are as follows:

1 Breast Cancer	Transplant entirely as an outpatient (17 days outpatient)
1 Hodgkin's Disease Lymphoma	Required hospitalization for high dose therapy and again for neutropenic fever. (10 days inpatient - 9 days outpatient)
1 Breast Cancer	In progress.
1 Non-Hodgkin's Lymphoma	

The disease sites for the inpatients are as follows:

2 Breast Cancer

1 Non-Hodgkin's Lymphoma .

Protocol Changes

1. The protocol has been changed to remove all references to the Carriage House and replace them with the "Bone Marrow Transplant apartment."

2. Changes were made to allow patients to receive the high dose therapy and stem cell reinfusion as an outpatient if possible. This will enable some patients to have their transplant entirely as an outpatient, unless it becomes medically necessary to admit them to the hospital.

3. The antibiotic regimens used for prophylaxis and for empiric treatment of neutropenic fever were revised. This was in response to the frequent changes in antimicrobial sensitivities found at this institution. The protocol has been revised to allow for use of the current antibiotic regimens recommended by the Infectious Disease service.

4. Additional instruments were added to measure quality of life. Also, instruments were added to include an evaluation of the caregiver's perception of the patient's experience and his or her own involvement in the patient's care. Also, a consent form for the caregiver was developed. The instruments currently being used for the quality of life analysis are as follows:

   Profile of Mood States (POMS) Brief Scale
   Impact of Events Scale (IES)
   Miller Behavioral Style Scale (MBSS)
   Caregiver Confidence Evaluation (CCE)
   Perceived Involvement in Care Scales (PICS)
   Functional Assessment of Cancer Therapy-Bone Marrow Transplant (FACT-BMT).

The timing for administration of the quality of life instruments was revised as described above.

Conclusions

The outpatient bone marrow transplant program has now been fully implemented. Despite a three month delay in implementing the program attributable to a change in the site of the outpatient apartment, the original goal of enrolling 36 outpatients and 36 inpatient controls by the end of the study will

be met given the current rate of accrual. Because of the interest that has developed in the outpatient bone marrow transplant program, the hospital is currently exploring options for expanding the program so that more than one patient may be transplanted as an outpatient at the same time.

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Appendices

Appendix 1 The patient and caregiver educational material
Appendix 2 Description of Instruments
Appendix 3 Cost diary
Appendix 4 Case report form

Patient Information Questionnaire

Project #1

Demographics:

1. Name: _____ _____
   First Last
2. Today's Date: __ __/__ __/1 9__ __
   m m / d d / y y y y
3. Social Security #: ___ ___ ___-___ ___-___ ___ ___ ___
4. Birthdate: __ __/__ __/1 9__ __
   m m / d d / y y y y
5. Ethnicity: ☐ Black ☐ White ☐ Asian ☐ Hispanic ☐ Other _____
6. Education: ☐ Less than High School ☐ High School Diploma ☐ College ☐ Graduate School
7. Occupation: ☐ Managerial, professional specialty (executive, administrative, professional occupation)
   ☐ Technical, sales, administrative support (support occupations, clerical, sales)
   ☐ Service Industry (health care, police, education, food services)
   ☐ Operators, laborers (factory, transport, construction work)
   ☐ Homemaker or housewife
   ☐ Other (_____)
8. Medical Insurance: ☐ HMO ☐ PPO ☐ Private (Commercial)
   ☐ Medicaid ☐ Medicare ☐ Medicare with Supplement ☐ None
9. Family Income/Year: ☐ Less than $10,000 ☐ $10-30,000 ☐ Over $30,000
   ☐ Prefer not to answer

Medical History:

FAMILY

10. Do any of your blood relatives have diabetes?
    ☐ Yes ☐ No
    If yes, ☐ Mother diagnosed at _____ years of age
    ☐ Father.....diagnosed at _____ years of age
    ☐ Sibling (# of sibs with diabetes: _____)
    Age diagnosis? _____
    ☐ Other relative: _____
    Age at diagnosis: _____ years of age

11. Have any of your blood relatives had ovarian cancer?
    ☐ Yes ☐ No
    If yes, ☐ Mother..diagnosed at _____ years of age
    ☐ Sister .....diagnosed at _____ years of age
    ☐ Daughter .....diagnosed at _____ years of age
    ☐ Other relative: _____
    Age at diagnosis: _____ years of age

12. Have any of your blood relatives had breast cancer?
    ☐ Yes ☐ No
    If yes, ☐ Mother..... diagnosed at _____ years of age
    ☐ Sister..... diagnosed at _____ years of age
    ☐ Daughter..... diagnosed at _____ years of age
    ☐ Paternal aunt..... diagnosed at _____ years of age
    ☐ Maternal aunt ..... diagnosed at _____ years of age
    ☐ Paternal grandmother .....at _____ years of age
    ☐ Maternal grandmother.....at _____ years of age
    ☐ Other relative: _____
    Age at diagnosis: _____ years of age

PERSONAL

13. How tall are you? ____ feet _____ inches

14. How much do you currently weigh? _____ lbs.

15. At approximately what age did you begin menstruating? ____ years old

16. Have your periods stopped completely?

☐ Yes ☐ No

If yes, a. What caused your periods to stop?

☐ Surgery ☐ Natural Causes

b. How old were you when your period stopped? _____ years old

17. Have you ever been pregnant? ☐ Yes ☐ No

If yes, a. How many pregnancies have you had? ___

b. How many live births have you had? ___

c. How old were you at the first live birth? ___

d. How old were you at the last live birth? ___

18. Are you currently taking hormones? ☐ Yes ☐ No

If yes, a. What kind?

☐ Estrogen replacement

☐ Oral Contraceptives

☐ Other: _____

b. When did you start taking them?

__ __ / 1 9 __ __

m m / y y y y

19. Have you ever taken hormones at any other time (NOT including current hormone medication from question 18)?

☐ Yes ☐ No

If yes, a. What kind?

☐ Estrogen replacement

☐ Oral Contraceptives

☐ Other: _____

b. How many months did you take these hormones?

_____ months

20. Do you have diabetes? ☐ Yes ☐ No

If yes, a. What age were you diagnosed?

_____ years

21. How often do you perform Breast Self Exams (BSE)?

☐ _____ times monthly

☐ Once a month

☐ Every other month

☐ Rarely

☐ Never

22. Have you had any breast biopsies before?

☐ Yes ☐ No

If yes, a. How many breast biopsies have you had? _____ biopsies

b. What was the result of your last biopsy?

☐ Atypical Hyperplasia

☐ Lobular Neoplasia

☐ Lobular Carcinoma In Situ

☐ Other (_____)

☐ Unknown

Alcohol and Tobacco Use:

23. Have you ever in your life drunk alcoholic beverages at least once a month for six continuous months or more? ☐ Yes ☐ No

IF NO, GO TO 25↓

24. How old were you when you first started drinking alcoholic beverages at least once a month for six months or more?
_____ years old

25. How often <u>on average over the past year</u> have you drunk 1 beer (1 glass, bottle, or can)?
☐ Never or less than once per month
☐ 1-3 per month
☐ 1 per week
☐ 2-4 per week
☐ 5-6 per week
☐ 1 per day
☐ 2-3 per day
☐ 4-5 per day
☐ 6+ per day

26. How often <u>on average over the past year</u> have you drunk one 4 oz. glass of wine?
☐ Never or less than once per month
☐ 1-3 per month
☐ 1 per week
☐ 2-4 per week
☐ 5-6 per week
☐ 1 per day
☐ 2-3 per day
☐ 4-5 per day
☐ 6+ per day

27. How often <u>on average over the past year</u> have you drunk 1 drink or shot of liquor (whiskey, gin, etc.)?
☐ Never or less than once per month
☐ 1-3 per month
☐ 1 per week
☐ 2-4 per week
☐ 5-6 per week
☐ 1 per day
☐ 2-3 per day
☐ 4-5 per day
☐ 6+ per day

28. Have you ever smoked cigarettes on a regular basis? (More than 100 cigarettes in your life)
☐ Yes ☐ No

IF NO, GO TO BOX AT BOTTOM OF PAGE↓

29. How old were you when you began smoking cigarettes on a regular basis?
_____ years old

30. On the average, during the entire time you smoked, how many cigarettes did you smoke per day?
_____ cigarettes per day

31. Do you smoke cigarettes now?
☐ Yes ☐ No
If yes, a. On the average, how many cigarettes do you currently smoke?
_____ cigarettes per day

IF YES, GO TO BOX AT BOTTOM OF PAGE↓

32. How old were you when you last stopped smoking?
_____ years old

THANK YOU! YOU ARE FINISHED.

If you have completed all the questions you are now finished. Please return this survey to the drop boxes located in the front and back waiting rooms. To ensure the accuracy of our survey, you may receive a brief phone call for quality control purposes. If you don't want us to call you, please indicate by checking the box below.

☐ I do **not** wish to receive a quality control call.

Thank you again for all your time and cooperation. You have made a valuable contribution to research efforts to improve women's health.

CHICAGO ETHNIC COMMUNITIES BREAST CANCER EDUCATION PROJECT
HEALTH BELIEF QUESTIONNAIRE

Name _____ **Agency** _____ **Date** _____ **Pre test** _____ **Post test** _____

5=Strongly Agree or Always	4=Agree or Sometimes	3=Neither Agree or Disagree or Neutral	2=Disagree or Rarely	1=Strongly Disagree or Never

2. My physical health makes it more likely that I will get breast cancer.	5	4	3	2	1
3. I feel that my chances of getting breast cancer in the future are high.	5	4	3	2	1
4. There is a high possibility that I will get breast cancer.	5	4	3	2	1
7. The thought of breast cancer scares me.	5	4	3	2	1
9. If I had breast cancer my daily home activities or career would be endangered.	5	4	3	2	1
18. If I had breast cancer, my whole life would change.	5	4	3	2	1
20. I have a lot to gain by doing self breast exams.	5	4	3	2	1
22. If I do monthly breast exams I may find a lump before it is discovered by regular health exams.	5	4	3	2	1
23. I would not be so anxious about breast cancer if I did monthly exams.	5	4	3	2	1
26. Self breast exams can be painful.	5	4	3	2	1
28. My family or significant others would make fun of me if I did self breast exams.	5	4	3	2	1
29. The practice of self breast exams interferes with my activities.	5	4	3	2	1
33. I always follow medical orders because I believe they will benefit my state of health.	5	4	3	2	1
37. I have the recommended yearly physical exams in addition to visits related to illness.	5	4	3	2	1
39. I exercise regularly--at least three times a week.	5	4	3	2	1

CHICAGO ETHNIC COMMUNITIES BREAST CANCER EDUCATION PROJECT
MAMMOGRAPHY QUESTIONNAIRE

NAME_____ **AGENCY**_____ **DATE**_____ **PRE TEST**_____**POST TEST**_____

5=Strongly Agree or always	**4=Agree or Sometimes**	**3=Neither Agree or Disagree Neutral**	**2=Disagree or Rarely**	**1=Strongly Disagree or Never**

1.	If I eat a healthy diet, I will lower my cancer risk enough that I probably do not need to have a mammogram	5	4	3	2	1
2.	If I have a mammogram, I have a big chance of having an operation that I don't need.	5	4	3	2	1
3.	I would probably not have a mammogram if the mammography facility were more than a few minutes drive away	5	4	3	2	1
4.	I would probably not have a mammogram unless I had some breast symptoms or discomfort.	5	4	3	2	1
5.	If a mammogram finds something, then it will be too late to do anything anyway.	5	4	3	2	1
6.	Once you have a normal mammogram, you don't need to have any more mammograms.	5	4	3	2	1
7	I probably would not have a mammogram if a doctor expressed even a little doubt that I needed one.	5	4	3	2	1
8.	I would be more likely to obtain a mammogram if a doctor told me how important it was.	5	4	3	2	1
9.	Having a yearly mammogram will give me a feeling of control over my health.	5	4	3	2	1
10.	If my doctor gives me a breast exam at the office, I don't need to have a mammogram.	5	4	3	2	1
11.	Mammograms are now a very common medical test.	5	4	3	2	1
12.	My family will benefit if I have a mammogram.	5	4	3	2	1

CHICAGO ETHNIC COMMUNITIES BREAST CANCER EDUCATION PROJECT

Name:_____ **Agency**_____ **Date**_____

Breast Cancer Facts Survey: Pre test_____ **Post test**____

In the blank space at the end of the statement, please indicate whether you consider it to be true or false.

1. In the United States, one of every nine women has breast cancer. _____
2. Doctors know what causes breast cancer. _____
3. Breast cancer is more likely to happen to women who were very young when they started to have children. _____
4. If no one in my family ever had breast cancer, then I cannot get it. _____
5. If you have breast cancer you would know it. _____
6. If a teen-ager has a lump in her breast it is likely to be breast cancer. _____
7. Old women are not as likely to get breast cancer. _____
8. If you have breast cancer you will die no matter what. _____
9. Breast cancer can be cured. _____
10. The best way to find an early breast cancer is to check yourself, have your doctor check you and have a mammogram. _____
11. You should have your first mammogram by the time you are 30. _____
12. Old women do not need to have mammograms. _____
13. You should check yourself for breast lumps every ____week, ____month, ____year.
14. You should have your doctor check you for breast lumps every ____week, ____month, ____year.
15. If you are over 50, you should have a mammogram every ____6 months, ____1 year, ____2 years,____5 years.

CHICAGO ETHNIC COMMUNITIES BREAST HEALTH EDUCATION PROJECT
STAGES OF ADOPTION LOG

Name:_____ **Telephone Number**_____

Age:_____ **Ethnicity:**_____

First Client Contact

Date:_____

Stage of Adoption for Mammography _____

Stage of Adoption for Breast Self-
Exam_____

Check if Pre Test was administered_____

Follow-Up #1

Date:_____

Stage of Adoption for Mammography _____

Stage of Adoption for Self-Breast
Exam_____

Follow-Up #2

Date:_____

Stage of Adoption for
Mammography_____

Stage of Adoption for Breast-Self
Exam_____

Check if Post Test was Administered_____

STAGES OF ADOPTION QUESTIONNAIRE

Mammography Questions:

A. When was your last mammogram? _____
B. How many mammograms have you ever had? _____
C. Do you plan to have a mammogram in the coming year? _____

Stage of Adoption for Mammography

1. No prior mammogram and no plan to have one in the coming year.

2. **Either:** (a) No prior mammogram but planning for one in the coming year.
   Or:(b) One or more mammograms inthe past, but no plan for one in the coming year.

3. One prior mammogram and planning for one in the coming year.

4. More than one prior mammogram and planning for one in the coming year.

Stage of Adoption (circle one) **1 2a 2b 3 4**

Breast Self Exam Questions

A. When was your last breast self exam? _____
B. How many breast self exams have you ever performed? _____
C. Do you plan to perform a breast self exam next month? _____

Stage of Adoption for Breast Self Exam

1. No prior breast self exam ever, and no plan for one in the next month.

2. **Either:** (a) No prior breast self exam ever, but planning to do one in the next month.
   Or: (b) One or more prior breast self exams, but no plan to do one in the next month.

3. One prior breast self exam ever, and planning for one in the next month.

4. More than one prior breast self exam ever, and planning for one in the next month.

Stage of Adoption (Circle one): **1 2a 2b 3 4**

CHICAGO ETHNIC COMMUNITIES BREAST CANCER EDUCATION PROJECT
Army Project Post Testing
Breast Self Exam Observation Scale

Name:_____ Agency_____ Date_____

Trainee demonstrates: Show me how you would start examining your breasts. You start by looking; show me what you would do.

N Y 1. Raises arms

N Y 2. Hands on hips

N Y 3. Leans over

Diagram: Here is a picture. Point to each part of the body you would examine.

N Y 4. Palpates axilla

N Y 5. Coverage includes "tail" of breast.

Models: Here are 2 breast models. They are each different. Examine them exactly the way you would examine yourself. Tell me if you find any lumps and point to them. (Score usual or most frequently used technique. Not best or worst.)

N Y 6. Uses pads of fingers

N Y 7. Small circular motion

N Y 8. Superficial, medium and deep pressure

N Y 9. Systematic (strips, spokes or centripetal spiral)

N Y 10. Squeezes nipple

Lump Detection

1. Model_____; # Correct_____; # Incorrect_____

2. Model_____; # Correct_____; # Incorrect_____

Examiner:_____

Rev: 4/29/97

Breast Health Information Pre-Test A

1. Breast self exam should be done in the week before a women is due to have her period.	True	False
2. Injury to the breast increases breast cancer risk.	True	False
3. Women who have no family history of breast cancer rarely develop the disease.	True	False
4. Women over the age of 40 should have a physician breast exam every 3 years.	True	False
5. Having lumpy breasts increases a woman's breast cancer risk.	True	False
6. Breast pain is a common symptom of breast cancer.	True	False
7. Women with breast lumps should begin annual screening mammography at age 25.	True	False
8. Exposure to radiation during mammography increases a woman's breast cancer risk.	True	False
9. Age is the most common breast cancer risk factor.	True	False
10. A woman whose mother had breast cancer at age 60 has a 50% risk of developing breast cancer in her lifetime.	True	False
11. Breast lumps that can be felt but cannot be seen on mammogram are benign and require no treatment.	True	False
12. The treatment of breast pain is to surgically remove the painful area.	True	False
13. A mammogram can detect breast cancer when it is too small to be felt by the most expert physician.	True	False
14. Breast ultrasound is used to determine if breast lumps are solid or fluid filled (cystic).	True	False
15. Women with large breasts have an increased risk of breast cancer development.	True	False
16. Mastectomy is the only surgical treatment for breast cancer.	True	False
17. Finding a breast lump is a medical emergency.	True	False
18. When performing breast examination you need to use enough pressure to cause mild pain.	True	False
19. All densities seen on a mammogram need to be biopsied.	True	False
20. The treatment of breast cysts is the drainage of the fluid with a needle.	True	False

Circle the correct answer.

Breast Health Education for Healthcare Providers

Sponsored By
Northwestern Memorial Hospital
Lynn Sage Comprehensive Breast Care Program

Dear Colleague:

Welcome to the course, **Breast Health Education for Health Care Providers.** In this course, you will attain the knowledge and skills that are essential in your clinical practice to assess your patients and educate them about breast health. When detected early, women have a better chance of surviving breast cancer. Your participation in this course can assist you in providing your patients with knowledge of the tools available to them for breast cancer screening.

The course consists of three classroom sessions and a BSE practice workshop. Each topic will be presented by an expert in the field who is associated with the Lynn Sage Comprehensive Breast Center. We hope that you find the course both enjoyable and educational.

On behalf of the conference planning committee, thank you for your participation.

Sincerely,

Kay Pearson
Nurse Clinician
Conference Planning Committee

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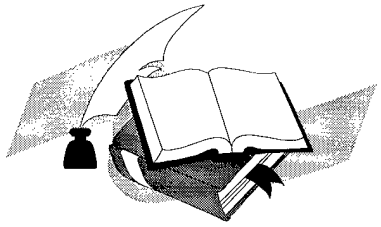


OBJECTIVES

By the completion of this program, the health care provider will be able to:

- Demonstrate baseline knowledge of breast health on written test.
- Identify major structures of the breast and their function.
- Identify women at increased risk for developing breast cancer.
- Discuss American Cancer Society guidelines for breast cancer screening.
- Demonstrate ability to instruct a woman in performing breast self exam.
- Identify barriers to breast cancer screening.
- Compare symptoms and pathophysiology of benign breast disease.
- Discuss breast cancer genetics.
- Compare screening vs. diagnostic mammograms as they relate to breast cancer.
- Describe the Breast Center as a resource for patients and professional staff.
- Discuss diagnosis and treatment for breast cancer.
- Identify common concerns of breast cancer survivors

WORKSHOP 1

AGENDA

8:00 Continental breakfast

8:30 Introduction and Welcome

8:45 Pretest

9:15 Physical exam on standardized patients.
Demonstrate breast exam on silicone models.

10:45 Break

11:00 Breast anatomy and physiology
Kay Pearson, RN, BSN

11:15 Risk factors for developing breast cancer
Kay Pearson, RN, BSN
- Myths regarding breast cancer
- Breast cancer risks

11:30 Screening and early detection
Cathy Bucci, RN, BS
- Breast health program
- Prevention

12:15 Questions/Discussion

12:30 Adjourn

WORKSHOP 1

OUTLINE

I. Welcome and Introduction

A. *Program overview*

B. *Current knowledge of topic*

C. *Physical exam on standardized patients*

II. Breast Anatomy and Physiology

A. *Anatomy*

1. Adult female breast lies on the anterior chest wall between the 2nd and 6th ribs, from the sternal border to the mid-axillary line. Breast tissue extends into the axilla as the axillary tail of Spence.

2. The breast is made up of three major structures: skin, subcutaneous tissue and breast tissue.

3. Twelve to twenty lobes occupy the central and upper portion.

4. Each lobe is connected by ducts to the nipple surface.

5. Nipple is surrounded by a circular pigmented area called the areola.

6. Critical structures which lie beneath the breast include the pectoralis major and minor muscles.

B. *Physiology*

1. Physiological function of the female breast or mammary glands is lactation.

2. In western culture, the breast is associated with sexuality and femininity as well as infant feeding.

3. During embryological development there is growth and differentiation of the breasts in both sexes.

4. After birth, there is normally little additional development in the male breast and the gland remains rudimentary. The female breasts continue extensive further development correlated with age and regulated by hormones that influence reproductive function.

5. By about age 20 the breast reaches its greatest development. It begins to atrophy by the age of 40. During each menstrual cycle with the changes in the ovarian hormonal levels, structural changes occur in the breast.

6. During pregnancy and lactation, changes occur not only in the functional activity of the breast but also in the amount of glandular tissue.

7. With hormonal changes that occur with menopause, the glandular component of the breast is replaced by fat and connective tissue.

8. Lymphatic flow moves toward the axillary and internal mammary lymph nodes. About 3% of lymph flow is to the internal mammary nodes and 97% to the axillary nodes. With breast cancer, metastatic dissemination is primarily by lymphatic routes.

III. Risks for developing breast cancer

A. *Myths*

1. Contagious

2. Related to injury or love making.

3. Large breasts increase the risk of developing breast cancer.

4. Too many mammograms can cause breast cancer

5. A lack of family history of breast cancer means little or no risk for developing breast cancer. Fact: Only 10-20% of women diagnosed with breast cancer have a positive family history. Only 5% of cancers are truly hereditary

6. Breast cancer develops only after the age of 50. Fact: 30% of all breast cancer occurs in women under age 50.

7. Cancer cannot be present unless a lump is felt. Fact: Early tumors are often first detected by mammograms

8. Breast feeding will cause or prevent breast cancer

B. *Risk for Developing Breast Cancer*

1. Age: 1 out of 8 women will develop breast cancer sometime during her lifetime

2. Family history: Breast cancer risk is increased 1.5 to 3 times when a mother or sister is affected

3. Hormonal history: Of 27 studies done on oral contraceptive use, only 2 showed an increase in risk for the entire study population. Most studies used higher doses of estrogen than are currently employed. Studies done on postmenopausal estrogen replacement therapy indicate that there is a small increase in risk with long term therapy (10-20 years). There have been variable dose effects reported. Minimal risk of breast cancer probably outweighed by proven benefits of ERT which include reduction in risk of death from heart disease and the reduction in risk for developing osteoporosis.

4. Reproductive history: At increased risk if never had children or having children after the age of 30. Abortion is not a protective measure and may actually increase risk. Increased risk associated with long, uninterrupted menstrual cycle. At decreased risk for each year after the age of twelve that menarche is delayed, if regular ovulatory cycles are delayed and if menopause (natural or surgical) occurs before age 45.

C. *Screening and Early Detection*

1. Breast Health Program American Cancer Society guidelines: we emphasize early detection because we do not yet know how to prevent breast cancer
   a. *Clinical exam by a health professional*
      1. Women age 20 to 40 every three years.
      2. Women over age 40 annually.
   b. *Mammogram*
      1. Radiation exposure is minimal.
      2. Baseline between ages 35 to 40.
   c. Age 40 to 49 every one to two years.
   d. Age 50 and up every year.

2. *Prevention*
   a. Exercise
   b. Nutrition
   c. Chemoprevention

WORKSHOP 2

AGENDA

8:00 Continental breakfast

8:30 Breast self exam
Susan Cox, RN, OCN
- Pros and Cons of BSE
- Perceived barriers
- Evaluation and compliance
- Demonstration

9:15 Lange Videotape on Breast self exam

9:30 Practice breast exam on silicone models

10:00 Break

10:15 Benign breast disease
Cathy Bucci, RN, BS
- Breast pain
- Glandular nodularity
- Nipple discharge
- Fibrocystic breast disease-atypical ductal hyperplasia
- Cysts
- Fibroadenoma

11:00 Genetics of breast cancer
Beth Fine, MS
- Introduction
- Counseling
- Testing procedures
- Informed consent
- Risk factors

12:15 Questions/Discussion

12:30 Adjourn

WORKSHOP 2

OUTLINE

I. Breast self exam

A. Pros and Cons

1. Pros
   a. Gives patient sense of being partners with the doctor.
      1. Doctor teaches patient what is normal
      2. Doctor is available to patient when patient feels changes
      3. Rapport with doctor reduces cancer treatment delays
   b. Consistency in observing changes.
      1. Practice reinforces efficiency and accuracy
      2. Same time of month reduces false problems
   c. Awareness of changes detects cancer earlier
      1. Cancer found is smaller size
      2. Patient won't delay seeking treatment

2. *Cons*
   a. False sense of security.
      1. Patient isn't aware of changes
      2. Patient doesn't report changes
   b. Makes patient anxious.
      1. Patient thinks every lump is cancer
      2. Patient has cancer phobia

B. Perceived Barriers

1. Belief they won't get breast cancer.
   a. Don't understand family histories
   b. Don't understand breast cancer statistics
   c. Youth

2. Faith in doctor exam.
    a. Doctor only examines once or twice a year
    b. Doctor is infallible
    c. Doctor's reputation

3. Mammograms find cancer.
    a. Mammograms find non-palpable masses & DCIS
    b. Belief that if mammo is clear, there is no cancer - even in presence of a symptom

4. Fear
    a. Of cancer
    b. Of dying
    c. Of treatments
        1. Disfigurement from surgery
        2. Side-effects of chemotherapy

5. Lack of confidence.
    a. Don't know what "normal" feels like
    b. Worries that everything she feels is cancer
    c. Has never been confident in any area of her life

6. Inadequate time and no privacy.
    a. Busy with family and/or career
    b. Thinks it takes a long time to do it
    c. Afraid of someone bursting in her room
    d. Ashamed to touch her body

7. Lack of exposure to messages and stimulation to perform breast self exam (BSE).
    a. Cannot read
    b. Ignores messages in doctor's office or health clinic
    c. Doctor's office or health clinic doesn't provide materials about BSE
    d. Nurses don't take opportunities to teach BSE
    e. Nurses and doctors don't talk to patient about breast changes and physically show patient what is normal

C. *BSE Instructions.*

1. When
   a. 3-4 days after period ends - every month
   b. If menopausal, same day of month

2. How
   a. Positions
      1. Standing up with arms at side, hands at waist and arms over head
      2. Lying down, slightly raise shoulder of side to be examined; side lying for large breasts
   b. Perimeter
      1. Collar bone to bra line
      2. Sternum to side
   c. Palpation
      1. Flat pads of 2nd & 3rd fingers
      2. Small massaging motions
   d. Pressure
      1. Light massage
      2. Medium massage
      3. Deep massage
      4. Then move to next spot
   e. Pattern
      1. Vertical strips
      2. Bull's-eye
      3. Wedge
   f. Practice makes perfect

D. *Evaluation & Compliance*

1. Provide education to patient
   a. Brochures
   b. Videos
   c. Instruction one on one
   d. Return demonstration

2. Consider culture and patient feelings of sexuality

II. Benign Breast Disease

A. *Breast Pain*

1. Normal occurrence in most women.

2. Caused by the cyclic fluctuation of hormones throughout the month.

3. Most common pattern is pain in the upper outer quadrant of both breasts, dull, ache maximal in premenstrual period. Pain may also be sharp, stabbing and in only one breast or one location.

4. Reassurance and analgesics is the only treatment needed for most women.

5. The pain decreases when women reach menopause.

6. Things which alter hormonal cycling such as menstrual irregularity and stress can also be associated with breast pain.

7. Pain is not a sign of cancer. More than 90% of breast cancers are painless.

8. Ineffective treatment is decreasing caffeine intake, rest or diuretics.

B. *Glandular Nodularity*

1. Normal in women who are premenopausal

2. Usually bilateral and located in the outer quadrants of the breast

3. Normal lumpy breast tissue

C. *Nipple Discharge*

1. Normal occurrence for many women when the nipple is checked/squeezed during a breast exam.

2. Clear, yellow, white or green discharge noted only when nipple is squeezed is normal

3. Spontaneous discharge whether bloody or not should be checked by a physician

4. Discharge of concern is usually unilateral and from a single duct

5. Nipple discharge is rarely a sign of cancer

D. *Fibrocystic breast/changes*

1. Sclerosing adenosis

2. Cysts - glandular elements of the breast filled with fluid

3. Fibroadenoma - solid benign lesion, usually noted in premenopausal women

4. Mastitis - may present itself as: breast pain, breast mass, nipple discharge, nipple retraction or breast abscess

5. Atypical hyperplasia - either ductal or lobular in type, have similar features to carcinoma in-situ, but lack complete criteria for that diagnosis

III. Genetics of breast cancer

A. *Introduction to Genetic Counseling*

1. Definition of genetic counseling.

Genetic counseling is a communication process which deals with the occurrence, or risk of occurrence, of a genetic disorder in a family. This process involves an attempt by one or more appropriately trained persons to help the individual or family to: (1) comprehend the medical facts, including the diagnosis, probable course of the disorder, and the available management; (2) appreciate the way heredity contributes to the disorder and the risk of recurrence in specified relatives; (3) understand the alternatives for dealing with the risk of recurrence; (4) choose the course of action which seems to them appropriate in view of their risk, their family goals, and their ethical and religious standards, and to act in accordance with that decision; and (5) to make the best possible adjustment to the disorder in an affected family member and/or to the risk of recurrence of that disorder (Epstein et al,1975).

2. Philosophy of genetic counseling

The goal of genetic counseling is to facilitate informed decision making regarding reproductive choices, genetic testing or screening, or relevant treatment or management of a variety of genetic conditions. These types of decisions must be made by individuals, couples and families within the context of their lives. The genetic counselor presents medical, genetic and technical information in an understandable way by assessing patient comprehension of the information. The genetic counselor explores the patient/family's perception of the condition, risks, and the testing process and possible outcomes. Psychosocial, ethnocultural and ethical issues all affect the genetic counseling relationship and process.

Traditionally, genetic counselors aim to practice "non-directive" counseling regarding reproductive decision making. That is, they attempt to present information to patients in an unbiased, non-judgmental manner which demonstrates extreme respect for patient autonomy. In most reproductive decisions, there is no one right choice for all individuals, couples and families. Therefore, the genetic counselor can provide anticipatory guidance to patients as they consider each decision and their possible reactions to each

option or outcome. If there is evidence that clearly and unequivocally one option is better for an individual or family than another, the ethical principal of beneficence must be considered.

3. Genetic counseling process for cancer risk

Genetic counseling and risk assessment for breast cancer is a new and emerging area of practice. Genetic counselors attempt to answer questions for individuals with a family history of cancer. While this program focuses on breast cancer and ovarian cancer, there are over 100 genetic syndromes which involve some type of malignancy. Each patient's family history must be evaluated individually to provide accurate risk assessment and appropriate recommendations for DNA-based susceptibility testing, surveillance, and prevention.

Also known as Familial Cancer Risk Counseling, the process is also a communication process that begins with ascertaining patients' questions, concerns and perceptions of their own risk and the risk of cancer in family members. A detailed family history, called a pedigree or genetic family tree, is elicited from the patient. The genetic counselor may request medical records on affected family members in order to conduct a risk assessment. Demographics and risk factor information on the patient seeking counseling are gathered in order to utilize one or more risk assessment models. The genetic counselor then performs a risk assessment and communicates this risk to the patient and/or family, framing the risks in a variety of ways to ensure comprehension.
A discussion of the meaning of the risk and the disease in question will follow, exploring these issues in light of the family's psychological, religious, social and cultural context.

A discussion of available genetic testing is the next step if the family history and risk demonstrates a significant prior probability of the presence of a BRCA1 or BRCA2 mutation in the family. In some cases, other genes may be involved in specific syndromes such as Li-Fraumeni Syndrome and p53. An informed consent process related to testing is described below.

B. *Update on breast cancer genetics*

1. Breast cancer genes

Genetic epidemiology indicates that the causes of breast cancer are quite heterogeneous. Only about 5% of all cases of breast cancer are caused by a mutation in a hereditary susceptibility gene such as BRCA1 or BRCA2. BRCA1 and BRCA2 are autosomal dominant genes that are passed from generation to generation, coding for a specific protein as most genes do. In most individuals, these genes function normally. When a mutation in either of these genes occurs, the proteins are not made properly or are absent; therefore the risk of breast and/or ovarian cancer increases substantially. Women with a BRCA1 mutation have an 85% lifetime risk of developing breast cancer, a 46% lifetime risk of developing ovarian cancer and an increased risk for colon cancer. Men with a BRCA1 mutation have a 50% risk of passing the mutation and susceptibility to daughters. They are also at increased risk for prostate and colon cancer. Individuals with BRCA2 mutations have an increased risk of breast cancer, though the exact risk is not known at present. Men who develop breast cancer often have BRCA2 mutations. BRCA2 does not appear to be associated with ovarian cancer. There are probably other, as yet undiscovered BRCA genes.

Approximately 13% of breast cancer cases are familial, but not necessary associated with a single gene susceptibility as described above. The genetic counselor must assess a variety of reasons for familial, but non-inherited cancers. Other syndromes and common environmental factors must be considered.

General features of hereditary cancer syndromes include: (1) cancer in two or more close relatives;(2)bilateral cancer in paired organs;(3)multiple primary tumors in the same individual; (4)early age of onset;(5)specific constellation of tumors that comprise a known cancer syndrome (Peters and Stopfer,1996).

Gene function is still being studied. It is thought that cancer-causing genes can function as oncogenes, tumor suppressor genes or DNA mismatch repair genes. BRCA1 and BRCA2 are believed to be tumor suppressor genes which code for proteins that keep cell division in check, at a normal rate. If a mutation in the gene occurs, the tumor suppressor protein does not function, and cell division accelerates, leading to a tumor. More work is needed to discover

normal function of these gene predicts in order to pave the way for the development of gene therapy treatment modalities and ultimately a cure.

2. Genetic testing

The testing process involves obtaining a blood sample from an affected relative, or in rare cases, from a tumor tissue block that is less than 5 years old. The detection of a known mutation in an affected individual may involve sequencing all or part of a very large gene. Once a mutation is identified, relatives can be tested in a more rapid, less expensive manner. Today, the testing is primarily limited to research protocols involving large families with many affected individuals. Clinical testing is available for a small number of families which demonstrate a significant likelihood of having a mutation. Several laboratories are offering a screen of 4 mutations known to be common among Ashkenazi Jewish individuals. While this does not mean cancer is more frequent in this group, at this time, we cannot accurately predict the risk of cancer in individuals with mutations who do not have a family history.

Once a family is identified as appropriate for testing and the family members agree to be tested, one of several laboratories is selected by the genetic counselor. These laboratories each have specific consent forms and policies. The genetic counselor will ensure the patient and family is fully informed before testing is initiated. A plan for follow up genetic counseling to disclose results, interpret reports, and to provide psychosocial support and recommendations for surveillance or prevention is established between the patient/family and genetic counselor.

The laboratory issues include cost, quality assurance (certification) and accuracy of results, DNA testing methodologies, and policies regarding confidentiality and privacy.
Genetic counselors work closely with laboratory personnel to prevent harm from testing and its outcomes.

3. Genetic testing and counseling

The Breast Cancer Risk Assessment and Genetic Counseling Program at the Lynn Sage Breast Center as well as the Genetic Counseling Program at Prentice Women's Hospital for other hereditary cancers are staffed by genetic counselors, a geneticist and consultants from surgical oncology, medical oncology, gynecologic oncology, radiation oncology, radiology, psycho-oncology, nursing and social work. Extensive genetic counseling and risk assessment precedes all genetic testing. If a family elects testing and their profile fits the criteria for testing established by our clinic and the laboratories, blood samples are drawn and sent to the laboratory after a detailed informed consent process.

The informed-consent process includes a discussion and exploration of the risks, benefits and limitations of testing. The genetic counselor will discuss all possible outcomes of testing (positive, negative and uncertain) and guide patients in anticipating their response to each outcome. Options for surveillance and prevention if an individual is found to have mutation that increases her risk of cancer are discussed in detail. Referrals are made to appropriate professionals, e.g. surgeon, psychologist, support group. Since there are no laws or policies fully protecting unaffected individuals found to be susceptible to cancer from these tests, patients are asked to consider the possible risks of genetic discrimination in insurance and employment. Costs range from $290 up to $1500 for BRCA1 and/or BRCA2 testing. The sharing of test results with family members is also discussed in genetic counseling.

For more information and to make a referral, call Aimee Wonderlick, MS, genetic counselor at (312)908-5737. Charges for genetic counseling range from $125 to $365.

WORKSHOP 3

AGENDA

8:00 Continental breakfast

8:30 Screening vs. diagnostic mammogram
Cathy Bucci, RN, BS

9:00 Introduction to Lynn Sage Comprehensive Breast Center
- Introduction and Tour

10:00 Break

10:15 Diagnosing breast cancer
Kay Pearson, RN, BSN
- Fine needle aspiration
- Core biopsy
- Excisional biopsy

10:30 Treatment options
Susan Cox, RN, OCN
- Surgical treatment
- Adjuvant therapy

11:20 Psychosocial issues
Kathleen O'Connell, MSW
- *Stages of adjustment*
- *Coping Strategies*
- Resources

12:00 Questions/Discussion

12:30 Adjourn

WORKSHOP 3

OUTLINE

I. Screening vs. diagnostic mammogram

A. *Screening*

1. A screening mammogram is an x-ray of an asymptomatic woman with a normal breast. This is done in an effort to detect nonpalpable (early) breast cancers.

B. *Diagnostic*

1. To further define a palpable mass.

2. To look for nonpalpable abnormalities in the same breast or contralateral breast.

C. *Barriers to screening.*

1. Fear of radiation

2. Cost - ranges from $50 to $200

3. Third party payers
   - Illinois law pays for screening but the patient may have to submit the bill.
   - If a reason is given other than screening, it may be considered a pre-existing condition later.

4. Inconvenient/no transportation

5. Physical and psychological discomfort-unnecessary if problem is benign.

6. Fear of discovering cancer

7. Unclear about the guidelines

8. Waited for symptoms to appear

D. *Rationale for screening mammograms - nursing implications for compliance.*

1. Promote good health habits

2. Review ACS guidelines

3. Be aware of patient support systems

4. Alleviate the fear with education

II. Lynn Sage Comprehensive Breast Center

A. *Multidisciplinary approach*

B. *Education*

III. Diagnosis of breast cancer

A. Fine Needle Aspiration (FNA)

1. Drawing cells from a palpable lesion using a syringe and small needle(20-25 gauge).

2. Done in an office setting with relatively little discomfort.

3. True positive rates (a positive result in the presence of tumor) are 75-96%. False negative rates (a negative result in the presence of tumor) are 4-15%. False positive rates (positive for tumor when no tumor present) are rare, 0-0.4%. If result is negative, a biopsy is still warranted.

B. *Core cutting needle biopsy*

1. Using a larger needle, a piece (core) of tissue is sampled from a palpable lesion.

2. Office procedure which is slightly more painful than a needle aspiration.

3. If nonpalpable, can be done with the use of ultrasound or stereotactic device.

C. *Excisional biopsy*

1. Removing entire lesion surgically

2. A portion of the specimen can be sent for estrogen and progesterone receptors.

3. Should be done with the anticipation of the need for subsequent surgical procedure.

4. For nonpalpable lesions, needle localization procedure is used. This is a mammographically controlled placement of a hooked wire into the nonpalpable lesion. With this technique, occult breast cancers can be localized successfully in more than 98% of patients.

IV. Breast cancer: Pathology, Surgeries, and Treatments

A. *Histologic classifications*

1. Ductal
   a. Intraductal (in situ) (non-invasive) (DCIS)
   b. Invasive - 85% of cases
   c. Inflammatory - skin involved
2. Lobular
   a. Intraepithelial lobular neoplasia (formerly known as lobular carcinoma in situ), (LCIS) non-invasive
   b. Invasive
   c. Tends to be bilateral risk

3. Nipple
    a. Paget's disease ;scaling, flaky, itchy nipple, sometimes bleeds
    b. With DCIS
    c. With invasive ductal

B. Histologic grades

C. Staging System

1. TNM system
    a. T for tumor size
    b. N for nodal status
    c. M for distant metastasis

2. Many subsets of each

3. Four stages basically
    a. Stage 0 for non-invasive
    b. Stage 1 and subsets for tumors less than 2 cm, no nodes, no mets
    c. Stage II and subsets for tumors more than 2 cm but not more than 5 cm, with or without involvement, no mets or tumors < 2cm with nodes
    d. Stage III and subsets for larger tumors and matted nodes, inflammatory cancer, skin involvement
    e. Stage IV, distant metastasis

D. Breast cancer surgeries - local therapy

1. Mastectomy alone
    a. Simple - no axillary dissection
    b. Total - with axillary dissection

2. Breast reconstruction
    a. Tissue expander
    b. Tissue transfer
        1. Latissimus dorsi flap (LAT flap)
        2. Transverse rectus abdominus myocutaneous flap(TRAM flap)
    c. Implant

3. Breast conserving surgery
    a. Public terminology is "lumpectomy"
    b. Partial mastectomy for invasive cancer
        1. Axillary dissection usually done
        2. Radiation therapy usually done
    c. Partial mastectomy for non-invasive cancer
        1. No axillary dissection done
        2. Radiation usually done

4. Considerations for local therapy
    a. Tumor size
    b. Breast size
    c. Tumor location and ability to resect
    d. Pathologic features
    e. Concurrent health conditions
    f. Cosmetic result
    g. Psychosocial concerns

E. Immediate post-op care

1. Drain care -can have up to 3 or 4
    a. Stripping/milking tubing
    b. Emptying and measuring
    c. Can shower

2. Mobility
    a. Exercises
    b. No lifting

3. Infection

4. Pain management

F. *Adjuvant(systemic) therapy*

1. Indications for chemotherapy
   a. Tumor size
   b. Nodal status
   c. Pathologic features
   d. Menopausal status
   e. Metastatic disease

2. Hormonal therapy

V. Psychological Aspects of the Breast Cancer Patient

A. *Psychological Response*

1. Clinical course/stage of treatment
   a. Initial stage similar
   b. Divergence of response dependent upon prognosis of cancer

2. Age and Developmental Stage (Erikson's Stages of Development)
   a. Young single women have issues of sexuality, marriage and child bearing (Intimacy vs. Isolation) Mid-life brings up issues of marriage, re-evaluation of life (Generativity vs. Stagnation).
   b. Older women may be dealing with issues of loss of independence, life review and ego integrity (Ego Integrity vs. Despair)

3. Support Systems
   a. Patient relies on support to maintain self worth, sense of belonging, and emotional understanding. Lack of solid support systems may leave the patient feeling alone and misunderstood

4. Coping style/adaptation skills
   a. Patient's inner mechanisms to cope with change, and ability to maintain a sense of equilibrium

5. Prior experience with cancer
    a. Negative experience with cancer may have lasting effects on any patient diagnosed with cancer

B. *After Diagnosis/ Before Treatment*

1. Initial emotional reaction
    a. Impact of cancer on individual/family, "what does this diagnosis mean to my life"

2. Information needs
    a. Sense of urgency, reliance on health care team, and issues of MD recommendations vs. individual choice

3. Potential loss/lack of control over situation
    a. Cancer diagnosis the first sign of decreased control
    b. Feeling that the body has let you down
    c. An abundance of medical issues the patient has no control over

4. Impact of decision making
    a. Stage of cancer may affect treatment making choices
    b. Early stage breast cancer has a variety of treatment choices
    c. Patients may become overwhelmed with the process

C. *Acute phase/During treatment*

1. Initial emotional reaction
    a. Management of side effects may result in a disruption of normal routine
    b. Patients may have difficulty adapting to pain and other side effects

2. Role changes in family/partner/children
    a. Caretaker issues may change the dynamics of a family structure. Spouse and children may need to take care of the "caretaker".
    b. Single women may need to rely on family members to help them, meaning a change in their independence

3. Role of health care team
    a. Consistent maintenance and checking out symptoms provide a safety net, and access to support systems within health care setting

D. *Following Treatment*

1. Return to usual roles/responsibilities
    a. Family will want to readjust to prior roles, patient may not be ready
    b. Support from family and friends may lessen and change

2. Loss of health care team
    a. Patient now more responsible to monitor own symptoms
    b. Follow-up exams more infrequent

3. Physical changes/limitations
    a. The patient may experience permanent changes due to surgery, chemotherapy, radiation therapy and other treatments

4. Fear of recurrence/death
    a. "Will this cancer come back to kill me?"
    b. "How am I going to live with this fear for the rest of my life ?"

E. *Recurrence/Metastatic Disease*

1. Intensity of treatment side effects
   a. Aggressive treatments may provide damaging side effects

2. Communication issues
   a. Family and friends looking for a safe way of communicating, and at times this process becomes more difficult when the cancer is not curable

3. Loss of hope, depression, and changes in self image
   a. The patient may feel the impact of the finality of their cancer, and the emotional changes that they are feeling
   b. With healthy ego strength, some patients find new ways of living with their cancer

4. Death and Dying stages
   a. Denial, anger, bargaining, depression and acceptance are all part of the normal reactions to death and dying

F. *Coping Strategies*

1. Past experiences
   a. The patient's ability to cope with their diagnosis will be greatly determined by how they have dealt with difficult situations in the past

2. Use of denial and defenses
   a. Patients use both adaptive and maladaptive coping skills to deal with their situation. These skills may be analyzed individually, and patients should be encouraged to look at their coping

3. Psychological make-up
   a. Some patients have underlying anxiety disorders, personality disorders which may affect their coping styles

4. Support systems
    a. Groups and individuals who provide patients a "safe" and stable environment, will help internal development of coping mechanisms

5. Identifying high risk behavior
    a. Severe psychological distress, disruption of ability to function or persistent psychological distress

G. *Communication skills*

1. Active listening
    a. Try to be where that person "is" in the moment, allowing silence, tolerating intense feelings

2. Developing accurate empathy
    a. Showing respect and concern, avoid making statements like "I know what you are feeling"

3. Observing non-verbal behavior
    a. Recognizing non-verbal expressions, eye contact, avoidance of topics

4. Communicating understanding
    a. Acknowledge feelings and experiences
    b. "Normalization", clarifying "I hear you saying...", summarizing, restating

5. Avoiding judgment
    a. Avoid judging
    b. Become aware of your own attitudes

H. *Support Services*

1. Support groups and peer/buddy systems
    a. Instillation of hope, universality, the gift of giving back, helping someone else through the process
    b. Difficult for patients who need feedback, or in acute psychological distress

2. Individual counseling and Family/Couples counseling
    a. Therapy designed to increase coping and identify barriers to coping or communication

3. Alternative therapies
    a. Relaxation techniques
    b. Exercise
    c. Journal writing

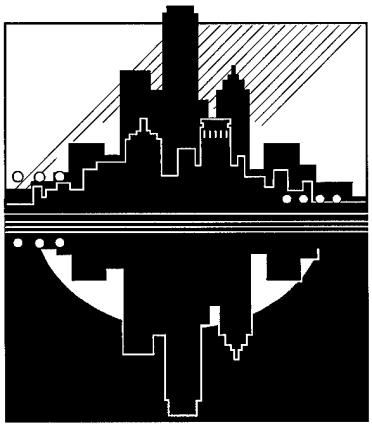
4. Individual belief systems/spirituality
    a. Places of worship
    b. Prayer groups

5. Hospice
    a. Psychological support for patients, family and friends throughout the dying process

WORKSHOP 4

AGENDA

8:00	Continental breakfast Review/Questions
8:45	Post Test
9:15	Physical exam on standardized patients
10:45	Distribute BSE certificates
11:00	Comments and adjournment



GLOSSARY

Adjuvant therapy: Treatment given in addition to the primary treatment.

Areola: The area of dark colored skin that surrounds the nipple.

Aspiration: Removal of fluid or cells from a lump, often a cyst, with a needle.

Atypical hyperplasia: A benign (noncancerous) condition in which breast tissue in breast cancer development has certain abnormal features

Axilla: The underarm.

Axillary dissection: Surgery to remove lymph nodes under the arm

Benign: Not cancerous; does not invade nearby tissue or spread to other parts of the body.

Biopsy: The removal of a sample of tissue, which is then examined under a microscope to check for cancer cells. Excisional biopsy is surgery to remove an entire lump and an area of normal tissue around it.

Bone marrow: The soft, sponge-like material inside some bones. Blood cells are produced in the bone marrow.

Bone marrow transplantation: A procedure in which doctors replace marrow destroyed by high doses of anticancer drugs or radiation. The replacement marrow is taken from the breast cancer patient before treatment, and the procedure is called autologous bone marrow transplantation.

Cancer: A term for more than 100 diseases in which abnormal cells divide without control. Cancer cells can spread through the bloodstream and lymphatic system to other parts of the body.

Carcinoma: Cancer that begins in the lining or covering of an organ.

Chemotherapy: Treatment with anticancer drugs.

Clinical Trials: Research studies that involve patients. Each study is designed to answer scientific questions and to find better ways to prevent or treat cancer.

Cyst: A closed sac or capsule filled with fluid.

Duct: A small channel in the breast through which milk passes from the lobules to the nipple. Cancer that begins in a duct is called ductal carcinoma.

Ductal carcinoma in situ: Abnormal cells that involve only the lining of a duct. The cells have not spread outside the duct to other tissues in the breast. Also called DCIS or intraductal carcinoma.

Hormonal therapy: Treatment of cancer by removing, blocking, or adding hormones.

Hormones: Chemicals produced by glands in the body. Hormones control the actions of certain cells or organs.

Hormone receptor test: A test to measure the amount of certain proteins, called hormone receptors, in breast cancer tissue. Hormones can attach to these proteins. A high level of hormone receptors means hormones probably help the cancer grow.

Infiltrating cancer: See invasive cancer.

Inflammatory breast cancer: A rare type of breast cancer in which cancer cells block the lymph vessels in the skin of the breast. The breast becomes red, swollen and warm, and the skin of the breast may appear pitted or have ridges. Also called stage III breast cancer.

Invasive cancer: Cancer that has spread beyond the layer of tissue in which it developed. Invasive breast cancer is also called infiltrating cancer or infiltrating carcinoma.

Lobe: A part of the breast; each breast contains 6 to 9 lobes.

Lobular carcinoma in situ: Abnormal cells in the lobules of the breast. This condition is not invasive cancer. However, having lobular carcinoma in situ is a sign that the woman has an increased risk of developing breast cancer. Also called LCIS.

Lobule: A subdivision of the lobes of the breast. Cancer that begins in a lobule is called lobular carcinoma.

Local therapy: Treatment that affects cells in the tumor and the area close to it in breast cancer.

Lumpectomy: Surgery to remove only the cancerous breast lump and rim of normal tissue; usually followed by radiation therapy.

Lymph: The almost colorless fluid that travels through the lymphatic system and carries cells that help fight infection and disease.

Lymph nodes: Small, bean-shaped structures located along the channels of the lymphatic system. Bacteria or cancer cells that enter the lymphatic system may be found in the nodes. Also called lymph glands.

Lymphatic system: The tissues and organs (including the bone marrow, spleen, thymus, and lymph nodes) that produce and store cells that fight infection and disease. The channels that carry lymph also are part of this system.

Lymphedema: Swelling of the hand and arm caused by extra fluid that may collect in tissues when underarm lymph nodes are removed or blocked; sometimes called "milk arm."

Malignant: Cancerous; can spread to other parts of the body.

Mammogram: An x-ray of the breast.

Mammography: The use of x-rays to create a picture of the breast.

Mastectomy: Surgery to remove the breast

Menopause: The time of a woman's life when menstrual periods stop; also called "change of life."

Menstrual cycle: The hormone changes that lead up to a woman's having a period. For most women, one cycle takes 28 days.

Metastasis: The spread of cancer from one part of the body to another. Cells in the metastatic (secondary) tumor are like those in the original (primary) tumor.

Microcalcifications: Tiny deposits of calcium in the breast that cannot be felt but can be detected on a mammogram. A cluster of these very small specks of calcium may indicate that cancer is present.

Oncologist: A doctor who specializes in treating cancer.

Ovaries: The pair of female reproductive organs that produce eggs and hormones.

Palpation: A simple technique in which a doctor presses on the surface of the body with his or her fingers to feel the organs or tissues underneath.

Pathologist: A doctor who identifies diseases by studying cells and tissues under a microscope.

Progesterone: A female hormone.

Prognosis: The probable outcome or course of a disease; the chance of recovery.

Prosthesis: An artificial replacement of a part of the body. A breast prosthesis is a breast form worn under clothing.

Radiation therapy: Treatment with high-energy rays to kill cancer cells. Radiation therapy that uses a machine located outside the body to aim high energy rays at the cancer is called external radiation. When radioactive material is placed in the breast in thin plastic tubes, the treatment is called implant radiation.

Radiologist: A doctor who specializes in creating and interpreting pictures of areas inside the body. The pictures are produced with x-rays, sound waves, or other types of energy.

Remission: Disappearance of the signs and symptoms of cancer. When this happens, the disease is said to be "in remission." A remission can be temporary or permanent.

Risk factor: Something that increases a person's chance of developing a disease.

Screening: Checking for disease when there are no symptoms.

Stage: The extent of the cancer. The stage of breast cancer depends on the size of the cancer and whether it has spread.

Stem cells: The cells from which all blood cells develop.

Systemic therapy: Treatment that reaches and affects cells all over the body.

Thermography: A test to measure and display heat patterns of tissues near the surface of the breast. Abnormal tissue generally is warmer than healthy tissue. This technique is under study; its value in detecting breast cancer has not been proven.

Tissue: A group or layer of cells that performs a specific function.

Tumor: An abnormal mass of tissue.

Ultrasonography: A test in which high-frequency sound waves that cannot be heard by humans are bounced off tissues and the echoes are converted into a picture (sonogram). These pictures are shown on a monitor like a TV screen. Tissues of different densities look different in the picture because they reflect sound waves differently. A sonogram can often show whether a breast lump is a fluid-filled cyst or a solid mass.

Xeroradiograpy: A type of mammography in which a picture of the breast is recorded on paper rather than on film.

X-ray: High-energy radiation. It is used in low doses to diagnose diseases and in high doses to treat cancer.

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Enrollment Form - #1

Screening Mammography Adherence Enrollment Form

FOR PHYSICIANS

PLEASE
FILL OUT AND PUT IN BASKET WITH BILLING SHEET
and
ASK YOUR PATIENT TO STOP AT THE FRONT DESK ON THE WAY OUT

1. Has your patient had a mammogram in the past 12 months?

NO [0]

YES [1] **date:** (if **yes STOP here**)

IF THE ANSWER TO THE ABOVE QUESTION IS "**NO**", PLEASE RECOMMEND A SCREENING MAMMOGRAM TO THIS PATIENT.

2. Did you recommend a mammogram today?

NO [0] I did not recommend one because: _____

_____

YES [1]

Patient:_____ # _____

INCREASING ADHERENCE TO PHYSICIAN'S SCREENING MAMMOGRAPHY RECOMMENDATIONS

Consent Form

Study Description

- The Division of General Internal Medicine at Northwestern University Medical School is conducting an important study on mammography, and how to make it more convenient and acceptable for patients. **Participation in this study involves a review of your medical record by a research assistant, completion of a brief questionnaire, and a follow up phone call and / or mailing.**
- **Attached to this consent form is the questionnaire which women age 50 and older who visit the clinic will be asked to fill out. This questionnaire consists of questions about basic demographic information as well as some questions regarding your attitudes and past experience with breast cancer screening.**
- If your doctor recommends a mammogram today, in approximately three months, someone from your doctor's office will contact you to inquire whether or not you obtained this test, if there is no record of the test being performed at Northwestern Memorial Hospital.

Alternative Procedures

- You do not have to participate in this study.

Benefits / Risks

- By participating in this study, you may have the opportunity to have a screening mammogram performed the same day as your doctor recommends it, if it is convenient for you. Alternatively, you can schedule it at your own convenience as is the usual practice.
- **In addition, your participation in this study may benefit others, as it will help advance our knowledge about women's attitudes toward and acceptance of mammography**.
- There are no risks associated with participation in this study.

Costs

- There are no additional charges to you for study participation.

- Please turn to the back of this page -

Subject's Rights

- Participation in the study does not require that you obtain a mammogram if your doctor recommends one. We are interested in having all women participate in the study, regardless of whether or not one plans to obtain a mammogram in the future if it is offered. Participation is voluntary and refusal to participate will involve no penalty or loss of benefits. If you do not want to participate in the study, simple return the blank questionnaire to the reception desk.
- You are authorized all necessary medical care for injury or disease which is the **direct** result of your participation in this research. The US Army requires that this institution provide such medical care when conducting research with private citizens. There is no compensation available for your participation in this research study; however, you understand that this is not a wavier or release of your legal rights.

Confidentiality

- Your responses to the questionnaire will be kept strictly confidential, and will be identified only by a code number. If the study is published, only summary information, which will not contain any unique identifiers will be made available. No individuals will be identified in the published study. Research records may be reviewed by members of the Food and Drug Administration or the Department of Defense.

Participation

- If you agree to participate please complete the attached questionnaire and return it to the receptionist along with this signed consent form.
- If you choose not to participate just return the blank questionnaire to the receptionist.
- **If you have further questions regarding this study you may contact**
- **Dr. Nancy Dolan (investigator) or Jean Rizzo (research assistant) at (312) 908-0959.**

Patient signature _____

#_____

YES REFUSED NO SHOW (#4)

RECEPTIONIST PROTOCOL

Name: Date of visit:

SS #:

DOB:

Physician:

Insurance:

Primary:	**1**-Medicare	**2**-Private	**3**-PPO	**4**-HMO	**5**-Medicaid	**6**-None	**7**-Other_____
Secondary	**1**-Medicare	**2**-Private	**3**-PPO	**4**-HMO	**5**-Medicaid	**6**-None	**7**-Other_____

Check-out data collection form for Eligible women who received a screening mammography recommendation

1. Is the patient in the control group or intervention group? Refer to number chart to determine group patient will be assigned to.
   a. Control group
   b. Intervention group

2. Does patient intend to get a mammogram within the next 3 months?
   a. yes, definitely plans to get one in the near future
   b. is considering having a mammogram (not definite)
   c. not planning on having a mammogram

3. If patient intends to get mammogram, where?
   a. Prentice
   b. other _____

4. If patient does not intend to get a mammogram, why not? (please circle as many as apply)
   a. I am afraid of the test
   b. It's too expensive
   c. I don't think I need it
   e. I have too many other medical problems
   f. My doctor doesn't think I need one
   g. I'm too old
   h. It's too inconvenient
   k. I have transportation problems
   l. other _____

Control group patients are referred to check-out. Intervention patients continue on next page.

For intervention patients only:

Intervention I

5. Targeted message given
    a. None, accepts mammogram (skip next question)
    b. targeted message - unnecessary
    c. targeted message - too old
    d. targeted message - expensive
    e. targeted message - afraid of test
    f. targeted message - inconvenient
    g. targeted message - transportation
    h. targeted message - other medical problems

6. Patient response
    a. Still does not want mammogram
    b. Is now *thinking about* having a mammogram within the next three months
    c. Has decided to have the mammogram - is going to schedule appointment

Intervention II

7. Patient accepts same-day mammography
    a. no
    b. yes

8. If patient accepts same-day mammography, please take down a phone number where she can be reached the following day : _____

End

Do not complete below this line.

Duration of test

9. How long did process take from leaving doctors office to getting mammogram?
    _____minutes

10. On a scale from 1 to 5, with 1 being least satisfied to 5 being very satisfied, how satisfied were you with the screening service? 1 2 3 4 5

BREAST CANCER RISK REDUCTION
MUJERES FELICES - POR SER SALUDABLES
MANUAL OF OPERATIONS

TABLE OF CONTENTS

PREFACE

In 1996, Dr. Monica Morrow, Director of the Lynn Sage Breast Center at Northwestern University Medical School and Northwestern Medical Hospital received a Breast Cancer Center Program award from the United States Army Medical Research and Material Command. The title of the program is Increasing Access to Modern Multidisciplinary Breast Cancer Care. The basic premise of the program is described below.

In the past two decades enormous improvements have occurred in the diagnosis and treatment of breast cancer. These include: the early diagnosis of breast cancer by screening mammography, the use of breast conservation and breast reconstruction to reduce the morbidity of local therapy, and the use of adjuvant systemic therapy to improve survival. Advances in research made these improvements possible. However, the majority of women with breast cancer are not diagnosed and treated at institutes with specialized interest and expertise in breast cancer care. Thus, many women receive inadequate care. Inadequate care is a particularly pronounced problem among underserved minority populations. The Breast Cancer Center Program proposes to improve access to modern multidisciplinary care through several interrelated approaches.

One approach is through the Breast Cancer Risk Reduction in Hispanic Women project (Mujeres Felices - Por Ser Saludables). Mujeres Felices is a trial of cancer risk reduction through a dietary and breast health educational intervention in Hispanic women. Consistent with the goals of the larger overall program, Mujeres Felices will work with established community organizations and health centers to develop culturally sensitive recruitment/retention strategies and interventions. Cultural and linguistic factors that may be related to Hispanic women's under representation as consumers of health care will be addressed. Mujeres Felices hopes to increase this population's access to information and services in the area of breast health.

The projects proposed in the Breast Cancer Center program grant will undergo administrative review on a monthly basis. This will be led by Dr. Morrow and include the principal investigators of the individual projects. For the Mujeres Felices study, participant recruitment will be the primary item monitored in the first year. During the second and third years of the grant, completeness of data collection will be assessed , as well as, the success of the project in achieving its specific aims. In the fourth year, the primary goals will be outcome analysis and dissemination of results. In addition, a working group, led by Susan Gapstur, Ph.D., will be formed which will meet quarterly to share preliminary data and successful implementation strategies among similar projects. This group will report annually to the Robert H. Lurie Cancer Center Advisory Board for Women's and Minority Issues. Finally, all of the grant participants will meet annually and each principal investigator will present a summary of work to date. Oversight and input from the Advisory Board for Women's and Minority Issues will allow these findings to be shared with other members of the Robert H. Lurie Cancer Center and the community.

Chapter 1
Introduction to Mujeres Felices - Por Ser Saludables: a Breast Cancer Risk Reduction Project

1.1 Overview

The overall goal of the Mujeres Felices project is to examine the effect of an intervention program aimed at reducing *breast cancer risk behavior* among low-acculturated, premenopausal, Hispanic women. The aims of the intervention sessions are to encourage women to: 1) reduce saturated fat; 2) increase fruit and vegetable consumption; 3) increase the frequency of breast self-examination (BSE); and 4) reduce anxiety surrounding issues of breast health.

1.2 Philosophy

Mujeres Felices represents is a first step towards the initiation and development of a cancer prevention and control program in Chicago's Hispanic/Latino communities. Proficiency with BSE and compliance with a low-fat/high-fiber diet are the primary outcome measures of the study. However, a secondary goal is to increase the community's awareness of preventive health practices, improve communication between individuals and primary health providers, and provide Hispanic women with more venues for learning about their own health and the health of their families'. By working with community health centers, information will be exchanged in a way beneficial to the health center as well as Northwestern University. This exchange will provide the university with better information about the community and allow Northwestern University to share the latest health and psycho-social findings with the community

1.3 Study Design

A randomized controlled trial is proposed. Participants will be screened to determine eligibility. Three hundred eligible participants will be randomly assigned to either the Classroom Group (Intervention) or the Mail Group (Control Group) during the eight month active intervention. The Classroom Group will attend 16 on-going dietary and breast health intervention sessions in order to achieve adherence to a low-fat/high-fiber diet and increase frequency of BSE and reduce anxiety related to breast health issues. Six booster sessions will be conducted following the active intervention. Data collection will occur at baseline (pre-intervention), eight months and 20 months (post-intervention).

1.4 Proposed timeline

The total time period for Mujeres Felices is 4-years.

August 1996 - December 1997 Staff hired, protocol, manual of operations, forms and data management systems developed, logo/name contest, needs assessment, sub-contracts set-up (University of Pittsburgh, Erie Family Health Center and University of Illinois - Chicago)

Jan. 97 Recruitment begins

	Baseline HCV	**8 mo. Active Intervention**	**8- month HCV**	**20-month HCV**
Cohort 1	May/June '97	May '97 - Jan. '98	Jan/Feb '98	Jan/Feb '99
Cohort 2	Sept/Oct '97	Sept. '97 - May. '98	May/June '98	May/June '99
Cohort 3	March/April ' 98	March '98 - Nov '98	Nov/Dec '98	Nov/Dec '99

Dec. 99 End of Data Collection

1.5 Staff Communication and Organization

1.5.1 Lines of Communication

Weekly staff meetings will be scheduled throughout the study. Each Friday at 3:30 p.m. the Principal Investigators and primary staff members meet to discuss progress and other issues related to the project. Primary staff members include the data analyst, the nutrition coordinator, study coordinator, assistant study coordinator, recruitment and retention coordinator and the senior research assistant.

1.5.2 Organizational Chart

The Principal Investigator for Mujeres Felices is Marian L. Fitzgibbon, Ph.D. (Behavioral/Psychological Interventions). The Co- principal Investigator is Susan Gapstur, Ph.D. (Biological Specimens/Anthropometric Measures). The Co-Investigators are Sara Knight, Ph.D. (Breast Health Intervention) and Kiang Liu, Ph.D (Statistical Analysis).

The Data Manager (DM) is Mary Avellone, Ph.D.; the Nutritional Coordinator is Sharon Sugerman, R.D., M.A.; the Project Coordinator (PC) is Kristin Krueger-Mendoza; the Assistant Project Coordinator (APC) is Margarita Hernandez; the Senior Research Assistant (SRA) is Kim Hogan; the Recruitment and Retention Administrator is Georgina de la Torre; the Registered Dietitian is Christine Eilers; the Programmer is Joe Shayka and the Health Advocates are..... (See Appendix I for Mujeres Felices organizational chart.) The Budget Managers are Sasi Kumar and Laura Cundiff. Administrative Assistant related to the Breast Center Program is Kathleen O'Connell.

1.6 Contact with Primary Care Physicians

This section will be elaborated once we have more specific guidelines. Feel free to write suggestions right on here.

The Health Center Visits in the Mujeres Felices study should not be considered a replacement for a participant's regular check-up. We do not anticipate any contact with a participant's primary care physician unless the participant specifically makes a request that we do so. However, if Health Center staff detect an unusual or possibly suspicious occurrence within the course of study treatment (e.g. a lump in a breast exam), they should contact the Project Coordinator or one of the PIs for guidance.

APPENDIX 1

Department of Defense Grant: Breast Cancer Risk Reduction in Hispanic Women Project
Northwestern University Medical School

Community Advisory Committee
Eva Hernandez
Erlinda Binghay
Kathy Kilbane

Coordinating PIs
Marian Fitzgibbon, Ph.D.
Co-PI Susan Gapstur, Ph.D.

Co-Investigators
Sara Knight, Ph.D.
Kiang Liu, Ph.D.

Budget Management
Sasi Kumar, Laura Cundiff, Kathleen O'Connell, K.K.-Mendoza

Data Processing and Analysis
Mary Avellone, Ph.D.
Joe Shayka

Project Coordinator
Kristin Krueger-Mendoza

Assistant Project Coordinator
Margarita Hernandez

Recruitment/Retention Coordinator
Georgina de la Torre

Senior Research Assistant
Kim Hogan

Nutrition Coordination
Nutrition Coordinator - Sharon Sugerman, MA. R.D.

Dietitian - Christina Eilers, R.D.

Chapter 2
General Operations Guidelines

2.1 Introduction

The Principal Investigators of Mujeres Felices and members of the Erie Family Health Center (1701 W. Superior, Chicago, IL) have established a collaborative agreement for the rental of space on the third floor of the Health Center which will be designated for the project. This space will be used for 1) recruitment, 2) Health Center Visits (data collection), and 3) class-room intervention sessions.

2.2 Equipment and Supplies

2.2.1 Equipment/Supplies

The following equipment are necessary at the health center to conduct the Mujeres Felices project: scale, weights to calibrate scale, Tanita Bodyfat Analyzer, anthropometric tape, tape recorders, tapes, dietary assessment models, lap-top computer and a printer.

2.2.2 Ordering Equipment/Supplies

All supplies necessary for Mujeres Felices will be ordered by the PC and the APC, delivered to either the NU Outreach Center or to the Department of Psychiatry (Time Life) and labeled Mujeres Felices. The PC and APC will inventory the Mujeres Felices supplies as needed. However, if other Mujeres Felices health center staff notice the supplies are low, they should notify the PC and APC before the supplies are depleted to assure a sufficient stock of supplies at all times. A detailed list of supplies can be seen in each relevant chapter.

2.3 Health Center Visit Staffing

The HCVs will be held Monday through Saturday between the hours of 8:00 am and 12:00 noon. the PC, APC, RC and two Health Advocates (subcontracted through EFHC will be cross-trained in the six stations of the HCV. For details on the HCV see Chapter 4. The Nutrition Coordinator will oversee the conduct of the 24 hour recalls. The PC will oversee the entire HCV with the assistance of the ASC and the SRA.

2.4 Contacts with Participants

Each time a Mujeres Felices staff member contacts a participant by telephone, the Mujeres Felices staff member should identify herself by name and affiliation with Mujeres Felices. If calling the participant at her place of employment, Mujeres Felices staffers should only state their name. If pressed for more information, they should state they are calling from Northwestern University. Under no circumstances should a Mujeres Felices staff member leave a message for a participant with a receptionist, co-worker, boss, etc., unless the participant specifically instructs

the Mujeres Felices staff to do so. Mujeres Felices staff should refer to the participant as Mrs. or Miss (or Ms.) *name* unless the participant has requested otherwise. In some cases, the participant may have to be contacted in her home, particularly if she does not have a telephone or she cannot be reached by telephone within a reasonable period of time.

2.5 Participant Files

Information on Mujeres Felices participants will be stored in two different file systems. Each participant will have a **permanent file (file),** a comprehensive file that is maintained throughout the study. This file will be kept in the Mujeres Felices office in the Department of Psychiatry (303 E. Ohio, Chicago, IL). In addition to this, there will be an **HCV folder (folder)** that keeps the HCV forms from each HCV until they are data entered. These folders will be collected at the end of each HCV and stored in the NU Outreach Resource Center. At the end of each week the Project Coordinator will transport the files from the Outreach Resource Center to the Department of Psychiatry office.

All files and folders should have fasteners on top. Forms must be completed in pen with legible printing or writing. If a mistake is made, DO NOT USE WHITEOUT to correct it. Instead, put a slash mark through the mistake, write the correct answer next to it and initial the new answer.

2.5.1 Organization of Contents of Permanent Files

Participant files will be alphabetized by last name and maintained in a locked file cabinet (in the Department of Psychiatry and Behavioral Sciences). The PC, the Nutrition Coordinator and one other staff member will have keys to the cabinet. The file will be labeled with the participant's name and study ID number and will contain all forms, notes, letters, phone call logs, etc. that pertain to Mujeres Felices participation. The only information that will not be contained in these files will be the information on randomization and any forms relating to intervention.

The first forms to be inserted into the permanent file are the completed phone screen eligibility form and the signed and dated consent form. The Tracking Form must always be kept on the top of the forms in the chart. After the HCV file is data entered, the forms will be removed and placed in the permanent file.

When permanent files are to be removed from the file cabinet for data entry, an "out-guide" will be inserted into the place where the file is kept. The person that removes the file for data entry should enter the file name and dates on the "out-guide" and initial it. This will allow all Mujeres Felices staff at-a-glance information on the location of permanent files. When the files are returned from data entry, the "out-guide" will be taken from the cabinet and the file will be returned to its proper place.

2.5.2 HCV Folders

At each HCV a participant will be given a six section file folder with all the appropriate forms necessary to complete all six stations of the HCV. The organization of the HCV folders will be as follows:

Section 1:	Consent forms
Section 2:	Blood Draw
Section 3:	Body Measures
Section 4:	Health Interview
Section 5:	Breast Health forms
Section 6:	Diet Interview

A check list will be included in the first section on top of the consent forms. The health advocate will sign her initials on the check list in **green** pen after each participant completes the station. After each HCV, the HCV forms will be kept in the HCV folders until they are data entered. After data entry the HCV forms will then be removed from the HCV folder and placed in the participant's permanent file. The HCV forms should be placed in chronological order according to section with section 1 at the top. The HCV folders will be labeled with the participant's name and will be reused for her other HCVs.

Prior to a participant's departure from the HCV, all forms should be checked for completeness. In addition, the check list should be initialed where appropriate to indicate the procedures completed at that visit.

Following an HCV, the HCV folders will be kept in a locked file cabinet in the NU Outreach Resource Center until the Friday of each week. Each Friday, the PC will transport the files to the Department of Psychiatry and placed in the locked file cabinet that contains the permanent files. HCV folders will be filed behind the corresponding participant's permanent file.

When an HCV folder is removed for data entry, the person removing them will write the date and initial the "out-guide" for the particular file that is removed.

2.6 Health Center Internal Procedure Manual

The Health Center's procedures should be utilized for such areas as general facility operation, general supplies, service and equipment maintenance, staffing, general policies and procedures, and health center safety and emergency procedures.

2.7 Emergency Procedures

The Mujeres Felices staff does not anticipate any emergencies as a result of participating in the HCV or in any aspect of the study. However, it is possible that a participant may faint at the HCV as a result of blood drawing, especially since the participant will have fasted prior to the blood draw. In the event any emergency staff should treat it seriously, quickly and calmly. The emergency should be handled via regular health center procedures.

All emergencies should be documented in the participant's file and the PC should be notified immediately. The emergency should be brought to the attention of the research team, so that everyone will be aware of the problem and discuss how to prevent future emergencies.

Chapter 3
Recruitment/Retention

3.1 Introduction

This 20-month project requires a substantial commitment in time and effort from the volunteer participants in both the intervention group and the control group. Participants attend three Health Center Visits that will last approximately 2.5 hours each. In addition to the HCV, the Intervention group will attend eight months of intensive educational sessions and a less intensive follow-up year (see Chapter 7 for a more detailed description of the intervention schedule). Based on previous recruitment experience by the investigators, it may be necessary to contact a minimum of 3000 women to yield 300 eligible volunteers for randomization.

This project will recruit Hispanic women only, and therefore, is vulnerable to a higher drop-out rate (attrition) due to migration (transient trends in this population). Recruitment is scheduled to occur over one year, but may be extended if necessary to obtain the optimum number of participants. A series of strategies is proposed to meet this challenge.

3.2 Overview

Initial recruitment strategies will focus on Hispanic/Latina women who visit the Erie Family Health Center (EFHC) located at 1701 W. Superior, or the WIC (Women Infant Children Center) located at 1924 W. Chicago Ave. EFHC serves the neighborhoods of West Town, Humboldt Park, and Logan Square, however, it is expected that the majority of participants will be residents of West Town (North - South boundaries: Grand Ave. to Division, East - West boundaries: Ashland to Western), due to proximity to EFHC.

The population of Hispanic women involved in this study is expected to represent the women that EFHC serves. It should be noted that while Hispanics make up 62% of the West Town neighborhood (1990 census data), they account for 83% of the population that EFHC serves. Furthermore, at least 74% of EFHC's clients live below the federal poverty level and 41% have no form of public or private insurance.

The population of Hispanic women is expected to represent the ethinic diversity of different Hispanic groups that live in and around West Town, and will include Mexican/Mexican-American, Puerto Rican, Central American and Cuban women. We also anticipate a large number of working women to be interested in the project.

Sequential recruitment efforts will reach out to Erie's satellites, and neighborhood stores, Laundromats, park districts and churches, etc. in West Town, Humboldt Park, and Logan Square.

Marketing materials will include Breast Cancer Risk Reduction in Hispanic Women Project logo/name, Mujeres Felices - Por Ser Saludables, which was designed by a member of the community. Public service announcements on both English and Spanish speaking networks are available at a minimum cost. Other marketing vehicles include posters and flyers displayed around the neighborhood and group announcements at community social and political events.

Participant incentives include food coupons, social gatherings and a chance to participate in an exciting project for the advancement of Hispanic Women's health.

3.3 Recruitment Plan

3.3.1 Contacting Women from Erie Family Health Center via Telephone

Erie Family Health Center will provide the names and telephone numbers of Hispanic/Latina women, between the ages of 18 and 40, who have visited the center in the last year. Women on this list will be contacted via telephone.

The RC will follow the standard procedures when contacting a woman on this list via telephone. The RC will identify herself, tell how she received the woman's name and number and give a brief explanation of the project. If a woman expresses interest, the RC will explain the Health Center Visits in more detail, the time commitment and monetary/non-monetary benefits (participating in a community project, social interactions and learning new information). The RC will ask the potential participant if she has any questions.

If a woman expresses interest, the RC should administer Section A of the Eligibility form (see Forms, Ch. 4, Appendix). This type of pre-screen will save time by determining ineligibility on items that are easily administered over the telephone. If a woman is currently ineligible due to pregnancy or breast-feeding, the RC will inform her that she is ineligible at this time, but may be eligible in the future. Her name and number will be recorded and she will be informed that she will be contacted when the new wave of recruitment begins.

The remaining eligibility items and Quick Check do not lend themselves to telephone administration and should be done in person. Therefore, if a woman wants to participate and is potentially eligible, the RC should make an appointment for her to come to Erie to establish eligibility and complete the Quick Check. If necessary, arrangements for transportation to and from Erie can be made. Alternatively, the eligibility form can be administered in a woman's home if for some reason she cannot come to Erie Health Center.

3.3.2 In-Person Contact at Erie Family Health Center and WIC

From previous experiences working in community health projects, the Investigators have established the need to do the majority of recruitment in person. Therefore, the Recruitment Coordinator (RC) will focus the majority of her time on in-person recruitment. The two main recruitment sites are the Erie Family Health Center and WIC.

The RC will approach women in the waiting room and give a brief explanation of the project. The RC will follow the same procedures in person as she does via telephone to explain the project. If the woman expresses interest, the entire eligibility form and

Quick Check should be administered. The RC will not be able to tell women their eligibility status at this meeting because the Quick Checks require computer analysis.

3.3.3 Eligibility Determination and Scheduling a Health Center Visit

Before a Health Center Visit is scheduled, it is important to determine eligibility. If at any point during eligibility screening a woman's answer constitutes ineligibility, the RC politely ends the interview and informs her she is ineligible for the project. Whenever eligibility status is questionable, the interview should be completed and brought back to the weekly research meeting to make a final decision. If the woman successfully completes eligibility, the interviewer should inform her that she appears to be eligible (or that at this point she cannot see anything that makes her ineligible) at this time and someone will contact her within **two weeks** with more information.

All responses are documented and, if administered by anyone other than the RC, forwarded to the RC for review. Once eligibility or ineligibility is decided, the RC will contact potentially eligible participants by telephone or in person to schedule their first HCV. All participants will receive a letter informing them of their eligibility status.

3.4 Marketing Materials

3.4.1 Logo Contest

Before recruitment began, a Logo/Name contest was advertised throughout the community to involve the community in naming and designing the project. Posters and entry forms were displayed at Erie Family Health Center, WIC, Laundromats and community stores. In October (1996) the Logo/Name Contest was advertised at a booth at Erie Family Health Center's **40 Fest**, a health fair celebration. Entrants were given a water bottle (donated by the American Dietetic Association) for designing a logo.

The final logo for the project was chosen by staff concensus and formatted by computer. Tony Baer, a graphic artists from Targetcom, Inc. donated his time and expertise to format the logo and name designed by Mario Espinosa, a 40-fest contest participant. The name and logo are positive representations of the project goals and spirit, and is intended to be easily identified by people of the community as a symbol for a healthier future. The logo/name will be used on all printed material, including stationary, brochures, posters and flyers.

3.4.2 Brochure/Pamphlet

The brochure was designed by the RC, written in both English and Spanish. It will be used to promote the project and give potential participants a project summary as well as a short self screening eligibility list. The back page of this three section brochure will serve as an HCV appointment keeper as well.

3.4.3 Posters and Flyers

The poster was designed by the RC, Georgina de la Torre. It is adaptable for a large poster and for a smaller flyer. It will contain a scaled down version of the information in the brochure. The poster will attract attention in locations that do not allow individual solicitation. The logo is intended to help recruitment by presenting information, and motivation for participants already involved in the project. Posters will be displayed in neighborhood businesses and stores.

3.4.4 Press Releases

In February of 1997, a press release announcing the project and asking potential volunteers to call the project number was submitted by Northwestern University Public Relations to the major Chicago newspapers, West Town neighborhood newspapers and in particular the major Spanish language broadcast media.

The Spanish television station 66 responded immediately to the announcement and agreed to support us in terms of public service announcements.

3.4.5 Health education Classes, Seminars, Fairs and Events

Mujeres Felices will be present at community health fairs, such as EFHC 40-Fest and the International Women's Day Health Faire at Harrison Park to promote the project and recruit volunteers.

3.4.6 Breast Cancer Organizations

Y-Me will help Mujeres Felices to plan the breast health component of the curriculum, provide brochures for participants and arrange for a Latina breast cancer survivor.

Chapter 4
Eligibility and Health Center Visits

4.1 Introduction

This chapter outlines the eligibility criteria and the Health Center Visits (HCV). Eligibility will be established in two steps: 1) Eligibility Form completion, and 2) percent of calories from fat assessed. The HCVs will occur at baseline, eight months and 20 months.

4.2 Initial Eligibility

It is important to determine eligibility prior to the HCV to save time and effort. The initial eligibility criteria, outlined in table 4.1, must be considered before a woman can participate in this project.

Eligibility will be determined in two steps. First, an interviewer will administer the Eligibility Form (see Forms in Chapter 4) and determine language preference. If the participant is eligible thus far, the Spanish version of *Quick Check for Fat and Coronary Risk* (Quick Check) will be administered to determine the participant's dietary intake of percent calories from fat.

If at any point during eligibility screening a woman's answers constitutes ineligibility, the Mujeres Felices staff politely ends the interview and informs the woman she is ineligible for the study. Whenever eligibility status is questionable, the interview should be completed and brought back to the research meeting in order to make a final decision. If the woman successfully completes the Eligibility Form and Quick Check, the interviewer should inform her that she appears to be eligible at this time and someone will contact her in the near future with more information.

All responses are documented and forwarded to the RC for review. Once eligibility or ineligibility is decided, the coordinator will contact the participant by telephone or in person to schedule her first HCV. A letter will be sent to all participants informing them of their eligibility status (see Eligibility/Ineligibility letters in Chapter 4, Forms).

TABLE 4.1	INITIAL ELIGIBILITY CRITERIA
• **Age**	- 20 - 40 years old
• **Gender**	- Female
• **Ethnicity**	- Hispanic/Latina
• **Pregnant**	- Not currently pregnant or planning a pregnancy in the next 20 months - Not currently breast feeding
• **Health**	- Has never been diagnosed with cancer (besides skin cancer) - Has never been diagnosed with diabetes (besides gestational) - Has never been diagnosed with an eating disorder
• **Substance use**	- Consumes fewer than two alcoholic drinks per day - No illegal drug use
• **Availability**	- Willing to attend required number of sessions over 20 months
• **Diet**	- Fat intake must be ≥30% of total calories

4.2.1 Age

All Mujeres Felices participants will be pre-menopausal and between the ages of 20 and 40 years old. If the participant is 19 years old at the time of pre-screening, her information will be recorded and she will be contacted after her 20th birthday.

4.2.2 Ethnicity

Participants that consider themselves Hispanic/Latina and have one or both parents that are of Hispanic/Latino origin will be eligible for the study.

4.2.3 Pregnant/Breast Feeding

Women who are pregnant or are planning a pregnancy in the next 20 months are ineligible for the study. Women that are breast feeding are also considered ineligible. However, it is possible that a woman who is pregnant or breast feeding during the recruitment of the first cohort might be eligible by the third cohort. If a woman expresses interest in the study but is not eligible due to being pregnant or breast feeding, her information will be recorded and she will be contacted during recruitment for the third cohort and screened for eligibility.

4.2.4 Health

Women will be excluded if they have ever been diagnosed with: 1. cancer, other than skin cancer; 2. diabetes, other than gestational diabetes or 3. an eating disorder.

4.2.5 Substance Abuse

A woman will be considered ineligible if substance abuse is strongly suspected or if she admits to drinking more than two drinks a day or using illegal drugs.

4.2.6 Availability

Women who are interested in this study must be available for approximately 20 months. To assess this, the participant will be asked whether she can commit to the required number of sessions and if she plans to live in the Chicago area for the next 20 months.

4.2.7 Diet

Participants will be administered the *Quick Check for Fat and Coronary Risk* - Spanish version. Only participants who show 30% or more fat intake, as figured out by the Quick Check will be eligible for the study.

4.2.7.1 Administering the Quick Check

All Quick Checks must be administered in person. The RC will ask the participant which language she prefers to complete the Quick Check. This project will use the Spanish version of *Quick Check for Fat and Coronary Risk.* Therefore, the English translation will be attached to the form for any participant requesting an English version. The Quick Check will be evaluated, and participants whose Quick Check reveals a dietary intake of $\geq$ 30% calories from fat will be eligible for the project.

4.3 Eligibility for Randomization Criteria

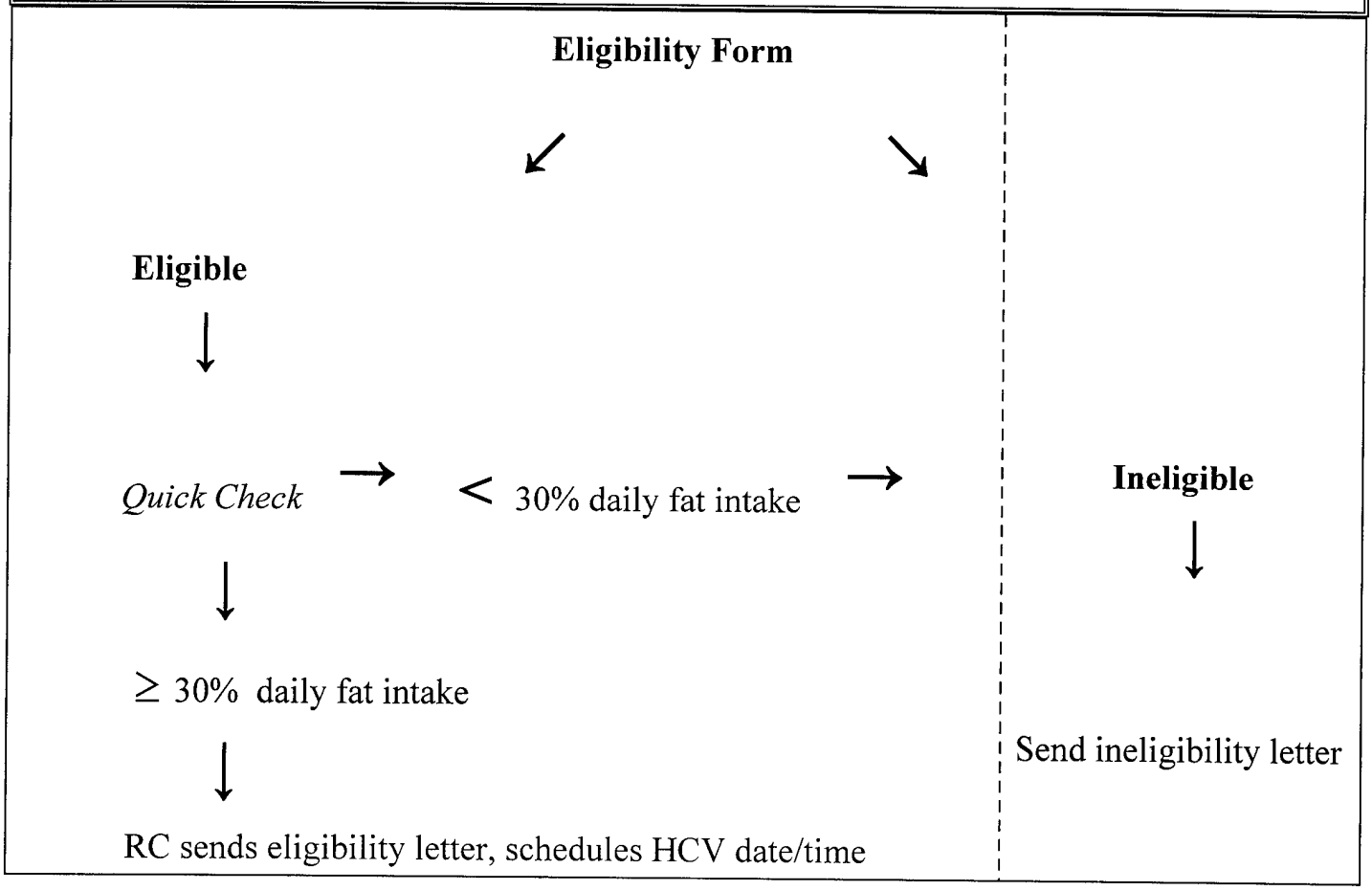
Initial eligibility is established before the first Health Center Visit. However, a participant may provide information on the Health Interview that differs from the information she provided on the Initial Eligibility Form. If this information renders her ineligible according to the Initial Eligibility Criteria above, her name will be pulled out of the randomization pool and she will be considered ineligible. A Mujeres Felices staff member will explain to her via telephone and letter that she is ineligible.

Besides Initial Eligibility, the Health Interview will address medical history in section **B. Medical History** and medication use in section **C. Medication Use**.

Medications.

If the participant admits to using Laxatives twice a week or more she will be considered ineligible.

Figure 4.1 **INITIAL ELIGIBILITY FLOW CHART**



4.4 Health Center Visits

All HCVs, at baseline, eight months and 20 months, will be run in essentially the same manner except **HCV One** which will include an explanation of the general project plan and require participants to sign a consent form. The first station of HCV One will be Greeting/Consent where a health promoter will explain the entire project. Stations 2 - 6 will be in private or semi-private areas. Private areas will be closed off by screens and semi-private areas will be only partially screened off. See Ch. 4 for the specific forms for each station.

4.4.1 Scheduling an HCV Appointment

When scheduling a HCV appointment, the RC tells the participant the following important information. After the project has been explained, a small blood sample will be collected to measure the nutrients in the blood. Therefore, the participant should fast from 11:00 pm the night before the HCV until the blood draw and she will receive a snack afterwards. She should try to wear light clothing underneath her outer clothing (sweaters, etc.) because she will be weighed. Finally, she will receive a $5.00 Jewel food certificate at the end of the HCV and one for each diet interview she completes after the HCV.

4.4.2 Greeting/Consent

When a participant arrives to the HCV the first station she will go to will be Greeting/Consent. The health promoter at this station will greet the participant and ask the participant which language she prefers for the project explanation. The health promoter will explain the overall project in a uniform way by using a written narrative and standard visuals (see Appendix). The health promoter will explain the project design, the time-line, the concept and purpose of randomization, the time commitment involved in participating, risks and benefits. The participant will be asked if she has any questions and the health promoter should address any questions and clarify any confusing points.

After the project is explained, the health advocate will read the consent form to the participant and ask if the participant has any questions. If the participant agrees to participate, she should sign the consent form at this time and go the next appropriate, available station. The original signed, dated and IRB stamped consent form should be filed in each participant's folder and a copy can be provided to the participant upon request.

4.4.3 Blood Draw/ Body Measurements

Station Two is for the Blood Draw/Body Measurements. A trained, bi-lingual phlebotomist will take 30 ml of blood from the participant and measure height, weight, waist and hip circumferences, and percent body fat. Following the Blood Draw, the participant will be asked to go to the one of the next three stations and encouraged to eat a snack. The next three stations can be completed in any order as long as they are done after the blood draw and before the Forms Completion station. This station will be in a semi-private area.

4.4.4 Health Interview

The Health Interview is a comprehensive interview that includes the Marlow-Crowne Social Desirability Questionnaire and QEWP (Questionnaire on Eating and Weight Patterns) as well as questions on demographics, physical activity, acculturation and medical history. The Health Interview will be interviewer administered in either Spanish or English depending on the participant's preference.

4.4.5 Breast Health Forms

At the Breast Health Forms station, the participant will be instructed by a nurse or nurse practitioner to examine a breast model for lumps. The nurse will rate the participant's performance on this task with the Nurse's Rating of BSE form. This station will be in a private area. The participant will also fill out a Breast Health Questionnaire.

4.4.6 Diet Interview

At the Diet Interview station the health promoter will collect information on the participant's eating habits and previous days diet. When the diet interview is completed, the health promoter will schedule the next diet interview with the participant.

4.4.7 Forms Completion

Participant will take her completed HCV folder to the Greeting/Consent station where the health advocate will check the check-list and folder for completeness. If everything is complete, the health advocate can give the participant the $5.00 Jewel coupon and thank her for coming to the HCV. The health advocate will remind the participant that we look forward to seeing her on the date of her next scheduled diet interview.

4.4.8 HCV One Estimated Time Allocation

Station	**Form #**	**Time in Minutes**
1. Greeting/consent		15
2. Blood Draw/Body Measurements		20
3. Health Interview		50
4. Breast Health Forms		20
5. Diet Interview		50
6. Form Completion and Check-out		10
Total estimated time of visit		**2 hours 35 mins**

Do we want a Study Design Randomization Schema?

Chapter 5
Anthropometry

5.1 Introduction

The following anthropometric measurements will be taken at baseline, 8 months and 20 months: body weight and height, sagittal diameter, waist/hip circumference, body mass index and percent body fat. If the status form administered at 8 months and 20 months indicates that a woman is pregnant, she should not be measured.

All measurements should be taken after participants take off their shoes and heavy clothing. Participants should completely empty their pockets prior to the measurements; if the participant is wearing an excessive amount of jewelry that could affect weight measurement, she should remove the jewelry.

A trained health advocate will take and record each measurement, with the exception of body mass index which will be calculated after each HCV. Any modification in measurement techniques, such as left-side rather than right-side measurements because of amputations, casts or abnormal conditions such as decreased height from a hunched position, should be noted on the appropriate anthropometric form. This information can be taken into consideration in data analysis.

All values should be rounded to the nearest unit indicated for each measure. Specific rounding rules are provided for each measure (weight, height, and circumferences), and should be posted in the anthropometry station.

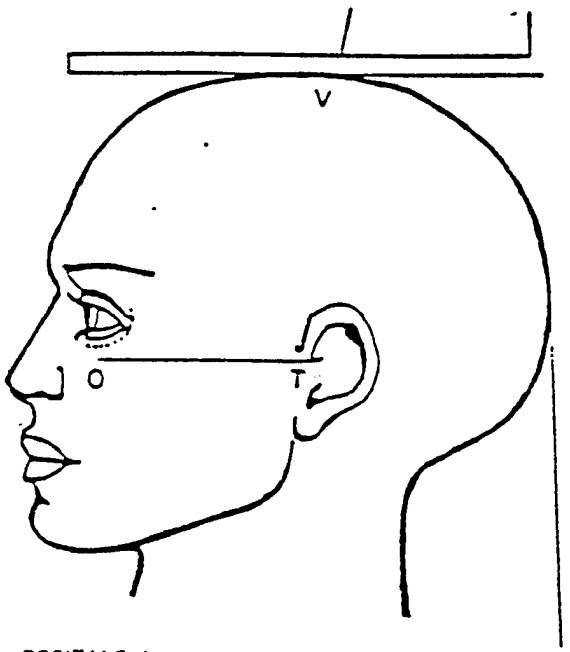
5.2 Measuring Height

The participant should stand erect on the horizontal Health-O-Meter platform with feet or knees together, whichever come together first. The most important point is to position the participant in a vertical plan - see Figure 1). The participant should look straight ahead with her arms relaxed and hanging loosely at her side. Instruct the participant to inhale deeply and record the reading just before she exhales by bringing the metal bar snugly but not tightly on top of the head. Record measurement to the nearest 0.1 cm on the appropriate Anthropometric Form. Round down if necessary.

5.3 Measuring Weight

Balance the scale so that the indicator is at zero when no weight is on the scale. The scale should be leveled and on a firm surface (not a carpet). Instruct the participant to stand in the middle of the platform on the balance scale with head erect and eyes looking straight ahead. Adjust the weight on the indicator until it is balanced. Record the results to the nearest 0.1 pounds according to the scale being used. Round down if necessary. Record weight measurement on the appropriate Anthropometric Form.

Figure 1. Frankfort Plane for Measuring Body Height



ORBITALE: Lower margin of eye socket

TRAGION: Notch above tragus of ear or at upper margin of zygomatic bone at that point

FRANKFORT PLANE: Orbitale-tragion line horizontal

5.3.1 Calibration Check of Scales

Scales should be checked weekly for accuracy. When no weight is on the scale, check for the scale to read "0". Place known weights on the scale and record the expected value (i.e., value of the weights) and the actual value (actual scale reading) on the Scale Calibration Log. The value obtained should be within 1.00 pound (or 0.4 kg) of the expected weight. If the value exceeds this limit, the scale should be calibrated by the manufacturer or by the appropriate clinic staff.

When the scale is not in use, move the large weight to the highest value to keep the tension off the internal spring mechanism.

5.4 Waist and Hip Circumference

A Gulick II 150 cm anthropometric tape should be used in making the waist and hip circumference measurements. When making readings from the tape, one hand should hold the plastic casing while the other hand should hold the spring casing. The tape should be pulled until the red ball in the spring casing is just fully visible.

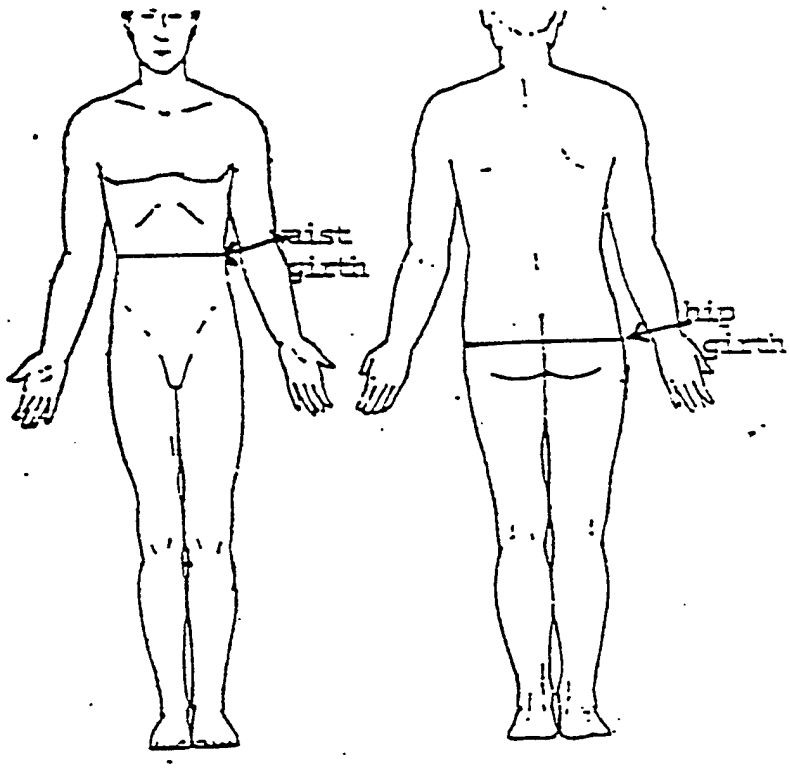
5.4.1 Waist Circumference

To determine the waist circumference, a Gulick II anthropometric tape is applied horizontally at a lateral level midway between the iliac crest and the lowest lateral portion of the rib cage and anteriorly midway between the xiphoid process of the sternum and the umbilicus. This level usually is the natural waist line and is identified as the level of minimal abdominal width when the site profiles are slightly concave. The observer should stand in front of the participant to determine the minimum waist site. Have the participant bend sideways to identify the natural indentation at the waist; place finger on this spot before the participant stands upright again. The objective is to measure the smallest circumference around the waist (see Figure 2). **The technician should move to the participant's right side to take the measurement; do not take this measurement from the front.** Be sure that the tape is kept horizontal when making the measurement. The measurement is made at the end of a normal expiration and recorded to the nearest 0.1 in. Repeat the measurement during the second round of measurements. Round down if necessary.

5.4.2 Hip Circumference

To determine the hip circumference, the participant should stand with feet together and the technician should stand on the participant's right side rather than in front. Hip circumference is measured at the level of the symphysis pubis anteriorly, and posteriorly at the level of the maximal protrusion of the gluteal muscles. The level, usually but not always, is the greatest circumference of the hips (see Figure 2). Keep the anthropometric tape horizontal at this level and

Figure 2. Waist and Hip Girth Measurement Sites.



record the measurement to the nearest 0.1 in (refer to rounding rule for waist circumference above). repeat the measurement during the second round of measurements. Round down if necessary.

Record both hip circumference measurements on the appropriate Anthropometric Form.

5.5 Bioelectrical Impedance Analysis (BIA) Measurement of Body Fat %

5.5.1 BIA Equipment Test

5.6 Body Mass Index

Each participant's Body Mass Index (kg/m*) will be calculated after each HCV. BMI is determined by 1st multiplying a participant's weight in pounds by 0.4536 to determine kilogram. The height in inches is multiplied by .0254 to determine meters. BMI is then compiled as kg/m . The formula is : $\frac{\text{weight in lbs} \times .4536 \text{ kg/lb}}{(\text{height in inches} \times .0254)^*}$

5.7 Training, Certification and Quality Control

The training and quality control program for taking body size measurements consists of the following components:

- Two to three technicians will be trained by the designated anthropometry trainer (i.e. someone previously certified).

- Each anthropometry technician will be required to obtain all body size measurements on at least five volunteers. Each trainee must document the measurements for each volunteer.

- Each anthropometry technician will be required to obtain all body size measurements twice from at least five volunteers, with a one-week time interval between the two measurements. Measurements will be recorded on separate forms for each cycle of measurement, then compared. Three out of five measurements for height, weight, sagittal diameter and waist and hip circumference must be within 2 cm. of each other. If these anthropometric measurements are not within the above specifications, the trainee will take the measurements again.

- If new or additional personnel are hired, they will be required to complete the same cycle of training as described above.

- Instrument checks are to be performed as detailed earlier in this chapter.

- Each anthropometry technician will be trained and certified according to the above procedures for the BIA machine in addition to the other body measurements. The attached checklist (appendix x) should be used by the trainer for each person being certified for BIA.

- Each technician will be trained and certified for blood pressure according to the procedures previously described in this chapter.

Chapter 6
Collection and Processing of Biological Samples

6.1 General Information

6.1.1 Safety

The Breast Cancer Risk Reduction in Hispanic Women project will adhere to OSHA and Erie Family Health Center general safety guidelines already in daily use in the clinic and laboratory. Blood and all contaminated material should be handled as though the participant has a blood-borne transmissible disease. Therefore, the following precautions should be observed:

a. Gloves and a lab coat must always be worn when drawing blood and handling blood samples. Eye protection also must be available for use.
b. All personnel must use extreme caution to avoid accidentally sticking themselves with a contaminated needle. If the phlebotomist or clinic technician sustains a contaminated needle stick or is otherwise exposed to a participant's blood, the affected area should be thoroughly cleaned with soap and water (except for the eyes where soap would cause damage). The laboratory director should be notified immediately.
c. Needles must be disposed of in proper disposal containers (i.e., sharps container).
d. All used vacutainer tubes and pipettes are to be placed in the proper disposal container (i.e., sharps container).
e. Caution must be used to avoid spilling the blood. Cleaning material is available to decontaminate areas in which blood was spilt. If an area has been contaminated, notify the laboratory director immediately.

6.1.2 Training and Certification

One or more trained bi-lingual phlebotomists will be hired for this project. The phlebotomist(s) will be trained in the standard system currently in place in the laboratories at Erie Family Health Center and the Department of Preventive Medicine. She/he will trained by Cheryl Westbrook and Dr. Susan Gapstur in the Department of Preventive Medicine at NUMS, and by Miriam Salazar at Erie Family Health Center.

6.1.3 Facilities

The following facilities will be used for the collection, processing and storage of all blood samples:

a. Blood collection - blood will be drawn at Station 2 during the Health Center Visits. This station is located in the Cancer Resource Center, 3rd Floor, Erie Family Health Center.
b. Blood processing - blood will be centrifuged and aliquotted in the clinical laboratory at the Erie Family Health Center, 2nd Floor.

c. Short-term freezer storage - serum samples can be stored in small white boxes at -20°C for up to 48 hours in the Erie Family Health Center laboratory.
d. Long-term freezer facility - serum samples must be transferred to a -70°C freezer located in the Department of Preventive Medicine's long-term freezer facility (Freezer #3), basement of 680 Nth Lake Shore Drive.

6.1.4 Labeling

Preprinted labels will be used for blood collection and storage. There will be three different categories of labels for the blood collection and processing for each Health Center Visit. Each label should be read carefully before placing it on the respective form or tube.

a) One label should be placed at the top right hand corner of the Blood Collection and Processing Form. This label will have three lines of information as follows,
   103 - Blood
   Baseline (or 8 month, or 20 month)
   ID#
b) Three labels will be printed for each of the red-top vacutainer tubes. These labels should be firmly placed on the tubes and the three lines of information are,
   Red Top Blood 1 (or 2, or 3)
   Baseline (or 8 month, or 20 month)
   ID#
c) Nine labels will be printed for each of the 2.0 ml lavender microfuge tubes. These labels should be firmly applied to the microfuge tubes and then covered in clear plastic tape so that the labels do not come off during storage. These labels have the following information listed on them,
   Serum 1.0 - 1 (or 2, or 3, etc to 9)
   Baseline (or 8 month, or 20 month)
   ID#

6.1.5 Storage

All serum samples will be aliquotted into 2 ml lavender, snap-top microfuge tubes. For each women at each visit, up to 9 microfuge tubes containing 1 ml of serum each will be placed in a single row in white 9 x 9 boxes. The boxes will be place in the -20°C short-term storage freezer located in the clinic laboratory. At the end of each day the boxes should be transferred to the long-term freezer facility at 680 Nth Lake Shore Drive. If it is not possible to transfer the boxes daily, then they can be brought over the following day.

6.2 Blood Collection (see figure 6.1)

6.2.1 Timing of Collection

Blood will be drawn from 8:30 a.m. - 10:30 a.m. on the days of the Health Center Visits. For each Health Center Visit in which blood will be drawn, participants will fast from

11:00 p.m. the night prior to a visit (no food and only water to drink). In addition, the participant should have refrained from exercise for the 12 hrs prior to her appointment. This is necessary because exercise may affect the levels of cholesterol and other compounds.

6.2.2 Set-up for Venipuncture Procedure

a. Three 10 ml red-top vacutainer tubes labeled "Blood #1", "Blood #2" and "Blood #3" should be placed in a test tube rack.
b. tourniquet
c. gauze pads, alcohol swabs, bandages
d. 21 g, 1 1/2 in. vacutainer needles
e. vacutainer holder
f. biohazard container for needles
g. test tube rack placed inside a cooler with frozen ice-bags

6.2.3 Drawing Blood

a. The participant should be seated comfortably for the blood draw.
b. Ask the participant their name and any necessary questions on the Blood Collection and Processing Form. Record the time of the blood draw.
c. Follow the usual procedures to prep the arm: apply the tourniquet, find the vein, swab the area with alcohol, then insert the needle.
d. Every effort should be made to completely fill each of the three vacutainer tubes. After each tube is filled place in the test tube rack.
e. After all three tubes have been filled, remove the needle, apply gauze and firm pressure on the arm at the site of the venipuncture. After 30 seconds place a bandage over the gauze.
f. Wrap the three vacutainer tubes with aluminum foil and place in the test tube rack inside the cooler bag.

6.3 Blood Processing

6.3.1 Set-up for Blood Processing

a. 9 - 2.0 ml lavender, snap-top microfuge tubes.
b. plastic, graduated pipettes for aliquotting serum
c. refrigerated centrifuge cooled to 4°C
d. biohazard containers

6.3.2 Blood Processing

a. Remove the foil wrapped tubes from the cooler bag and allow the blood to clot by sitting at room temperature for at least 20 minutes but no more than 60 minutes.
b. Remove the foil and centrifuge the tubes for 20 minutes at 2600 rcf in a refrigerated centrifuge cooled to 4°C. Record the time of centrifugation on the Blood Collection and Processing Form.
c. After removing the red-top tubes from the centrifuge, aliquot 1.0 ml of serum to each of the 9 - 2.0 ml lavender snap-top microfuge tubes labeled "Serum - 1.0 ml). If the volume of serum is not sufficient to deliver 1.0 ml to all 9 tubes then only add 1 ml to as many tubes as possible.
d. Store the microfuge tubes in the next available row in the white storage boxes located in the -20°C short-term storage freezer.
e. Record the time of freezing and the number of microfuge tubes filled, and the volumes on the Blood Collection and Processing Form.

6.4 Blood Storage

6.4.1 Short-term Storage Freezer

a. For each woman at each visit, all lavender, snap-top microfuge tubes should be placed in a single row in the 9 x 9 white freezer storage boxes (see grid below).
b. The freezer storage boxes should be placed in the -20°C short-term storage freezer in the laboratory at Erie Family Health Center.

Microfuge tube labeled "Serum 1.0 - #1, 2, 3, etc"

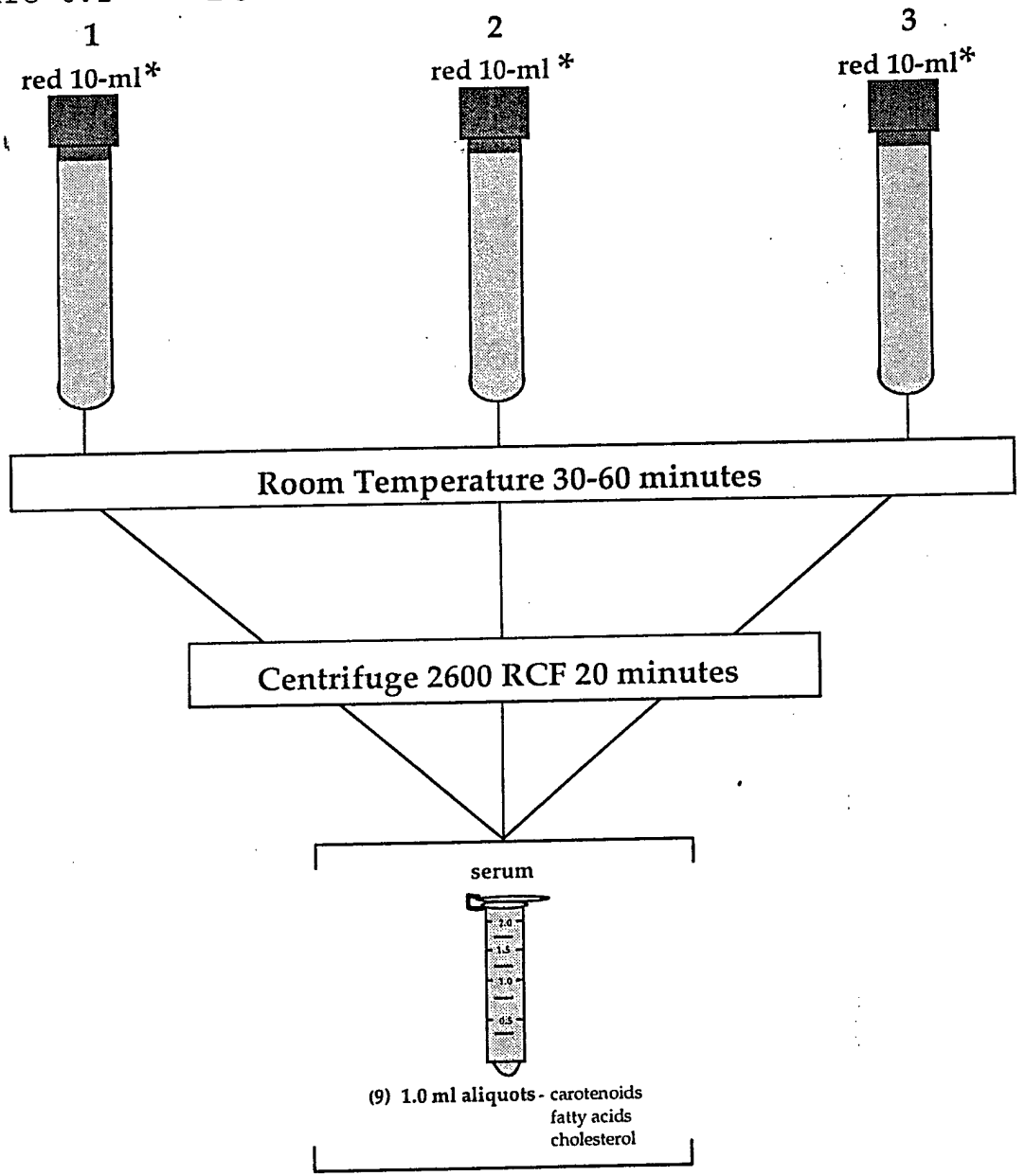
Participant 1, baseline visit
Participant 2, baseline visit
Participant 3, baseline visit
etc

1	2	3	4	5	6	7	8	9
2								
3								
4								
5								
6								
7								
8								
9								

6.4.2 Long-term Storage Freezer

At the end of each day the boxes should be transferred to the long-term freezer facility located in the basement of 680 Nth Lake Shore Drive. The Mujeres Felices freezer is freezer #3. If it is not possible to transfer the boxes daily, then they can be brought over to the long-term freezer facility on the following day.

Figure 6.1 BCRRHW BLOOD COLLECTION & PROCESSING



* Wrap red tubes in aluminum foil ASAP to protect from light during blood coagulation and aliquotting

= 2ml lavender snap-top microfuge tubes

Chapter 7
General Intervention

7.1 Processes of Change

Over the past decade, health professionals have begun to examine the steps that contribute to positive behavior change as a way to reduce chronic disorders. Diets that are high in fat and low in fiber, fruits and vegetables may contribute to increased risk for some cancers (NRC, 1989; USDHHS, 1988). Specifically, there is growing evidence that diet influences the risk of breast cancer.

Although there are inconsistencies in dietary data to prove an association between diet and cancer, there is more evidence to show the importance of early detection for breast cancer. However, in spite of its importance in breast cancer survival, recommendations for breast screening are not met in the U.S. This is true for all racial/ethnic groups, but Hipanic women participate less in breast screening activities (Stein, et al., 1991; Fox & Stein, 1991).

The primary aims of our intervention are to 1) reduce saturated fat intake; 2) increase fruit and vegetables intake; 3) increase frequency of breast self-exam; and 4) decrease anxiety related to breast self-exam. In order to address these aims, we need to have a framework to understand the factors that influence how behavior changes.

One theoretical model that seems to be particularly promising in our understanding of behavior change is the stages of change model. This model was originally developed from the transtheoretical model of intentional behavior change (Prochaska et al., 1992). this model conceptualizes change as a dynamic process that involves several discrete changes.

7.1.1 Stages of Change

Precontemplation. This is the stage where there is no intention to change now or in the near future. During this stage individuals may be unaware that a change is needed. related to our intervention, in this stage individuals may be unaware that a diet high in fat and low in fiber is unhealthy or that BSE is an important aspect of breast health.

Contemplation. This is the stage where individuals are aware there is a problem and are thinking about addressing it. However, they have not yet made the commitment to actually change the behavior. In this stage individuals may be aware that a high fat diet is less healthy and want to change it, but are not motivated to make the change immediately. Additionally, women in this stage may be thinking about the importance of BSE, but have not begun practicing it yet.

Preparation. This is the stage that requires more behavioral intention. Individuals are planning to take action in the next month and may have taken action unsuccessfully during the past year. In our intervention, we may recruit more women who are in this stage. They re actively thinking about changing their diet and breast health activities, but haven't taken action to change the specific behaviors.

Action. This is the stage where individuals begin to modify their behavior. It requires that overt action is taken. Individuals are in the action stage if they successfully change the behavior for a period of six months. Therefore, individuals who lower their fat and eat more fruit and vegetables, and perform monthly BSE for a period of six months would be considered in the action stage.

Maintenance. This is the stage where individuals need to work to prevent relapse. They need to work to solidify the gains they have made in the action stage. Avoiding relapse is the most important aspect of the maintenance stage.

This model was originally conceptualized as a linear process (Prochaska et al., 1992). However, it became apparent that behavior does not change in a linear fashion. Individuals can go from contemplation to preparation to action, but many will relapse before they reach maintenance. We will be sensitive to that in the delivery of our intervention. In contrast to other addictive behaviors for which the transtheoretical model has been used, we are not looking for cessation of a behavior (e.g., smoking, drinking alcohol) as much as refining and modification of behavior. We realize that knowledge and behavior acquisition are important components of change related to diet and breast health.

Chapter 8
Dietary Assessment - Mujeres Felices por ser Saludables
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Chapter 8
Dietary Assessment

8.1 Quick Check for Fat and Coronary Risk

Quick Check for Fat and Coronary Risk is a 30-item semi-quantitative food frequency questionnaire. It will be used as an **eligibility screening instrument** to identify the approximate percentage of fat being eaten by potential participants. For eligibility, the score should be 30% or greater of diet from fat since a study aim is to reduce fat intake. This is the final step of eligibility determination.

There is a discrepancy between foods named on the Spanish form and on the English form of the standard questionnaire. Since Mujeres participants will be both Spanish-primary and English-primary speakers, the Spanish form, which is more culturally appropriate, has been translated into English will be used for all potential participants

See Appendix A, Quick Check Para Grasa y Riesgos Coronariaos and English translation.

8.1.1 Quick Check Administration

During pre-screening, measurement of a participant's baseline dietary fat intake is done through an interviewer-administered quantitative brief food frequency measure, the Quick Check for Fat and Coronary Risk - Spanish version. The eligibility screener will read the questionnaire to each potential participant. A blank form will be given to the respondent in order to facilitate identification of portion size.

8.1.2 Quick Check Data Entry and Eligibility Determination

The information coded on the Quick Check questionnaire form should be entered into the computer within 2 working days of its collection, using the User's Manual provided by Nutrition Scientific as a guide. When entry is completed, the following steps will be followed:

1. Print the report to the screen. Determine % of diet from fat.
2. Fill in Eligibility Screening Form.
3. Inform participant.
4. At the end of each week, before coming to weekly project meeting, use the ASC2 command to create a data file for that week's participants. Begin each week with a new data file.

8.1.3 Citation article/Training reading

Schaefer D, Selzer RH, Rosenfield F, Darnall CJ, and Blankenhorn DH, Quick Check for Fat: a bar-coded food frequency analysis to accompany blood cholesterol screening; Nutr Metab Cardio Diseases, 174-177.

8.2 Initial Diet Survey

To be written

A Baseline Diet Survey will be collected prior to the first 24 hour recall at the Health Assessment visit...

8.3 Food Habits Questionnaire

To be written

A Food Habits Questionnaire will be collected prior to the 3rd 24 hour diet recall...

8.4 Twenty-four Hour Recall

The primary outcome measure of dietary intake in Mujeres Felices is multiple 24 hour recalls. Measurement of dietary intake in Mujeres Felices will be evaluated and compared within and between study groups. A set of three 24 hour recalls will be collected at baseline, 8 months (post-intervention), and 20 months (one-year follow-up). They are interviewer administered. During each of these time points the participants will report one face-to-face recall at the multi-hour Health Screening visit and two face-to-face recalls within two weeks and will include one weekend day.

8.4.1 Face-to-Face Recall Instructions

8.4.1.1 Prior to Visit

Prior to the interview with the participant, the Nutrition Interviewer should be sure the following items are in place and ready to go:

24 Hour Recall Form.
The interviewer should affix a label on the top of the form and fill in the interviewer's ID.

Clock.
The interviewer should assure there is a clock available to record the time of the beginning and end of the interview.

Computer.
The interviewer should run NDS 2.91. Enter into the appropriate project and press the insert key to enter a new dietary recall. The NDS prompts the participant's identification number; enter the number and name (if you know it), the "Date of intake", i.e., today's date (the date of the interview), and your interviewer ID.

Estimation Tools. The interview should assemble food models and other estimation tools to be used if not in a common area.

Tape Recorder and Tapes. The interviewer should have a tape recorder ready loaded with a cassette tape labeled with the participants ID, interviewer ID, date and visit number. An extra set of batteries should be available. The interviewer should test the tape to assure of proper functioning. (If we tape record)

8.4.1.2 Introduction to 24 Hour Recall: Health Screening Visit 1

Upon meeting the participant the interviewer should introduce herself/himself and introduce this section of the visit and relate its purpose to the study. This helps establish rapport with the participant and enlists her cooperation. Briefly review the purpose of the study and the importance of the diet information to be obtained from the participant. Explain that you intend to ask her everything she ate or drank during the previous day (from midnight to midnight). Stress that all information is confidential and reassure the participant that there is no right or wrong answer. Explain that the study aims to provide more knowledge on the relationship between diet and the risk of breast cancer. The interviewer should not speculate on which foods or nutrients are hypothesized to relate diet and cancer. The interviewer should not at any time convey remarks or non-verbal signs of judgment over the food or beverage reported by the participant. Explain and gently emphasize the importance of the participant giving **complete and accurate** dietary information. If the participant asks about the quality of her diet or food intake, tell her that at the completion of the study she will receive a dietary analysis and she can meet with a nutritionist if she prefers. **Emphasize that the interviewer is blinded (does not know which group the participant is in) and the participant should not tell to the interviewer her group assignment (applies to 8 month and 20 month interview).**

8.4.1.3 24 Hour Recall Instruction

At baseline, 8 months, and 20 month follow-up, the participant is to meet with the Nutrition Interviewer, who will collect 3 24 hour recalls. At the first recall, the interviewer will explain the recall process, demonstrate/review tools to use in determining portion size, and have the participant practice estimating portion size.

Sample Script to Prepare Participant for Dietary Data Collection (used only at Health Screening Visit 1; not for Recalls 2 and 3)

- English

"Hello (Mrs., Ms.) _____, my name is _____. In this part of your visit I'll ask you to tell me about the foods and drinks you eat. Your answers will help us learn more about how what people eat may be related to their risk of breast cancer and other medical problems. Your answers are very important to this study. They will not be shared with the staff members who teach your classes. There are no right or wrong answers. It is very important to give complete and accurate information about what you eat and drink. We want you to remember everything you ate and drank yesterday. We use several tools (show them) to help you better guess the amount you ate or drank.

"We will conduct this interview today and two more times during the next week or two. We will set up an appointment for your next two interviews before you leave today. Since people eat more on some days than on others, we do 3 interviews to get a better picture of your usual eating. If you will agree, we would like, with to tape record this part of your visit. Everything you say is confidential. The tape recording is done to help us double check if I correctly marked down the foods you told me. It is erased after that checking is done. After I record what you ate yesterday, I have few other questions to ask relating to your diet. Do you have any questions?

Spanish

"Before we start, I will explain how we can use these tools together to estimate the amounts you ate or drank."

8.4.1.3.1 Materials

The nutrition interviewer should have the following tools available when collecting the 24 hour recalls.

Portion Size Materials

NASCO model set
"authentic food" model set
standard dinner plate - white
smaller dessert plate - white
small bowl - white (marked at ___)
medium bowl - clear (marked at ___)
large bowl - clear (marked at ___)
mug - white (marked at ___)
24 ounce glass - plastic (marked at ___)
16 ounce glass - clear (marked at ___)
12 ounce glass - clear (marked at ___)
6 ounce glass - clear (marked at ___)
wine glass - clear (marked at ___)
set of measuring cups
set of measuring spoons
2 large "family style" serving spoons

Data Collection Materials

laptop or desktop computer with NDS 2.91 installed
tape recorder?
cassette tape?
"Squares and Rectangles" 2-dimensional models, clipped together
"Did we remember...?" prompting sheet
quality control forms (?)
an 18-inch ruler

8.4.1.3.2 Portion Size Practice

Briefly demonstrate how to use the amount estimation tools. Familiarize the participant with the tools to be used during the interviews.

1. Show the measuring cups, measuring spoons, serving spoons, circles, squares, and the ruler. Explain that, even if the person does not usually measure their food, you'd like them to try to picture their serving fitting into a cup, spoon, or shape. Explain the difference between "heaping" spoonfuls and level spoonfuls.

Sample Script for Portion Size Practice (Health Screening Visit 1 only)

- English	**- Spanish**
Most of us do not usually measure our food. But today we will be using measuring tools and food models to help us determine what size serving of food you ate. I will ask you to try to picture your usual serving of food and compare it to one or more of these. When you tell me you had a spoonful of food, it will be helpful if you tell me which size spoon and whether you had a level spoonful or a rounded or "heaping" spoonful.	

2. Next, show the participant a plate with NASCO food models (i.e., serving of meat, mound of potatoes and two different size servings of vegetables and a glass of water). Point out the difference in serving sizes and how a person can combine several portions to be a different size. Conversely, a person can describe a portion as "part of" one of the models.

Here is a plate with some models of food. Look at the potatoes and the vegetables. The potatoes and the [1/2 cup vegetable] are different foods but they are the same size. Now, look at the vegetables: are they the same size or different (different is correct)? If you ate a food, you might tell me it was about the same size as the [1/2 cup vegetable], about the same size as the [1/4 cup vegetable], the same size as both put together or bigger or smaller. Any size serving you ate is fine. Do you have any questions?	

3. Ask the participant to look closely at each item. Setting the plate to the side, ask the participant to use the various tools (measuring cups, measuring spoons and grid) to describe the amount of each food on the plate and water in the glass she just saw. This helps the participant understand how to use the amount estimation tools. Explain that these will be the same tools you will be using together to collect today's recall and the next two. Suggest she measure her favorite glass and bowl when she gets home to make reporting easier. Also suggest she use a measuring cup for her next few meals to give her an idea of what different portion sizes look like for the different foods she eats. This exercise also helps to identify situations where a participant is unable to explain the amounts of foods and beverages she ate or drank. After the exercise be sure the participant understands all the tools to be used when describing the amounts eaten.

Now we are going to practice. I'm going to put the plate away and will ask you to use your memory and these tools to describe how much food and drink was on the plate and in the cup. [let participant give guesses]. Okay, you've got it. When you go home today, i'd like you to measure the glass and bowls you use most often at home. You may even want to use a measuring cup at your next few meals to get an idea of what different size servings look like for the foods you eat. Do you have measuring cups at home? [If not, are we going to give them a set?]

Notify the Study Coordinator if you think there is a problem with a given participant's level of understanding. After instruction is complete, initial the tracking form and move on to using NDS to collect the diet recall.

8.4.1.4 Inquiry of Vitamin/Mineral or Other Supplement Intake

Before the actual food interview begins, you will be asking the participant if she has taken any vitamins, minerals, herbs or other supplements during the time frame of the recall. If she replies she has taken a supplement during this time frame enter it on to the Quick List as an "Other" for type of meal at the correct time(s). You will fill in details when you move to the Food Entry Screen:

8.4.1.5 Collection of 24 Hour Recall

Before collection of the 24 hour recall begins be sure to do the following:

Request Permission to Tape. After your introductory remarks, confirm that the participant agrees to tape recording of her interview. (If we decide to do this)

Record Time Recall Begins. On the 24 Hour Recall Form record the time you begin the recall.

8.4.1.5.1 Conducting the Recall

Begin by giving a brief explanation of the process of 24-hour recall.

Suggested Script for NDS Quick List for Diet Recalls

- English	***Spanish***
"What we want to do first is to make a list of **all the foods <u>and</u> beverages** that you have had in a **24-hour period** of time, a complete day. This includes all **<u>alcoholic and non-alcoholic beverages</u>**, soda, mineral water, including tap or spring water.	
"Today is Wednesday. I would like you to tell me everything you ate and drank all day Tuesday starting from Monday at midnight to midnight last night. This means if you went to bed late on Monday after midnight (for example, if you worked the late shift), and you ate or drank something before bed, you start there. If you got up in the middle of the night and had something to eat or drink, please tell me what and how much. If, on the other hand, you were asleep at midnight and slept through the night, start with the first thing you ate or drank after you woke up yesterday.	
"I would like you to tell me what time	

you had the food or drink. For example, 'at 8:00 a.m. I had this, at 10:00 I had that.

"We'll make a very general list first, then we'll go back and fill it in with more detail.

"Before we begin with your food intake, did you take any vitamins, minerals or other dietary supplement yesterday?" (ENTER ONTO QL)

Now, I'd like you to think back and remember what you did yesterday--work, take care of children, clean house, visit a friend, go shopping. Think about your activities and tell me everything you had to eat or drink on Tuesday (day of week) (ENTER QL)

The interviewer leads the participant in recalling her activities yesterday to help refresh the person's memory regarding food and beverages consumed yesterday. This information may be helpful in probing. (See **Appendix D** and **Common Items** handout for additional probing techniques.)

8.4.1.5.1.1 Using NDS

If the participant brings a food record to the interview, thank her for her effort, and then explain that you must first conduct the dietary recall because the information must be collected in the same way for all participants. Indicate you will look at the written record afterward. After the recall is complete, you may use the participant's food record for additional probing.

First ask the participant to simply list foods and beverages consumed yesterday, including the time she ate them. The interviewer simultaneously records this information on the NDS Quick List screen. (For details regarding entering foods into the NDS, refer to your NDS 3.91 User's Manual)

Following are the types of questions you ask at each screen, but this is not all inclusive.

NDS SCREEN	PROBE
QUICK LIST	"After midnight, what was the first time you had something to eat or drink?" "Did you have anything else at that time?" "What was the next time you had something to eat or drink?" At end of quick list, review list and probe for beverages and additional foods that might have been missed.
FOOD ENTRY	Next, the nutrition interviewer obtains more detail on all foods and beverages, including amount estimates. At the component 1 prompt, enter the food from the quick list. Next, component 2 prompt appears, ask, "Did you add anything to the item?" The NDS will prompt for added salt within recipes and during food preparation. However, it does not prompt for salt added at the table. Seventy-five percent of salt in American diets is from processed foods. About 10-15% of sodium comes from discretionary sources, that is salt added in cooking and at the table. If a participant indicates she added salt at the table, ask the participant to say if she salted "lightly", "medium", or "heavily" and use an F8 note; default values will be determined. Do not over probe for added salt at the table, because it is difficult for most individuals to accurately describe the amount of added salt used at the table.
FOOD DESCRIPTION	"Can you tell me more about the (item)?" "What brand was this?" "What type of (item) was it?" If a specific food item is not found in the database, press F7 and record all pertinent information about this food on the missing food screen. A missing food should not be recorded under the note (F8) function (but, if you're having trouble locating F7 it is okay). For additional information on the Missing Food screen refer to the NDS User's Manual.

AMOUNT Avoid overuse of amount estimation tools.	"Describe how much of the (item) you ate or drank. (pause first before mentioning amount estimation tools) Use whatever props you think would be helpful in your description." If an amount of food exceeds the NDS maximum amount, the NDS system prompts the question, "is this amount correct?" Check with the participant to be sure the amount is correct, if so press F8 (NOTE) and type "verified amount". This documents that although the amount exceeded the NDS limit, it is the true amount reported by the participant. If the participant uses a prop to describe the amount and that needs further calculation or conversion before entering into the NDS, press F8 and record in the note section precisely what dimensions the participant reports. After the interview has ended, convert the amount and enter it, deleting the note.
RECORD REVIEW Offer her the "Did you remember..." sheet. Think about your day again. Did you remember beverages, snacks, desserts, and food such as: coffee, tea, soft drinks, juice, beer, wine, cocktails, chips, candy nuts, pretzels, rolls, fruit muffins, crackers, cheese, cookies, cake, ice cream and pastries	It is important to carefully review the 24-hour recall record with the participant before moving on to the next part of the interview. Review each meal stating the name of the food and the amount reported. At the end of each meal, ask the participant if she can think of anything else she ate or drank at that time. When reviewing the recall make sure no information was inadvertently omitted. Explain that people often forget to include some foods, and give the "Did you remember..." cue card to the participant to read. Ask again if any of these foods listed, or any others that may come to mind, were eaten and in what amount.
END REVIEW	When you have finished reviewing the dietary recall record with the participant, press F10. A message asks if the record was reviewed. If you have not reviewed the record, enter "N" and the system returns to Record Review; if reviewed, enter "Y" and proceed with the trailer information.

Did We Remember? - Final Checklist Items Often Omitted from 24 Hour Recalls[1]

Since the foods you have described will help us work together to improve your personal health, I would like to make sure our record is as complete as possible. Here are some foods and drinks that other people often forget to mention. Let's read them now:

- Crackers, Breads, Rolls
- Tortillas, Beans, Rice
- Hot and cold cereals
- Cheese, like cheese topping on vegetables, cheese on sandwiches
- Chips, Candy, Nuts, Seeds
- Fruit eaten with meals or as a snack
- Coffee, Tea, Soft Drinks, Juices
- Beer, Wine, Cocktails, Brandy, Any other drinks made with liquor

Can you think of anything else you ate or drank yesterday that we have not mentioned?

[A]Adapted from NHANES-III Dietary Interviewer's Manual, Westat, Inc., Rockville, MD; 1992, Commonly Forgotten Foods question; pp.423-4239

RECORD TRAILER	Ask the participant if this day was typical of her intake. Answer the remaining questions shown in the trailer section silently. For visit number enter the appropriate code (see Appendix A).

8.4.1.5.2 Completing the Interview

After the interview is complete, close the screen for this 24 hour recall and immediately print the record report. Continue with the post 24 hour recall review by completing the 24 Hour Recall Tracking Form. Inform the participant her visit with the Nutrition Interviewer is complete and thank her for her cooperation. Set up an appointment for her next additional recall. After the participant leaves, initial the tracking form and proceed with the post recall review unless you have another participant immediately waiting (we will try not to let this occur).

This ends the edits for Mujeres Felices - remainder of DHS manual still needs editing.

Chapter 12
Follow-Up Contacts / Retention

12.1 Health Center Visit Schedule - Intervention Schedule

Health Center Visits	Follow-up
Baseline: Health Center Visit I	Two Diet Recalls
8-months: Health Center Visit II	Two Diet Recalls
20-months: Health Center Visit III	Two Diet Recalls

12.2 Retention Phone Calls

Mujeres Felices staff will contact participants prior to Health Center Visits and classes in order to remind them of the appointment, check on their general well-being, answer any project-related questions and assess their continued commitment to the project.

A phone log will be used in order to keep track of the participant phone contacts.

12.2.1 Phone Call Structure

Introduction. The Mujeres Felices staff will begin every call by introducing herself and stating the purpose of the call. The following is an example:

Hello, (participant's name). This is (caller's name) from Mujeres Felices - Por Ser Saludables at Erie Family Health Center. I am calling to find out how you're doing, how you're managing with the project and to answer any questions you may have. This will take 5-10 minutes. Is this a good time to talk?

Health Center Visit Reminder Call. When the purpose of the call is to remind the participant about her upcoming HCV, the Mujeres Felices staffer can simply state she is reminding the participant that her clinic visit is on _____ day and also inform her of the following information.

- Blood will be drawn at the HCV and remind the participant to fast (no food and only water to drink) from 11:00 p.m. the night prior to a visit.
- Participants should refrain from exercise for the 12 hours prior to her appointment.
- Participants should wear light clothing (underneath heavier clothing if winter) because they will be weighed and measured.
- If participant plans on bringing her children with her, the caller will ask how many and their ages.

Class Reminder Calls - Phone Chain. A phone chain will serve to remind each woman about the next class time. A list (see Table 1) will be distributed in class and used to

contact all women. In each class two or three women will be appointed to begin the phone chain; their names will be the top name in the column. These women will call the next woman on the list and remind her about the upcoming meeting time and instruct her to call the next woman on the list.

Table 1. Phone Chain

Set-up	Example
1. Lead Caller calls #2	1. Sandra H. calls Lorenza
2. 2nd caller calls #3	2. Lorenza calls Martha
3. 3rd caller calls #4	3. Martha calls Christina
4. 4th caller calls Lead Caller	4. Christina calls Sandra

There will be three lists for each class so that no chain is too long and thus vulnerable to breakage. Short lists will help to ensure that everyone is notified in a timely fashion.

12.3 Missed Appointments

If a participant misses her HCV or Diet Recall appointment, the Mujeres Felices staff should simply reschedule for another day. If a participant misses a class, she should be encouraged to attend an identical make-up class.

12.4 Retention Strategies

Retention refers to strategies and procedures used by Mujeres Felices staff to assure a participant's adherence, performance, participation and contact in the study.

Gifts

- T-shirts
- tote bags
- coupons
- magnets
- beauty products

Activities

- phone calls
- parties/outings
- reminder letters

12.5 Locating Participants

In the event that a current participant cannot be contacted after three phone calls, Mujeres Felices staff will contact a friend or relative whose number was provided on the *Health and Activities Questionnaire*.

In the event a current participant does not arrive for a scheduled appointment and the Mujeres Felices staff cannot contact her due to an unannounced move or phone number change, Mujeres Felices staff will attempt to locate the participant's new address and phone number via directory assistance or the name and number service. In the event Mujeres Felices staff are unable to locate the participant via these standard methods, they

will contact a family member or friend not living with the participant. If after the above methods are employed and Mujeres Felices staff are still unable to find the participant and she has already missed an HCV, the participant will be considered a drop-out. The statistician and/or the Principal Investigator will be contacted to determine if a substitute participant must be registered in place of the drop-out.

Chapter 13
Mujeres Felices Data Management
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Chapter 13
MUJERES FELICES Data Management

13.1 Overview

The data management protocol developed emphasizes quality control. From initial contact of the participant to analysis of results, quality control measures are implemented at the earliest possible point and at all applicable points in the process. These measures will insure data integrity.

13.2 Participant Identification and Randomization

Participants are assigned a study ID when the Eligibility Form is entered into the database. All participants who agree to begin the Eligibility Form are to be assigned an ID whther they have been found to be eligible or not.

The computer assigns a 5 digit number along with a calculated check digit that is appended on the end of the 5 digit number. The check digit is calculated from the original 5 digits. This six digit number becomes the study ID number. The program prevents access to data and data entry when an invalid ID number is used. In this way, the check digit provides a partial safety net against entering information for the wrong participant.

One point of randomization occurs during the course of the study. After the Health Interview Visit 1, if a participant is deemed eligible to participate in the study and all forms are complete and all biological samples collected for baseline, they are randomized to the control group or to the intervention group. Two conditions, which are documented on the Check-out Form, trigger the randomization: 1) The OK from the Data Editor that the data on the Health Visit form is complete 2) The OK form the Diet-Recall Interviewer that the all three diet recalls are complete. When the Check-out Form is entered and verified, the randomization takes place.

13.3 Data Identification

Labels for forms and samples are pre-printed on sheets prior to the appropriate visit. The study ID, visit, and form/biological sample identification are on each label. A participant's label sheet(s) is stored in their folder until needed. The database monitors which labels have been printed and prompts where necessary.

As each participant enters the center for a particular visit a forms packet consisting of all the forms associated with that visit is assembled and placed into a folder which accompanies the participant from station to station during the visit. Forms labels for that particular visit are taken from the participant's chart and affixed to the appropriate forms in the packet prior to the visit. Biological sample labels are included in the forms packet but will not be affixed to samples until visit time (in the event that a participant not show).

13.4 Databases

The databases are stored and managed in MS Access. There are two databases: one housing the raw data, and a second consisting of attached tables (from the raw data database), queries, forms, reports, and Access Basic code. A database management application written in Access Basic allows tracking of potential and actual participants, data entry and data verification, biological samples storage and queries, randomization assignment, intervention group tracking, and running reports and labels.

Tables for Study IDs and status, forms, tracking information, biological samples storage, and laboratory results form the data database. Explicit relationships between fields in the tables allow queries that cross more than one table, and at the same time, limit the amount of duplicated data. Direct access to these tables is limited to the data manager. All other end users have access only through forms and reports that filter access to and updating of the data.

13.5 Data Entry

Forms to be data entered are placed in the data entry bin. All forms must be edited by the center technician prior to placing the forms into data entry. Forms are edited prior to the participant leaving the center, so that any missing or incomplete data can be obtained. When editing forms, all changes are made in a different colored marker and annotated with the initials of the editor and the date the changes were made. A single line should be placed through incorrect data, and the correct value written to the side. The single line should not obscure the underlying data, but should indicate to the data entry person not to enter this value. NEVER ERASE.

On a routine and continuing basis the data entry clerk enters the forms from the folders into the database management application on the MUJERES FELICES computer. If a form is problem-free and is completely entered into the database, the form is moved to the data verification bin. When the data entry clerk discovers a problem on a form, either through manual inspection or because the data entry system rejects a particular value or form (e.g., an impossible blood pressure or weight, or an invalid condition such as a third visit before the second visit has been entered) the clerk flags the problem on the form. Problems involving the nutrition forms will be directed to the study nutritionist. Problems involving all other forms will be directed to the study coordinator.

MS Access forms (data entry screens) will be created for all data entry and updating purposes. These forms will filter invalid data using range, skip pattern, and logic checks, and update the underlying tables. As a quality control, direct data entry to tables will be prevented.

A menuing system allows the data entry person to select between data entry and data verification, and then which form(s) to enter. The application determines the "state" of

the form (partially entered, completely entered, verified) for a particular Study ID. Verification of a form not completely entered is prohibited.

Two exceptions to the above procedures follow. The biological samples collection data are data entered directly into the data entry system after processing and before being stored in freezers. The database management system assigns box numbers and slot locations, if applicable. The exact data entered is dependent on the biological sample type. In general, the following format is used. For those biological samples collected by the participants themselves, there is a set of questions answered by the participants concerning collection of the samples and is returned with the samples. State of the samples upon arrival is noted by the technician. In addition to descriptive and quality control variables, sample volumes are also entered into the database.

The status of form data entry and verification is tracked by the program. Reports specifying incomplete records are available for output.

Entry of lab results.

Lab results will arrive in three formats depending on the source. In some cases lab results will arrive on hand-written or computer generated forms with one participant's values on each page. Another format is hand-written or computer generated forms in spreadsheet format with many participant's values on one page. A third format involves computer generated data that arrives on diskette. In addition, any of these formats may be one-of-a-kind formats or routinely generated formats. One-of-a-kind formats will result from special studies that are done only once at a particular visit or on a subset of the participants.

One-of-a-kind lab results will be handled by the data manager with the help of the data entry clerk. One-of-a-kind lab results that arrive on paper will be key entered into an Excel spreadsheet by the data entry clerk and carefully proofread. The data manager will then create the appropriate database records and merge the Excel data into the database. One-of-a-kind lab results that arrive on diskette will also be merged into the database by the data manager. The procedures and methods used to handle these data will vary with the format of the data. Each batch of results will require special ad-hoc processing.

Routine lab results that arrive on diskette will be handled by standardized programs and procedures that will be written by the data manager. To the extent possible, these procedures will be automated so that the minimum of manual data entry and manipulation is required to move the data from the source diskette into the data database.

Routine lab results that arrive on paper forms will be treated like forms that originate in the center. Specialized data entry screens will be developed by the data manager to support data entry and verification. When results arrive they will be logged on a data entry manifest page in the center and sent to the data entry station to be processed in

the same manner as other batches of data entry forms. Paper forms with one participant per page will be returned to the center to be stored in the chart. Forms that have more than one participant per page will be held by the study coordinator.

Every three months the data manager will run a special report program that will print all lab results thus far obtained in a standard format with one page per participant. These pages will be filed in the chart in the center so that all lab results, whether obtained on paper or from diskettes, will be available in a single place in the chart. In this way, the chart will include all data obtained from a participant regardless of its source.

13.6 Data Verification

To insure quality in the data entry step all data, except biological samples, are entered twice. The data form is first entered and then, later, it is re-entered into a program that blinds the entry clerk from the original data values. This second step is called verification. The data entry program is designed to facilitate verification. When the data entry operator enters a different value the second time from the first, the program stops and requests a careful re-entry of the data value. In this way, casual errors in the first entry pass are corrected by the data entry clerk during the second pass.

Whenever possible, a second batch of folders should be entered before the first batch is verified to give the data entry clerk a chance to "forget" the first batch. However, to insure that the database is always as up-to-date as possible and to minimize the time a batch of forms is out of the center, all forms must be verified within 48 hours of initial data entry. The data entry clerk will verify each batch of forms in the order they were first entered.

During the verification step, the data entry clerk corrects any data fields where the first entry does not match the second. When the data entry program indicates that the value of a field has been entered differently during the verification step the data entry clerk uses careful judgment to insure that the final value entered is the correct value. From time to time the clerk will not be able to make a final decision about a value. When this happens the form will be turned over to the appropriate individual (see data entry above) for a final decision. Extra care must be given to problems at this stage as it is the last check on the data. After verification, all forms are filed in the participant's final folder.

13.7 Tracking Application

There are four stages of tracking. Three are related to recruitment and one to post-eligibility participant tracking. The first involves the pool of potential participants whose addresses already reside in the database. The list is generated from current center clients. Batch mailings and follow-up phone calls will be made. When labels for a batch are printed, the application updates the underlying table with the date of the mailing. Results from the phone calls are data entered by recruitment personnel.

Forms and reports based on user-defined queries assist recruitment personnel with this task.

The second procedure is a hand generated log tracking persons contacted who are not on the list or persons on the list to whom repeated calls were made. This list will indicate whether a person contacted agreed to complete the eligibility form. The log will indicate if call-back are scheduled, and the status of the recruitment process.

In the third stage, once a potential participant's eligibility questionnaire is filled out and entered and found eligible or refuse, their status as eligible or not is no longer tracked in stage one and two. If eligible, any data from Helath Visits is entered as above and the fourth stage will track. If a presentliy ineligible but willing potential participant might at a later date become eligible, she will continue to be traked in the stage two prcoess above.

The last group tracked will be the participants who are eligible and who have been randomized. The tracking of this group involves defining a participant's status by what data has been entered into the computer. Status reports may be run on an as-needed basis. These reports range from status counts for different time points (e.g., number of cases who have reached a certain stage in the study; number of cases to be entered, entered (partially or in full), verified, etc.) to lists of problem cases for various stages to status of individual participants.

13.8 Quality Control

When the participant is ready to leave the center the forms packet is reviewed by the study coordinator or data editor to insure completeness. Forms are inspected for the proper identification labels, blanks, ambiguous entries, and illegible values. Every effort is made to insure that the forms are complete before the participant leaves the center. The folder is also inspected to determine that all the biological samples labels for the visit have been used.

The data entry system will also provide an extensive set of audit reports detailing counts of the number of forms entered by visit and by date and a listing of all forms that remain unverified.

Quality Control Procedures for Laboratory Results.

Since all lab results will be stored in the database system, the data manager will perform statistical reporting for laboratory technical error on a routine basis. All split samples will be identified by predetermined quality control ID numbers. These numbers will be assigned at random from the list of possible ID numbers prior to the start of the study. The label packets for split sample participants will be generated on an as-needed basis. The data manager will then perform the appropriate statistical tests for technical error and will maintain a database for the assessment of laboratory drift.

All MUJERES FELICES Health Visit Interviewers, other than the Study Assistant Coordinator, who have contact with study participants are blinded from group assignments. Passwords are needed to access group assignment data within the application.

13.9 Database Backup

All data will be initially stored on a network computer. Daily backups (Monday through Friday) are made onto two separate computers. The first houses a single copy of the data for that day. The second houses five copies of the data from that day and the previous four days. At the end of each week one copy of the data is transferred to diskette and taken off site.

13.10 Analysis Data

Data from all tables will be exported to ASCII file(s) with fixed width formats or with delimiters. These data can then be read into an analysis package (e.g., SAS, SPSS) as single records consisting of all or partial data, or as multiple records depending on the needs of the analyst. SAS programs constructing permanent SAS datasets with variable labels and value formats will be used as the standard and available for modification for specialized needs.

FOCUS GROUPS

The project Mujeres Felices Por Ser Saludables/Healthy, Happy Women is a program that is aiming at changing women's behaviors and attitudes towards breast health and nutrition to try to reduce the risk of breast cancer in Hispanic/Latina women. In order to find out what the current behaviors and attitudes towards these topics are, we decided to put together focus groups. The purpose of the focus groups is to assess what are the current needs and concerns of this population in terms of breast health and nutrition.

METHODS

Procedure

We began with consulting people who had prior experience with focus groups. Unknowingly, we met with two of these people who were in fact running a focus group with us as the subjects. The conversation was on what we as Chicagoans had to say to recommend or dissuade others to move to Chicago. As the "conversation" progressed we were told we were in a focus group session. Focus Groups can happen as easily as that "conversation" took place, but usually require much more detail and preparation.

Our second step was in meeting with Eva Hernandez from Erie Family Health Center. She recommended that we invite women from the Erie area and it's surrounding neighborhoods who were already exposed to some kind of organized group. We were given group leader's names to contact. These group leaders then recommended certain people from their groups that were of Hispanic/Latina backgrounds and were between the ages of 20-40. We then called about 15-20 of these women over the phone and invited them to be part of focus groups. In calling them, we got an idea of the days and times most convenient for them. The best time for most of them was in the late afternoon. Of these women, the majority spoke more Spanish than English. Therefore, we decided to hold the focus groups in Spanish. The focus groups took place between November 1996 and January 1997. Refreshments were served at all focus group meetings. In addition, $5 Jewel Food Coupons were given to each participant as an incentive.

Subjects

We had a total of four focus groups. There were 12 women total that took part. They were between the ages of 24-44. We did allow one participant's mom to sit in and she was the oldest at the age of 64. We put together a form to that would enable us to know the demographics of our participants. Eight of the women were Mexican and 4 were Puerto Rican. Six of these women were married, 5 were single and 1 was divorced. Two women could not read and had no schooling or only a 1st grade education. Half of them had a 5th or 6th grade level education. The other three had high school education and one had 3 ½ years of college courses. The majority of the Mexican women studied in Mexico. Most of them have been in the United States for more than 5 years.

The four focus groups took place at Erie Family Health Center on a Tuesday between the hours of 4-8 p.m. They were set to take an hour and a half in time but actually went closer to 2 hours or more. We provided child care at all of them. The focus groups were either audio taped and/or videotaped. The participants all signed consent forms in order for us to videotape and audio tape. The consent forms, demographic information form , audio tapes and videotapes are all archived in one place and available for review. The first three focus groups were led by Eva Hernandez and co-led by Margarita Hernandez & Georgina De La Torre. The last focus group was led by Margarita Hernandez and co-led by Georgina De La Torre. We did have structured agendas and questions for all focus groups. (See attached)

RESULTS

Focus Group I - Summary:

These women want to learn about health issues in general, all types of cancer and of course, breast cancer. They were also concerned with colon cancer and vaginal cancer. They were under the impression that by coming to this focus group, they would be given answers to many of their questions and not that we would have questions for them.

Their knowledge and/or experience with Breast Self Examination was very limited. Out of 9 women, 5 said they knew how to do it and 4 said no. However, those that said they knew were not very sure of their knowledge. They all agreed on being comfortable with the topic. They associate cancer with pain, no treatment, and death. When they think of breast cancer, they think of removal of breast and/or death. They were not sure how age made a difference with BSE, Mammogram, cancer, etc. They felt that they receive wrong or confusing information. They heard that not breast feeding can cause breast cancer because the milk would accumulate in the breast.

They felt that diet does affect health. They recognize that it plays a role but not sure to what extent. They would like to learn healthy eating habits. They did know that diet affects their health but felt that this is mostly the case if one is overweight. They buy and cook the foods that they do because of their family , how they were raised, cultural and economic reasons. Economics seemed to play the most important role. They realize what they eat matters but they continue to eat those things because of the above factors and lack of knowledge of healthier options. They had some knowledge of the food groups, 5 a Day , eating balanced meals three times a day, and WIC programs. They felt that bad foods are fat, lard and pork meat. They raised many myths and stereotypes of typical Mexican and Puerto Rican foods. They did recognize that exercise is beneficial to their health along with healthy eating habits. They agreed that what they eat and how it is prepared are two different issues. They felt that how they prepare their food may be the problem.

Their interest and motivation on these subjects was very high. They all agreed that their favorite teaching methods are a combination of things (i.e., Videos, reading materials, breast models, breast cancer survivor). In addition, they all felt strongly that reading materials were the least favorite. Their reasons for this varied from not being able to read, language is usually too sophisticated and difficult, to simply getting bored with too much context. When given reading materials they prefer forms to be in English and Spanish on the same page. They would love to be in a project to learn more about these issues.

Other issues that came up were lack of insurance and in turn, medical care. They have more faith in doctors than other health professionals. Immigration status, social security numbers (for both Mexican and Puerto Rican women) were also concerns. They also believe that religion and family support affects their health.

Focus Group II - Summary

First a summary was given of the last focus group and the participants were asked what motivated them to come back. The reasons for coming back varied from learning more about cancer, the symptoms, techniques on BSE, early detection methods, how it varies from other diseases, to simply being informed.

Only 2 women out of 6 reported having medical insurance. Therefore, those with no insurance usually wait until they are very ill to go to a doctor. The differences between care in the United States vs. Mexico came up. In comparison to Mexico the wait is not very long and the care is better. One woman felt that people who have cancer and are treated in the US have a better chance of being cured because they are treated more quickly than in Mexico. The other difference raised was between private doctors, health centers like Erie, and hospitals. At a private doctor's office the wait is less but it costs more. In a health center, getting an appointment is even hard and the wait in the center is very long, but the cost is usually less. They also feel that in the United States one can go to a hospital and receive emergency care. Cook County Hospital was really identified as a resource for those with poor or no insurance at all. They all felt that if they had to, they would borrow money from family and/or friends, which is commonly done in Mexico. Home remedies and witchcraft also came up on the topic of treatment. All in all, in the US, they wait a couple of hours in a private doctor's office, health center or hospital. They recognize that it's a bad habit too wait until the illness is very bad and recognize that it is better to prevent such emergencies.

Other medical issues that came up were Diabetes, Leukemia, Rectal Cancer and Arthritis. They wanted to know the symptoms. They also wanted to know of resources other than Cook County.

In terms of our project, they were given handouts with the outlines of the health center visit and of the actual project. They were very hesitant to look at the outlines, therefore, we proceeded to explain thoroughly and they did start to ask questions. Questions that were raised were: Is this project free? What are the benefits? What if they find a lump on their breast? What if they miss a class? Can a friend join and be in the same group?

Overall, they felt that they would all take advantage of a project like ours. They feel that there is always more to learn. They repeated this in terms of motivating factors to coming back to each and every class. They all viewed the mail group as negative. They felt it would be "favoritism" for those picked for the classroom group. They would all like to be in the classroom group and did not seem to understand randomization or its purpose.

The best time for most is in the early evening and some said daytime. They all agreed that this depends on their families. The health center visits would be okay on Saturday mornings. The length of the classes should be about 90 minutes but no less than an hour. They again stressed that their favorite teaching method would be a little of everything with the least favorite being reading materials. The idea of report cards for the classroom group would be good. They feel that pamphlets should be developed for recruitment purposes, going to the schools, and to established groups like the ones they all belong to. They all felt that their families may or may not be supportive depending on how much of their time it would require. They would miss a class or stop coming if someone in their family got sick or if it interfered with family commitments.

Focus Group III - Summary

The third focus group was the lowest in attendance which we believe was due to the bad weather and because it was the closest to the holidays. A short summary was given and since their was a new participant, we also did short introductions. Dr. Sara Knight was also present at this focus group to observe the section on Breast Health.

Of the three participants, 1 had learned BSE in the past. She learned from her own doctor and liked being taught by her. Simply being assertive enough to ask for instruction would help anyone learn about BSE. Breast models were not introduced to any of these three participants in the past. (At this point the breast models were passed around and they each got a chance to practice on them). They all found lumps in the models. The person with prior experience to BSE found the most lumps. However, none of the three women did BSE correctly. They all felt it was somewhat fun and funny to practice on these models but did in fact believe that the models would help women learn how to recognized breast lumps. They believe that like in their case, other women will not react ashamed or embarrassed to models like these. They thought the shower reminders would be helpful.

We introduced the topic of Nutrition- Recipes and Reading Materials. These three women were all Mexican, therefore, they admitted that their favorite foods to cook

were authentic typical Mexican dishes. They believe that the food they eat in itself is healthy. However, they recognize that the way they prepare it is not good. They admit using too much fat/grease. They all follow recipes once in a while but would follow some if they were given to them. Of the examples given to them, they liked the ones with the nicest illustrations and fewer words. One stated that as long as she recognized all the ingredients in the recipe, she would follow it. The recipes with the most writing seemed more difficult, boring and it would make them less likely to try them. They would like to learn new foods of different countries, as well as different ways of preparing those from their own country. However, they did admit that their husbands and children would have great influence on this.

Other issues that came up in terms of the project as a whole, were that they felt that there is lack of information but mostly lack of interest among people in their communities. People have a hard time asking questions. They do not go for health checkups until they are very ill. Prevention of illness really needs to be identified and taught. The way they are treated somewhere either motivates someone to go back or not. Meeting new people can be a motivating factor for people to participate in our project. These women also recognized that exercise, weight and nutrition go hand in hand.

Focus Group IV- Summary

Six women were in attendance at the fourth focus group. Three were Puerto Rican and the other three were Mexican. One of the Mexican women arrived halfway through the session. In the breast health portion of the focus group, none of the women appeared to know how to do the breast self-exam even though some thought they knew. Sources of their BSE knowledge were their own doctors, TV, and magazines. The group was split on which gender of doctors they prefer to perform the breast exam with the Puerto Rican women favoring male doctors because they are more gentle and the Mexican women favoring female doctors because they have the same parts. Few women do BSE, but when they do it is only once in a while. All of the women have heard of mammography, but none of them have actually had one. Most of the women admitted to being afraid of getting one because of the pain involved. The women liked the breast models for teaching aids and agreed that a step by step BSE aid for the shower would be helpful. They also liked the idea of a calendar to remind them when to do BSE. The women commented that they preferred colorful pamphlets with illustrations in lighter colors with bigger text and that were not too long. One of the participants liked the question and answer format of one of the pamphlets.

In the nutrition segment of the group, the participants admitted that they follow recipes and like foods from different Latin cultures. They all cook for themselves and their families and are interested in getting recipes from different cultures. The women got very animated in their discussion about food and wanting to share recipes. When presented with the nutrition materials, they seemed to like the pamphlets that included both English and Spanish. They agreed that they would like more information about calories and fat, homework assignments, and exams. They liked the fat guide as well. As

far as the use of computers as a teaching guide, they seemed hesitant but thought it would be interesting as long as one woman who is not as familiar with computers is paired with one who knows more about computers.

LIMITATIONS

The women we dealt with were mostly of a low-income, low literacy group which may not be the case for all the recruited women of this project. These women were from the Erie Family Health Center neighborhoods and are in fact a sample of the women we will be dealing with in our future project. In addition, the only two ethnic groups we had involved in the focus groups were Mexican and Puerto Rican. Therefore, we cannot say what different issues are of concern to other Hispanic/Latina subgroups living in these same communities.

These focus groups were only in Spanish because we had the most request for Spanish speaking. However, we had some people who were interested but preferred an English speaking group. We had to turn them down for that reason and because we could only do one language at a time in a focus group. Whether the results would be different if they had been done in English is also an unanswered question.

SUMMARY & RECOMMENDATIONS

Despite the different obstacles, these women did give us some very important information that can guide our project to produce the intended results. The health center visits would be most beneficial to everyone, because of their possible length, if they are held on Saturday mornings and/or several days during the week. We will have to explain very thoroughly each written form so that we know everyone fully understands what they are filling out and/or signing. We need to assure all participants when doing all the questionnaire's that there are no right and wrong answers and to give us their own honest opinions. Child care needs to be assured at every health center visit, as well as classroom sessions. We may, in fact, need to offer transportation reimbursement for those who are not from the immediate Erie neighborhoods.

It needs to be made clear to these women that randomization is necessary and why. It was very evident in the focus groups that the women did not understand this process or the importance of having both groups. It should also be pointed out to them that randomization is done by a computer so that they do not feel that "favoritism" was involved in this process. Great concern needs to be given to the type and amount of information we send to the mailroom group. This group is at an immediate disadvantage because reading material clearly was the least liked method of being taught. Therefore, it will be hard to keep this group involved. We may need to focus our attention more to the type and amount of group events that we could have for them.

In terms of the classroom group, it would be of great importance to use the results of the focus groups to tailor a curriculum that is both fun and educational. The content of the sessions should be simple, focused and fun. Activities, however, should be mostly structured because there is a tendency to go off in tangents with this population. Reading materials and handouts should be tailored for lower literacy levels. We should also include families in some of the group events to help the entire family towards changing the behaviors that this project is aiming to achieve.

C. Marketing/Recruitment Material

1. Stationery
2. Brochure
3. English and Spanish Posters

Erie Family Health Center
1701 West Superior
Chicago, IL 60622
(312) 226-7245
Fax (312) 226-7382

por ser saludables

Downtown Office
303 East Ohio, Suite 550
Chicago, IL 60611
(312) 908-9537
Fax (312) 908-5010

The Healthy, Happy Women Project is a program that focuses on the health of Latina women. We want to help people in our community learn more about healthy eating habits, and how to understand breast cancer risk reduction and early detection.

If you:

- are in good health
- are between 20 and 40 years of age
- do not have diabetes or cancer
- are not pregnant or breastfeeding...

you may be eligible to participate.

Erie Family Health Center
1701 West Superior
Chicago, IL 60622
(312) 226-7245
Fax (312) 226-7282

por ser saludables

Downtown Office
303 East Ohio, Suite 550
Chicago, IL 60611
(312) 908-9537
Fax (312) 908-5010

Healthy, Happy Women

por ser saludables

Un Proyecto Para Reducir el Riesgo del Cáncer del Seno

A Project To Reduce the Risk of Breast Cancer

El Proyecto *Mujeres Felices Por Ser Saludables* es un programa que se enfoca en la salud de las mujeres latinas. Queremos ayudar a las personas en nuestra communidad a aprender más acerca de hábitos saludables de alimentación, y como entender la reducción del riesgo del cáncer del seno y la detección temprana.

Si Usted:

 goza de buena salud

 tiene entre 20 y 40 años de edad

 no tiene diabetes o cáncer

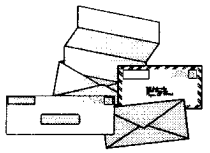
 no está embarazada o amamantando...

puede ser eligible para participar.

Habrá 2 grupos en este proyecto, un "Grupo de la Clase" y un "Grupo del Correo." La separación de grupos se va a hacer por computadora y es como una lotería o rifa. Todas las clases y actividades tomarán lugar e n el Centro de Salud Erie (1701 West Superior).

Por 2 años, mujeres en el "Grupo de la Clase" van a:

- atender clases acerca de la salud de los senos y la nutrición
- participar en actividades divertidas en el grupo
- recibir incentivos



Por 2 años, mujeres en el "Grupo del Correo" van a:

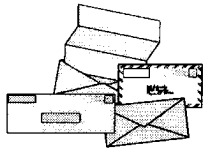
- recibir información por el correo sobre temas de salud
- participar en actividades divertidas en el grupo
- recibir incentivos

Para más información, por favor llame al 312-908-9537.

There will be 2 groups in this project, a "Classroom Group" and a "Mail Group." Assignment into one or the other group is done by computer and is similar to a lottery or drawing names from a hat. All classes and activities will take place at the Erie Family Health Center (1701 West Superior).

For 2 years, women in the "Classroom Group" will:

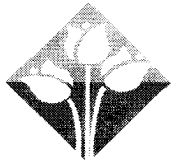
- attend classes on breast health and nutrition
- participate in fun group activities
- receive rewards and incentives



For 2 years, women in the "Mail Group" will:

- receive mail on health issues
- participate in group activities
- receive rewards and incentives

For more information, please call 312-908-9537.



Mujeres Felices

por ser saludables

Healthy, Happy Women

Join a project that focuses on the health of Latina women.

If you:

- are in good health
- are between 20 and 40 years of age
- do not have diabetes or cancer
- are not pregnant or breastfeeding...

you may be eligible to participate.

We want to help people in our community learn more about healthy eating habits and how to understand breast cancer risk reduction and early detection.

For more information, please call 312-908-9537.

Mujeres Felices

por ser saludables

¿Merece ser saludable? ¡Claro que sí!

Participe en un proyecto que se enfoca en la salud de mujeres latinas.

Si Usted:

- goza de buena salud
- tiene entre 20 y 40 años de edad
- no tiene diabetes o cáncer
- no está embarazada o amamantando...

puede participar.

Queremos ayudar a las personas en nuestra comunidad aprender más acerca de hábitos saludables de alimentación, y como entender la reducción del riesgo del cáncer del seno y la detección temprana.

Para más información, llame al 312-908-9537.

D. Data Collection Forms/Questionnaires

1. Procedures for Piloting Questionnaires
2. Greeting Consent Form
3. Status of Forms
4. Consent Forms
5. Eligibility Form
6. Blood Collection and Processing Form
7. Blood Collection and Processing Form - Quality Control
8. Anthropometric Form
9. Anthropometric Form - Quality Control
10. Breast Health Form
11. Diet Interview Form
12. Health Interview Form
13. Food Habits Questionnaire

Draft: Procedures for Piloting Questionnaires

General Outline
Should we mention piloting the narrative explanation for HCVs?

11/96 - 12/96 Health Interview was piloted

3/4/97 Breast Health Short Questionnaire and Pilot form
Kristal Questionnaire
Diet Interview

3/11/97 Breast Health Short Questionnaire and chart
Kristal Questionnaire
Diet Interview

Individual Piloting

Health Questionnaire
The Health Interview was piloted to test for a general flow of questions, comprehensibility and timing. This questionnaire was piloted with three women in their homes. The questionnaire was interviewer administered and participants were instructed that all the information would be confidential. Two women were Anglo, English speaking and the questionnaire was administered in English. The third woman was Guatemalan, bi-lingual and the questionnaire was administered in Spanish.

Results
The Health Interview was found to read well and to be comprehensible to the women who took it. The average administering time was 45 minutes.

Group Piloting

On 3/4/97 and 3/11/97 the PC, APC and RC piloted the Kristal Questionnaire, Diet Interview and Breast Health Pilot Form. All forms were piloted in Spanish with Hispanic women who live in the neighborhood around Erie. The piloting took place in the afternoon at Erie Family Health Center. Three interviewers interviewed three women simultaneously in the same room, but separated by a short distance.

Breast Health Pilot form
A shortened version of the Breast Health Form was created to test the comprehension of specific items and to see if the response choices elicited a range of responses. Numbers 4, 14 - 22, 26, 31 and 33 were included in this form.

On 3/4/97 a series of questions were asked in order to find out how the participants were internalizing the feelings described in the questionnaire. See Appendix 1 Part I and Part

II). For example, the questions would probe, When I used the word *nervous* in this item, what does that word mean to you.

On 3/11/97 these questions were replaced with two charts that allowed two participants to complete a scale with their own labels. For example, a sloped line was labeled with the numbers 1 through 5. Number 1 was labeled *Not at all Embarrassed* and number 5 was labeled *Extremely Embarrassed.* Participants were asked to rate numbers 2, 3 and 4. See Appendix 1.

Results

The shortened version of the Breast Health Questionnaire worked well. However, the series of questions that were asked on 3/4/97 along with the questionnaires did not work as well. Instead, the women seemed quite irritated by the questions. They were not able to give clear answers to the questions and resorted to saying " I don't know" type of responses. They were able to give synonyms to the terms *nervous* and *embarrassed.*

The procedure that was used on 3/11/97 of placing the terms on a chart in which they could complete a scale with their own words, worked more effectively. They understood the concept of gradation better. An interesting result of these questionnaires was that one of the women was very "judgmental" in the way she classified people in terms of the chart. Another woman felt her feelings of nervousness or embarrassment depended on the sex of the doctor. In addition, one woman felt that conflicting information is given by different doctors. The example she gave was that her doctor told her to practice BSE on a daily basis.

Kristal Questionnaire

This questionnaire was piloted in order to test comprehension of the questions and food items. Some of the food questions contain hard-to-translate items and a picture file was used to clarify items such as *no-stick spray, lunch meats and brown rice.*

Results

The Kristal Questionnaire was found to be comprehensible in general, but participants were somewhat confused on the exact meaning of the response choice *Does Not Apply* for certain items. It was decided that this questionnaire would be changed to reflect a more recent version that controls for this confusion. The newer version breaks each question into two questions and asks initially whether or not a participant eats the specified item. If participant answers *yes*, the second (original question) is asked. If participant answers *no*, the second question is skipped, therefore eliminating the *Does Not Apply* option.

After the piloting sessions, a thank-you letter was sent to each woman who participated.

Diet Interview

The Diet Interview was piloted to test participants comprehension of questions. No extra aids were necessary to administer this questionnaire.

Results

The Diet Interview was found to be comprehensible to the participants in the pilot study. After piloting, a few items were moved around to facilitate the flow of questions. Two words were changed in Spanish (stove and freezer) to reflect regional differences in language.

Conclusion

The participants' comprehension of the questionnaires was adequate. However, the interviewers found that they often needed to clarify or re-phrase certain questions. special attention should be given to keeping uniformity in administering each question.

Furthermore, the interviewers believed that the participants tried to please the interviewers with a "correct" answer.

Name/Age:_____

Date:_____

BREAST HEALTH QUESTIONNAIRE

Pilot Form

I will ask you some questions about your understanding of breast cancer screening. I will also ask you about how you use breast cancer screening techniques.

First, I will read some questions and response choices to you. There are no right or wrong answers. What you think is what we want to know about. Do you have any questions? GIVE PARTICIPANT A COPY OF THE QUESTIONS AND RESPONSE CHOICES TO LOOK AT AS YOU READ THE QUESTIONS. Here is a copy of the questions so that you can see them as I read them to you. Are you ready?

4. When was the last time you did breast self-examination (BSE)?	____One month ago or less ____Two to six months ago ____Seven to twelve months ago ____More than a year ago ____Never
14. How nervous are you about practicing BSE?	____Not at all nervous ____A little nervous ____Moderately nervous ____Quite a bit nervous ____Extremely nervous
15. How nervous do you feel about having a doctor examine your breasts?	____Not at all nervous ____A little nervous ____Moderately nervous ____Quite a bit nervous ____Extremely nervous
16. How nervous are you about having a mammogram?	____Not at all nervous ____A little nervous ____Moderately nervous ____Quite a bit nervous ____Extremely nervous

17. How nervous are you about asking your doctor questions about your breasts?	____Not at all nervous ____A little nervous ____Moderately nervous ____Quite a bit nervous ____Extremely nervous
18. How embarrassed are you about practicing BSE?	____Not at all embarrassed ____A little embarrassed ____Moderately embarrassed ____Quite a bit embarrassed ____Extremely embarrassed
19. How embarrassed are you about having a mammogram?	____Not at all embarrassed ____A little embarrassed ____Moderately embarrassed ____Quite a bit embarrassed ____Extremely embarrassed
20. How embarrassed are you about having your doctor examine your breasts?	____Not at all embarrassed ____A little embarrassed ____Moderately embarrassed ____Quite a bit embarrassed ____Extremely embarrassed
21. How embarrassed are you about asking your doctor questions about your breasts?	____Not at all embarrassed ____A little embarrassed ____Moderately embarrassed ____Quite a bit embarrassed ____Extremely embarrassed
22. I will practice BSE in the future.	____I will never practice it ____I probably will not practice it ____I probably will practice it ____I definitely will practice it

26. When or on what occasion should a woman have her breasts examined by a physician, nurse or other health care provider for the first time?	____At first intercourse ____When she first starts having her period ____When she becomes pregnant ____Less than 20 years of age ____From 20 to 30 years of age ____From 30 to 40 years of age ____From 40 to 50 years of age ____Over the age of 50 ____Only when there is a problem ____Don't know/Not sure
31. How often do you think a healthy woman your age should do a breast self-examination?	____More than once a month ____Once a month ____6 to 11 times a year ____3 to 5 times a year ____Once every year ____Once every 2 years ____Once every 3 years ____Once every 4 years ____Once every 5 years ____Only when there is a problem ____Only when pregnant ____Don't know/Not sure
33. How likely do you think it is that a breast exam performed by a physician, nurse or other health care provider can detect breast cancer?	____It cannot detect it ____It probably cannot detect it ____It probably can detect it ____It definitely can detect it

Item 14 - Part I (#2)

Tell the participant that now you would like to ask her some questions about the iems and her responses.
Dile a la participante que ahora te gustaría hacerrle algunas preguntas sobre las pregumtas y su respuestas.

When I use the word nervous in this item, what does that word /nervous/ mean to you? How would you interpret the word nervous?	Cuando uso la palabra 'nerviosa' en esta pregunta, que significa la palabra 'nerviosa' para tí? Como interpreta usted la palabra 'nerviosa'?

What are other ways to talk about how nervous a person is? (Ask the person to think about how she would describe someone who is nervous.)	Cuales otras maneras hay de hablar de que tanto alguien se siente nerviosa? (Pidele a la persona que piense de como ella describiría alguien que está nerviosa?
When you think about someone when they are nervous, how would you describe that person? How would you describe someone who is nervous about something?	Cuando piensa en alguien, cuando ella está nerviosa como describiría esa persona? Como describiría a alguien que está nerviosa?

Item 14 - Part II (#3)

Tell the participant that you are going to ask her about having nervous feelings. *Dile a la participante que le vas a hacer preguntas acerca de sentirse nerviosa.*

Some people have no nervousness at all when they practice BSE and others are as nervous as they can possibly be when they practice BSE. How would you describe someone who has only a small amount of nervousness about practicing BSE?	Algunas personas no se sienten nerviosa para nada cuando practican el auto-examen de los senos y otras personas se sienten lo más nerviosa posible. Cómo describiría a alguien que solamente se siente solo un poquito nerviosa de practicarlo?

Someone who has only a little nervousness is...
Alguien que solo se siente poquito nerviosa es....

How would you describe someone who has the most nervousness possible?	Como desribiría a alguien que se siente lo más nerviosa posible?

Someone who has the most nervousness possible is...
Alguien que se siente lo más nerviosa posible es...

How would you describe someone who falls in the middle between someone who is not nervous at all and someone who has the most nervousness possible?	Como desribiría a alguien que cae en medio entre una persona que solo se siente poquito nerviosa y alguien que se siente lo más nerviosa posible?

Item 18 - Part I (#2)

Tell the participant that now you would like to ask her some questions about the items and her responses.
Dile a la participante que ahora te gustaría hacerle algunas preguntas sobre las pregumtas y su respuestas.

When I use the word embarrassed in this item, what does that word embarrassed mean to you? How would you interpret the word embarrassed?	Cuando uso la palabra 'penoso' en esta pregunta, que significa la palabra 'penoso' para tí? Como interpreta usted la palabra 'penoso'?

What are other ways to talk about how embarrassed a person is? (Ask the person to think about how she would describe someone who is embarrassed.)	Cuales otras maneras hay de hablar de que tanta pena siente alguien? (Pidele a la persona que piense de como ella describiría a alguien que está apenada?)
When you think about someone when they are embarrassed, how would you describe that person? How would you describe someone who is embarrassed about something?	Cuando piensa en alguien, cuando ella está apenada como describiría esa persona? Como describiría a alguien que está apenada de algo?

Item 18 - Part II (#3)

Tell the participant that you are going to ask her about having feelings of embarrassment.
Dile a la participante que le vas a hacer preguntas acerca de sentir pena.

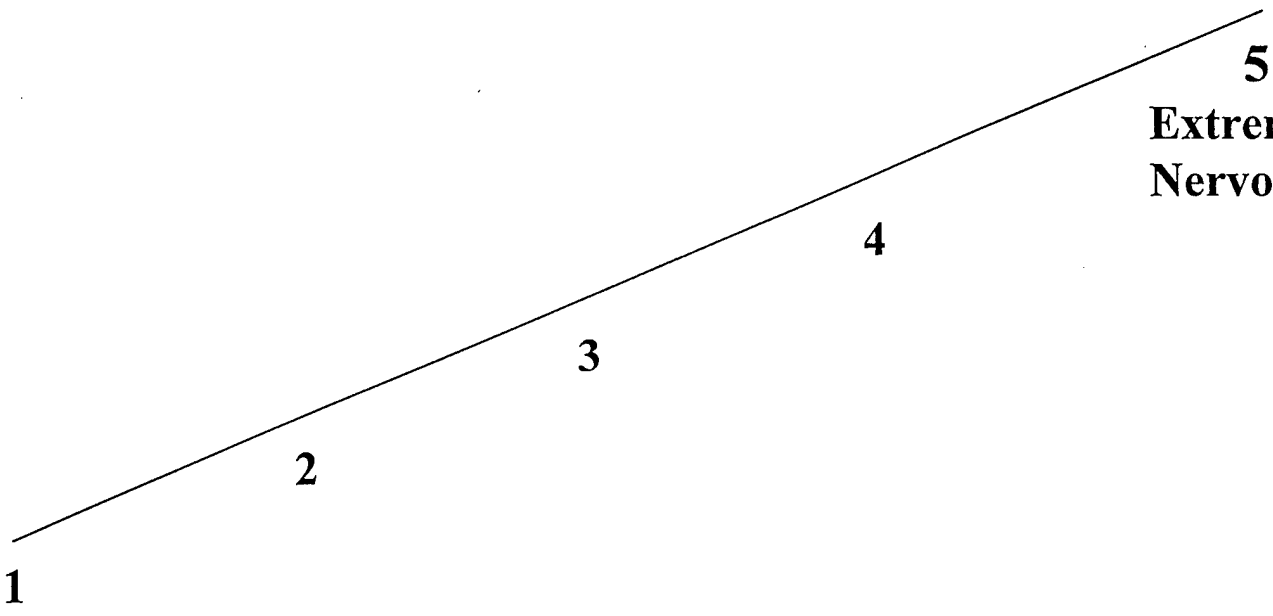
Some people have no embarrassment at all when they practice BSE and others are as embarrassed as they can possibly be when they practice BSE. How would you describe someone who has only a small amount of embarrassment about practicing BSE?	Algunas personas no sienten pena para nada cuando practican el auto-examen de los senos y otras personas sienten la más pena posible. Cómo describiría a alguien que solamente tiene poquita pena sobre practicarlo?

Someone who has only a little embarrassment is...
Alguien que solo tiene poquita pena es....

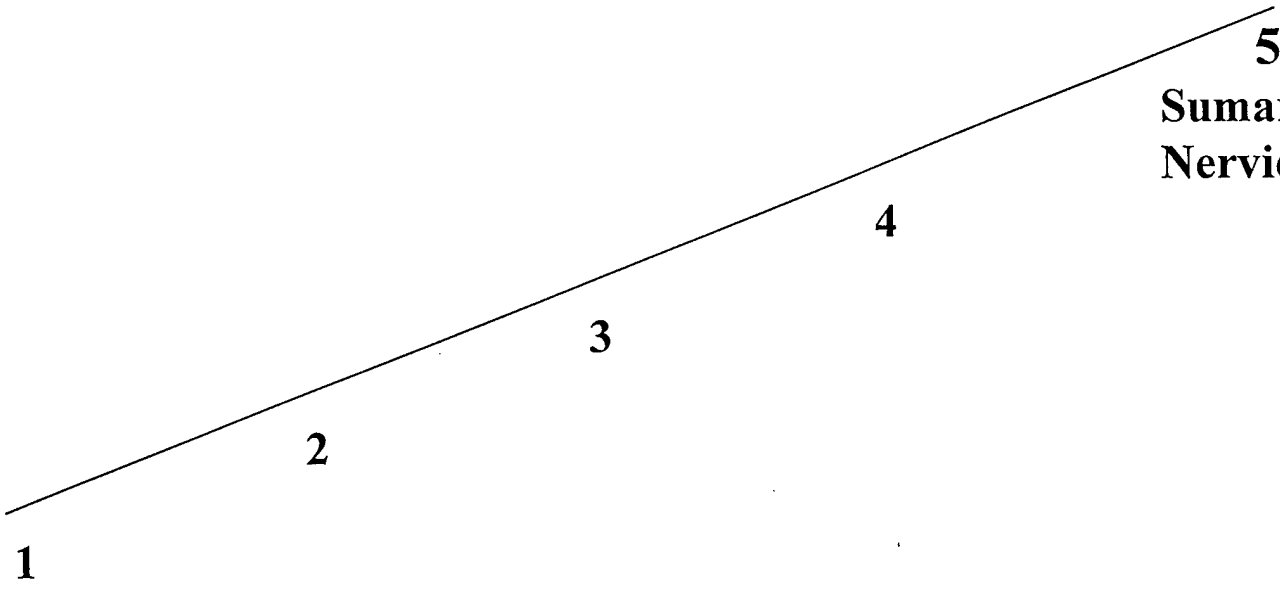
How would you describe someone who has the most embarrassment possible?	Como desribiría a alguien que tiene la más pena posible?

Someone who has the most embarrassment possible is...
Alguien que tiene la más pena posible es...

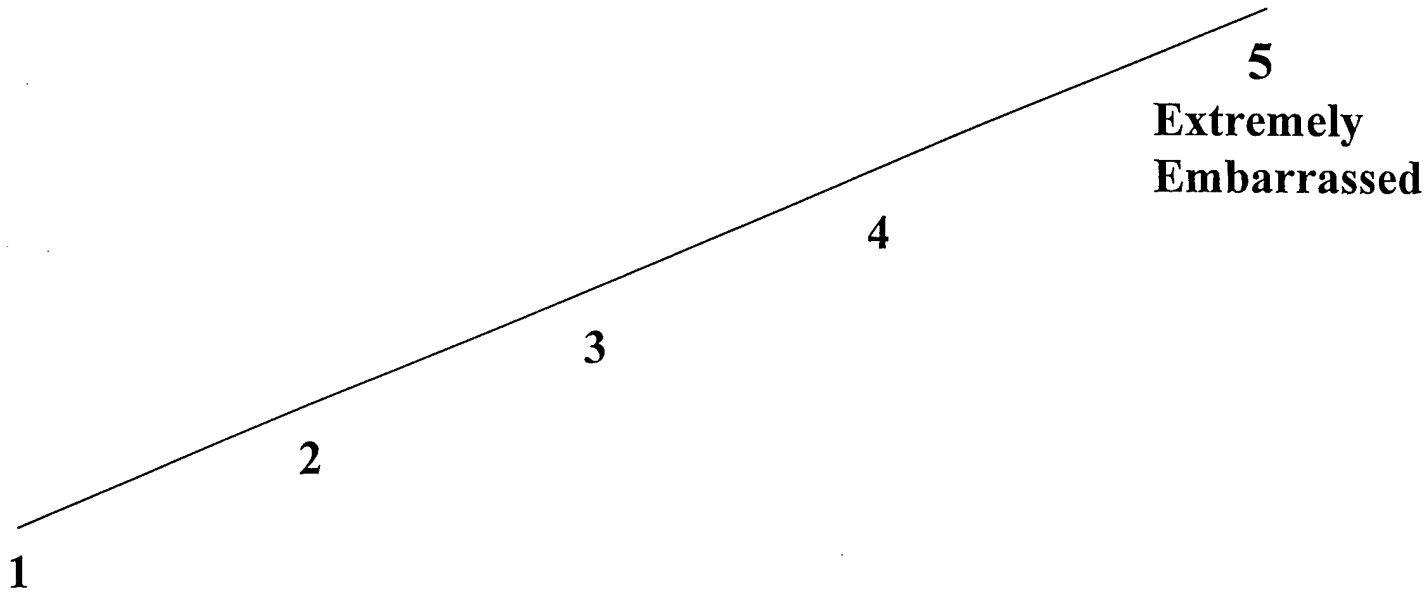
How would you describe someone who falls in the middle between someone who is not embarrassed at all and someone who has the most embarrassment possible?	Como desribiría a alguien que cae en medio entre una persona que solo tiene poquita pena y alguien que tiene la más pena posible?



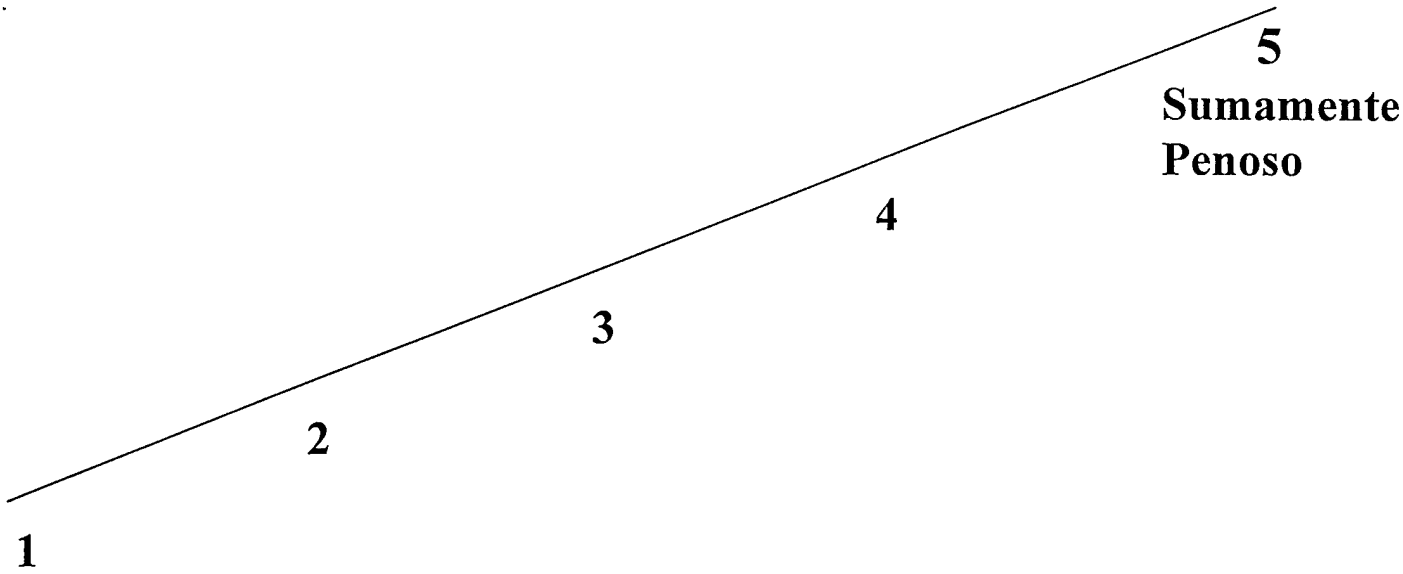
Not at all
Nervous



Nada de
Nerviosa



Not at all
Embarrassed



No es
Penoso

GREETING CONSENT

Explanation to Participant before Signing Consent Form

(FOR THIS SECTION USE THE OVERALL PROJECT PLAN HCV VISUAL AS YOU DESCRIBE THE PROJECT. POINT TO APPROPRIATE BOXES AND ICONS AS YOU EXPLAIN TO HELP PARTICIPANTS FOLLOW ALONG AND UNDERSTAND.)

Good Morning. Thank you for coming to our Health Center Visit this morning. First, I would like to tell you more about the project and I want to be sure you would like to take part in our project, ***Mujeres Felices - Por Ser Saludables***.

Now I will explain:

- The overall project plan
- Today's health center visit
- The consent form

Let's look at this page for a general picture of the project.

The first box on the chart is for today's ***Health Center Visit 1***. This is the first of three ***Health Center Visits*** that you will be attending over the next 20 months.

The next box is the ***Group Placement*** box. In the ***Group Placement*** box you see two groups. After you complete today's health center visit and your three diet interviews, you will be assigned - by chance - to either the ***Mail Group*** or to the ***Classroom Group***. This assignment will be done by a computer and no one will be able to chose who goes to which of the two groups. It is just like a lottery or drawing names from a hat. This way of assigning people to groups is typical in projects like *Mujeres Felices*, because there is a better chance of having a variety of people in each group. Also, each group will contain the same mix of people with diverse characteristics. For example, we want there to be people of different ages and jobs in each group.

Why do we divide everyone into two groups?

We want to help people in our community learn more about healthy eating habits, and how to understand breast health behavior and early detection. The only way to know if our program works, is if some people come to a classroom group and some people don't. That is why we will have two groups. Each group is very important to the project, and every women in each group is very important.

After ***Group Placement*** you will be called, or visited if you don't have a telephone, and told if you have been assigned to the ***Mail Group*** or the ***Classroom Group*** (POINT TO THE RESPECTIVE BOXES).

The first eight months of the project is called the ***Active Period.*** The year after that is called the

Follow-up period. It is not as active as the first 8 months. Now, I will tell you about what happens during the first 8 months - the Active Period - to people who are assigned to the ***Mail Group***.

(THE INFORMATION IN PARENTHESIS IS FOR CLARIFICATION ONLY AND IT SHOULD NOT TO BE READ)
In this group you will receive mail once a week for 2 months (8 times in 2 months). The mail will be on different topics, such as safety tips, health issues for you and your family, etc. Then you will receive mail once every 2 weeks for 2 months (4 times in 2 months) and finally once a month for 4 months (4 times in 4 months).

During the same 8 months that the **Mail Group** is receiving information, the **Classroom Group** will meet either here or at the *WIC Center (Women, Infant, Children Center)* to talk about healthy eating habits and about breast health. They will meet just as often as the Mail Group receives mail. First, each group will meet every week (once a week) for 8 weeks, then every 2 weeks (every other week) for 8 weeks and finally every month (once a month). Also, child care will be provided for your children free of charge at each of the sessions. Please just let us know how many children you have and their ages at least a day before the session.

Both groups will receive $5.00 Jewel gift certificates several times for participating in the project.

The final hand in each box points to ***Group Activities***. Sometime during the active 8 months, there will be special group activities for everyone in your group. Group Activities may be a party or a trip to a museum or something fun for everyone in the group.

After the first 8 months - **the active period** - you will complete the ***Health Center Visit 2*** which appears in the next box.

During the Follow-up period, if you are in the **Mail Group,** you will receive mailings every 2 months (6 times for a year) as you see in this box. If you are in the **Classroom Group,** you will meet with your group every 2 months, as you see in this box. Again, during this year, both groups will attend **Group Activities**.

Finally, after 1 year and 8 months, both groups will complete the third and last ***Health Center Visit***.

Do you have any questions before I continue?

****

Health Center Visit

(FOR THIS SECTION USE THE HCV FLOW CHART VISUAL.)
Now I will describe what you will do today at the 1st Health Center Visit.

There are 6 main stations. (POINT TO THEM AS YOU GO ALONG.)

The first box on the chart is the ***Greeting /Consent*** station. That's where you are right now. In this station the first thing you do is decide if you would like to be a participant in the project by signing the consent form. We will read it together and you can ask me any questions to help you understand the form.

After we finish here, we will collect a small blood sample from you at station 2: *Blood Draw/Body Measurements*. We will use these blood samples to measure the total cholesterol level in your blood and nutrients that are absorbed by your body from the foods that you have eaten. After the blood draw, you'll go to the ***Body Measurements*** station. Here, the health promoter will measure your height, weight, waist and hip measurements and % body fat. When you finish this station, you will receive a ***Snack*** at one of the next three stations. It is important for you to have something to eat and drink especially since you fasted all night.

In the next area there will be three stations: ***Health Interview - Breast Health Forms - Diet Interview***. The health promoter will tell you which station to go to. At each station, the health promoter is just gathering information about you, the participant. There are no wrong answers, your **best** answer is the right answer. Please remember, the computer decides your group assignment and your answers have nothing to do with this assignment.

When you complete the Diet Interview, the health promoter will schedule 2 more Diet Recalls with you for a later date. You will receive a $5.00 gift certificate for Jewel Food Stores for each Diet Recall you complete.

When you finish one of the 3 stations - stations 3, 4, or 5, you'll go to the next available station. There's no specific order for these 3 stations.

Finally, you will go to station 6 where you will turn in your folder and the health promoter will revise your forms to make sure it is complete. Then you will receive a $5.00 gift certificate for Jewel Food Stores.

Do you have any questions before I continue?

Now I will read the consent form to you and answer any questions you have.
(READ CONSENT FORM)

Do you have any questions about the consent form or the project.

Here's your folder. Inside is a check list that the health promoter will sign as you complete each station.

Mujeres Felices - Por Ser Saludables

Health Center Visit 1

Group Placement

MAIL GROUP

Active Period - 8 months

- Once a week for 2 months
- Every 2 weeks for 2 months
- Once a month for 4 months
- Group Activities

CLASSROOM GROUP

Active Period - 8 months

- Once a week for 2 months
- Every 2 weeks for 2 months
- Once a month for 4 months
- Group Activities

Health Center Visit 2
After 8 months

MAIL GROUP

Follow-Up Period - 1 year

- Every 2 months
- Group activities

CLASSROOM GROUP

Follow-Up Period - 1 year

- Every 2 months
- Group Activities

Health Center Visit 3
After 20 months

Health Center Visit

Greeting/Consent
1

Blood Draw

Body Measurements

- height
- weight
- waist/hip measurement
- % body fat

2

Snack

Health Interview

3

Breast Health Forms

4

Diet Interview

5

Turn in Folder
Check-out

6

Mujeres Felices - Por Ser Saludables

Healthy, Happy Women

- Information on a diet that may reduce the risk of breast cancer
- Information on breast health for early detection
- 16 classes over 8 months
- 6 classes in follow-up period
- Participants share ideas

Revised 12/6/96

CONSENT FORM

Project Title: Breast Cancer Risk Reduction in Hispanic Women

Principal Investigators: Marian Fitzgibbon, Ph.D.
Susan M. Gapstur, Ph.D.

Purpose: In this project women in our community will meet with health advocates to talk about diet and breast health. The purpose of the project is to learn if these educational meetings help the women in our community change their diet and other behaviors that may be related to breast cancer risk. If you want to take part in this project, please initial the first page and sign the second page.

Procedure: To participate in this project we will ask you to participate in a Health Center Visit. In the Health Center Visit you will:

- answer questions about what you eat, what you know about nutrition, what language you speak and about breast self-exam
- have your height, weight and percent body fat measured
- meet with a dietician and discuss your eating habits **and**
- have 3 tubes of blood (1 ounce/6 teaspoons) drawn from a vein in your arm.

The Health Center Visit takes about two hours and can be done at one visit or over two visits. To help us plan a better project we may need to video or audiotape some of the Health Center Visits or classroom sessions.

After you finish the Health Center Visit, you will be assigned by chance to one of two groups. (This process is very much like drawing names out of a hat.) If you are in the Mail Group you will receive mailings on a monthly basis about important health issues If you are assigned to the Classroom Group you will attend approximately 25 sessions (2 hours each) over the next two years where you will learn about changing your diet and doing breast self-exam.

Mail Group: receive mailings **Classroom Group:** approximately 25 sessions

Both Groups: Health Center Visits after 8 months and after 20 months.

Benefits: You will be paid for each of the three Health Center Visits and for your cooperation. Each participant will receive

- a $5.00 grocery coupon after each Health Center Visit.
- a $5.00 grocery coupon for completing each of the two diet interviews.

Please initial and date: Participant_____ **Witness**_____

Risk: There is a small risk that you may get a bruise or infection as a result of the blood draw. There might also be redness or inflammation. The nurses will take special care to prevent this from happening.

If you become sick or injured as a direct result of being in this project, medical care will be provided for you at McGaw Medical Center of Northwestern University. This center provides medical care for private citizens participating in projects such as this one. The benefits that have been mentioned are the only monetary benefits you will receive. However, we feel that you may learn important information about your own health. By signing this form you are not giving up your legal rights.

Confidentiality: All project records will be confidential and your name will not be used in any publications that might result. Representatives from the U.S. Army (which provides funding for the study) may inspect the results of this project as part of their responsibility to protect human subjects in research.

Your participation is voluntary and you are free to withdraw without penalty or loss of benefits (already earned). Any questions you have may be answered by Dr. Marian Fitzgibbon, 303 E. Ohio, Suite 550, Chicago, IL 60611 (312) 908-4257, or by Dr. Susan Gapstur, 680 N. Lake Shore Drive, Suite 1102, Chicago, IL 60611 (312) 908-0306.

The Office of Risk Management at Northwestern University at (847) 491-5610 can give you more information about your rights as a research participant. This is where you should report any research-related injury.

Consent: I agree to participate in the research project described above. I understand that I can receive a copy of this consent form if I ask for one.

_____ _____

Signature Date

_____

Address

_____

Social Security #

_____ _____

Witness Date

Revised 12/6/96

FORMA DE CONSENTIMIENTO

Título del estudio: Reducción de los Riesgos de Cáncer del Seno en Mujeres Hispanas

Investigadores Principales: Marian Fitzgibbon, Ph.D.
Susan M. Gapstur, Ph.D.

Propósito: En este estudio se reunirán mujeres de nuestra comunidad con ayudantes de salud para platicar sobre dieta y salud del seno. El propósito del estudio es aprender si estas reuniones educativas ayudan a las mujeres de nuestra comunidad cambiar su dieta y hábitos que pueden ser relacionados con el riesgo de cáncer del seno. Si usted quiere tomar parte en este proyecto, por favor, ponga sus iniciales en las primeras dos páginas y firme la última página.

Pasos a Seguir: Para participar en este estudio, le pedimos que tomen parte de una Visita al Centro de Salud. En la Visita al Centro de Salud, le pedimos que usted:

- conteste preguntas sobre qué come usted, qué sabe usted de la nutrición, qué idioma habla y sobre el auto-examen de los senos
- permitirnos obtener las medidas de altura, de peso y porcentage de la grasa del cuerpo
- platicar de sus hábitos de comer con una nutricionista **y**
- permitirnos obtener 3 tubos de sangre (1 onza/6 cucharitas) sacado de la vena de su brazo.

Esta Visita al Centro de Salud durará alrededor de 2 horas y se puede hacer en una visita o a través de 2 visitas. Para ayudarnos planear un proyecto mejor, quizas necesitamos grabar en video o cita parte de la Visita al Centro de Salud o las sesiones de la clase.

Después de hacer una visita clínica, su nombre será asignado (sin prejuicio) a uno de dos grupos. Este proceso es parecido a una rifa. Si usted es asignada al Grupo de Correo usted recibirá información por correo cada mes sobre temas importantes de salud. Si usted es asignada al Grupo de la Clase, usted asistirá approximadamente 25 sessiones (de dos horas) durante dos años en el cual usted aprenderá información sobre como cambiar su dieta y el auto-examen de los senos.

Grupo de Correo: recibirá información por correo **Grupo de la Clase:** 25 sesiones

Ambos Grupos: Visitas al Centro de Salud después de 8 meses y después de 20 meses.

Por favor escriba la primera inicial de su nombre y apellido al igual que la fecha:

Participante_____ **Testigo**_____

Beneficios: Usted será compensada por cada Visita al Centro de Salud y por su cooperación. Cada participante recibirá:

- un cupón de $5.00 válido en el supermercado después de la Visita al Centro de Salud.
- un cupón de $5.00 válido en el supermercado al terminar las dos entrevistas de dieta.

Riesgos: Hay un riesgo muy pequeño que resultará la extraída de sangre en un moretón o infección pequeña. Puede ser también que habrá inflamación o enrojecimiento. Las enfermeras tomarán cuidados especiales para prevenir estos resultados.

Si como resultado directo al tomar parte de este estudio usted resulta enferma o herida, servicios medicos serán otorgados en McGaw en el Centro Medico de la Universidad del Northwestern. Este centro asiste con cuidado medico a cuidadanos privadamente participando en estudios como éste. Este servicio medico y los beneficios ya mencionados son los únicos beneficios monetarios que usted recibirá. De todas formas, nosotros estamos seguros que usted obtendrá y aprenderá información muy importante de su salud. Al firmar esta forma usted no está comprometiendo sus derechos legales.

Confidencialidad: Todos los archivos de este estudio serán confidenciales y su nombre no será usada en publicaciones que puedan resultar. Representantes del ejército de los Estados Unidos (que dan fondos para el estudio) tienen derechos de revisar los resultados de este estudio como parte de su responsibilidad de proteger sujetos humanos en investigaciones.

Su participación es voluntaria y usted es libre de salir del estudio sin castigo o perder sus beneficios (ya ganados). Cualquier pregunta que usted tenga puede ser contestada por Dra. Marian Fitzgibbon, 303 E. Ohio, Suite 550, Chicago, IL 60611, (312) 908-4257, o por Dra. Susan Gapstur, 680 N. Lake Shore Drive, Suite 1102, Chicago, IL 60611 (312) 908-0306.

La Oficina de Administración de Riesgo en la Universidad de Northwestern (847) 491-5610 le puede dar más información de sus derechos como participante en investigaciones. Si como resultado de este estudio usted resulta herida, usted deberá comunicarse con esta oficina.

Consentimiento: Acepto participar en este estudio descrito arriba. Yo entiendo que puedo recibir una copia de esta FORMA DE CONSENTIMIENTO si la pido.

_____ _____

Firma Fecha

_____

Dirección

_____

Número de Seguro Social

_____ _____

Testigo Fecha

FOR OFFICE USE ONLY

Place ID label here

FORM: 101

Technician ID: ___ ___ ___

Data entry initials: ___ ___ ___

Date of interview: ___ ___ / ___ ___ / ___ ___

Verification initials: ___ ___ ___

Healthy Happy Women

Eligibility Form

Name: _____
Last First Middle

Social Security Number: ___ ___ ___ / ___ ___ / ___ ___ ___ ___

Address: _____
Street Apt #

_____
City State Zip

Home Phone: ___ ___ ___ - ___ ___ ___ - ___ ___ ___ ___

Work Phone: ___ ___ ___ - ___ ___ ___ - ___ ___ ___ ___

Preferred place to be called: *(circle one)* Home.....1 Work.....2

Please continue on next page...

SECTION A. ELIGIBILITY QUESTIONS	
1. How old are you?	___ ___ years
2. Are you pregnant?	Yes.....1 No.....2
3. Are you currently breastfeeding?	Yes.....1 No.....2
4. How long do you plan on breastfeeding?	___ ___ months
5. Have you ever been diagnosed with cancer (except skin cancer)?	Yes.....1 No.....2
6. Have you ever been diagnosed with diabetes (not when pregnant)?	Yes.....1 No.....2
7. Which group best describes your ethnic or racial background? *If other, please specify:* _____	Caucasian, not Hispanic.....1 African-American, not Hispanic.....2 Hispanic.....3 Native Am./Alask. Native.....4 Asian or Pacific Islander.....5 Other *(specify in blank to the left)*.....6

FOR OFFICE USE ONLY

Participant is eligible: Yes.....1 No.....2

If YES, have the participant complete the rest of the form.

SECTION B. ADDITIONAL QUESITONS	
8. Do you plan on becoming pregnant in the next two years?	Yes.....1 No.....2
9. How often do you drink alcohol?	Never.....1 Less than one drink per month.....2 1-3 drinks per month.....3 3-7 drinks per week.....4 7-10 drinks per week.....5 10-14 drinks per week.....6 More than 14 drinks per week.....7
10. Do you use any recreational drugs?	Yes.....1 No.....2
11. Have you ever been diagnosed with an eating disorder?	Yes.....1 No.....2
12. How many years of education have you completed?	___ ___ years
13. Do you have any children who would need a sitter if you participated in this study?	Yes.....1 No.....2
14. If you participate in this study, what language would you prefer to use?	English.....1 Spanish.....2

Comments:

FOR OFFICE USE ONLY

Participant is eligible: Yes.....1 No.....2

If YES, have the participant complete the **Quick Check** for fat.

FOR OFFICE USE ONLY

Place ID label here

FORM: 103

Technician ID: ___ ___ ___

Data entry initials: ___ ___ ___

Date of interview: ___ ___ / ___ ___ / ___ ___

Verification initials: ___ ___ ___

Healthy Happy Women

Blood Collection and Processing Form: Baseline, 8 months, 20 months

1. Has the participant had anything to eat or drink other than water in the last 12 hours, including gum or candy? *If yes, please specify*: _____ _____	Yes.....1 No.....2 *(If Yes, specify in blank to the left)*
2. What was the first day of the participant's last period?	___ ___ / ___ ___ / ___ ___ month day year
3. Was blood collected at this visit?	Yes.....1 No.....2 *(IF YES, SKIP TO QUESTION #5)*
4. Why was blood not collected? *If other, please specify:* _____ _____	Vein problem.....1 Patient refused.....2 Patient fainted or became ill.....3 Other *(specify in blank to the left)*.....4

5. What time was the sample collected?	____ ____ : ____ ____ (24 hour clock)
6. What time was the sample centrifuged?	____ ____ : ____ ____ (24 hour clock)
7. What time was the sample placed in the freezer at Erie?	____ ____ : ____ ____ (24 hour clock)

Serum	Aliquot #	Box	Slot Number	Volume
Serum - 1.0 #1	1	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #2	2	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #3	3	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #4	4	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #5	5	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #6	6	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #7	7	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #8	8	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #9	9	____ ____ ____ ____	____	____ . ____

FOR OFFICE USE ONLY

Place ID label here

FORM: 103q

Technician ID: ___ ___ ___

Data entry initials: ___ ___ ___

Date of interview: ___ ___ / ___ ___ / ___ ___

Verification initials: ___ ___ ___

Healthy Happy Women

Blood Collection and Processing Form: Baseline, 8 months, 20 months

Quality Control

1. Has the participant had anything to eat or drink other than water in the last 12 hours, including gum or candy? *If yes, please specify*: _____ _____	Yes.....1 No.....2 *(If Yes, specify in blank to the left)*
2. What was the first day of the participant's last period?	___ ___ / ___ ___ / ___ ___ month day year
3. Was blood collected at this visit?	Yes.....1 No.....2 *(IF YES, SKIP TO QUESTION #5)*
4. Why was blood not collected? *If other, please specify:* _____ _____	Vein problem.....1 Patient refused.....2 Patient fainted or became ill.....3 Other *(specify in blank to the left)*.....4

5. What time was the sample collected?	____ ____ : ____ ____ (24 hour clock)
6. What time was the sample centrifuged?	____ ____ : ____ ____ (24 hour clock)
7. What time was the sample placed in the freezer at Erie?	____ ____ : ____ ____ (24 hour clock)

Serum	Aliquot #	Box	Slot Number	Volume
Serum - 1.0 #1	1	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #2	2	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #3	3	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #4	4	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #5	5	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #6	6	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #7	7	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #8	8	____ ____ ____ ____	____	____ . ____
Serum - 1.0 #9	9	____ ____ ____ ____	____	____ . ____

FOR OFFICE USE ONLY

Place ID label here

FORM: 104

Technician ID: ___ ___ ___

Data entry initials: ___ ___ ___

Date of interview: __ __ / __ __ / __ __

Verification initials: ___ ___ ___

Healthy Happy Women

Anthropometric Form: Baseline, 8 months, 20 months

1. Height	___ ___ . ___ inches
2. Weight	___ ___ ___ . ___ pounds
3. Waist circumference (measure twice)	___ ___ ___ . ___ inches ___ ___ ___ . ___ inches
4. Hip circumference (measure twice)	___ ___ ___ . ___ inches ___ ___ ___ . ___ inches
5. Percent body fat (obtain from body fat machine report and staple to back of this form)	___ ___ . ___ %
6. Was this protocol modified in any way? If yes, please explain _____ _____	Yes.....1 No.....2

FOR OFFICE USE ONLY

Place ID label here

FORM: 104q

Technician ID: ___ ___ ___

Data entry initials: ___ ___ ___

Date of interview: __ __ / __ __ / __ __

Verification initials: ___ ___ ___

Healthy Happy Women

Anthropometric Form: Baseline, 8 months, 20 months

Quality Control

1. Height	___ ___ . ___ inches
2. Weight	___ ___ ___ . ___ pounds
3. Waist circumference (measure twice)	___ ___ ___ . ___ inches ___ ___ ___ . ___ inches
4. Hip circumference (measure twice)	___ ___ ___ . ___ inches ___ ___ ___ . ___ inches
5. Percent body fat (obtain from body fat machine report and staple to back of this form)	___ ___ . ___ %
6. Was this protocol modified in any way? If yes, please explain _____ _____	Yes.....1 No.....2

FOR OFFICE USE ONLY	
FORM: 107	Place ID label here
Technician ID: ___ ___ ___	Data entry initials: ___ ___ ___
Date of interview: ___ ___ / ___ ___ / ___ ___	Verification initials: ___ ___ ___

Healthy Happy Women

Breast Health Form: Baseline, 8 months, 20 months

INTRODUCTION: At this station I will ask you questions about your understanding of breast cancer screening. I will also ask you about how you use breast cancer techniques. First, I will read some questions and response choices to you and then I would like you to select the response choice that best shows what you think or what you do. There are no right or wrong answers. What you think is what we want to know about. Do you have any questions?

1. Have you ever heard of breast self-examination (BSE)?	Yes.....1 No.....2 Not sure/doesn't know.....3 *(IF NO OR NOT SURE, SKIP TO QUESTION #5)*
2. Have you ever practiced breast self-examination (BSE) before?	Yes.....1 No.....2 Not sure/doesn't know.....3
3. In the last year, how often did you perform breast self-examination (BSE)? *SHOW CARD A*	More than once a month.....1 Once a month.....2 Every few months.....3 One or two times per year.....4 Not at all in the last year.....5

4. When was the last time you did breast self-examination (BSE)? *SHOW CARD B*	One month ago or less.....1 Two to six months ago.....2 Seven to twelve months ago.....3 More than a year ago.....4 Never.....5
5. Have you ever heard of a breast exam that is performed by a physician, nurse, or other health provider?	Yes.....1 No.....2 Not sure/doesn't know.....3
6. Has a doctor or nurse ever examined your breasts before?	Yes.....1 No.....2 Not sure/doesn't know.....3 *(IF NO OR NOT SURE, SKIP TO QUESTION #8)*
7. When was the last time a doctor or nurse examined your breasts? *SHOW CARD C*	One year ago or less.....1 One to two years ago.....2 Three to four years ago.....3 Five to six years ago.....4 More than six years ago.....5

8. Have you ever heard of a mammogram?	Yes.....1 No.....2 Not sure/doesn't know.....3 *(IF NO OR NOT SURE, SKIP TO QUESTION #11)*
9. Have you ever had a mammogram before?	Yes.....1 No.....2 Not sure/doesn't know.....3 *(IF NO OR NOT SURE, SKIP TO QUESTION #11)*
10. When did you last have a mammogram? *SHOW CARD C*	One year ago or less.....1 One to two years ago.....2 Three to four years ago.....3 Five to six years ago.....4 More than six years ago.....5
11. When was the last time a doctor or nurse talked with you about your breasts or the early detection of breast cancer? *SHOW CARD C*	One year ago or less.....1 One to two years ago.....2 Three to four years ago.....3 Five to six years ago.....4 More than six years ago.....5

12. In the last five years, how many times have you asked your doctor or nurse questions about your breasts? *SHOW CARD D*	Not at all.....1 One or two times.....2 Three to five times.....3 More than five times.....4
13. How worried are you about breast cancer? *SHOW CARD E*	Not at all worried.....1 A little worried.....2 Moderately worried.....3 Very worried.....4 Extremely worried.....5
14. How nervous are you about practicing breast self-examination (BSE)? *SHOW CARD F*	Not at all nervous.....1 A little nervous.....2 Moderately nervous.....3 Very nervous.....4 Extremely nervous.....5
15. How nervous are you about having a doctor or nurse examine your breasts? *SHOW CARD F*	Not at all nervous.....1 A little nervous.....2 Moderately nervous.....3 Very nervous.....4 Extremely nervous.....5

16. How nervous are you about having a mammogram? *SHOW CARD F*	Not at all nervous.....1 A little nervous.....2 Moderately nervous.....3 Very nervous.....4 Extremely nervous.....5
17. How nervous are you about asking your doctor or nurse questions about your breasts? *SHOW CARD F*	Not at all nervous.....1 A little nervous.....2 Moderately nervous.....3 Very nervous.....4 Extremely nervous.....5
18. How embarrassed are you about practicing breast self-examination (BSE)? *SHOW CARD G*	Not at all embarrassed.....1 A little embarrassed.....2 Moderately embarrassed.....3 Very embarrassed.....4 Extremely embarrassed..... 5
19. How embarrassed are you about having a mammogram? *SHOW CARD G*	Not at all embarrassed.....1 A little embarrassed.....2 Moderately embarrassed.....3 Very embarrassed.....4 Extremely embarrassed..... 5

20. How embarrassed are you about having your doctor examine your breasts? *SHOW CARD G*	Not at all embarrassed.....1 A little embarrassed.....2 Moderately embarrassed.....3 Very embarrassed.....4 Extremely embarrassed..... 5
21. How embarrassed are you about asking your doctor questions about your breasts? *SHOW CARD G*	Not at all embarrassed.....1 A little embarrassed.....2 Moderately embarrassed.....3 Very embarrassed.....4 Extremely embarrassed..... 5
22. I will practice breast self-examination (BSE) in the future. *SHOW CARD H*	I <u>never</u> will.....1 I probably will <u>not</u>.....2 I probably will .....3 I definitely will.....4
23. I will have a doctor examine my breasts in the future. *SHOW CARD H*	I <u>never</u> will.....1 I probably will <u>not</u>.....2 I probably will .....3 I definitely will.....4
24. I will have a mammogram in the future. *SHOW CARD H*	I <u>never</u> will.....1 I probably will <u>not</u>.....2 I probably will .....3 I definitely will.....4

25. Would you find it very hard or even refuse to have your breasts examined if only a male doctor or nurse were available?	Yes.....1 No.....2
26. When or on what occasion should a woman have her breasts examined by a physician, nurse, or other health care provider for the first time? *SHOW CARD I*	At first intercourse.....1 When she starts having her period.....2 When she becomes pregnant.....3 Less than 20 years of age.....4 From 20 to 30 years of age.....5 From 31 to 40 years of age.....6 From 41 to 50 years of age.....7 Over the age of 50.....8 Only when there is a problem.....9 Don't know / not sure.....10
27. How often do you think a healthy woman your age should have her breasts examined by a physician, nurse, or other health care provider? *SHOW CARD J*	More than once a year.....1 Once every year.....2 Once every 2 years.....3 Once every 3 years.....4 Once every 4 years.....5 Once every 5 years.....6 Only when there is a problem.....7 Only when pregnant.....8 Don't know / not sure.....9

28. When or on what occasion should a woman have her first mammogram? *SHOW CARD I*	At first intercourse.....1 When she starts having her period.....2 When she becomes pregnant.....3 Less than 20 years of age.....4 From 20 to 30 years of age.....5 From 31 to 40 years of age.....6 From 41 to 50 years of age.....7 Over the age of 50.....8 Only when there is a problem.....9 Don't know / not sure.....10
29. How often do you think a healthy woman your age should have a mammogram? *SHOW CARD J*	More than once a year.....1 Once every year.....2 Once every 2 years.....3 Once every 3 years.....4 Once every 4 years.....5 Once every 5 years.....6 Only when there is a problem.....7 Only when pregnant.....8 Don't know / not sure.....9

30. When or on what occasion should a woman start doing breast self-examination (BSE)? *SHOW CARD I*	At first intercourse.....1 When she starts having her period.....2 When she becomes pregnant.....3 Less than 20 years of age.....4 From 20 to 30 years of age.....5 From 31 to 40 years of age.....6 From 41 to 50 years of age.....7 Over the age of 50.....8 Only when there is a problem.....9 Don't know / not sure.....10
31. How often do you think a healthy woman your age should do a breast self-examination (BSE)? *SHOW CARD K*	More than once a month.....1 Once a month.....2 6 to 11 times a year.....3 3 to 5 times a year.....4 Once every year.....5 Once every 2 years.....6 Once every 3 years.....7 Once every 4 years.....8 Once every 5 years.....9 Only when there is a problem.....10 Only when pregnant.....11 Don't know / not sure.....12

For questions #32-#37, please answer "Yes" or "No" as to whether the following symptom(s) or physical sign(s) might indicate that a woman has breast cancer.	
32. Lump in the breast	Yes.....1 No.....2
33. Bleeding from nipples	Yes.....1 No.....2
34. Discharge from nipples	Yes.....1 No.....2
35. Pain or tenderness in breast area	Yes.....1 No.....2
36. Hardness in breast(s)	Yes.....1 No.....2
37. Dimpling on or around breast(s)	Yes.....1 No.....2
38. How likely do you think it is that a breast exam performed by a physician, nurse, or other health care provider can detect breast cancer? *SHOW CARD L*	Never will.....1 Probably will not.....2 Probably will .....3 Definitely will.....4
39. How likely do you think it is that a mammogram can detect breast cancer? *SHOW CARD L*	Never will.....1 Probably will not.....2 Probably will .....3 Definitely will.....4
40. How likely do you think it is that breast self-examination (BSE) can detect breast cancer? *SHOW CARD L*	Never will.....1 Probably will not.....2 Probably will .....3 Definitely will.....4

FOR OFFICE USE ONLY	
FORM: 108	Place ID label here
Technician ID: ___ ___ ___	Data entry initials: ___ ___ ___
Date of interview: __ __ / __ __ / __ __	Verification initials: ___ ___ ___

Healthy, Happy Women

Diet Interview Form: Baseline

INTRODUCTION: I'd like to ask you about foods you eat. We are going to begin with some questions about shopping, cooking, and food, then we will talk about the types and amounts of foods you ate and drank yesterday. That is called a 24 Hour Food Recall (remembering).

1. Do you usually do the food shopping for your household?	Yes.....1 No.....2 *(IF YES, SKIP TO QUESTION #3)*
2. Who usually does the food shopping for your household? *SHOW CARD A* *If other, please specify:*_____	Grandmother.....1 Mother.....2 Sister/Sister-in-law.....3 Daughter.....4 Husband.....5 Other *(specify in blank to the left)*.....6
3. Do you usually do the cooking for your household?	Yes.....1 No.....2 *(IF YES, SKIP TO QUESTION #6)*

4. Who usually does the cooking for your household? *SHOW CARD A* *If other, please specify:* _____	Grandmother.....1 Mother.....2 Sister/Sister-in-law.....3 Daughter.....4 Husband.....5 Other *(specify in blank to the left)*.....6
5. Do you know how (*the person who does most cooking*) prepares most of the meals -- what kinds of ingredients does he or she use?	Yes, usually.....1 No.....2 Sometimes or not sure.....3
6. In your job, do you work in any way with food? *(for example, in a restaurant, grocery store, food service department, or any position in which you prepare or cook food)*	Yes.....1 No.....2
7. Do you usually make your own sauces or do you usually buy canned or bottled sauces? Examples include salsa, sofrito, mole, enchilada sauce. *SHOW CARD B*	Usually make.....1 About half make and half buy.....2 Usually buy.....3 Not sure/no answer.....4 Hardly ever use this type of food.....5
8. Has a doctor ever told you that you are allergic to any foods?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #10)*

9. What foods are you allergic to? *SHOW CARD C* *If other, please specify:* _____	Peanuts.....1 Corn.....2 Milk or other dairy.....3 Fish.....4 Eggs.....5 Wheat.....6 Other *(specify in blank to the left)*.....7
10. Are you on a special diet for health reasons?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #19)*
What kind of diet is it? **11.** Low fat	Yes.....1 No.....2
12. Low cholesterol	Yes.....1 No.....2
13. Low calorie/weight loss	Yes.....1 No.....2
14. Low salt/sodium (for blood pressure)	Yes.....1 No.....2
15. Diabetes	Yes.....1 No.....2
16. Vegetarian	Yes.....1 No.....2
17. Weight gain	Yes.....1 No.....2

Please continue this section on the next page...

18. Other *(please specify)*_____ _____	Yes.....1 No.....2
19. Are you on a special diet for religious reasons? *(please specify)*_____ _____	Yes.....1 No.....2
Now I'm going to ask you about what you eat prepared away from home, for example, at restaurants, taquerias, carryout or fast food places.	
20. How many times a week do you eat breakfast at a fast food restaurant (for example, Dunkin' Donuts, White Hen, McDonalds)?	_____
21. How many times a week do you eat lunch at a fast food restaurant?	_____
22. How many times a week do you eat dinner at a fast food restaurant?	_____

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Place ID label here

FORM: 105

Technician ID: ___ ___ ___

Data entry initials: ___ ___ ___

Date of interview: __ __ / __ __ / __ __

Verification initials: ___ ___ ___

Healthy Happy Women

Health Interview Form: Baseline

INTRODUCTION: During this interview I will ask you about your birthdate, education, medical history and other important factors. As we move through the interview, you may remember information about a question we have already completed or that a date is incorrect. Please feel free to interrupt me at any time to make corrections or additions. Again, let me assure you that all the information you provide will be kept confidential.

SECTION A. BACKGROUND INFORMATION: First I am going to ask you some questions about your birthdate, education and other background information.	
1. What is your birthdate?	___ ___ / ___ ___ / ___ ___ mo day year
2. Where were you born?	
City: _____	___ ___ code
State: _____	___ ___ code
Country: _____	___ ___ code
3. How many years have you lived in the United States?	___ ___ years

Please continue this section on the next page...

4. What was the highest grade of school that you completed? ***SHOW CARD A***	1 - 4 years.....1 5 - 8 years.....2 9 - 10 years.....3 11 - 12 years.....4 High school graduate.....5 Vocational beyond H.S.....6 Some college, not graduate.....7 College graduate.....8 Graduate/prof. school.....9
5. In what country did you complete your highest grade in school? *If other, please specify:*_____	United States.....1 Mexico.....2 Puerto Rico.....3 Cuba.....4 Central America (other than Mexico)...5 Other *(specify in blank to the left)*.....6
6. Which category best describes your primary occupation? *SHOW CARD B* *If other, please specify:*_____	Work full-time outside home.....1 Work part-time outside home.....2 Home-based occupation.....3 Not employed.....4 Other *(specify in blank to the left)*.....5

7a. At your current or most recent job, what kind of work do (did) you do? _____ *Job title*	
7b. What are (were) your most important activities? _____ (For example: patient care, directing hiring policies, supervising order clerks, operating grinding mill)	____ subject's occfacts code
8. What is your marital status?	Single/Never married.....1 Married.....2 Widowed.....3 Separated.....4 Divorced.....5 *(IF NOT MARRIED, SKIP TO QUESTION #12)*
9. What was the highest grade of school that your spouse completed? *SHOW CARD A*	1 - 4 years.....1 5 - 8 years.....2 9 - 10 years.....3 11 - 12 years.....4 High school graduate.....5 Vocational beyond H.S.....6 Some college, not graduate.....7 College graduate.....8 Graduate/prof. school.....9

10. Which category best describes your spouse's primary occupation? *SHOW CARD B* *If other, please specify:*_____	Work full-time outside home.....1 Work part-time outside home.....2 Home-based occupation.....3 Not employed.....4 Other *(specify in blank to the left)*.....5
11a. At your spouse's current or most recent job, what kind of work does (did) he do? _____ *Job title*	
11b. What are (were) his most important activities? _____ (For example: patient care, directing hiring policies, supervising order clerks, operating grinding mill)	_____ spouse's occfacts code
12. Do you currently participate in any regular activity program (either on your own or in a class) designed to improve or maintain your physical fitness?	Yes.....1 No.....2
13. On average, how many hours a day do you watch television?	____ ____ hours

SECTION B. MEDICAL HISTORY: This next section asks questions about certain health related conditions or surgical procedures you may have had. Have you ever been told by a **doctor** that you have any of the following conditions?	
	circle one response below
14. High blood pressure	Yes.....1 No.....2
15. High blood cholesterol	Yes.....1 No.....2

16. Heart disease (e.g., heart attack)	Yes.....1 No.....2
17. Hepatitis	Yes.....1 No.....2
18. Cirrhosis of the liver	Yes.....1 No.....2
19. Gall bladder disease	Yes.....1 No.....2
20. Irritable bowel syndrome	Yes.....1 No.....2
21. Rectal/colon polyps	Yes.....1 No.....2
22. Bladder/kidney disease	Yes.....1 No.....2
23. Sugar diabetes	Yes.....1 No.....2
24. Thyroid disease	Yes.....1 No.....2
25. Benign breast lumps/fibrocystic breasts	Yes.....1 No.....2
26. Other *(please specify)*_____	Yes.....1 No.....2

SECTION C. MEDICATION USE: Now I am going to ask you about your medication use in the last month.	
In the **LAST MONTH** have you used any of the following medications on a regular basis, that is **4 or more times per week for at least two weeks?**	
	circle one response below
27. Antibiotics	Yes.....1 No.....2
28. Isoniazid/Rifampin (i.e., for tuberculosis infection)	Yes.....1 No.....2

29. Thyroid medication	Yes.....1 No.....2
30. Phenobarbitol (or other barbiturates)	Yes.....1 No.....2
31. Fiber supplement (e.g., Metamucil)	Yes.....1 No.....2
32. Anti-depressant medication (e.g., Zoloft, Prozac)	Yes.....1 No.....2
33. Sedative or sleep medication (e.g., Valium, Xanax)	Yes.....1 No.....2
34. Diabetes medication (insulin or other drug)	Yes.....1 No.....2
35. Allergy medication	Yes.....1 No.....2
36. Aspirin or other anti-inflammation/pain reliever (e.g., Ibuprofen, Naproxen)	Yes.....1 No.....2
37. Blood pressure medication	Yes.....1 No.....2
38. Laxatives	Yes.....1 No.....2
39. There are some providers of health care that we sometimes go to, such as curanderos, sobadores, herbalists, spiritualists, and others. Have you seen or talked to any of these persons for health care in the last 12 months?	Yes.....1 No.....2

Please continue onto the next section...

SECTION D. MENSTRUAL HISTORY: The next set of questions is about your menstrual history.	
40. How old were you when you menstruated for the first time?	___ ___ years old
41. Currently, on average, how many days are there between your menstrual periods, starting with the first day of your period up to, but not including, the first day of your next period? Estimate as closely as you can, to the day. *SHOW SUBJECT THE CALENDAR TO HELP COUNT THE DAYS*	___ ___ days
42. Are you currently taking oral contraceptives?	Yes.....1 No.....2 *(IF YES, SKIP TO QUESTION # 46)*
43. Have you taken oral contraceptives in the last 12 months?	Yes.....1 No.....2
44. Are you currently using other hormones for birth control (e.g., Depo-Provera, Norplant)?	Yes.....1 No.....2 *(IF YES, SKIP TO QUESTION # 46)*
45. Have you taken other hormones for birth control in the past 12 months?	Yes.....1 No.....2

SECTION E. PREGNANCY HISTORY: The next section of the interview concerns your pregnancy history. Because pregnancy may affect hormone levels, it is important that we have this information.	
46. Have you ever tried for at least one straight year to become pregnant, and during that time **not** become pregnant?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #49)*
47. Did you or your partner ever visit a doctor because you had trouble getting pregnant?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #49)*

48. What is the reason you had a problem getting pregnant? *SHOW CARD C*	Problems with ovaries.....1 Problem with Fallopian tubes.....2 Problem with uterus/cervix.....3 Partner had problem.....4 Other fertility problem.....5 No problem found.....6 Don't know.....7
49. Have you ever been pregnant? (Including: live births, stillbirths, miscarriages, ectopic pregnancies and induced abortions)	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #60)*

Now I'm going to ask you some detailed questions about each of your pregnancies **STARTING WITH YOUR FIRST PREGNANCY:**

What was the month and year your ... pregnancy ended?	How many months did the ... pregnancy last?	Was the outcome of the ... pregnancy a live birth?	*IF LIVE BIRTH* How many months did you breastfeed?
		circle one response below	
50. __ __ / __ __ mo year	__ __ . __	Yes.....1 No..... 2	__ __ . __
51. __ __ / __ __ mo year	__ __ . __	Yes.....1 No..... 2	__ __ . __
52. __ __ / __ __ mo year	__ __ . __	Yes.....1 No..... 2	__ __ . __
53. __ __ / __ __ mo year	__ __ . __	Yes.....1 No..... 2	__ __ . __
54. __ __ / __ __ mo year	__ __ . __	Yes.....1 No..... 2	__ __ . __

55. __ __ / __ __ mo year	__ __ . __	Yes.....1	No..... 2	__ __ . __
56. __ __ / __ __ mo year	__ __ . __	Yes.....1	No..... 2	__ __ . __
57. __ __ / __ __ mo year	__ __ . __	Yes.....1	No..... 2	__ __ . __
58. __ __ / __ __ mo year	__ __ . __	Yes.....1	No..... 2	__ __ . __
59. __ __ / __ __ mo year	__ __ . __	Yes.....1	No..... 2	__ __ . __

SECTION F. WEIGHT HISTORY: Please answer the following questions about your weight history.	
60. What was your lowest weight since age 18?	___ ___ ___ lbs.
61. What was your heaviest weight since age 18?	___ ___ ___ lbs.
62. What is your desired weight?	___ ___ ___ lbs.

SECTION G. SMOKING: This section asks questions about your smoking history. Some of the following questions may not apply to you.	
63. Have you ever smoked cigarettes on a regular basis, that is, more than 100 cigarettes in your life?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #69)*
64. How old were you when you first started smoking cigarettes on a regular basis?	___ ___ years old
65. During the entire time you smoked, how many cigarettes did you smoke per day, on average?	___ ___ cigarettes

66. Do you currently smoke cigarettes?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #68)*
67. On average, how many cigarettes per day do you currently smoke?	___ ___ cigarettes *(SKIP TO QUESTION #69)*
68. How old were you when you last stopped smoking?	___ ___ years old

SECTION H. FAMILY HISTORY OF CANCER: In this section, we wish to obtain information about living and deceased members of your family. We are only interested in your **blood** relatives, that is, those who are your natural parents, grandparents, brothers, sisters, or children. Please indicate half-brothers or sisters.

69. Have any of your **blood** relatives ever been diagnosed with cancer?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #77)*

Which relative was diagnosed with cancer?	What type of cancer were they diagnosed with?	What was their age at diagnosis?
70. ___ ___	___ ___	___ ___ years
71. ___ ___	___ ___	___ ___ years
72. ___ ___	___ ___	___ ___ years
73. ___ ___	___ ___	___ ___ years
74. ___ ___	___ ___	___ ___ years
75. ___ ___	___ ___	___ ___ years

SECTION I. ATTITUDES AND TRAITS: I will read a number of statements concerning your attitudes and traits. As you listen to each statement, please decide whether the statement is true or false.	
	circle one response below
76. I am always willing to admit when I make a mistake.	True.....1 False.....2
77. I always try to practice what I preach.	True.....1 False.....2
78. I never resent being asked to return a favor.	True.....1 False.....2
79. I have never been irked when people expressed ideas very different from my own.	True.....1 False.....2
80. I have never deliberately said something that hurt someone's feelings.	True.....1 False.....2
81. I like to gossip at times.	True.....1 False.....2
82. There have been occasions when I took advantage of someone.	True.....1 False.....2
83. I sometimes try to get even rather than to forgive and forget.	True.....1 False.....2
84. At times I have really insisted on having things my own way.	True.....1 False.....2
85. There have been occasions when I felt like smashing things.	True.....1 False.....2

Please continue onto the next section...

SECTION J. EATING PATTERNS: This section contains questions about your eating patterns.

86. During the past six months, did you often eat within any two-hour period what most people would regard as an unusually large amount of food?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #94)*
87. In general, during the past six months, how upset were you by overeating (eating more than you think is best for you)? *SHOW CARD D*	Not at all.....1 Slightly.....2 Moderately.....3 Greatly.....4 Extremely.....5
88. During the times when you ate this way, did you often feel you couldn't stop eating or control what or how much you were eating?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #94)*
89. In general, during the past six months, how upset were you by the feeling that you couldn't stop eating or control what or how much you were eating? *SHOW CARD D*	Not at all.....1 Slightly.....2 Moderately.....3 Greatly.....4 Extremely.....5
90. During the past six months, how often, on average, did you have times when you ate this way -- that is, large amounts of food plus the feeling that your eating was out of control? (There may have been some weeks it was not present -- just average those in). *SHOW CARD E*	Less than one day a week.....1 One day a week.....2 Two or three days a week.....3 Four or five days a week.....4 Nearly every day.....5

91. How old were you when you first had times when you ate large amounts of food and felt that your eating was out of control? If you are not sure, what is your best guess?	___ ___ years old
92. Did you usually have any of the following experiences during these occasions? **92a.** Eating more rapidly than usual?	Yes.....1 No.....2
92b. Eating until you felt uncomfortably full?	Yes.....1 No.....2
92c. Eating large amounts of food when you didn't feel physically hungry?	Yes.....1 No.....2
92d. Eating alone because you were embarrassed by how much you were eating?	Yes.....1 No.....2
92e. Feeling disgusted with yourself, depressed, or feeling guilty after overeating?	Yes.....1 No.....2
93. Think about a typical time when you ate this way -- that is, large amounts of food plus the feeling that your eating was out of control. **93a.** What time of day did the episode start? *SHOW CARD F*	Morning (8 AM to 12 Noon).....1 Early afternoon (12 Noon to 4 PM).....2 Late afternoon (4 PM to 7 PM).....3 Evening (7 PM to 10 PM).....4 Night (After 10 PM).....5
93b. Approximately how long did this episode of eating last, from the time you started to eat to when you stopped and didn't eat again for at least two hours?	___ ___ Hours ___ ___ Minutes

As best as you can remember, please tell me everything you might have eaten or drunk during that episode. If you ate for more than two hours, describe the foods eaten and liquids drunk during the two hours that you ate the most. Be specific -- include brand names where possible and amounts as best as you can estimate.

93c. Binge #1 What did you eat or drink?	What brand of .... did you eat or drink?	How much did you eat?
93d. Binge #2 What did you eat or drink?	What brand of .... did you eat or drink?	How much did you eat?

94. During the past six months, how important has your weight or shape been in how you feel about or evaluate yourself as a person -- as compared to other aspects of your life, such as how you do at work, as a parent, or how you get along with other people? *SHOW CARD G*	Weight and shape were not very important.....1 Weight and shape played a part in how you felt about yourself.....2 Weight and shape were among the main things that affected how you felt about yourself.....3 Weight and shape were the most important things that affected how you felt about yourself.....4
95a. During the past three months, did you ever make yourself vomit in order to avoid gaining weight after binge eating?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #96a)*
95b. How often, on average, was that? *SHOW CARD H*	Less than once a week.....1 Once a week.....2 Two to three times a week.....3 Four to five times a week.....4 More than five times a week.....5
96a. During the past three months, did you ever take more than twice the recommended dose of laxatives in order to avoid gaining weight after binge eating?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #97a)*
96b. How often, on average, was that? *SHOW CARD H*	Less than once a week.....1 Once a week.....2 Two to three times a week.....3 Four to five times a week.....4 More than five times a week.....5

97a. During the past three months, did you ever take more than twice the recommended dose of diuretics (water pills) in order to avoid gaining weight after binge eating?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #98a)*
97b. How often, on average, was that? *SHOW CARD H*	Less than once a week.....1 Once a week.....2 Two to three times a week.....3 Four to five times a week.....4 More than five times a week.....5
98a. During the past three months, did you ever fast -- not eat anything at all for at least 24 hours -- in order to avoid gaining weight after binge eating?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #99a)*
98b. How often, on average, was that? *SHOW CARD H*	Less than once a week.....1 Once a week.....2 Two to three times a week.....3 Four to five times a week.....4 More than five times a week.....5
99a. During the past three months, did you ever exercise for more than an hour specifically to avoid gaining weight after binge eating?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #100a)*
99b. How often, on average, was that? *SHOW CARD H*	Less than once a week.....1 Once a week.....2 Two to three times a week.....3 Four to five times a week.....4 More than five times a week.....5

100a. During the past three months, did you ever take more than twice the recommended dose of a diet pill in order to avoid gaining weight after binge eating?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #101a)*
100b. How often, on average, was that? *SHOW CARD H*	Less than once a week.....1 Once a week.....2 Two to three times a week.....3 Four to five times a week.....4 More than five times a week.....5
101a. During the past six months, did you go to any meetings of an organized weight control program (e.g. Weight Watchers, Optifast, Nutrisystem) or a self-help group (e.g. TOPS, Overeaters Anonymous)?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #102)*
101b. Which program did you attend? *SHOW CARD I* *If other, please specify*:_____	Weight Watchers.....1 Overeaters Anonymous.....2 Jenny Craig.....3 Optifast.....4 Other *(specify in blank to the left)*.....5
102. Since you have been an adult -- 18 years old -- how much of the time have you been on a diet, been trying to follow a diet, or in some way limiting how much you were eating in order to lose weight or keep from regaining weight you had lost? *SHOW CARD J*	None or hardly any of the time.....1 About a quarter of the time.....2 About half of the time.....3 About three-quarters of the time.....4 Nearly all of the time.....5

103. Have you ever lost at least 10 pounds by dieting?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #105)*
104. How old were you the first time you lost at least 10 lbs. by dieting, or in some way limiting how much you ate? If you are not sure, what is your best guess?	___ ___ years old
105. Now I will show you some silhouettes. Please take a look at them and tell me the number of the silhouette that most resembles the body build of your natural mother at her heaviest. *(CIRCLE "0" IF THE SUBJECT HAS NO KNOWLEDGE OF HER BIOLOGICAL MOTHER)* *SHOW CARD K*	Silhouette # _____ No biological mother.....0
106. Now look at these silhouettes and tell me the number of the silhouette that most resembles your natural father at his heaviest. *(CIRCLE "0" IF THE SUBJECT HAS NO KNOWLEDGE OF HER BIOLOGICAL FATHER)* *SHOW CARD L*	Silhouette # _____ No biological father.....0
FILL IN THE ALHPABETICAL ANSWERS IN THE LEFT HAND COLUMN AND FILL THE CORRESPONDING NUMERICAL ANSWER IN THE RIGHT HAND COLUMN. *SHOW CARD M* Letter **107.** Which drawing looks most like you? _____	Silhouette # - coded by interviewer _____
108. Which drawing would you like to look like? _____	_____
109. Which drawing do most of your friends look like? _____	_____
110. Which drawing would you look like if you weighed 10 more pounds? _____	_____

111. Which drawing would you look like if you weighed 10 less pounds? _____	_____
112. Which drawing shows how your family members would like you to look? _____	_____
113. Which drawing do men find most attractive? _____	_____
114. Which drawing do most women want to look like? _____	_____
115. Which drawing do you think is the most attractive? _____	_____

SECTION K. STAGES OF CHANGE: Now I have a couple of questions for you about eating fruits and vegetables and practicing breast self-examination.

116. How many servings of fruit and vegetables do you eat each day? *SHOW CARD N*	None.....1 1-2 servings.....2 3-4 servings.....3 5-6 servings.....4 7-8 servings.....5 9-10 servings.....6 11 or more.....7
117. About how long have you been eating this number of daily servings of fruit and vegetables? *SHOW CARD O*	Less than one month.....1 1-3 months.....2 4-6 months.....3 Longer than 6 months.....4

118. Are you seriously thinking about eating more servings of fruit and vegetables starting sometime in the next six months?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #120)*
119. Are you planning to eat more servings of fruits and vegetables during the next month?	Yes.....1 No.....2
120. How often have you practiced breast self-examination in the past year? *SHOW CARD P*	Every month.....1 Every two or three months.....2 Every four or five months.....3 Every six or seven months.....4 Every eight or nine months.....5 Every ten or eleven months.....6 Every twelve months or more.....7
121. About how long have you been practicing breast self-examination this often? *SHOW CARD O*	Less than one month.....1 1-3 months.....2 4-6 months.....3 Longer than 6 months.....4
122. Are you seriously thinking about practicing breast self-examination starting sometime in the next six months?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #124)*
123. Are you planning to practice breast self-examination during the next month?	Yes.....1 No.....2

SECTION L. ACCULTURATION: I only have a few more questions and we will have completed this interview.	
124. In general, what language do you read and speak? *SHOW CARD Q*	Only Spanish.....1 Spanish more than English.....2 Both equally.....3 English more than Spanish.....4 Only English.....5
125. What language do you usually speak at home? *SHOW CARD Q*	Only Spanish.....1 Spanish more than English.....2 Both equally.....3 English more than Spanish.....4 Only English.....5
126. In which language do you usually think? *SHOW CARD Q*	Only Spanish.....1 Spanish more than English.....2 Both equally.....3 English more than Spanish.....4 Only English.....5
127. What language do you usually speak with your friends? *SHOW CARD Q*	Only Spanish.....1 Spanish more than English.....2 Both equally.....3 English more than Spanish.....4 Only English.....5

Please provide the name and telephone number of a relative or friend who does not live with you but who will know your whereabouts if we cannot locate you.

Friend/relative's name:

_____

last first

Friend/relative's telephone number:

(___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

FOR OFFICE USE ONLY

Place ID label here

FORM: 110

Technician ID: ___ ___ ___

Data entry initials: ___ ___ ___

Date of interview: __ __ / __ __ / __ __

Verification initials: ___ ___ ___

Healthy, Happy Women

Food Habits Questionnaire: Baseline, 8 months, 20 months

INTRODUCTION: The following questions ask you to think about your general eating habits over the **past three months**. If you don't eat the food the question asks about, tell me so. Next we will talk about the types and amounts of foods you ate and drank yesterday. This is called a 24 Hour Food Recall.

START ALL QUESTIONS WITH THE PHRASE: *IN THE PAST THREE MONTHS...* **1.** Did you eat chicken?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #5)*
2. When you ate chicken, how often was it broiled, boiled, or baked? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
3. When you ate chicken, how often was it fried? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4

4. When you ate chicken, including in soup, how often did you take off the skin? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
5. Did you eat fish?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #8)*
6. When you ate fish, how often was it broiled, baked, poached, or cooked in soup? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
7. When you ate fish, how often was it fried? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
8. Did you eat spaghetti, noodles, or rice?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #13)*
9. When you ate spaghetti or noodles, how often did you eat it without meat (including poultry)? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4

10. When you ate spaghetti or noodles, how often did you eat the whole-wheat types? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
11. When you ate rice, how often was it brown rice? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
12. When you ate rice and noodles, how often was the rice or noodles fried in fat before adding liquid? This includes all rice and noodle dishes like sopa seca, arroz con pollo, fideos, and Ramen noodles. *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
13. When you ate red meat, how often did you cut off the fat or buy trimmed meat? This includes beef, pork, goat, or lamb. *SHOW CARD B*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4 Not applicable.....5
14. When you ate ground meat in hamburgers, picadillo, tacos, and similar food, how often did you choose extra lean ground beef or ground turkey (90%, 93%, or very low fat)? *SHOW CARD B*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4 Not applicable.....5

15. When you ate ham, lunchmeat, or hot-dogs, how often did you choose ham, lunchmeat, or hot-dogs that were labeled "low-fat" or "lean"? Lunchmeat includes bologna, salami, luncheon loaf, or similar meats. *SHOW CARD B*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4 Not applicable.....5
16. When you ate bacon or sausage, how often did you choose turkey bacon or sausages that were labeled low-fat? Sausage includes all kinds of sausage like breakfast sausage, Vienna sausage, chorizo, morcillo, Polish sausage, Italian sausage, and pepperoni. *SHOW CARD B*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4 Not applicable.....5
17. How often at dinner (or your main meal) did you have **no** meat, fish, eggs, or cheese? An example would be a meal of rice, beans, and tortillas, or arroz con gandules. *SHOW CARD B*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4 Not applicable.....5
18. Did you eat bread, rolls, muffins, or crackers?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #21)*
19. When you ate bread, rolls, muffins, or crackers, how often did you eat them without butter, margarine, or mayonnaise? This includes all types of bread like croissants, bagels, pita bread, and sandwich buns. *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4

20. When you ate bread, rolls, muffins, or crackers, how often were they whole grain types or made with bran (whole-wheat, pumpernickel, rye)? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
21. Did you eat tortillas or food made with masa?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #25)*
22. When you ate tortillas, how often did you eat corn tortillas instead of flour tortillas? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
23. When you ate foods made with tortilla or masa, how often was the tortilla or masa fried? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
24. When you ate dishes made with tortillas, like tacos, how often was the filling potatoes, beans, vegetables, chicken, or fish, instead of steak, carnitas, chorizo, ground meat, or tongue? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4

25. When you ate breakfast, how often did you eat cereal (hot and cold)? *SHOW CARD B*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4 Not applicable.....5
26. When you ate cereal, how often did you eat a bran or whole-grain cereal? This includes Raisin Bran, oat and whole-wheat cereals, Shredded Wheat, or cereals with the words "fiber" or "bran" in the name. *SHOW CARD B*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4 Not applicable.....5
27. Did you drink milk or use milk on cereal?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #29)*
28. When you had milk, how often was it very low fat (1%) or nonfat, skim milk? This includes milk used in cafe con leche, licuados, and chocolate drinks. *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
29. When you ate cheese, how often was it specially made low fat (diet) cheese? This includes cheese used on sandwiches, quesadillas, pizza, and in cooking. Some low-fat cheeses include queso rancherito, queso cotija, and mozzarella. *SHOW CARD B*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4 Not applicable.....5

30. Did you eat cooked vegetables	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #33)*
31. When you ate cooked vegetables, how often did you add butter, margarine, salt pork, bacon fat, sour cream, crema, or mayonnaise? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
32. When you ate cooked vegetables, how often were they fried? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
33. Did you eat potatoes, plantains, or viandas	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #37)*
34. When you ate potatoes, how often were they fried (french fries, hash browns, etc.)? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
35. When you ate boiled or baked potatoes, how often did did you eat them without butter, margarine, or sour cream? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4

36. When you ate plantains or viandas (ñame, boniatos, yuca), how often were they boiled or baked without added fat? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
37. When you ate chiles and salsas, how often were they fried or prepared with added fat or oil? *SHOW CARD B*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4 Not applicable.....5
38. When you ate dishes flavored with sofrito and achiote, how often did you eat sofrito and aciote made without lard or oil? *SHOW CARD B*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4 Not applicable.....5
39. Did you eat green salad?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #42)*
40. When you ate lettuce or green salads, how often did you use low calorie diet dressing, lime juice, lemon juice, salsa, vinegar, or no dressing at all? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4

41. When you used mayonnaise or mayonnaise-type dressing, how often did you use the low-fat or fat free types? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
42. When you ate beans or peas like pintos and gandules, how often were they refried or stewed with added fat? *SHOW CARD B*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4 Not applicable.....5
43. When you ate soup, how often was it made with lots of vegetables, or beans and peas like pintos and gandules? *SHOW CARD B*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4 Not applicable.....5
44. Did you eat dessert or sweets?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #49)*
45. When you ate dessert, how often did you eat only fruit? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4

46. When you ate frozen desserts, how often was it fat free or low-fat ice cream, frozen yogurt, or sherbet? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
47. When you ate sweets, how often did you eat pan dulce like polverones, empanadas, cheesecakes, and conchas? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
48. When you ate sweets, how often did you eat non-Hispanic cakes, cookies, pastry, and pies? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
49. Did you eat snacks?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #53)*
50. When you ate snacks, how often did you eat raw vegetables? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4

51. When you ate snacks, how often did you eat fresh fruit? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
52. When you ate snacks, how often did you eat popcorn or chips, candy bars or nuts? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
53. Did you drink sweet drinks?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #55)*
54. When you drank sweet drinks, how often did you drink diet pop or sugar free punches and Kool-Aid instead of regular? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4
55. Did you pan fry or sauté any food?	Yes.....1 No.....2 *(IF NO, SKIP TO QUESTION #57)*
56. When you sautéed or pan fried foods, how often did you use Pam or other non-stick spray instead of oil margarine, or butter? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4

57. Did you bake cake, cookies, or pies?	Yes.....1 No.....2 *(IF NO, STOP QUESTIONNAIRE)*
58. When you baked cookies, cakes or pies, how often did you change the recipe to use less butter, margarine, shortening, lard or oil? *SHOW CARD A*	Usually or always.....1 Often.....2 Sometimes.....3 Rarely or never.....4

E. Intervention Materials

Nutrition Guidelines for Refreshments and Educational Messages, Mujeres Felices

Nutrition outcomes to be measured:

- Increased intake of fiber, fruit and vegetable servings, and carotenoids
- Decreased intake of dietary fat, especially saturated fat

Food Group, Food Constituents, Portions	Guideline
Grain Items:	At least part whole grain
Fruit/Vegetables:	Promotion of seasonally available items; high vitamin a, c and folacin
Dairy Items:	Reduced fat, part skim and skim products, depending on planned usage and taste acceptability
Protein Foods	Any lean protein foods as described in exchanges for meal planning
Fat Sources	Least possible saturated fat; promotion of mono-unsaturated fats
Sugar and Sugary Foods	No special advantages to any particular sweetener; use in moderation
Artificial Sweeteners, Colorings, And Additives	To be determined on an individual item basis
Salt	Food to be prepared with minimal added salt and with no more than one or two high sodium seasonings or convenience products per recipe
Herbs and spices used in food preparation	Encourage as an alternative flavoring agent to excess fat, salt, and sugar; document during data collection
Portion Sizes	In agreement with Food Guide Pyramid
Herbal cancer prevention and cures and herbs as cures for other diseases	*Needs a decision by Marian, Sue and Sara - May wish to consider a very reliable reference book, such as Varro Tyler's The Honest Herbal. This is usually one of the first questions that arises when Hispanic people discuss cancer prevention and cure because herbals for this purpose are widely promoted on Spanish language television*

Coordination of BCRR information with other public health messages

NOTE: We will not be teaching all these messages, but will use them to facilitate the delivery of consistent answers from staff as questions arise during the course of the intervention.

(Table needs to be completed)

Public Health Organization	Recommendations	Reference Source Material
American Cancer Society	- less total fat, more high fiber, Vits A and C, cabbage family vegetables, limit alcohol and cured foods, healthy weight	
National Cancer Institute		
USDA Food Guide Pyramid	- variety, proportionality, moderation; further understanding of combination foods	Food Guide Pyramid Guideline - has not been translated
US Dietary Guidelines	- food variety; healthy weight; more F/V and grains; less fat/sat fat/cholesterol; moderate salt, sugar, alcohol	Guías para su dieta, tercera edición, 1990. (4th ed. in English)
Nutrition Facts label	designations for good/excellent sources of key nutrients; definitions for low fat, low calorie, and low salt foods	Label Facts for Healthful Eating Educator's Guide if Nabisco will donate; AHA brochures Eng/Sp
WIC	- reinforce messages for foods rich in iron, calcium, Vits A and C, fiber and protein	Check with Erlinda about present standards
American Heart Assn.	- less fat/sat fat/cholesterol; more monofat; more F/V; grains; healthy weight; moderate salt	
NHLBI		AHA
CDC	- reinforce good folic acid foods for women of childbearing years	Recommendations for the Use of Folic Acid to Reduce...Neural Tube Defects. CDC Morbidity and Mortality Weekly Report, Sept. 11, 1992

Ideas for ***Mujeres Felices*** study foods - all bread items should be at least part whole grain -- Please add your ideas

Baked corn tortillas chips
Whole wheat, rye, or pumpernickel bagels
"Real" black bread, rye bread, 100% whole wheat
RyeKrisp crackers, Triscuits
Whole wheat pita
Whole wheat tortillas and mid-Eastern flatbreads
Homemade popcorn

Vegetables with various dips, dressings, mayonnaises

Spreads and related:

Low fat peanut butter, "beanut" butter(a blend of regular PB and cooked beans)
Low fat margarine spreads
A blend of olive oil and soft margarine
Fat free cream cheese - plain and mixed with salsa or sofrito
Hummus - various types - Cedars will probably provide a tasting
Other beans dips
Regular salsa and salsa with extra chopped vegetables
Fruit salsa
Low fat cheeses

Drinks:

Aguas frescas
Licuados
Batidos/refrescos
Sparkling water blended with juice
Low sugar cranberry juice cocktails
Flor de Jamaica drink
Cafe con leche
Hot chocolate made with skim milk and Ovaltine
Hot cider
Orange juice with added calcium
Fruit tea (blend of tea with juice like OJ)
Cranberry sangria for potluck
Atole

Mujeres Felices Por Ser Saludables - Initial 12-week Integrated Basic Lesson Plans

Session 1

45 min.--	Introduce Your Partner icebreaker and program introduction; concurrent snack
35 min.--	Short talk by Y-Me Latina breast cancer survivor, followed by Q/A
10 min.--	Explain home activities; talk about phone tree and refreshments, solicit volunteer helper if needed for food shopping and prep for next session; attendance raffle

Scripts, Handouts and A/V materials	**Name**	**Source**
Script	Introduction	-- Maggie based on Por la Vida?
HO	Healthy Eating to Reduce the Risk of Breast Cancer	-- developed in-house by Marian, Sharon and Maggie
	Logo magnet	-- Georgina to obtain
A/V	Healthy food posters	Sharon to donate

Home activity	**Outcomes reinforced**
Call your partner for reminder	Helping each other remember to take care of our own health

Food Type	**Name**	**Potential Sources**
Snack Food	Cheese and crackers	Kraft, V & V, Wasa (Rye Krisp) and Nabisco (Triscuits)
	Hot or cold cider	Apple juice company
	Apples?	Grocery store

Knowledge Question of the week: From the healthy food posters

Session 2

20 min.--	Change Can Be Positive icebreaker (adding a new behavior) - Sara/Sharon to write intro and stimulus questions
30 min.--	Breast Facts, the Basics Video with short discussion
15 min.--	Healthy Eating and Cancer introduction - live presentation based on NCI script with food models and "real" food
15 min.--	Enlisting family support: involving family
10 min.	Explain Pantry "Check-Up"; talk about phone tree, solicit volunteer helper if needed for food shopping and prep for next session

Scripts, Handouts and A/V materials	**Name**	**Source**
Script	Change Can Be Positive	-- ? Introduction and stimulus questions
HO	Give Your Pantry a "Check-Up"	-- to be developed in-house by Sharon
HO	Early Detection Handout	-- to be developed in-house- Sara
A/V	Breast Facts, the Basics video	-- HealthEdCo? Do we have this in Spanish?
Display	Breast models, tumor size chart, breast health flip chart	-- already have models, need to order others

Home activities	**Outcomes reinforced**
Pantry Check-Up (survey)	Increase in intake of foods low in fat and high in fiber
Call your partner for exchange of information on Pantry survey	Helping each other remember to take care of our own health

Food Type	**Name**	**Potential Sources**
Meal tasting	Picadillo Tacos with Corn Tortillas, vegetable garnishes	Tortilla company, grocery store - should probably plan to pay for this
	Canned and bottled juices, regular and low sugar	Home Juice, Ocean Spray, Coca Cola (Minute Maid), Tropicana
	Mini carrots?	Grocery store

Knowledge Question of the week: From breast visual aid display

Session 3

20 min. --	Build a Healthy Pantry (cancer risk reduction foods; work in pairs)
20 min. --	Focus on Fiber foods - Interactive fiber handout; Choosing whole grain bread
40 min.--	BSE video and demonstration of palpation techniques
10 min.	Explain BSE home activity; talk about phone tree, solicit volunteer helper if needed for food shopping and prep for next session

Scripts, Handouts and A/V materials	**Name**	**Source**
Scripts	Build a Healthy Pantry	-- Sharon and ?
	BSE, Part 1 intro and demo	-- Sara
HO	Aumentando La Fibra En Su Dieta (Eating More Fiber)	-- Nutrition Prescriptives xerox master; can change color, paper, add our logo; Sharon to develop intro and stimulus questions
	Choosing a High Fiber Bread	-- bread cutout - make in house-Society for Nutrition Education idea; interventionists?
A/V	Several plastic containers w. handles	-- Dollar store
	Additional 3-D food models	-- Nasco foods

Home activities	**Outcomes reinforced**
Think of a question you have about BSE; write it down	Increase in participant breast self exam
Call your partner to discuss BSE home activity (Sara to structure)	Helping each other remember to take care of our own health

Food Type	**Name**	**Potential Sources**
Snack	Whole grain breads	Great Harvest, Whole Foods, Pepperidge Farms, Natural Ovens;
	A variety of reduced saturated fat margarines and spreads	Fleischmans, other margarine companies
	Cafe con leche and/or hot chocolate or atole made with 1% milk and Ovaltine	Grocery store or dairy; Ovaltine company
	Fruit or vegetable	Grocery store

Knowledge Question of the Week: About identifying high fiber foods in the market

Session 4

40 min.	BSE, Part 2 - Answering questions, other breast symptoms, timing, identifying menstrual period, Distribute and explain use of shower card reminder
40 min.	Eating more fruits and vegetables -- Display and discuss serving sizes and costs of F/V, including dried, canned, and frozen F/V -- Discuss "best" fruits/vegetables, ACS Cancer Reduce Your Risk poster -- Stretching your F/V dollar using seasonal produce handout, PMI posters
10 min.	Explain F/V Checklist; talk about phone tree, solicit volunteer helper if needed for food shopping and prep for next session

Handouts and A/V materials	**Name**	**Source**
Scripts	BSE	-- Sara
	Eating More F/V (better title?)	-- Sharon
HO	Fruits and Vegetables In Season	-- develop in-house-Sharon
	Fruit Vegetable Magnet	-- Georgina
	BSE Shower card reminders	-- Maggie/Sara
A/V	Additional 3-D food models	-- Nasco foods - see Session 4
	Cancer - Reduce Your Risk poster	ACS - Sharon will donate one for Resource Center; can ACS donate 1 for each intervention participant to take one home?
	Seasonal produce posters	PMI - Sharon will donate

Home activities	**Outcomes reinforced**
5 a Day checklist	Increase in fruit/vegetable servings
Call your partner to share info about a produce bargain	Reminding each other to take care of our own health
Identify the day this month when you think you will do BSE	Reminding each other to take care of our own health

Food Type	**Name**	**Potential Sources**
Snack	Baked tortilla chips	Frito-Lay, Jays, Guiltless Gourmet?
	Several varieties of salsa, including black bean-corn salsa, maybe fruit salsa	Want suggestions from Maggie, Georgina and Kristin
	Fat free sour cream?	Kraft (Breakstone) or other dairy food company
	Citrus tea, homemade or bought	Lipton, Coca Cola (Minute Maid), Tropicana, Quaker (Snapple)

Knowledge question of the week: About produce from Reduce Your Risk poster

Session 5

40 min. 5 a Day Checklist activity - Fruit and Vegathon?
40 min. Breast cancer survivor talk #2 - Communicating with your health care givers
10 min. Talk about phone tree, solicit volunteer helper if needed for food shopping and prep for next session

Script, Handouts and A/V materials	**Name**	**Source**
Scripts	Intro to and structuring of survivor talk	-- Sara
	Fruit and Vegathon and other F/V activity	-- Sharon
HO	Guía Para La Buena Alimentación (Guide to Good Eating)	-- National Dairy Council

Home activities	**Outcomes reinforced**
Call in questions for next session's M.D. guest	Increase in comfort level when discussing breast health with one's doctor
Call your partner to ... (something relating to BSE)	Helping each other remember to take care of our own health

Food Type	**Name**	**Potential Sources**
Snack	Whole wheat pita bread Several types of hummus, baba ghanouj, and lentil-vegetable salad	Ziyad, Cedars of Lebanon, Chef Earl, Jewel/Dominicks vendors
	Homemade liçuaudos and/or aguas frescas	Grocery store for milk and fruit; Ovaltine for the chocolate powder

Knowledge question: ?

Session 6

40 min. Physician presentation with Q & A Sara to indicate topic
40 min. All about fat - body fat, food fat, best fat - slide show?
10 min. Explain home recipe activity, talk about phone tree, solicit volunteer helper which will be needed for food shopping and prep for next session

Handouts and A/V materials	**Name**	**Source**
Scripts	Physician presentation intro and stimulus questions	-- Sara
	Intro on different types of fat; Modify Por la Vida lesson, incorporate Eating Lean slides	-- Sharon
HO	Medidas Para Reducir el Consumo de Grasa (Lowering Your Fat Intake) or Compre, Cocine y Cene con Poca Grasa (Shop, Cook, and Eat with Less Fat)	-- Nutrition Prescriptives - can change color, title; add logo -- California Project LEAN, $.17 each
A/V	How much fat in this? using pictures, food models and real butter/margarine pats or lard	Nasco for models Buy fat at the grocery store

Home activities	**Outcomes reinforced**
Find a recipe that has several high fat ingredients and bring it to class	Decrease intake of dietary fat
Call your partner to talk about the recipes you chose	Helping each other remember to take care of our own health

Food Type	**Name**	**Potential Sources**
Snack	Whole wheat, rye, and pumpernickel bagels	Bagel companies
	- Fat free and reduced fat cream cheese, plain and flavored	Kraft, major grocery chains (store brand)
	- Reduced fat peanut butter	Peter Pan, Skippy, Smuckers
	- Apple butter	Bertolli Olive Oil
	- Blend of light olive oil or canola oil and soft margarine	Fleischman's, Promise
	Homemade liçuaudos and/or aguas frescas - whatever we didn't have the week before	Grocery store for milk and fruit; Ovaltine for the chocolate powder

Knowledge question: ?

Session 7 - Consider 2 hour session since we have a major mealtime?

20 min. BSE Check in and discussion
30 min. Building a Better Meal, How do you do it? In class activity with handout
30 min. Reading a Label for better fat and fiber using interactive computer program
10 min. Distribute extra $5.00 grocery certificates and discuss next week's potluck; encourage participants to invite guests; staff will do all other prep work for Session 8 since participants will need to prep their own recipe
20 min. Enjoy vegetarian meal; *Children from baby-sitting join moms (need earlier brief discussion of how to encourage children to try new foods)*

Script, Handouts and A/V materials	**Name**	**Source**
Script	BSE Check in	-- Sara
	Building Meal	-- Sharon
HO	Build a Better Recipe	-- modify and translate handout used by the Illinois Cancer Center
	Cómo Leer la Nueva Etiqueta de los Alimentos (How to Read the New Food Label)	-- American Heart Assn.- one in English and one in Spanish for each participant; .$.10 each
A/V	Computer program - large screen	From WIC Nutrition Center

Home activities	**Outcomes reinforced**
Use the Build a Better Recipe handout to change a favorite recipe you make	Decrease intake of dietary fat, increase intake of fiber, fruits and vegetables
Call at least one other person (not from study) to invite them to mammogram meeting and luncheon	Helping each other remember to take care of our own health

Food Type	**Name**	**Potential Sources**
Meal	Vegetarian Spanish rice	Uncle Ben's for brown rice
	Stewed black beans or lentils	Goya for beans
	Cabbage salad	Kraft for Jello
	Jello made with yogurt and fruits	Otherwise purchase
	Flor de Jamaica drink or punch made by blending sparkling water and fruit juices	Grocery store for Flor de Jamaica, cinnamon sticks; juice and water vendors

Knowledge Question?

Session 8 - Consider 2 hour session since we have major meal and may wish to consider giving some type of certificate for taking part in basic curriculum? Participants invite 1) a woman 40 years old or older; and/or 2) someone else who is eligible to be screened for Mujeres Felices

40 min.	Build a Better Recipe, How did you do it? In class discussion with flip chart
50 min.	Mammograms
20 min.	Enjoy meal with your guests
10 min.	Looking forward; discuss the shift to biweekly sessions; Do we want to award an attendance certificate at this point?

Handouts and A/V materials	**Name**	**Source**
HO	Cocinando por Placer y Salud (Cooking for Pleasure and Health)	-- Univ. of Wisconsin Cooperative Extension, about $.50 each
	Something for mammogram and the 7 Warning Signs of Cancer in English/Spanish	-- Sara, Maggie
A/V	Mobile unit arrangements and Mammogram video	-- Sara, Maggie coordinate through Cook County and Erie
	Flip chart for writing people's recipe changes and documenting beginning recipe work for future study cookbook	-- Kristin to purchase/has bought?

Home activities	**Outcomes reinforced**
Talk to an older family member or friend to see if they have had a mammogram; share a simple handout	Increase comfort level for discussing breast health Increase knowledge of breast cancer risk reduction factors
Call your partner to talk about...?	Helping each other remember to take care of our own health

Food Type	**Name**	**Potential Sources**
Meal - Plan for twice as much food as usual	An interesting vegetable tray with reduced fat salad dressings and dips	Treasure Island or Whole Foods for tray, Kraft, Seven Seas, and more "gourmet" companies for dressings; Dean foods for dips or homemade
	Cranberry or citrus sangria and fruit juices	Sam's Liquors for the wine; Ocean Spray for cranberry juice

Knowledge question: ?

Curriculum Template

Session _9_ - To be held at the Chicago Nutrition Center

min.	Barriers to breast health
min.	Explanation and distribution of shower card
min.	All about breakfast
min.	A breakfast foods cooking demo and tasting

Handouts and A/V materials	**Name**	**Source**
HO	Coupons for non-WIC breakfast food items	
A/V		

Home activities	**Outcomes reinforced**
Identify your own main barrier or facilitator for BSE	
Identify your own main barrier or facilitator for healthy breakfast eating	
Try out and rate one new breakfast recipe	

Food Type	**Name**	**Potential Sources**
	Cold or hot cereal bar with dried fruit	
	Turkey Breakfast meats?	
	Egg dish	
	Assorted juices	
	Homemade licuados	

Curriculum Template

Session _10_

min.	Facilitated discussion of personal barriers to achieving breast health goals and brainstorm problem solving solutions
min.	Fast food, good food
min.	Contest - Eating a Healthy Fast Food Meal
min.	

Handouts and A/V materials	**Name**	**Source**
HO	Mammography basics Sources of low-cost mammograms	
A/V	Display - with fat "chips" of paired fast food meals	

Home activities	**Outcomes reinforced**
Go out with your partner and eat and record nutrition-rich fast food meal	

Food Type	**Name**	**Potential Sources**
Fast food - carry in	Simple hamburgers, cut into quarters Grilled chicken breasts, non-mayo sauce or roasted chicken pieces Submarine sandwich slices Torta slices with lower fat fillings Assorted snack chips Salads from fast food place Soft drinks and alternate FF beverages	

Knowledge questions for Meeting 9:
Guess which of the fast food meals on the poster has the most fat? Guess which meal has the most fiber?

Curriculum Template

Session _11_

min.	Calculate fast food meal nutritents; Award prizes for 1) best fiber; 2) lowest sat fat; 3) best Vitamin A from fruits/veg (beta-carotene); 4) best Vitamin C
min.	Discussion on BSE
min.	Role play interacting with doctor and nurse
min.	Bag lunches and quick snacks
min.	Taste and Rate low fat cold cuts and snack chips
min.	

Handouts and A/V materials	**Name**	**Source**
HO		
A/V		

Home activities **Outcomes reinforced**

Food Type	**Name**	**Potential Sources**
	Reduced fat .cold cuts	
	Reduced fat cheeses	
	Hummus	
	Sandwich bread, pita bread	
	Condiments	
	Assorted chips	
	Vegetables and dips	
	Beverage - TBD	

Session _12_

40 min.	Review of BSE
25 min.	Dinners in a hurry - casseroles, tortilla foods, pizza, and other family favorites - short talk with demo, participant activity; outside activity assignment and foods to taste (during next 2 parts)
15 min.	Pleasing everyone's tastes in the household
10 min.	Attendance raffle and answer to Knowledge Question; Discuss the shift to monthly sessions; Complete Stages of Change Measure in meeting

Handouts and A/V materials	**Name**	**Source**
HO	Build a Better Easy Dinner in class activity and home worksheet	Will be adapted from EFNEP flyer
	BSE?	Up to Sara/Maggie
	Stages of Change questionnaire	In house - Kim?
A/V	none - hands-on food demo	Sharon/Chris

Home activities	**Outcomes reinforced**
Make a quick one dish meal using vegetables, veggie burgers, ground turkey or fish as the main filling and write down how you fixed it	Increase vegetable eating Increase eating of low fat foods

Food Type	**Name**	**Potential Sources**
Quick meal	Turkey and veggie burgers	Green Giant, Boca Burger, Morningstar Farms, Turkey Store, Louis Rich, Purdue
	Fat free/reduced fat cheese?	Kraft, Sargento
	Buns/Whole wheat tortillas/Pita	Bakery companies (see list)
	Condiments	See list
	Tamale casserole	Sponsor?
	Veggie w/purchased LF dip	Sponsor?

Knowledge question:

Recipes: Fish tacos, Veggie burger burritos, Tamale casserole

Session _13_ Stages of Change - Shift to monthly sessions

10 min.	Review Stages of Change measure filled in at Session 12 - How the stage you are at relates to what you can do to move forward or maintain
35 min.	Stages of Change activity and discussion - breast health
25 min.	Stages of Change activity and discussion - healthy eating
10 min.	Practical application of stages of change -- dessert buffet continuum
10 min.	Attendance raffle and answer to Knowledge Question; Discuss Stages of Change Measure home activity

Handouts and A/V materials	**Name**	**Source**
HO	Initial lists of ideas that work and do not work	Sara, Maggie, Sharon, Chris, Marian
A/V	Flip chart for lists of 1) what works 2) what doesn't work 3) what others (i.e., the study) can provide that would make it easier to achieve success 4) what has to come from within	

Home activities

Write down something you will try this month to help you with breast health based on today's talk

Outcomes reinforced

Serious topic - want some "fun food" here

Food Type	**Name**	**Potential Sources**
Dessert Buffet!	Angel cake - low fat	Cake mix company or Bakery
	Sliced fruit sauce, made with frozen fruit - low fat, high fiber	Frozen fruit company
	Fat free chocolate/vanilla pudding - low fat	Jello (Kraft)
	Food Guide Pyramid Capriotada - reduced fat, high fiber	Sponsor?
	Pineapple Sandwiches	Dole, Kraft

Knowledge Question:

Recipes: Food Guide Pyramid Capriotada, Pineapple Sandwiches; Fruit Sauce

Session _14_ **Participants start to take active role**

May need to take part at the Nutrition Center between the mess of the Fat Busters game and the need for oven space to heat frozen foods

35 min.	You Bet Your Health (Jeopardy type game show) - breast health knowledge and good nutrition- 2-person teams; good prize to best team (with "commercials" by staff?)
15 min.	Food break
30 min.	Fat Busters - participant activity - given a raw chicken, some greasy soup, buttered bread, a fatty chop, and a few other such items, who can get rid of the most fat. (by weight)
10 min.	Raffle, contest, volunteers for next session

Handouts and A/V materials	**Name**	**Source**
HO	Game show Q & A - 2-sided cards with pictoral Q & A	In house, based on curriculum
	Pictoral directions for Fat Busters	In house
A/V	Game set up Food items, knives for Fat Busters	Marian to ask Melinda

Home activities **Outcomes reinforced**

Food Type	**Name**	**Potential Sources**
Donated frozen entrees		Healthy Choice, Lean Cuisine, Hispanic companies
Beverage	To be decided	Beverage companies

Session _15_ **Participants continue active role**

40 min.	Breast health video followed by discussion; additional discussion on interaction with technicians, M.D.s and other health care staff
15 min.	Food break
25 min.	Whole grain, high fiber cooking demo and discussion of upcoming pot luck fiesta celebration - staff with volunteer participants
10 min.	Raffle, contest, explanation of ending session

Handouts and A/V materials	**Name**	**Source**
HO	Introduction and probe questions, breast video	Maggie
	Cooking high fiber foods	Chris
	Guidelines for pot luck recipes	Sharon
A/V	Breast health video	Maggie/Sara to identify
	Materials for cooking demo	Chris

Home activities	**Outcomes reinforced**
Prepare a recipe for the final class party	Prepare food with less fat Prepare food with more fruits, vegetables, and fiber

Food Type	**Name**	**Potential Sources**
Great Grains	Quinoa salad with w/wheat pita	Edens Foods, pita bakeries
	Brown rice stuffed peppers	Uncle Ben's
	Flavored rice cakes	Quaker
	Reduced fat oatmeal raisin cookies	Reduced fat cookie companies
	Citrus punch	Coca Cola (Minute Maid), Tropicana

Session _16_ **Ending Event - 2 hours**

40 min.	Sharing appreciation for participation and each other; solidifying support for the future; future risk reduction plans; **maintenance goals?**
5 min.	Washroom break
35 min.	Presentation of pot luck dish by participants with description of the way in which it meets cancer risk reduction suggestions
15 min.	Awarding of certificates of completion and participation gift
5 min.	Schedule health screenings of participants
20 min.	Pot luck meal

Handouts and A/V materials	**Name**	**Source**
HO	Certificates of completion Participant gifts	
A/V		

Home activities **Outcomes reinforced**

None

Beverages by Mujeres; All other by participants?

Food Type	**Name**	**Potential Sources**

Mujeres Felices Por Ser Saludables
-- An integrated Curriculum for Breast Cancer Risk Reduction

Incorporates curriculum meeting discussion of 4/29/97

Structure - Initial 8 weeks, 90 - 120 minute sessions, held weekly, groups of 8-12 women plus two interventionists and one health educator; also needed - one child care worker/helper with food prep

Handouts - Limit handouts to 4 points.

Food - A grain and easy fruit/veg snack and pitcher of beverage; more involved refreshment served during at sessions 2, 7, and 8 and later sessions when meetings are less frequent.

What are we feeding the kids at baby-sitting?

1. We have to find out if Erie has any restrictions
2. Foods that would reinforce what we teach the moms would be a good idea, but everything needs to be safe for children 2 and under also.

See Antohitos/Snacks list from Eating a la Culture

Nutrition Guidelines for Refreshments and Educational Messages, Mujeres Felices

Nutrition outcomes to be measured:

- Increased intake of fiber, fruit and vegetable servings, and carotenoids
- Decreased intake of dietary fat, especially saturated fat

Food Group, Food Constituents, Portions	Guideline
Grain Items:	At least part whole grain when feasible
Fruit/Vegetables:	Promotion of seasonally available items; high vitamin A, C and folacin, encourage citrus fruits and cruciferous veg
Dairy Items:	Reduced fat, part skim and skim products, depending on planned usage and taste acceptability
Protein Foods	Any lean protein foods as described in Exchanges for Meal Planning (ADA/ADbA)
Fat Sources	Least possible saturated fat; promotion of mono-unsaturated fats
Sugar and Sugary Foods	No special advantages to any particular sweetener; use in moderation
Artificial Sweeteners, Colorings, And Additives	To be determined on an individual item basis
Salt	Food to be prepared with minimal added salt and with no more than one or two high sodium seasonings or convenience products per recipe
Herbs and spices used in food preparation	Encourage as an alternative flavoring agent to excess fat, salt, and sugar; document during data collection
Portion Sizes	In agreement with Food Guide Pyramid
Herbal cancer prevention and cures and herbs as cures for other diseases	*Use reference book- Varro Tyler's The Honest Herbal. This is usually one of the first questions that arises when Hispanic people discuss cancer prevention and cure because herbals for this purpose are widely promoted on Spanish language television*

Coordination of BCRR information with other public health messages

NOTE: We will not be teaching all these messages, but will use them to facilitate the delivery of consistent answers from staff as questions arise during the course of the intervention.

(Table needs to be completed)

Public Health Organization	Recommendations	Reference Source Material
American Cancer Society	- less total fat, more high fiber, Vits A and C, cabbage family vegetables, limit alcohol and cured foods, healthy weight	CA - A Journal for Cancer Clinicians, 1996
National Cancer Institute	- similar to ACS	Identify most recent article
USDA Food Guide Pyramid	- variety, proportionality, moderation; further understanding of combination foods	Food Guide Pyramid Guideline - has not been translated
US Dietary Guidelines	- food variety; healthy weight; more F/V and grains; less fat/sat fat/cholesterol; moderate salt, sugar, alcohol	Guías para su dieta, tercera edición, 1990. (4th ed. in English)
Nutrition Facts label	designations for good/excellent sources of key nutrients; definitions for low fat, low calorie, and low salt foods	Label Facts for Healthful Eating Educator's Guide if Nabisco will donate; AHA brochures Eng/Sp
WIC	- reinforce messages for foods rich in iron, calcium, Vits A and C, fiber and protein	Check with Chicago Nutrition Education and WIC Center about present standards
American Heart Assn.	- less fat/sat fat/cholesterol; more monofat; more F/V; grains; healthy weight; moderate salt	AHA Guidelines article
NHLBI	- similar to AHA	Identify recent publication
CDC	- reinforce good folic acid foods for women of childbearing years	Recommendations for the Use of Folic Acid to Reduce...Neural Tube Defects. CDC Morbidity and Mortality Weekly Report, Sept. 11, 1992

Ideas for ***Mujeres Felices*** study foods - all bread items should be at least part whole grain
-- Please add your ideas

Baked corn tortillas chips
Whole wheat, rye, or pumpernickel bagels
"Real" black bread, rye bread, 100% whole wheat
RyeKrisp crackers, Triscuits
Whole wheat pita
Whole wheat tortillas and mid-Eastern flatbreads
Homemade popcorn

Vegetables with various dips, dressings, mayonnaises

Spreads and related:

Low fat peanut butter, "beanut" butter(a blend of regular PB and cooked beans)
Low fat margarine spreads
A blend of olive oil and soft margarine
Fat free cream cheese - plain and mixed with salsa or sofrito
Hummus - various types - Cedars will probably provide a tasting
Other beans dips
Regular salsa and salsa with extra chopped vegetables
Fruit salsa
Low fat cheeses

Drinks:

Aguas frescas
Licuados
Batidos/refrescos
Sparkling water blended with juice
Low sugar cranberry juice cocktails
Flor de Jamaica drink
Cafe con leche
Hot chocolate made with skim milk and Ovaltine
Hot cider
Orange juice with added calcium
Fruit tea (blend of tea with juice like OJ)
Cranberry sangria for potluck
Atole

Mujeres Felices Por Ser Saludables - Initial 12-week Integrated Basic Lesson Plans

Session 1

40 min.--	Introduce Your Partner icebreaker and program introduction
10 min.	Break, Snack
30 min.--	Short talk by Y-Me Latina breast cancer survivor, followed by Q/A
10 min.--	Explain home activities; talk about phone tree and refreshments, solicit volunteer helper if needed for food shopping and prep for next session; attendance raffle

Scripts, Handouts and A/V materials	**Name**	**Source**
Script	Introduction	-- Maggie based on Por la Vida?
HO	Healthy Eating to Reduce the Risk of Breast Cancer	-- developed in-house by Marian, Sharon and Maggie
A/V	Healthy food posters	Need to find some in Spanish; have some of produce pictures w/o words

Home activity	**Outcomes reinforced**
Call your partner for reminder	Helping each other remember to take care of our own health

Food Type	**Name**	**Potential Sources**
Snack Food	Reduced fat cheese and crackers	Kraft, V & V, Wasa (Rye Krisp) and Nabisco (Triscuits)
	Hot or cold cider	Apple juice company
	Apples (different varieties, sliced)	Grocery store

Knowledge Question of the week: From the healthy food posters or based on program introduction

Session 2

20 min.--	Change Can Be Positive icebreaker (adding a new behavior)
30 min.--	Breast Facts, the Basics Video with short discussion
15 min.--	Healthy Eating and Cancer introduction - live presentation based on NCI script with food models and "real" food
15 min.--	Enlisting family support: involving family
10 min.	Explain Pantry "Check-Up"; talk about phone tree, solicit volunteer helper if needed for food shopping and prep for next session

Scripts, Handouts and A/V materials	**Name**	**Source**
Script	Change Can Be Positive	-- In house write-up of Introduction and stimulus questions
	Eating for Good Health	-- Adapted from NCI slide show - Sharon
HO	Give Your Pantry a "Check-Up"	-- In-house - Sharon
HO	Early Detection Handout	-- to be developed in-house- Sara
A/V	Breast Facts, the Basics video	-- HealthEdCo? Do we have this in Spanish?
Display	Breast models; Breast display	-- already have models, need to order others

Home activities	**Outcomes reinforced**
Pantry Check-Up (survey)	Increase in intake of foods low in fat and high in fiber Increase in fruits/vegetables
Call your partner for exchange of information on Pantry survey	Helping each other remember to take care of our own health

Food Type	**Name**	**Potential Sources**
Recipe tasting	Picadillo Tacos with Corn Tortillas, vegetable garnishes Canned and bottled juices, regular and low sugar Mini carrots	Tortilla company, grocery store - should probably plan to pay for this Home Juice, Ocean Spray, Coca Cola (Minute Maid), Tropicana Grocery store

Knowledge Question of the week: From breast visual aid display

Session 3

20 min. -- Build a Healthy Pantry (cancer risk reduction food s; work in pairs)
20 min. -- Focus on Fiber foods - Interactive handouts
40 min.-- BSE video and demonstration of palpation techniques
10 min. Explain BSE home activity; talk about phone tree, solicit volunteer helper if needed for food shopping and prep for next session

Scripts, Handouts and A/V materials	**Name**	**Source**
Scripts	Build a Healthy Pantry: Focus on Fiber	-- Intro talk and stimulus questions based on NCI slide presentation - Sharon
	BSE, Part 1 intro and demo	-- Sara
HO	Aumentando La Fibra En Su Dieta (Eating More Fiber)	-- Nutrition Prescriptives xerox master; can change color, paper, add our logo;
	Choosing a High Fiber Bread	-- bread cutout - In house-Society for Nutrition Education idea; Chris
A/V	Several plastic containers w. handles or mini grocery carts	-- Dollar store or garage sales
	Additional 3-D food models	-- Nasco foods

Home activities	**Outcomes reinforced**
Think of a question you have about BSE; write it down	Increase in participant breast self exam
Call your partner to discuss BSE home activity (Sara to structure)	Helping each other remember to take care of our own health

Food Type	**Name**	**Potential Sources**
Snack	Whole grain breads	Great Harvest, Whole Foods, Pepperidge Farms, Natural Ovens;
	A variety of reduced saturated fat margarines and spreads	Fleischmans, other margarine companies
	- Reduced fat peanut butter	Peter Pan, Skippy, Smuckers
	- Apple butter	
	Celery	Grocery store
	Cafe con leche and/or hot chocolate or atole made with 1% milk and Ovaltine	Grocery store or dairy; Ovaltine company
	Orange wedges	Grocery store

Knowledge Question of the Week: About identifying high fiber foods in the market

Session 4

40 min.	BSE, Part 2 - Answering questions, other breast symptoms, timing, identifying menstrual period, Distribute/explain use of shower card reminder
10 min.	Break
30 min.	Eating more fruits and vegetables -- Display of F/V, including dried, canned, and frozen F/V, legumes, chiles, F/V products -- Discuss "best" fruits/vegetables, ACS Cancer Reduce Your Risk poster -- Stretching your F/V dollar using seasonal produce handout, PMI posters
10 min.	Explain F/V Checklist; talk about phone tree, solicit volunteer helper if needed for food shopping and prep for next session

Handouts and A/V materials	**Name**	**Source**
Scripts	BSE	-- Sara
HO	Fruits and Vegetables In Season	-- In-house-Sharon
	Cancer - Reduce Your Risk	-- ACS mini poster
	Fruit Vegetable Magnet	-- Georgina to price
	Fruit/Veg Self Monitor Tool	-- In house - Sharon (from AHA)
	BSE Shower card reminders	-- Maggie/Sara
A/V	Additional 3-D food models	-- Nasco foods - see Session 4
	Cancer - Reduce Your Risk poster	ACS - Large one for Resource Center
	Seasonal produce posters	PMI - Sharon will donate

Home activities	**Outcomes reinforced**
5 a Day checklist	Increase in fruit/vegetable servings
Call your partner to share info about a produce bargain	Reminding each other to take care of our own health
Identify the day this month when you think you will do BSE	Reminding each other to take care of our own health

Food Type	**Name**	**Potential Sources**
Snack	Baked tortilla chips	Frito-Lay, Jays, Guiltless Gourmet?
	Several varieties of salsa-- black bean-corn salsa, homemade fruit salsa	Want suggestions from Maggie, Georgina and Kristin
	Fat free sour cream	Kraft (Breakstone) or other dairy food company
	Bell pepper wedges	Grocery store
	Citrus tea, homemade or bought	Lipton, Coca Cola (Minute Maid), Tropicana, Quaker (Snapple)

Knowledge question of the week: About produce from Reduce Your Risk poster

Session 5

40 min. Review 5 a Day Checklist activity - Fruit and Vegathon? Serving sizes for F/V
40 min. Breast cancer survivor talk #2 - Communicating with your health care givers
10 min. Talk about phone tree, solicit volunteer helper if needed for food shopping and prep for next session

Script, Handouts and A/V materials	**Name**	**Source**
Scripts	Intro to and structuring of survivor talk	-- Sara
	Fruit and Vegathon and other F/V activity for serving size	-- Sharon
HO	Guía Para La Buena Alimentación (Guide to Good Eating)	-- National Dairy Council

Home activities	**Outcomes reinforced**
Call in questions for next session's M.D. guest	Increase in comfort level when discussing breast health with one's doctor
Call your partner to ... (something relating to BSE)	Helping each other remember to take care of our own health

Food Type	**Name**	**Potential Sources**
Snack	Whole wheat pita bread	Ziyad, Cedars of Lebanon, Chef Earl, Jewel/Dominicks vendors
	Several types of hummus, baba ghanouj	
	Homemade liçuaudos and/or aguas frescas	Grocery store for milk and fruit; Ovaltine for the chocolate powder

Knowledge question: ?

Session 6

35 min. Physician presentation with Q & A Sara to indicate topic; Video alternative
10 min. Break
35 min. Trim the Fat talk with handout activity
10 min. Explain home recipe activity, talk about phone tree, solicit volunteer helper which will be needed for food shopping and prep for next session

Handouts and A/V materials	**Name**	**Source**
Scripts	Physician presentation intro and stimulus questions	-- Sara
	Intro on types of fat, sources of fat, ways to reduce fat	-- Sharon
HO	Medidas Para Reducir el Consumo de Grasa (Lowering Your Fat Intake) or Compre, Cocine y Cene con Poca Grasa (Shop, Cook, and Eat with Less Fat)	-- Nutrition Prescriptives - can change color, title; add logo -- California Project LEAN, $.17 each
A/V	How much fat in this? using pictures, food models and real butter/margarine pats or lard	Nasco for models Buy fat at the grocery store

Home activities	**Outcomes reinforced**
Find a recipe that has several high fat ingredients and bring it to class	Decrease intake of dietary fat
Call your partner to talk about the recipes you chose	Helping each other remember to take care of our own health

Food Type	**Name**	**Potential Sources**
Snack	Whole wheat, rye, and pumpernickel bagels	Bagel companies
	- Fat free and reduced fat cream cheese, plain and flavored	Kraft, major grocery chains (store brand)
	- Blend of light olive oil or canola oil and soft margarine	Bertolli Olive Oil Fleischman's, Promise
	Vegetable from Reduce Risk poster	Grocery store
	Homemade liçuaudos and/or aguas frescas - whatever we didn't have the week before	Grocery store for milk and fruit; Ovaltine for the chocolate powder

Knowledge question: ?

Session 7 - Consider 2 hour session since we have a major mealtime?

20 min. BSE Check in and discussion
30 min. Building a Better Meal, How do you do it? In class activity with handout
30 min. Reading a Label for better fat and fiber using interactive computer program
10 min. Distribute extra $5.00 grocery certificates and discuss next week's potluck; encourage participants to invite guests; staff will do all other prep work for Session 8 since participants will need to prep their own recipe
20 min. Enjoy vegetarian meal; *Children from baby-sitting join moms (need earlier brief discussion of how to encourage children to try new foods)*

Script, Handouts and A/V materials	**Name**	**Source**
Script	BSE Check in	-- Sara
	Building Healthy Meals	-- Sharon
HO	Build a Better Recipe	-- modify and translate handout used by the Illinois Cancer Center
	Cómo Leer la Nueva Etiqueta de los Alimentos (How to Read the New Food Label)	-- American Heart Assn.- one in English and one in Spanish for each participant; .$.10 each
A/V	Computer program - large screen	From WIC Nutrition Center

Home activities	**Outcomes reinforced**
Use the Build a Better Recipe handout to change a favorite recipe you make	Decrease intake of dietary fat, increase intake of fiber, fruits and vegetables
Call at least one other person (not from study) to invite them to mammogram meeting and luncheon	Helping each other remember to take care of our own health

Food Type	**Name**	**Potential Sources**
Meal	Vegetarian Spanish rice	Uncle Ben's for brown rice
	Stewed lentils	Goya for beans
	Cabbage salad	Kraft for Jello
	Jello made with yogurt and fruits	Otherwise purchase
	Flor de Jamaica drink or punch made by blending sparkling water and fruit juices	Grocery store for Flor de Jamaica, cinnamon sticks; juice and water vendors

Knowledge Question?

Session 8 - 2 hour session since we have major meal and may wish to consider giving some type of certificate for taking part in basic curriculum? Participants invite 1) a woman 40 years old or older; and/or 2) someone else who is eligible to be screened for Mujeres Felices

40 min. Mammogram discussion by mobil unit staff or video
10 min. Break
40 min. Build a Better Recipe, How did you do it? In class discussion with flip chart
10 min. Looking forward; discuss the shift to biweekly sessions; Do we want to award an attendance certificate at this point?
20 min. Enjoy meal with your guests

Handouts and A/V materials	**Name**	**Source**
HO	Cocinando por Placer y Salud (Cooking for Pleasure and Health)	-- Univ. of Wisconsin Cooperative Extension, about $.50 each
	Something for mammogram and the 7 Warning Signs of Cancer in English/Spanish	-- Sara, Maggie
A/V	Mobile unit arrangements and Mammogram video	-- Sara, Maggie coordinate through Cook County and Erie
	Flip chart for writing people's recipe changes and documenting beginning recipe work for future study cookbook	-- Kristin to purchase/has bought?

Home activities	**Outcomes reinforced**
Talk to an older family member or friend to see if they have had a mammogram; share a simple handout	Increase comfort level for discussing breast health Increase knowledge of breast cancer risk reduction factors
Call your partner to talk about...?	Helping each other remember to take care of our own health

Food Type	**Name**	**Potential Sources**
Meal - Plan for twice as much food as usual	An interesting vegetable tray with reduced fat salad dressings and dips	Treasure Island or Whole Foods for tray, Kraft, Seven Seas, and more "gourmet" companies for dressings; Dean foods for dips or homemade
	Cranberry or citrus sangria and fruit juices	Sam's Liquors for the wine; Ocean Spray for cranberry juice

Knowledge question: ?

Session _9_ - To be held at the Chicago Nutrition Center

20 min.	Barriers to breast health
15 min.	Explanation and distribution of shower card
10 min.	Break
15 min.	All about breakfast
20 min.	A breakfast foods cooking demo and tasting - egg dish
10 min.	Attendance/knowledge, home activity
30 min.	Breakfast tasting

Handouts and A/V materials	**Name**	**Source**
HO	BSE Shower card	
	Choosing the Best: Breakfasts	In house
	Coupons for non-WIC breakfast food items, such as egg substitute	Manufacturers
A/V	Cooking equipment	

Home activities	**Outcomes reinforced**
Identify your own main barrier or facilitator for BSE	
Identify your own main barrier or facilitator for healthy breakfast eating	
Try out and rate one new breakfast recipe that includes vegetables or fruit	

Food Type	**Name**	**Potential Sources**
	Cold or hot cereal bar with dried fruit	Quaker, Kellogg, General Mills Prune/Raisin assns.
	Turkey breakfast meats	Louis Rich, Swift-Eckrich
	Egg dish w. egg substitute	Fleischman's
	Assorted juices	Minute Maid, Tropicana, Ocean Spray
	Coffee	

Session 10

40 min.	Facilitated discussion of personal barriers to achieving breast health goals and brainstorm problem solving solutions
10 min.	Break
10 min.	Fast food, good food - short talk
20 min.	Contest - Choosing a Healthy Fast Food Meal description and practice
10 min.	Attendance, knowledge, home activity

Handouts and A/V materials	**Name**	**Source**
Scripts	Intro and Stimulus questions - breast health goals	Sara and Maggie
	Fast Food, Good Food	Sharon
HO	Mammography basics	Sara
	Sources of low-cost mammograms	
	Fast food record	In House - Sharon
	Fast Food	Diabetes Assn. Greater Cleveland
A/V	Display - with fat "chips" of paired fast food meals	In House - Chris

Home activities	**Outcomes reinforced**
Go out with your partner and eat and record nutrition-rich fast food meal	

Food Type	**Name**	**Potential Sources**
Fast food - carry in	Simple hamburgers, cut into quarters	Neighborhood fast food place
	Grilled chicken breasts, non-mayo sauce or roasted chicken pieces	Neighborhood fast food place, Boston Market/supermarket
	Submarine sandwich slices	Subways
	Torta slices with lower fat fillings	Grocery store tacqueria
	Salads from fast food place	Most fast food places
	Soft drinks and alternate FF beverages	

Knowledge questions for Meeting 9: From fast food ads - Guess which of the fast food meals on the poster has the most fat? Guess which meal has the most fiber?

Session 11

30 min.	Discussion on BSE
20 min.	Role play interacting with doctor and nurse
10 min.	Break
15 min.	Calculate fast food meal nutritents; Award prizes for 1) best fiber; 2) lowest sat fat; 3) best Vitamin A from fruits/veg (beta-carotene); 4) best Vitamin C
35 min.	Bag lunches and quick snacks - short talk, followed by discussion of barriers; Taste and Rate low fat cold cuts and snack chips
10 min.	Attendance, knowledge, home activity

Handouts and A/V materials	**Name**	**Source**
Scripts	BSE stimulus questions and role play	Sara and Maggie
	What's in the Bag?	Sharon
HO	Smart Snacks	In house - Sharon
	Build a Better Lunch Bag	In house - Sharon
A/V	Lunch bags and photos of possible components of a good lunch	Chris

Home activities **Outcomes reinforced**

Food Type	**Name**	**Potential Sources**
"Bag" lunch	Reduced fat .cold cuts	Oscar Meyer, Swift Eckrich, Butterball, Louis Rich
	Reduced fat cheeses	Kraft, Sargento
	Tuna salad	Chicken of the Sea
	Prepared hummus	Chef Earl's, Cedars of Lebanon
	Sandwich bread, pita bread	Pepperridge Farm, Natural Ovens, Thomas
	Condiments	from earlier
	Potato, pasta, and cabbage salads made with reduced fat dressings	Grocery store, Kraft, Hellman's, Wishbone, Seven Seas
	Reduced fat chips	Jays, Lays, Frito-Lay, Guiltless Gourmet, Presidents Choice
	Beverage - flavored teas	Lipton

Knowledge question:

Session 12

40 min.	Review of BSE
25 min.	Dinners in a hurry - casseroles, tortilla foods, pizza, and other family favorites - short talk with demo, participant activity; outside activity assignment and foods to taste (during next 2 parts)
15 min.	Pleasing everyone's tastes in the household
10 min.	Attendance raffle and answer to Knowledge Question; Discuss the shift to monthly sessions; Complete Stages of Change Measure in meeting

Handouts and A/V materials	**Name**	**Source**
HO	Build a Better Easy Dinner in class activity and home worksheet	Will be adapted from EFNEP flyer
	BSE?	Up to Sara/Maggie
	Stages of Change questionnaire	In house - Kim
A/V	none - hands-on food demo	Sharon/Chris

Home activities	**Outcomes reinforced**
Make a quick one dish meal using vegetables, veggie burgers, ground turkey or fish as the main filling and write down how you fixed it	Increase vegetable eating Increase eating of low fat foods

Food Type	**Name**	**Potential Sources**
Quick meal	Turkey and veggie burgers	Green Giant, Boca Burger, Morningstar Farms, Turkey Store, Louis Rich, Purdue
	Fat free/reduced fat cheese	Kraft, Sargento
	Buns/Whole wheat tortillas/Pita	Bakery companies (see list)
	Condiments	See list
	Stir fried vegetables	Sponsor?

Knowledge question:

Recipes: Veggie burger burritos, Stir fried vegetables and chicken, Shrimp pizza

Session 13 **Stages of Change - Shift to monthly sessions**

10 min.	Review Stages of Change measure filled in at Session 12 - How the stage you are at relates to what you can do to move forward or maintain
35 min.	Stages of Change activity and discussion - breast health
10 min.	Break; get dessert
25 min.	Stages of Change activity and discussion - healthy eating; dessert buffet continuum
10 min.	Attendance raffle and answer to Knowledge Question; Discuss Stages of Change Measure home activity

Handouts and A/V materials	**Name**	**Source**
HO	Initial lists of ideas that work and do not work	Sara, Maggie, Sharon, Chris, Marian
A/V	Flip chart for lists of 1) what works 2) what doesn't work 3) what others (i.e., the study) can provide that would make it easier to achieve success 4) what has to come from within	

Home activities
Write down something you will try this month to help you with breast health based on today's talk

Outcomes reinforced

Serious topic - want some "fun food" here

Food Type	**Name**	**Potential Sources**
Dessert	Angel cake - low fat	Cake mix company or Bakery
	Sliced fruit sauce, made with frozen fruit - low fat, high fiber	Frozen fruit company
	Fat free chocolate/vanilla pudding - low fat	Jello (Kraft)
	Food Guide Pyramid Capriotada - reduced fat, high fiber	Sponsor?
	Pineapple Sandwiches - low fat, fruit	Dole, Kraft

Knowledge Question:

Session 14 **Participants start to take active role**

May need to take part at the Nutrition Center between the mess of the Fat Busters game and the need for oven space to heat frozen foods

35 min.	You Bet Your Health (Jeopardy type game show) - breast health knowledge and good nutrition- 2-person teams; good prize to best team (with "commercials" by staff?)
15 min.	Food break
30 min.	Fat Busters - participant activity - given a raw chicken, some greasy soup, buttered bread, a fatty chop, and a few other such items, who can get rid of the most fat. (by weight)
10 min.	Raffle, contest, volunteers for next session

Handouts and A/V materials	**Name**	**Source**
HO	Game show Q & A - 2-sided cards with pictoral Q & A	In house, based on curriculum
	Pictoral directions for Fat Busters	In house
A/V	Game set up Food items, knives for Fat Busters	Marian to ask Melinda

Home activities **Outcomes reinforced**

Food Type	**Name**	**Potential Sources**
Donated frozen entrees		Healthy Choice, Lean Cuisine, Hispanic companies
Beverage	To be decided	Beverage companies

Session 15 **Participants continue active role**

40 min.	Breast health video followed by discussion; additional discussion on interaction with technicians, M.D.s and other health care staff
15 min.	Food break
25 min.	Whole grain, high fiber cooking demo and discussion of upcoming pot luck fiesta celebration - staff with volunteer participants
10 min.	Raffle, contest, explanation of ending session

Handouts and A/V materials	**Name**	**Source**
HO	Introduction and probe questions, breast video	Maggie
	Cooking high fiber foods	Chris
	Guidelines for pot luck recipes	Sharon
A/V	Breast health video	Maggie/Sara to identify
	Materials for cooking demo	Chris

Home activities	**Outcomes reinforced**
Prepare a recipe for the final class party	Prepare food with less fat Prepare food with more fruits, vegetables, and fiber

Food Type	**Name**	**Potential Sources**
Great Grains	Quinoa salad with w/wheat pita	Edens Foods, pita bakeries
	Brown rice stuffed peppers	Uncle Ben's
	Flavored rice cakes	Quaker
	Reduced fat oatmeal raisin cookies	Reduced fat cookie companies
	Citrus punch	Coca Cola (Minute Maid), Tropicana

Session 16 **Ending Event - 2 hours**

40 min.	Sharing appreciation for participation and each other; solidifying support for the future; future risk reduction plans; **maintenance goals?**
5 min.	Washroom break
35 min.	Presentation of pot luck dish by participants with description of the way in which it meets cancer risk reduction suggestions
15 min.	Awarding of certificates of completion and participation gift
5 min.	Schedule health screenings of participants
20 min.	Pot luck meal

Handouts and A/V materials	**Name**	**Source**
HO	Certificates of completion Participant gifts	
A/V		

Home activities **Outcomes reinforced**

None

Beverages by Mujeres; All other by participants?

Food Type	**Name**	**Potential Sources**

Recommended changes based on multiple presentations at SBM, especially Stanford self-help group seminar:

-- Maintain same order at each class (ritual important):

Greetings
Breast health
Break with refreshments
Nutrition
Attendance raffle and knowledge prizes
Home learning activity

-- Refreshment break in the middle of the session (1 1/2 - 2 hours is a long time to sit still, not use bathroom, etc.)

-- Give out recipes used in class at each session

-- Provide a mechanism that participants can let us know they tried a new food product (a sample provided by us or something they bought) and/or healthy recipe and give us their opinion of it, using a simple checklist or 3-item Likkert scale.

-- Perhaps simplify some of the menus, unless we want the opportunity to work with the health educators to have them shop for and fix some of the food

-- But serve at least one fruit or vegetable from the ACS poster Cancer: Reduce Your Risk, at each session in recognizable form; have whole examples of the F/V and a fact sheet for each one (prep tips, season, how to use it, maybe an interest "fact").

-- Stated personal goal setting at regular intervals (not necessarily at every session; maybe 1/month for breast and nutrition would be enough); could use a personal diary format in their notebooks

V. REFERENCES

Jepson C., Kessler L.G., Portnoy B., Gibbs T. (1991). Black - white differences in cancer prevention knowledge and behavior. American Journal of Public Health, 81 (4), 501-504.

Freeman, H.P. (1989). Cancer and the poor. A report to the nation. Atlanta: American Cancer Society.

Project #6: Equipment purchased

Item	Qty	Number	Description
1	1	127TCLddm	TC1000 Team Conference System, to include quad BRI multiplexer (HISP512QB) for 384 kbps operation; 27" monitor
2	3		Network Terminal Adapter
3	1		Installation of TC1000 System
4	1	DOC400	Document camera and stand for transparent and reflective copy
5	1	WRLS-ES	Wireless package
6	1	ENH-I/O	VCR support and enhanced I/O option for TC1000
7	1		Electronic tablet and pen option for TC1000
8	1	SV	SmartView document control software
9	1	SST-384	SmartStation for 384 kbps operation
10	1		Installation of SST-384 (at ISG)
11	5	SST-128	SmartStation for 128 kbps operation
12	8		Network Terminal Adapter

CAREGIVER RESPONSIBILITIES

As a part of the Outpatient Bone Marrow/Peripheral Stem Cell Transplant Program, patients will spend most of the day away from the hospital. There are a number of activities that will need to be done during that time, as well as information that needs to be kept for the doctors to evaluate at the next day's visit. The patient may be able to do most of these things themselves, however, at times they may require your assistance or your encouragement. These activities may include:

* Measuring and recording intake and output
* Encouraging and monitoring daily exercise/activity
* Administering medications and documenting them on the form
* Monitoring for signs and symptoms of infection
* Taking vital signs and recording them on the flow sheet
* Preparing meals following the guidelines given and encouraging eating
* Notifying the contact person following the guidelines outlined
* Assisting the patient with regular activities of daily living.

This information will review all of these activities and give you a source to refer back to when needed. For questions or more information, contact your nurse.

GENERAL GUIDELINES
FOR THE CAREGIVER

NEUTROPENIC PRECAUTIONS

Following high dose chemotherapy, the patient's white blood cell count will be very low until the stem cells begin producing new cells. During this time, the patient's ability to fight infection is impaired. Here is a list of guidelines to be followed by you and the patient. You will need to use these when planning meals for you and the patient and may also need to remind the patient of these precautions at times.

* Both patient and caregiver should wash their hands thoroughly after using the toilet, before preparing meals or eating, and upon returning to the apartment after any outing.

* The caregiver and all visitors should wash his/her hands thoroughly upon entering the apartment and before any contact with the patient.

* When the patient leaves the apartment, they must wear a mask.

* The patient should eat well balanced meals, high in protein and drink plenty of fluids.

* Try to exercise or engage in light physical activity at least twice a day for a short period of time.

* Avoid crowded public places and people with infections (colds, sneezing, coughing, flu, etc.).

* Check the patient's temperature every 4 hours as instructed. If temperature is greater than or equal to 100.5°F, call the contact person immediately.

* If the patient has a shaking chill, call the contact person immediately.

* Watch for signs and symptoms of infection (redness, swelling, pain or drainage from anywhere). If any symptoms develop, notify the contact person immediately.

* The patient should wear slippers or shoes at all times to prevent injuring your feet.

* No fresh plants or flowers are allowed in the apartment. The patient may not have contact with plants or do any gardening upon discharge.

* Follow the dietary guidelines given in the diet section.

* Perform oral care at least 5 times per day as instructed. Leave dentures out if they do not fit properly or if mouth sores develop. Also, keep lips lubricated with a lip balm.

* The patient should not wear contact lenses during this time and even after discharge until approved by the doctor.

* The patient should avoid heavy make-up during this time period. Lipstick and blush or powder is okay. Eye make-up should be avoided.

* Inspect the patient's scalp daily. If any rashes or irritation is noted, the patient should not wear their wig.

* The patient should avoid contact with pets and animals. After discharge, excretions of animals should be avoided until specific approval is given by your doctor.

* The patient should follow the hygiene guidelines provided.

* The patient should sleep in a bed alone while in the bone marrow transplant apartment.

* The patient should not be in a room while it is being cleaned. Also, the patient should not do any cleaning even after discharge, until approved by the doctor.

* The patient and the caregiver should not clip or cut fingernails and toenails.

HYGIENE AND ORAL CARE GUIDELINES

When a person's immune system is compromised, as is the case after high dose chemotherapy and bone marrow transplant, the normal bacteria from the body can potentially cause infections. This is why it is important to follow strict hygiene and oral care guidelines. When patients are not feeling well and lack energy, they may need your help and encouragement to follow these guidelines and perform daily tasks.

Hygiene

* The patient should shower or bathe daily. After doing so, they should be certain to dry off well. Special attention should be given to skin folds, genital area, and rectal area. They may find that using a blow dryer on a cool or low setting may be helpful.

* The patient's skin should be inspected daily for any changes, i.e. bruising, wounds, or rash. Notify the physician during your clinic visit. The patient may use a mild non-perfumed lotion if desired.

* After each bowel movement, the patient should gently wash the rectal area with warm water and pat dry. Again they may use a blow dryer on a cool setting. If soreness or ulcers develop, notify the doctor durign the daily visit. Do not apply any creams or ointments until discussing with the doctor.

* A straight edge or regular razor should not be used. If necessary, only an electric razor should be used.

* Patients should avoid cutting nails during this time period.

* *For women:* After using the bathroom, be certain to wipe from front to back. This helps to decrease bacteria that may cause urinary tract infections.

Oral Care

The best way to minimize mouth discomfort and soreness is to perform oral care on a routine basis. This should include the following:

* Brush teeth with a soft toothbrush or sponge toothette 5 times per day. Run hot water over the toothbrush for one minute before using it. This will soften the bristles even more and decrease the trauma to the gums.

* Have a new toothbrush when you start the transplant process.

* Rinse you mouth with the salt and soda solution at least five times per day. If you vomit, you should rinse afterward.

* Keep lips lubricated with a lipbalm.

* Rinse with the chlorhexidine solution that is provided three times each day.

* If ulcers, lesions, or blisters develop, notify the physician at the time of your daily visit.

EXERCISE AND ACTIVITY

During and after the transplant, it is very common for patients to experience profound fatigue and have a lack of energy. This happens for a variety of reasons, some of which are not clearly understood. This sometimes makes it difficult for the patient to be as active as we would like and also may make them want to be in bed more than we would like. We know that it is important for

patients to engage in some type of regular physical activity each day. Also, we would like for the patient to be out of the bed as much as possible during the daytime hours. We realize that patients require frequent rest periods and suggest that these be in a comfortable chair with their feet up rather than in bed. Putting a mask on and taking a walk twice a day if weather permits, or walking inside the buildings (not in crowded areas) with a mask on twice a day is encouraged. Your encoragement will be needed when patients are not feeling well or not having a good day. It is difficult to encourage people to be active when they are feeling bad, but this is an important part of their recovery and must be done. While no formal log or record of activity is kept, we will be asking about this when the patient comes for daily visits.

WHEN TO CALL THE PHYSICIAN

It is important that you keep a watchful eye on the patient and call the physician at _____ immediately if you or the patient notice these signs and symptoms. The physician will tell you what action you need to take. It may involve coming to the hospital.

- ⌦ Fever greater than 100.5°F
- ⌦ Systolic blood pressure (top number) higher than _____ or lower than _____
- ⌦ Diastolic blood pressure (bottom number) higher than ____ or lower than ____
- ⌦ Pulse higher than _____ or less than _____
- ⌦ Shaking chills
- ⌦ Productive cough
- ⌦ Tenderness, redness or drainage at the IV catheter site
- ⌦ Sinus/facial tenderness
- ⌦ Pain, burning or frequency on urination
- ⌦ Sore throat
- ⌦ Ear ache
- ⌦ Vaginal discharge
- ⌦ Mouth sores or blisters
- ⌦ Rash, blisters or hives
- ⌦ Change in thought processes or mental status
- ⌦ Headache, dizziness, or blurred vision
- ⌦ Persistent diarrhea and/or increased nausea and vomiting
- ⌦ New onset of abdominal pain
- ⌦ Chest pain, pressure or shortness of breath
- ⌦ Heart palpitations
- ⌦ Bleeding from IV catheter, gums, nose, ears, vagina or rectum
- ⌦ Blood in vomit, urine or stool
- ⌦ Black tarry stools
- ⌦ Emesis that looks coffee-ground

OVERVIEW OF OUTPATIENT BONE MARROW TRANSPLANT PROGRAM

As a part of the Outpatient Bone Marrow/Peripheral Stem Cell Transplant Program, you will spend most of the day away from the hospital. There are a number of activities that will need to be done during that time, as well as information that needs to be kept for the doctors to evaluate at the next day's visit. You may be able to do most of these things yourself, however, at times you may require your "caregiver's" assistance or your encouragement. These activities may include:

* Measuring and recording intake and output
* Encouraging and monitoring daily exercise/activity
* Administering medications and documenting them on the form
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* Taking vital signs and recording them on the flow sheet
* Preparing meals following the guidelines given and encouraging eating
* Notifying the contact person following the guidelines outlined
* Assisting the patient with regular activities of daily living.

This information will review all of these activities and give you a source to refer back to when needed. For questions or more information, contact your nurse.

GENERAL GUIDELINES
FOR OUTPATIENT BMT PATIENTS

NEUTROPENIC PRECAUTIONS

Following high dose chemotherapy, your white blood cell count will be very low until the stem cells begin producing new cells. During this time, your ability to fight infection is impaired. Here is a list of guidelines to be followed by you and your caregiver.

* Both patient and caregiver should wash their hands thoroughly after using the toilet, before preparing meals or eating, and upon returning to the apartment after any outing.

* The caregiver and all visitors should wash his/her hands thoroughly upon entering the apartment and before any contact with the patient.

* When you leave the apartment, you must wear a mask.

* You should eat well balanced meals, high in protein and drink plenty of fluids.

* Try to exercise or engage in light physical activity at least twice a day for a short period of time.

* Avoid crowded public places and people with infections (colds, sneezing, coughing, flu, etc.).

* Check your temperature every 4 hours as instructed. If temperature is greater than or equal to 100.5°F, call the contact person immediately.

* If you have a shaking chill, call the contact person immediately.

* Watch for signs and symptoms of infection (redness, swelling, pain or drainage from anywhere). If any symptoms develop, notify the contact person immediately.

* You should wear slippers or shoes at all times to prevent injuring your feet.

* No fresh plants or flowers are allowed in the apartment. You may not have contact with plants or do any gardening upon discharge.

* Follow the dietary guidelines given in the diet section.

* Perform oral care at least 5 times per day as instructed. Leave dentures out if they do not fit properly or if mouth sores develop. Also, keep lips lubricated with a lip balm.

* You should not wear contact lenses during this time and even after discharge until approved by the doctor.

* You should avoid heavy make-up during this time period. Lipstick and blush or powder is okay. Eye make-up should be avoided.

* Inspect your scalp daily. If any rash or irritation is noted, you should not wear your wig.

* You should avoid contact with pets and animals. After discharge, excretions of animals should be avoided until specific approval is given by your doctor.

* You should follow the hygiene guidelines provided.

* You should sleep in a bed alone while in the bone marrow transplant apartment.

* You should not be in a room while it is being cleaned. Also, you should not do any cleaning even after discharge, until approved by the doctor.

* You should not clip or cut fingernails and toenails.

HYGIENE AND ORAL CARE GUIDELINES

When a person's immune system is compromised, as is the case after high dose chemotherapy and bone marrow transplant, the normal bacteria from the body can potentially cause infections. This is why it is important to follow strict hygiene and oral care guidelines

Hygiene

* You should shower or bathe daily. After doing so, be certain to dry off well. Special attention should be given to skin folds, genital area, and rectal area. You may find that using a blow dryer on a cool or low setting may be helpful.

* Your skin should be inspected daily for any changes, i.e. bruising, wounds, or rash. Notify the physician during your clinic visit. You may use a mild non-perfumed lotion if desired.

* After each bowel movement, you should gently wash the rectal area with warm water and pat dry. Again, you may use a blow dryer on a cool setting. If soreness or ulcers develop, notify the doctor durign the daily visit. Do not apply any creams or ointments until discussing with the doctor.

* A straight edge or regular razor should not be used. If necessary, only an electric razor should be used.

* Avoid cutting nails during this time period.

* *For women:* After using the bathroom, be certain to wipe from front to back. This helps to decrease bacteria that may cause urinary tract infections.

Oral Care

The best way to minimize mouth discomfort and soreness is to perform oral care on a routine basis. This should include the following:

* Brush teeth with a soft toothbrush or sponge toothette 5 times per day. Run hot water over the toothbrush for one minute before using it. This will soften the bristles even more and decrease the trauma to the gums.

* Have a new toothbrush when you start the transplant process.

* Rinse your mouth with the salt and soda solution at least five times per day. If you vomit, you should rinse afterward.

* Keep lips lubricated with a lip balm.

* Rinse with the chlorhexidine solution that is provided three times each day.

* If ulcers, lesions, or blisters develop, notify the physician at the time of your daily visit.

EXERCISE AND ACTIVITY

During and after the transplant, it is very common to experience profound fatigue and have a lack of energy. This happens for a variety of reasons, some of which are not clearly understood. This sometimes makes it difficult to be as active as we would like and also may make you want to be in bed more than we would like. We know that it is important for patients to engage in some type of regular physical activity each day. Also, we would like for you to be out of the bed as much as possible during the daytime hours. We realize that patients require frequent rest periods and suggest that these be in a comfortable chair with your feet up rather than in bed. Putting a mask on and taking a walk twice a day if weather permits, or walking inside the buildings (not in crowded areas) with a mask on twice a day is encouraged. While no formal log or record of activity is kept, we will be asking about this when the patient comes for daily visits.

WHEN TO CALL THE PHYSICIAN

It is important that you call the physician at _____ immediately if you or your caregiver notice these signs and symptoms. The physician will tell you what action you need to take. It may involve coming to the hospital.

- ⌦ Fever greater than 100.5°F
- ⌦ Systolic blood pressure (top number) higher than _____ or lower than _____
- ⌦ Diastolic blood pressure (bottom number) higher than ____ or lower than ____
- ⌦ Pulse higher than _____ or less than _____
- ⌦ Shaking chills
- ⌦ Productive cough
- ⌦ Tenderness, redness or drainage at the IV catheter site
- ⌦ Sinus/facial tenderness
- ⌦ Pain, burning or frequency on urination
- ⌦ Sore throat
- ⌦ Ear ache
- ⌦ Vaginal discharge
- ⌦ Mouth sores or blisters
- ⌦ Rash, blisters or hives
- ⌦ Change in thought processes or mental status
- ⌦ Headache, dizziness, or blurred vision
- ⌦ Persistent diarrhea and/or increased nausea and vomiting
- ⌦ New onset of abdominal pain
- ⌦ Chest pain, pressure or shortness of breath
- ⌦ Heart palpitations
- ⌦ Bleeding from IV catheter, gums, nose, ears, vagina or rectum
- ⌦ Blood in vomit, urine or stool
- ⌦ Black tarry stools
- ⌦ Emesis that looks coffee-ground

DIETARY GUIDELINES

During and following the high dose chemotherapy and bone marrow/peripheral stem cell transplant, it may be difficult at time to eat. Depending on the treatment regimen that you are on, you may have mouth sores, diarrhea, taste changes, and/or nausea and vomiting. If these problems occur, it is important to tell the physicians about them.

Also, during this time period, your protein and calorie needs will be increased and it may be difficult at times to meet these increased needs. We generally do not like for patients to lose weight during this phase of their treatment. Adequate nutrition is needed for recovery. Many patients find that at some time during the chemo and transplant, that it becomes difficult for them to eat. This is normal and the Bone Marrow Transplant team will be monitoring this on a daily basis. If the need arises, IV nutritional supplementation will be given. This will continue until you are again able to eat.

Since your white blood cell count will be low for a period of time following the high dose chemotherapy, you will need to follow certain diet restrictions to help prevent any infection

Following is a list of food guidelines to be followed and some tips for helping to manage some of the side effects you may have.

Infection precautions

- Fresh fruits and vegetables must be scrubbed well before preparing. This needs to be done by the caregiver and not by you. Once they have been scrubbed well, you may have them as long as they are peeled and then eaten right away. If they cannot be peeled, you may not have them.
- Avoid bulk foods and try to use single serving items if at all possible.
- Leftovers are allowed but must be refrigerated or frozen immediately and should be eaten within 24 hours.
- Food should be eaten at the temperature that it is intended. Hot food should be hot and not just lukewarm and cold food should be very cold and not room temperature.
- Avoid handling raw meat.
- Be certain foods are fresh and are used before the expiration date.
- Be certain that all food is cooked thoroughly.

Restaurants

- Restaurant food is allowed from the list of restaurants supplies
- When ordering from a restaurant, no fresh fruits or vegetables should be eaten. You do not know how they were washed or prepared. This includes salads and garnishes.
- Specifically ask for no garnishes or condiments on the plate with the food.
- Ask that food be well cooked. If anything looks as though it is not well done, send it back and ask for another one that is well done.
- Go only to restaurants that prepare food freshly and not in large quantities at the beginning of the day.

Tips for helping appetite

- Large plates of food can be overwhelming when you don't have a desire to eat. Eat smaller quantities more frequently. Six smaller meals or "snacks" spaced throughout the day are recommended.
- Cool foods are often better tolerated than hot foods.
- Odors from cooking may bother you. If so, go to another area of the apartment while your caregiver is preparing foods.

Suggestions for adding protein and calories to your diet

- Melt cheese on sandwiches, meats, fish vegetables and desserts or add it to casseroles, vegetables, potatoes, breads or sauces.
- Add powdered milk to casseroles, meatloaf, breads, soups, puddings, and milkshakes.
- Spread cream cheese on sandwiches, fruits or crackers.
- Add small pieces of meat to soups, salads, biscuits, or omelets.
- Spread peanut butter on sandwiches, toast, muffins, crackers, and fruit slices.
- Drink high protein, high calorie supplements (2 - 3 8 oz. servings per day).
- Use margarine, oil, and gravies whenever possible.

Daily Diet Diary

- Write down everything you eat. Include liquid and solid foods along with the approximate amount that was eaten.
- Use a new sheet for each day.
- Bring with to the hospital for the daily visit.

Dietician

You and your caregiver should have already met with the dietician. The dietician will continue to be a part of the Bone Marrow Transplant Team and should see you at least once a week. If there are problems or questions that arise, let the doctor or nurse know and they can arrange a consultation with her.

FOODS NOT ALLOWED

Black pepper
Hot peppers
Yogurt with active cultures
Raw honey
Buttermilk
Blue cheese dressing
Refrigerated salad dressings
Aged cheeses:
- cheddar
- feta
- Gouda
- Farmer's cheese
- ricotta cheese
- hot pepper cheese

Ice cream
Fresh fruits and vegetables not peeled and scrubbed.
Raisins and dried fruits
Raw fish or sushi
Raw or runny eggs
Undercooked meats
Deli meats sliced on a slicer
Smoked or pickled meats and fish

FOODS ALLOWED

Salt
Processed honey
Pasteurized milk and milk products
Yogurt not containing active or live cultures.
Bottled salad dressings
- French
- Thousand Island
- Ranch

Non-aged cheeses:
- Swiss
- mozzarella
- parmesan
- American
- provolone
- muenster
- Velveeta

Well cooked meats
Well cooked eggs
Pre-packaged deli meats

Name: _____

NMH MR#: _____

DAILY DIET DIARY
FOR ___/___/___

BREAKFAST

SNACK

LUNCH

SNACK

DINNER

SNACK

DIETARY GUIDELINES
FOR CAREGIVERS

During and following the high dose chemotherapy and bone marrow/peripheral stem cell transplant, it may be difficult at times for patients to eat. Depending on the type of treatment the patient received, he or she may have mouth sores, diarrhea, taste changes, and/or nausea and vomiting. When these problems occur, it is important that the physicians be made aware of them. Also, during this time period, calorie and protein needs are generally increased. Your help in preparing or choosing foods that are appealing to the patient, as well as your encouragement in getting them to eat is a very important role. We do not like for patients to lose weight during this phase of their treatment. Adequate nutrition is needed for recovery. The Bone Marrow Transplant team will be monitoring the patient's nutritional status daily. If the need arises, IV nutritional supplementation will be given.

Because the patient will be susceptible to infection during this time, there are some dietary restrictions that need to be followed. Also, following are some tips for helping manage some of the side effects the patient may have that can effect diet.

Infection Precautions

- Attached is a list of foods that are and are not allowed to be eaten by the patient.
- Before preparing any food, be certain to wash hands thoroughly.
- Fresh fruits and vegetables must be scrubbed well before preparing. This needs to be done by you and not by the patient. Once they have been scrubbed well, the patient may have them as long as they are peeled and then eaten right away.
- Be certain foods are fresh when they are prepared and are used before the expiration date.
- If you are handling raw meat or chicken, wash all utensils and work areas well (scrub vigorously) with hot, soapy water before using it for other food preparation. Also, be certain to then wash hands well.
- Avoid bulk foods and try to use single serving items if at all possible.
- Leftovers are allowed but must be refrigerated or frozen immediately and should be eaten within 24 hours.

- Food should be served at the temperature that it is intended. Hot food should be hot and not just lukewarm and cold food should be very cold and not room temperature.

Restaurants

- Restaurant food is allowed from the list of restaurants supplied.
- When ordering from a restaurant, no fresh fruits or vegetables should be eaten. You do not know how they were washed or prepared. This includes salads and garnishes.
- Specifically ask for no garnishes or condiments on the plate with the food.
- Ask that food be well cooked. If anything looks as though it is not well done, send it back and ask for another one that is well done.

Tips for helping appetite

- Large plates of food can be overwhelming to patients when they don't have a desire to eat. Offer smaller quantities.
- Offer six smaller meals or "snacks" spaced throughout the day.
- Cool foods are often better tolerated than hot foods.
- Odors from cooking may bother patients. If so, the patient should try to go to another area of the apartment when you are preparing foods.

Suggestions for adding protein and calories to the patient's diet

- Melt cheese on sandwiches, meats, fish vegetables and desserts or add it to casseroles, vegetables, potatoes, breads or sauces.
- Add powdered milk to casseroles, meatloaf, breads, soups, puddings, and milkshakes.
- Spread cream cheese on sandwiches, fruits or crackers.
- Add small pieces of meat to soups, salads, biscuits, or omelets.
- Spread peanut butter on sandwiches, toast, muffins, crackers, and fruit slices.

- Have the patient drink high protein, high calorie supplements (2 - 3 8 oz. servings per day).

- Use margarine, oil, and gravies whenever possible.

Daily Diet Diary

- If the patient is unable to keep the daily diary, we ask that you do it. Ask the patient if they did it.

- Write down everything eaten by the patient. Include liquid and solid foods along with the approximate amount that was eaten.

- Use a new sheet for each day.

- Bring with to the hospital for the daily visit.

Dietician

The patient and you should have already met with the dietician. The dietician will continue to be a part of the Bone Marrow Transplant Team and should see you and the patient at least once a week. If there are problems or questions that arise, let the doctor or nurse know and they can arrange a consultation with her.

FOODS NOT ALLOWED

Black pepper
Hot peppers
Yogurt with active cultures
Raw honey
Buttermilk
Blue cheese dressing
Refrigerated salad dressings
Aged cheeses:
- cheddar
- feta
- Gouda
- Farmer's cheese
- ricotta cheese
- hot pepper cheese

Ice cream
Fresh fruits and vegetables not peeled and scrubbed.
Raisins and dried fruits
Raw fish or sushi
Raw or runny eggs
Undercooked meats
Deli meats sliced on a slicer
Smoked or pickled meats and fish

FOODS ALLOWED

Salt
Processed honey
Pasteurized milk and milk products
Yogurt not containing active or live cultures.
Bottled salad dressings
- French
- Thousand Island
- Ranch

Non-aged cheeses:
- Swiss
- mozzarella
- parmesan
- American
- provolone
- muenster
- Velveeta

Well cooked meats
Well cooked eggs
Pre-packaged deli meats

Name: _____

NMH MR#: _____

DAILY DIET DIARY
FOR ___/___/___

BREAKFAST

SNACK

LUNCH

SNACK

DINNER

SNACK

MEDICATIONS

The medications prescribed for an individual patient will vary according to their needs. Some medications will be taken orally, some by injection, and some intravenously. Some medications will be scheduled medications (taken at scheduled times) and some will only need to be given on an as needed basis.

Scheduled Medications

Scheduled medications that the patient is likely to be taking include:

* antibiotics (fight bacteria)
* antifungals (fight fungi)
* antivirals (fight viruses)
* mineral supplements
* electrolyte supplements
* growth factor shots

⇒ All scheduled medications should be taken at the same time each day. It is important that scheduled medication be taken as close to the prescribed time as possible.

⇒ Bring all medications that will need to be taken during the time that the patient will be at the hospital for their daily visit. This is so that no doses will be missed.

⇒ If a dose is missed at the scheduled time, first determine how much time is normally between doses.
- If less than 1/2 of that time has passed, take the missed dose right way and return to the original schedule.
- If more than 1/2 of that time has passed, skip the missed dose all together and return to the original schedule.
- Never take 2 doses of a drug at the same time. Don't double up on doses.

⇒ If vomiting occurs:
- within 15 minutes of taking the medication **and** you can see the tablet or capsule, take another dose.
- if the medication was a liquid or was taken under the tongue, **do not** repeat the dose.

⇒ Do not crush or break any pills or capsules until first checking with the doctor or nurse.

⇒ If the patient has problems taking the medications ordered for any reason, be certain to notify the doctor or nurse. The drug may be able to be given in a liquid form or intravenously.

Unscheduled Medications

Medications that are sometimes given to people to use **only if needed** may include:

* antiemetics (control nausea and vomiting)
* pain medications
* sleep medications

⇒ Use these medications only for the indication that is noted.

Daily Medication Flow Sheet

You will be given a Daily Medication Flow Sheet for each day you are in the bone marrow transplant apartment. Below are guidelines for using it.

⇒ There will be 2 sides to the form. The first side will list scheduled medications and the second side will list as needed medications.

⇒ Use a new sheet for each day.

⇒ Bring the flow sheets with you to the hospital each day for the daily visit.

⇒ If you notice that the supply of a particular medication is getting low, be sure to let someone (the doctor or nurse) know at your daily visit.

For scheduled medications:

⇒ The drugs, doses, and scheduled times will be listed on the left of the flow sheet.

⇒ Across the top of the columns, there are times listed.

⇒ The box will be shaded in when there is a medication due.

⇒ When the drug is taken, put your initials in the box.

⇒ If for some reason the drug is taken at a different time, write the time in the shaded box and then put your initials in the box.

⇒ If for any reason the drug is not taken, put a zero (0) in the box with your initials.

For "as needed" medications:

⇒ The drugs, doses, and how often they may be taken will be listed in the left column.

⇒ There will be no times filled in at the top since these drugs are not scheduled.

⇒ When you take a medication, fill in the time it was taken and your initials in the boxes to the right of the drug name.

⇒ Use a new box each time a drug is taken.

NAME _____
NMH #: _____

MEDICATION FLOW SHEET
FOR ____/____/____

SCHEDULED MEDICATIONS	8 AM	9 AM	11 AM	12PM	2PM	5PM	8PM	9PM	10PM
Ciprofloxacin 750 mg orally every 12 hours at **9 am and 9 pm**									
Rifampin 300 mg orally every 12 hours at **9 am and 9 pm**									
Acyclovir 800 mg orally twice a day at **8 am and 8 pm**									
Fluconazole 400 mg orally every day at **12 noon**									
G-CSF _____mcg/_____ml SUBQ injection once daily at **10 pm**									
Salt and soda oral rinses at least 5 times/day at **8am, 11am, 2pm, 5pm, 8pm**									
Chlorhexidine rinses 15 cc swich and spit three times/day at **8am, 2pm, 8pm**									
Potassium Chloride _____ meq given _____ at _____, _____, _____, and _____									
Magnesium Oxide _____tabs orally at _____, _____, _____, and _____.									
Bactrim DS 1 tablet orally on **Mon., Wed., and Fri. only at 10 pm**									
Leucovorin 5 mg orally on **Mon., Wed., and Fri. only at 10 pm**									

NAME _____

NMH #: _____

MEDICATIO. . LOW SHEET

FOR ____/____/____

AS NEEDED MEDICATIONS	TIME	TIME	TIME	TIME	TIME	TIME	TIME	TIME	TIME
Magnesium sulfate _____ Gm IV at _____, _____, and _____.									
Ativan _____ mg given _____ every _____ hours **as needed** for nausea and anxiety									
Compazine _____ mg given _____ every _____hours **as needed** for nausea									
Kytril 1 mg orally at _____ and _____									

TAKING VITAL SIGNS

Every 4 hours, except at night when the patient is sleeping, you will need to take the patient's vital signs (temperature, pulse, and blood pressure). Also, you should take them anytime you or the patient notice new symptoms. The results are to be recorded on the vital sign flow sheet and brought with the patient to the daily visit at the hospital.

TEMPERATURE

1. You will be given disposable thermometers with which to take the patient's temperature. Wait at least 15 minutes after the patient has had anything to eat or drink before doing this. Follow the steps below:

2. Peel back top of wrapper and expose handle. Remove thermometer by pulling gently. Do not touch the end with the dots.

3. Place the thermometer in the patient's mouth, under the tongue, as far back as possible into the "pocket" on either side. Have the patient press their tongue down on the thermometer while keeping mouth closed.

4. After 60 seconds, remove the thermometer from the patient's mouth.

5. Read the temperature at the last blue dot.

6. Throw the used thermometer away.

BLOOD PRESSURE

You will be given a digital blood pressure cuff to use. Put the cuff around the arm above the elbow being certain that it is straight and not "kinked," wrinkled or folded. Turn the power on and then push start. The cuff will automatically inflate and give you a digital reading of the blood pressure. It will take 15 - 30 seconds to get a read out. Wait 10 to 15 minutes after any physical activity before doing this. Record the result on the vital sign flow sheet under Blood Pressure.

PULSE

At the same time you take the blood pressure, the cuff will take the pulse and give you a digital readout. Record the result on the vital sign flow sheet under Pulse.

Call the physician immediately if any of these results are outside the parameters below. The number to call is _____.

Systolic B/P (top number) higher than _____ or lower than _____.
Diastolic B/P (bottom number) higher than _____ or lower than _____.
Pulse higher than _____ or lower than _____.
Temperature higher than 100.5°F.

NAME._____
NMH#:_____

VITAL SIGN FLOW SHEET
FOR ___/___/___

VITAL SIGNS	TIME	TIME	TIME	TIME	TIME	TIME	TIME	TIME	TIME
TEMPERATURE									
PULSE									
BLOOD PRESSURE									

INTAKE AND OUTPUT

It is very important that we are able to keep track of the patient's fluid status during the transplant process. It is possible for people to retain fluids or to become dehydrated. This is why we ask you to keep track of everything that goes into the patient and everything that comes out of the patient.

INTAKE

* Put all fluids taken by mouth in the "Oral" column and all intravenous fluids in the "IV" column.

* Record any liquid that the patient takes by mouth on the Intake and Output Flowsheet. Include popsicles, jello and soup.

* Record amounts in either ounces (oz) or milliliters (ml) but indicate which unit of measure is being used.

* If the patient finishes only part of something, put the approximate amount the ate or drank on the flowsheet (i.e., 1/2 of a 4 oz. popsicle).

* Any IV fluids given in the CRC will be recorded by the nurse in the CRC.

* The home health RN will record any fluids that they administer.

* If you are responsible for giving any IV fluids, someone will tell you how much to record on the flowsheet.

* Use a new flow sheet for each 24 hour period. Begin at 6 am and end at 6 am the following day when you begin a new sheet.

OUTPUT

* Everything that comes out of the patient will need to be measured separately - urine, stool, and emesis.

* You will be given 2 plastic pans or "hats" to place in the toilet. One goes in the front to catch urine and one goes in the back to catch stool.

* The pans go under the seat and then the seat gets put back down.

* The pans have measurement markings in black. The amount should be read while the pan is sitting level.

* If urine and stool become mixed, try to estimate how much of each there is.

* If something is unable to be measured, estimate the quantity as small, medium or large and record that.

* Rinse the plastic pans with water after they are emptied.

* There will also be a container for emesis. There are subtle markings inside the pan for measuring this.

DAILY INTAKE & OUTPUT FLOWSHEET

NAME: _____

NMH ID #: _____

DATE: _____

INTAKE		OUTPUT		
ORAL INTAKE	IV INTAKE (To Be Completed by Clinic or Home Health Nurse)	URINE	STOOL	EMESIS
TOTAL:	TOTAL:	TOTAL:	TOTAL:	TOTAL:
TOTAL INTAKE:		TOTAL OUTPUT:		

NAME _____
NMH #: _____

MEDICATIO...LOW SHEET
FOR ____/____/____

SCHEDULED MEDICATIONS	8 AM	9 AM	11 AM	12PM	2PM	5PM	8PM	9PM	10PM
Ciprofloxacin 750 mg orally every 12 hours at **9 am and 9 pm**									
Rifampin 300 mg orally every 12 hours at **9 am and 9 pm**									
Acyclovir 800 mg orally twice a day at **8 am and 8 pm**									
Fluconazole 400 mg orally every day at **12 noon**									
G-CSF _____mcg/_____ml SUBQ injection once daily at **10 pm**									
Salt and soda oral rinses at least 5 times/day at **8am, 11am, 2pm, 5pm, 8pm**									
Chlorhexidine rinses 15 cc swich and spit three times/day at **8am, 2pm, 8pm**									
Potassium Chloride _____ meq given _____ at _____, _____, _____, and _____									
Magnesium Oxide _____tabs orally at _____, _____, _____, and _____.									
Bactrim DS 1 tablet orally on **Mon., Wed., and Fri. only at 10 pm**									
Leucovorin 5 mg orally on **Mon., Wed., and Fri. only at 10 pm**									

DAILY INTAKE & OUTPUT FLOWSHEET

NAME: _____

NMH ID #: _____

DATE: _____

INTAKE		OUTPUT		
ORAL INTAKE	IV INTAKE (To Be Completed by Clinic or Home Health Nurse)	URINE	STOOL	EMESIS
TOTAL:	TOTAL:	TOTAL:	TOTAL:	TOTAL:
TOTAL INTAKE:		TOTAL OUTPUT:		

NAME _____
NMH#:_____

VITAL SIGN _OW SHEET
FOR ____/____/____

VITAL SIGNS	TIME	TIME	TIME	TIME	TIME	TIME	TIME	TIME	TIME
TEMPERATURE									
PULSE									
BLOOD PRESSURE									

Name: _____

NMH MR#: _____

DAILY DIET DIARY
FOR ___/___/___

BREAKFAST

SNACK

LUNCH

SNACK

DINNER

SNACK

NORTHWESTERN MEMORIAL HOSPITAL
OUTPATIENT BONE MARROW TRANSPLANT
APARTMENT INFORMATION

You may receive mail at the apartment. Mail should be addressed as follows:

Your Name
c/o Bone Marrow
244 E. Pearson
Apartment 504
Chicago, IL 60611

Any mail received for you after you leave the apartment can either be sent directly to your house or can be brought to you at your clinic visit. Let us know which you prefer.

The apartment is equipped with a phone. Calls to Chicago and the surrounding areas (312, 773, 847, and 630) can be made free of charge. The phone number for the apartment is _____.

- When dialing out, you must dial "9" first, followed by 1 and the area code if it is not 312.

- If calling outside the above area codes, this can be billed to your credit card.

- If calling somewhere on the hospital campus, you only need to dial the last five digits of the phone number. (For example, if calling the BMT office, you only need to dial 8-5400.)

- When dialing for an emergency, you will need to dial 9-911. This will get the Chicago Police, Ambulance, or Fire Department.

Your caregiver will be given a pager so that we can contact him or her when you are finished at the hospital for the day. Your caregiver should leave the pager on at all times. If for some reason you need to operate the pager, do the following:

- From the apartment phone or any hospital phone, you only need to dial 5-7903 and then enter the return phone number when it tells you to do so.

- From an outside phone, dial 312-908-6999.

- Then enter 5-7903.

- Then enter your return phone number when it tells you to do so.

CHURCHES NEAR WORCESTER HOUSE

ROMAN CATHOLIC
Holy Name Cathedral
735 N. State
312-787-8040
Sunday Masses at 7, 8:15, 9:30, 11AM, 12:30 & 5:15pm
Saturday Evening: 5:15 and 7:30 pm
Weekday Masses: 6, 7, 8 am, 12:10 & 5:15 pm
Holy Days 6, 7, 8, 9 am, 12:10 & 5:15 pm

PRESBYTERIAN
4th Presbyterian Church
126 E. Chestnut
312-787-4570
Sunday Services at 8:30 am, 11:00 am, and 6:30 pm

EPISCOPAL
St. James Cathedral
312-787-7360

GROCERY STORES

Lake Shore Market
Full Service Market
Delivery free if order over $20
Can phone in order
900 N. Lake Shore Drive
312-642-8895

Treasure Island
Full Service Market
Delivery of items you shopped for $6
Phone in delivery and they shop $10
If phoning in talk with Jim
680 N. Lake Shore Drive
312-664-0400

Jewel Food Store
No delivery
1210 N. Clark
312-944-6950

Bockwinkel's
Full Service Market
Delivery, if over $50 free
Phone in order $5
Chicago Place
700 N. Michigan Avenue
312-482-9900

DRUG STORE

Walgreen's
757 N. Michigan
312-664-4000

High Dose Chemotherapy with Autologous Stem Cell Rescue in the Out-Patient Setting: A Quality of Life and Cost Analysis
June Winter, M.D., Principal Investigator

Care givers will complete the quality of life and psychosocial instruments at baseline (before the start of high dose chemotherapy) and at one week intervals up to the first week at home. The patient's nurse will administer the forms with instructions to ensure the completion of all items and to reduce burden. We have previous experience using this procedure in an inpatient high dose chemotherapy program (Mytko, Knight, Chastain, Mumby, Siston, and Williams, in press). The quality of life and psychosocial instruments include the Profile of Mood States Brief Scale, Impact of Events Scale and the Miller Behavioral Style Scale. We have revised the Perceived Involvement in Care Scale and the Functional Assessment of Cancer Therapy Scale for Bone Marrow Transplant in order to evaluate care givers perception of the patient. We have described these measures below.

Profile of Mood States (POMS) Brief Scale. (Guadagnoli and Mor, 1989). We will use a brief version of the POMS to evaluate negative and positive affect. It is a 14-item adjective rating scale. Instructions direct respondents to indicate on a five-point scale the degree that each adjective describes mood during the past week. Many studies of cancer treatment have used the 60-item POMS. Guadagnoli and Mor developed the brief POMS to reduce the burden of measurement in studies of cancer patients.

Impact of Events Scale (IES) (Horowitz, Wilner, Alvarez, 1979). We will use this brief 15-item instrument to assess the frequency and severity of intrusive thoughts and avoidant thoughts about high dose chemotherapy and autologous stem cell reinfusion. Previous studies of breast cancer and breast cancer risk notification have employed this measure.

Miller Behavioral Style Scale (MBSS) (Miller, 1987). The MBSS is a 32-item scale designed to measure coping style, particularly tendency to monitor the environment for information in response to stress. Previous studies of cancer patients have used this instrument to measure dispositional coping style which may heighten anxiety about cancer treatment and its risks.

Care giver Confidence Evaluation (CCE) We designed the CCE scale to evaluate the care giver's level of confidence in performing routine care to the patient during the outpatient high dose chemotherapy and autologous bone marrow transplant procedure. One goal of the present study is to evaluate the psychometric properties of this scale.

We have modified the following scales to evaluate care giver perception of involvement in care and patient quality of life:

Perceived Involvement in Care Scale (PICS). This is a thirteen item scale designed to assess perceived involvement in treatment. It provides an overall score and three subscale scores including doctor facilitation of patient involvement, patient information seeking and patient decision making. Coefficient alpha for the overall score was .73 in a sample of 131 general medicine patients, suggesting adequate internal consistency reliability. Factor analysis of its construct validity suggests that the subscales measure three independent dimensions.

Functional Assessment of Cancer Therapy-Bone Marrow Transplant (FACT-BMT). The FACT-BMT consists of a twenty-nine-item scale assessing five quality of life domains: physical, social, emotional, functional, and relationship with doctor. It includes a twelve-item subscale to

assess concerns specific to bone marrow transplant. Test-retest reliabilities for the FACT range from .82 to .88 and internal consistency reliabilities range from .82 to .94 for the subscales. Previous research on the instrument has supported its validity in a variety of cancers. The scale correlated with other measures of quality of life, but not with social desirability.

Cella DF, Tulsky, DS, Gray, G. et al. The Functional Assessment of Cancer Therapy (FACT) Scale: Development and validation of the general measure. *Journal of Clinical Oncology*. 1993;11:570-579.

Guadagnoli, E., Mor, V. (1989). Measuring Cancer Patients' Affect: Revision and Psychometric Properties of the Profile of Mood States (POMS). *Psychological Assessment, 1*, 150-154.

Horowitz, M., Wilner, M., Alvarez, W. (1979). Impact of Event Scale: A Measure of Subjective Stress. *Psychosomatic Medicine, 41*, 209-218.

Lerman CE, Brody, DS, Caputo, GC, Smith, DG, Lazaro, CG, Wolfson, HG. Patients' perceived involvement in care scale: Relationship to attitudes about illness and medical care. *Journal of General Internal Medicine*. 1990;5:29-33.

Miller, S. (1987). Monitoring and Blunting: Validation of a Questionnaire to Assess Styles of Information Seeking Under Threat. *Journal of Personality and Social Psychology, 52*, 345-353.

Mytko, J., Knight, S., Chastain, D., Mumby, P., Siston, A., Williams, S. (In press in the Journal of Clinical Psychology in Medical Settings). Coping Strategies and Psychological Distress in Cancer Patients Before Autologous Bone Marrow Transplant.

Patient ID:_____

PATIENT AND CAREGIVER COST DIARY

TO BE COMPLETED BY CAREGIVER DURING STAY AT OUTPATIENT FACILITY

Dear Patient and Caregiver,

This booklet will be used as a log to document the costs of caring for a transplant patient outside of the hospital.

This information is important to the study you are participating in and should only take a few minutes a day to complete. This information will also be useful in improving the treatment and support for future patients.

We ask that you complete the Personal Information sheets the first day, giving us some basic information about both of you. We also ask that you keep a daily list of costs on the provided ledgers. At the end of each week there are some additional questions regarding how the transplant process and caregiving has affected your lifestyles.

Please remember, there are no right or wrong answers. All the information you provide will be strictly confidential.

We thank you for your participation and we very much appreciate your efforts!

Day One: Caregiver Personal Information Today's Date_____

1. What is your relationship to the patient? (Circle One)

   Spouse Sibling Other Relative Friend

2. What is your age? _____

3. What is your gender? _____

4. Circle your highest level of education:

   High School Some College College Graduate Advanced Degree

5. Are you currently employed? Yes_____ No_____

6. Circle One: Full Time Part time Temporary Retired

7. What is (was) your occupation? _____

8. What is your approximate annual household income? (Circle One)

   <$20,000 $20,000-$50,000 $50,000-$80,000 >$80,000

Day One: Patient Personal Information **Today's Date_____**

1. Circle your highest level of education:

High School	Some College	College Graduate	Advanced Degree

2. Are you currently employed? Yes_____ No_____

3. Circle One: Full Time Part time Temporary Retired

4. What is (was) your occupation? _____

5. What is your approximate annual household income? (Circle One)

<$20,000 $20,000-$50,000 $50,000-$80,000 >$80,000

Day One **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Two **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Three **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Four **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Five **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Six **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Seven **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Eight **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Nine **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Ten **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Eleven **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Twelve **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Thirteen **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Fourteen **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Fifteen **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Sixteen **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Seventeen **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Eighteen **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Nineteen **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Twenty **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

Day Twenty-One **Today's Date_____**

In the table below, please list the total cost of items purchased for both the patient and yourself in each category:

Category	Total $
Groceries/Meals	
Toiletries	
Personal Comfort Items	
Prescription Medicines/ Co-payments	
Over the Counter Medicines	
Other	

After First Week **Today's Date_____**

Caregiver Lifestyle Information

1. How much of your time each day during the past week was spent collecting and reporting medical information (for example, taking temperature)?

   _____Hours

2. How much time of your time each day during the past week was spent assisting the patient with grooming and personal care tasks?

   _____Hours

3. What form of transportation brought you to the transplant center?

   _____

4. How much did this cost in total (cab fare, gas, parking)?

   $_____

5. How much have you spent on other transportation and/or parking during the past week?

   $_____

6. How much of your time during the past week has been spent dealing with the patient's illness-related finances or insurance questions?

   _____Hours

7. If employed, how many days have you taken off of work during the past week?

   _____Days

   How did you schedule your time off? (Circle answer(s))

   Vacation Time Sick Time Personal Days Unpaid Leave

8. In the past week, during your absence, was there any additional help required at your home? What did this approximately cost?

   Cleaning $_____

   Childcare $_____

   Pet Care $_____

   Transportation $_____

   Laundry $_____

   Meals $_____

9. In the past week, have you had to use any of your personal monetary savings to assist with your costs during caregiving?_____

After Second Week **Today's Date_____**

Caregiver Lifestyle Information

1. How much of your time each day during the past week was spent collecting and reporting medical information (for example, taking temperature)?

   _____Hours

2. How much time of your time each day during the past week was spent assisting the patient with grooming and personal care tasks?

   _____Hours

3. How much have you spent on other transportation and/or parking during the past week?

   $_____

4. How much of your time during the past week has been spent dealing with the patient's illness-related finances or insurance questions?

   _____Hours

5. If employed, how many days have you taken off of work during the past week?

   _____Days

   How did you schedule your time off? (Circle answer(s))

   Vacation Time Sick Time Personal Days Unpaid Leave

6. In the past week, during your absence, was there any additional help required at your home? What did this approximately cost?

Cleaning	$_____
Childcare	$_____
Pet Care	$_____
Transportation	$_____
Laundry	$_____
Meals	$_____

7. In the past week, have you had to use any of your personal monetary savings to assist with your costs during caregiving?_____

After Third Week **Today's Date_____**

Caregiver Lifestyle Information

1. How much of your time each day during the past week was spent collecting and reporting medical information (for example, taking temperature)?

   _____Hours

2. How much time of your time each day during the past week was spent assisting the patient with grooming and personal care tasks?

   _____Hours

3. How much have you spent on other transportation and/or parking during the past week?

   $_____

4. How much of your time during the past week has been spent dealing with the patient's illness-related finances or insurance questions?

   _____Hours

5. If employed, how many days have you taken off of work during the past week?

   _____Days

   How did you schedule your time off? (Circle answer(s))

   Vacation Time Sick Time Personal Days Unpaid Leave

6. In the past week, during your absence, was there any additional help required at your home? What did this approximately cost?

Cleaning	$_____
Childcare	$_____
Pet Care	$_____
Transportation	$_____
Laundry	$_____
Meals	$_____

7. In the past week, have you had to use any of your personal monetary savings to assist with your costs during caregiving?_____

After First Week **Today's Date_____**

Patient Lifestyle Information

1. What form of transportation brought you to the transplant center?

   _____

2. How much did this cost in total (cab fare, gas, parking)?

   $_____

3. If you have been employed, how many days have you taken off of work during the past week for your current treatment?

   _____Days

   How did you schedule your time off? (Circle answer(s))

   Vacation Time Sick Time Personal Days Unpaid Leave

4. During your current treatment, was there any additional help required at your home? What did this approximately cost?

   Cleaning $_____

   Childcare $_____

   Pet Care $_____

   Transportation $_____

   Laundry $_____

   Meals $_____

5. How soon after returning home has your doctor informed you that you can:

   Care for yourself physically _____weeks

   Complete your own household tasks _____weeks

   Return to a partial work schedule _____weeks

   Return to a full work schedule _____weeks

6. Does your insurance coverage require that you pay a deductible or a certain percentage of this treatment or stay?

   $_____ Deductible

   _____% Percentage of Bill

6. Will you have to use any of your personal savings to help cover costs during this treatment?_____

After Second Week **Today's Date_____**

Patient Lifestyle Information

1. If you have been employed, how many days during the past week have you taken off of work for your current treatment?

   _____Days

   How did you schedule your time off? (Circle answer(s))

   Vacation Time Sick Time Personal Days Unpaid Leave

2. During the past week, was there any additional help required at your home? What did this approximately cost?

   Cleaning $_____

   Childcare $_____

   Pet Care $_____

   Transportation $_____

   Laundry $_____

   Meals $_____

After Third Week **Today's Date_____**

Patient Lifestyle Information

1. If you have been employed, how many days during the past week have you taken off of work for your current treatment?

   _____Days

   How did you schedule your time off? (Circle answer(s))

   Vacation Time Sick Time Personal Days Unpaid Leave

2. During the past week, was there any additional help required at your home? What did this approximately cost?

   Cleaning $_____

   Childcare $_____

   Pet Care $_____

   Transportation $_____

   Laundry $_____

5. Meals $_____

Inpatient vs. Outpatient High-Dose Therapy Cost Study

Patient ID#_____ Last Name, First Initial_____

Age, at transplant_____ Sex_____

Date of Transplant_____

Circle One: Inpatient Outpatient

Date of PBSC Harvest_____

Dates of Chemotherapy Administration_____

Date of Stem Cell Reinfusion_____

Describe chemotherapy regimen, give common abbreviation (e.g., CA, FAC) and write out names of drugs._____

_____

Briefly describe any prior treatment for this disease_____

_____

For inpatient, date of discharge_____

For outpatient, date of discharge to outpatient facility_____

Date(s) of hospital admissions_____

_____

_____

Date(s) of emergency room visits_____

_____

_____

Use(s) of ambulance _____

_____

_____

Describe any supportive agents not listed as part of protocol, if growth factors are used describe purpose (stem cell mobilization, prophylaxis or treatment of neutropenia)_____

_____

Describe the following, write-out and use the number scale from attached ABMTR Registration Forms

Diagnosis_____

Disease State_____