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PRINCIPAL INVESTIGATOR: Monica Morrow, M.D.

CONTRACTING ORGANIZATION: Northwestern University  
Evanston, Illinois 60208

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<b>13. ABSTRACT (Maximum 200)</b> The purpose of the component studies in this grant is to increase the utilization of available interventions for the screening, diagnosis, and treatment of breast cancer, particularly by the medically underserved. Risk factor information has been obtained for 5000 healthy women. To date, 738 non-English-speaking women have had breast cancer teaching through a peer health educator, and 28% have gone on to have mammograms. 69 nurses from city/minority health clinics have undergone a 16-hour educational intervention, with post-test scoring above the 75 <sup>th</sup> percentile for 94% of participants vs 56% on pretesting, and 82% improving breast exam skills on a standardized patient. A randomized trial of the effect of same-day mammography on patient compliance, utilizing different practice settings, has enrolled 97 women in a public health clinic and 74 from an internal medicine private practice, and 79 Hispanic women have been randomized to a dietary intervention study. Interactive video conferencing is successfully occurring at off-site hospitals. Data has been collected on 476 core biopsies and 335 surgical biopsies for a study of cost-effectiveness of core biopsy, and 26 patients entered into a randomized trial of cost effectiveness of inpatient vs outpatient bone marrow transplantation			
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FOREWORD


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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 Database  
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 database will be expanded to include a few additional risk factor data points.

### Education Initiatives for Providers and Patients

Project #2: Chicago Ethnic Community Breast Cancer Education and Screening: Woman to Woman Outreach  
PI: Miriam Rodin MD PhD

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 PhD

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 Healthcare 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 Techniques

Project #7: Cost-effectiveness of stereotactic biopsy versus excisional biopsy for women with abnormal mammograms  
PI: Charles Bennett MD PhD

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 DATABASE

### 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 database 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 945 patients have been entered in this database 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. Conversion to Scannable Format

At the conclusion of year 1 of the grant, the decision was made to convert our databases to a scannable format. After testing a variety of software products, The Microtek Scannable E6 software was installed at the recommendation of our consultants. However, experience with this product over the past 5 months has demonstrated that it is not robust enough to meet our volume needs. The Fujitsu 15C scanner will be installed and tested shortly. Conversion to scannable format was not part of the statement of work on this project but was undertaken using outside funds to facilitate data collection. Paper data collection and manual data entry have continued during this time period.

#### B. Accrual of Research Subjects

Our target for patient accrual was 2000 patients in year 1 and 3000 patients in year 2. Due to operational changes in our screening mammography center, by the end of year 1 only 310 completed questionnaires had been received. With the opening of our dedicated screening mammography center in September 1997 we have been able to meet our target recruitment for years 1 and 2 of the study. As of July 10, 1998 risk factor data has been collected on 5061 women. This has actually exceeded our target of 5000 women by month 12 of year 2. Questionnaires have been screened for duplication, missing names, missing social security numbers, or grossly discrepant data, and 133 surveys (2.6%) have been excluded. At this time, data entry of these cases is ongoing and is expected to be complete within the next 8 weeks. Once data entry is complete, the first standardized report on patients in the risk database will be generated and a comparison of the demographics and risk factors of these 5061 patients made to those of the 945 cancer patients in our cancer database. In addition, the risk factor database will be used to assess the number of potentially eligible subjects for the upcoming trial of tamoxifen versus raloxifene.

### CONCLUSIONS

At the completion of year 2 of this project, we have fulfilled the major objective of our statement of work, the collection of breast cancer risk data on 5000 women. This sample is now of sufficient size to allow exploratory data analysis which will be undertaken in project year 3.

## PROJECT 2: CHICAGO ETHNIC COMMUNITY BREAST CANCER EDUCATION AND SCREENING WOMAN-TO-WOMAN OUTREACH

### INTRODUCTION

#### Subject

Breast cancer is the most common invasive cancer among US women. Only recently has lung cancer surpassed it as the leading cancer cause of death. To the extent that country of origin data are available, immigrant women, especially Asians, appear to be at lower absolute risk of breast cancer. But breast cancer for most immigrant women, as for US-born women, still represents the leading preventable cancer cause of death.<sup>1</sup> Regular mammography offers the best opportunity to reduce mortality. Although the appropriate age for population-based recommendations for mammography has been the subject of recent controversy, national guidelines agree on periodic mammography for all women aged 50 and older, combined with annual clinical exams and regular self-examination.<sup>2</sup> Achieving these goals will mean developing effective outreach to women in defined underutilizing groups. These include the elderly, low income, and low education women<sup>3</sup> and, as addressed in this project, minority and women with limited English.

#### Purpose

The purpose of the research is to determine the effectiveness of lay health educators in promoting breast cancer early detection practices among predominantly poor, limited English proficiency (LEP) minority and immigrant women. A theoretical structure for explaining the effectiveness (or ineffectiveness) of peer educators is tested. This report presents interim and preliminary results from an ongoing community-based research project. It also reports on project modifications evolving from field experience.

#### Scope

Seven ethnic communities have been sampled through subcontracts with community-based organizations (CBO) for services of staff community health advocates (CHA) and a team of peer (lay) educators (PHE). The CHA and PHE receive a standardized curriculum which includes breast cancer facts, screening guidelines and BSE technique. PHE trainees are assessed by pre-test and post-test measures of attitudes, knowledge and proficiency in BSE. PHE are then expected to teach the curriculum to other women in their communities. CHA monitor the PHE activity by collecting logs of peer teaching contacts. The logs are designed to record each woman's readiness to adopt mammography or BSE (Stage of Adoption) as defined by the Transtheoretical Model of behavioral change. Women taught by peers are invited to attend research sessions in which further data are gathered to measure their knowledge, beliefs and BSE proficiency.

#### Background

Women in LEP immigrant communities experience many objective barriers to breast cancer early detection. These include lack of information due to conditions in their home countries, inaccessibility to US mass media public health messages, poverty and competing demands of jobs, child care and family roles which may downplay women's autonomy. However, free and low cost breast screening is increasingly available. In pilot work among Southeast Asian women, we determined that lay educators could accurately transmit information about breast cancer screening and BSE technique. In the current project, we have expanded to consider a wider spectrum of communities and have developed a more comprehensive model to explore the impact of peer educational outreach. We have adapted instruments based on the Health Belief Model, Theory of Reasoned Action (Decisional Balance), Social Learning/Self-Efficacy and Transtheoretical Model of Health Behavior. A detailed exploration of the theoretical underpinnings is beyond the scope of this discussion. In brief however, the Health Belief Model, originally suggested that health action was related to the perception of susceptibility to the threat, the seriousness of the threat and likelihood of successful

intervention.<sup>4</sup> Champion applied this theory to BSE adoption.<sup>5</sup> Bandura's social learning theory proposed that practices would be adopted if they were perceived to be ego-syntonic, that is, "people like me" and if the woman felt confident (self-efficacious) of being able to accomplish the health task.<sup>6</sup> The lay health advisor, the model for our PHE, proposes that this social identification with a salient information source is effective in promoting health behavior change.<sup>7,8</sup> The Decisional Balance model, derived from the Theory of Reasoned Action, proposes that health practices will be adopted if the benefits outweigh the costs, or for mammography, the forces promoting adherence outweigh the reasons to avoid screening.<sup>9</sup> Finally, the Transtheoretical Model proposes that decisions take place over time, that is, intention precedes action.<sup>10</sup> As rates of mammography have risen, more recent attention has focused on the determinants of repeat mammography.<sup>11</sup> Our outcome measure is the Stage of Adoption, the categorization of women along a five-point scale of non-adoption through intention to adherence to periodic mammography or BSE.

## PROGRESS REPORT YEAR 2 OBJECTIVES

### Overview of Participant Recruitment

To date, 738 community women have received at least one documented teaching contact through this project. Of these 252 (34.1%) have a documented follow-up contact. Although data entry are incomplete, 204 (80.9%) of 252 women report having had a mammogram at a time subsequent to PHE intervention. Assuming a 100% reporting bias, that is, none of the women lost to follow-up having had a subsequent mammogram, 27.6% of PHE contacts resulted in women seeking mammography. Most of the mammograms reported on follow-up have been performed at one site, the Chicago Department of Health Uptown Community Clinic. A good rapport between CBO staff and the Uptown Clinic has developed during the past year and half. This has facilitated scheduling and increased women's satisfaction with their experiences.

Post-testing has been conducted with 315 community women. This number includes women initially taught by a PHE who subsequently agreed to complete research forms and women with no prior PHE contact who attended community-based workshops led by CHA and PHE that were followed immediately by post-testing. Many of these records are incomplete for reasons discussed below.

We projected a sample size of 350 community women for hypothesis testing. We have nearly accomplished this number to date, however as discussed below, the number of complete records is substantially lower and requires additional subject recruitment in order meet the data requirements of the project.

### PHE Recruitment and Training

As originally envisioned, Year 2 objectives were to replicate Year 1. However, the projected start-up was unrealistically short compared to the actual time required for PHE recruitment and training. As we have gained experience with this process we were able to complete recruitment and training of 42 PHE. Results of PHE recruitment and training are presented in Table 1 (Demographics) and Table 3 (Training Effects). As shown in Table 1, PHE are generally slightly younger, better educated, more often employed outside the home and more likely to rate their spoken and reading English as fluent. Over one-third of PHE however acknowledge difficulty with English. All PHE training is provided with translators as needed. All CHA but one (Korean) are native English (American Indian) or fully bilingual. PHE are slightly more likely to have health insurance (including private, Medicare or Medicaid) than community women. The higher proportion of community women identifying a regular source of care reflects the wide use of the Chicago Department of Health Uptown Clinic, rather than a particular physician, among them as compared with peer educators. Finally we continue to observe a volunteer bias among our participants. Rates of mammography are high among PHE, 60%, and only about one-fifth admit to being out of compliance with the recommended 1-2 year intervals. Rates however are not much lower among community women. After correcting for age eligibility, however, the nearly even split in the data if it persists will allow for

hypothesis testing in comparisons of adopters and non-adopters of mammography. The clear majority of women report that they examine their breasts, however, only about a third of the PHE and a quarter of community women report monthly BSE.

The PI and Project Coordinator have participated in further networking with programs of peer education in other areas including a local Chicago Americorps program, the SIG on popular education sponsored at the American Public Health Association and an invitational low-literacy conference sponsored by Pfizer Pharmaceuticals. These contacts have broadened our understanding of the dynamics of lay education. As result, we have come to understand better the national experience with peer educator motivation and retention. We are within expectation, that is, on average PHE tend to remain active for about 6 months. We had anticipated a 30% turnover but have experienced closer to 50%, similar to the experience of other projects. About half our complement of currently active PHE have expressed a desire to continue; the remainder will be replaced within the coming weeks.

We have initiated monthly problem-solving sessions with CHA, retaining the consultation services of an experienced PHE trainer and motivator, Ms. Peg Dublin currently with an Hispanic Americorps Project sponsored by the University of Illinois at Chicago. These sessions are themselves of considerable interest and will likely be the subject of a separate report on the management of lay health educators. Two of our CBO subcontractors have been sufficiently impressed with the model that they have submitted proposals to fund peer projects for other target groups. The original stipend system for covering PHE expenses has been replaced with an incentive payment system in which PHE are compensated for recruiting women they train for research sessions. In addition, community women participating in research receive an equivalent incentive for their participation as well. This has resulted in increased numbers of research participants.

Nonetheless we continue to encounter three areas of difficulty. First, follow-up contact logs have been sporadically returned. Emphasis on the importance of follow-up has resulted in improved productivity over the past few months, but this remains an area in need of improvement. Second, a variable proportion of PHE teaching contacts are undocumented either because community women request anonymity (most prevalent among Chinese) or to a lesser extent because PHE literacy affects their ability to keep written records (most prevalent among Ethiopians). Third, recruiting community women for research is proving to be slow outside of organized workshops. This is due to the fact that women in these communities have very little free time. Many work outside the home, or if they do not, they provide child care for other working women in their families. There is reluctance of women in these communities to appear ignorant. Some women are recruited to attend peer directed workshops in which training and post-test data can be obtained in one session. The limitation here is time. For low literacy women, the sessions are often quite lengthy. Child care obligations and fatigue intervene. Part of the work of this year has been to simplify and abbreviate the research tools. We are in the process of examining the effect of protocol modifications on data quality.

#### Measures: Preliminary Results and Instrument Refinement

Due to the burden of translation and literacy, instrument refinement is an on-going goal of this project as we seek cross-culturally valid instruments with wide-applicability. During Year 1 we employed a 15-item refinement of the 39-item Champion Health Belief Questionnaire. Using Year 1 data, and data obtained for a validation sample of Southeast Asian women, we were able to condense this instrument to two 4-item scales, Fear and Self-Efficacy, with fair reliability. Results are shown in Table 2. New to this project was the Mammography Decisional Balance Scale (Rakowski). The original 12-item scale was revised to two 3-item scales measuring Promoter and Barrier attitudes to mammography, also shown in Table 2. All items are rated on 5-point Likert scales with maximum 15-points on 3-item scales and 20 points on 4-item scales.

Compared to the full scales, presented last year, reliability is somewhat lower but within acceptable limits. These results reflect in part the expected lesser reliability of fewer items. Results by ethnic group also reflect small numbers of women tested in each group. For the pooled sample, Cronbach alpha values range from .58 to .68.

Training effects on scale scores of PHE are shown in Table 3. Training resulted in statistically significantly decreased perceived barriers to mammography and marginally increased promoter attitudes. No significant effect was seen on Health Beliefs, either Fear or Efficacy. With the PHE a ceiling effect may be occurring, in that self-selection as a PHE denotes a belief in one's susceptibility and self-efficacy. Future analyses will compare the scores of PHE to community women and will correlate scores with adoption of or intention to adopt screening.

A brief Breast Facts questionnaire was analyzed early in the year. Item analysis at that time showed poor performance of items with pronouns (e.g. old item 5), items requiring evaluation of relative quantitative facts (e.g. old items 1,3,7) and items judged by the translators as too threatening in content (e.g. old item 8). The instrument was revised and retranslated with results shown in Table 5. After training the majority of community women and PHE correctly answer ten true false items and three items eliciting knowledge of screening guidelines. Analyses will examine the association between knowledge and adherence to or intention to seek screening.

The original protocol called for BSE observation for technique and accuracy on four Mammatech breast models each with five lumps. Again, this proved too time consuming in the field and the protocol was cut to two models with five lumps each. For teaching purposes, the manufacturer customized replacement models as original models wore out. The replacements contain one very hard but less than 1 cm "abnormal" lump deep in the gel matrix. Table 4a shows the combined BSE performance of PHE and community women. A perfect technique score was uncommon. As shown in Table 4b, the most common omissions were the hands-on-hips, leaning forward inspection positions, use of a systematic pattern and gentle nipple squeeze. Median lump detection was 5 of 10. The median number of false positive lumps detected was 3.

## CONCLUSIONS

At this time, conclusions must be offered cautiously. Although much data has been collected, the process has led to considerable refinement and reworking of measurement tools and human resource management of lay educators.

Qualitative results indicate that:

Peer health educators are heterogeneous in their motivations for participation. Some derive greater satisfaction and display higher performance when performance incentives are given. Others are motivated by the desire to serve the community and incentives appear to make little difference.

Peer health educators typically participate until they have exhausted their personal networks of kinswomen, close friends and work mates. Peer health educators who can integrate breast cancer education with their jobs, e.g. social service workers, or social positions, e.g. women's leader at the mosque, can sustain a longer commitment to the project.

Peer educators express a desire for additional training in health related topics.

Quantitative results: Peer educators demonstrate little change in Health Belief pertaining to Fear (of breast cancer, susceptibility) or in Self-Efficacy due to training. However, perceived Barriers to mammography decrease significantly and marginal increase is seen in perceived Promoters of mammography. The abbreviated scales appear to be reliable. When data collection is complete, analysis will compare the community women's attitudes to those of the PHE. PHE and community women demonstrate adequate understanding of Breast Cancer Facts, item results generally 75% correct or better. When data collection is complete, further analysis will examine whether factual knowledge affects Health Beliefs or Decisional Balance. BSE proficiency was less than desired

among both PHE and community women. Additional training and modification of the gel models will address this deficiency. Finally, Stage of Adoption as determined at follow-up will be examined for associations with measures of Health Belief (Fear, Self-efficacy), Decisional Balance (Promoters, Barriers), Knowledge and BSE proficiency.

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#### APPENDICES

Health Brief Questionnaire  
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Table 1: Demographic Characteristics of Peer Health Educators at Baseline (N=42) and Post-Tested Community Women (N=315)

<u>Characteristic</u>	<u>Peer Educators</u>	<u>Community Women</u>
AGE years per cent	Range 30-76	16-87
Younger than 40	21.3	20.6
40-49	39.4	17.0
50-64	24.1	42.2
65 and older	15.1	22.2
Mean (sd)	48.1 (12.2)	52.8 (14.1)
<b>MARITAL STATUS</b>		
Married with spouse	67.7	57.9
Single/Separated/Divorced	23.5	23.7
Widowed	8.8	18.4
<b>EDUCATION years per cent</b>		
None	-	5.9
1-7	18.2	21.0
8-10	--	20.2
11-12	18.2	27.3
13 or more	63.6	25.6
<b>EMPLOYMENT per cent</b>		
Yes, outside the home	84.8	41.1
No	15.2	58.9
<b>SPEAK ENGLISH per cent</b>		
Fluently	61.8	34.3
Some	38.2	62.7
None	--	3.0
<b>READ ENGLISH per cent</b>		
Fluently	64.7	40.9
Some	35.3	56.8
None	--	2.3
<b>HAS MEDICAL INSURANCE</b>		
Yes (private or public)	64.7	57.0
No	35.3	43.0
<b>HAS REGULAR SOURCE OF HEALTH CARE</b>		
Yes	44.1	71.5
No	55.9	28.5
<b>EVER HAD A MAMMOGRAM</b>		
Yes	60.0	54.3
More than 2 years ago	12.5	12.8
Never	40.0	44.6
<b>EVER PRACTICE BSE</b>		
Yes	83.9	72.2
Monthly	35.5	26.8
Never	16.1	27.8

Table 2: Subscale Reliabilities Revised Forms (Cronbach's Alpha, N=328)

Scale	Total Sample	IndoPak	Pil	Ethio	Bosn	Chin	Kor	NAm
Decisional Balance								
Barriers	.61	.84	.67	.65	.49	.73	.36	.44
Promoters	.58	.44	.78	.48	.35	.47	.46	.55
Health Beliefs								
Fear	.58	.43	.79	.64	.60	.43	.24	.62
Self Efficacy	.68	.30	.92	.56	.44	.85	.46	.69

Table 3: Paired Analysis Training Effect on Peer Health Educators (N=42)

Scale	Pre-test	Post-test	t-value
Decisional Balance			
Barriers	6.9 (2.9)	5.2 (2.5)	4.36***
Promoters	12.7(1.9)	13.4(2.0)	-1.97*
Health Beliefs			
Fear	13.4(3.9)	13.2(4.2)	NS
Self Efficacy	17.9(2.2)	18.1(1.9)	NS

\* p<.06    \*\*\*p<.001



Table 4a: BSE Observational Score (Partial Data for Combined Peer Educators and Community Women, N=122) Percentage Distribution

Score	Behavior/Technique (Max 10)	Correct Lumps (Max 10)	Incorrect Lumps (No upper limit)
0	2.5	4.8	13.7
1	7.4	9.5	12.3
2	6.6	12.0	14.1
3	10.7	8.4	9.3
4	13.1	12.6	7.0
5	9.0	4.8	11.9
6	9.0	6.6	11.0
7	11.5	11.4	6.6
8	12.3	6.6	4.8
9	13.9	13.8	3.1
10	4.1	9.5	2.2
>10	--	-	3.8

Table 4b: Item Percentage Demonstrating Correct BSE Technique (N=122)  
Inspection

1.	Raises arms	70.6
2.	Hands on hips	46.8
3.	Leans over	44.4
Palpation		
4.	Uses pads of fingers	81.3
5.	Small circular motion	63.0
6.	Varies levels of pressure	53.5
7.	Systematic pattern	47.6
Coverage		
8.	Palpates axilla	75.8
9.	Covers tails of breast	69.7
10.	Squeezes nipple	26.3

Table 5: Breast Facts Knowledge, Revised Form. Item Percentage Correct Combined Peer Educators and Community Women

1.	Most common cancer	84.7
2.	Doctors know the cause	61.4
3.	If no one in my family	70.5
4.	Breast pain is a sign	64.5
5.	More common in old women	78.6
6.	Contagious	76.5
7.	Can be cured	85.9
8.	Old women should	95.0
9.	Best way to detect (CBE, BSE, Mam)	97.1
10.	What age start mammo?	
	20 years	7.0
	30	14.2
	40	56.0
	50	19.1
	60	3.7
11.	How often BSE?	
	Weekly	9.4
	Monthly	74.9
	Yearly	15.7
12.	How often CBE?	
	Weekly	6.8
	Monthly	19.6
	Yearly	69.9
13.	How often Mammo, women over 50?	
	Every 6 months	12.3
	Yearly	72.6
	Every 2 years	14.2
	Every 5 years	1.0

## 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.<sup>1</sup> 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.<sup>2,3</sup> 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.<sup>4</sup> 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. Patients are recalled one year after completing the course to assess skills retention, again using both a written examination and a standardized patient.

### WORK TO DATE

#### A. Course Participants

Nine courses have taken place, with a total of 74 participants completing the course. Self-reported information on age, ethnicity, education, and work experience for the participants was collected. The mean age of participants was 46 years, with a range of 23 to 64 years.

<u>Ethnic Background</u>	<u>n</u>	
African American	45	(60.8%)
Hispanic	13	(17.5%)
Caucasian	13	(17.5%)
Asian	2	(2.7%)
Not stated	1	(1.4%)
<u>Highest Degree Attained</u>		
LPN	6	(8.1%)
RN	55	(74.3%)
MS	8	(10.8%)
*other (healthcare advocates)	5	(6.7%)
<u>Years of Work Experience</u>		
<5	17	(23.0%)
5-10	10	(13.5%)
>10	47	(63.5%)

**B. Results of Intervention**

Of the 74 participants, 82% (n=61) stated that they instruct women on breast self-examination and 81% (n=60) indicated that they teach the American Cancer Society breast cancer screening guidelines to their patients. Pre- and post-test scores are summarized below. At course entry, 37 participants (50%) scored at the 75<sup>th</sup> percentile or higher. At the end of the intervention this increased to 69 (93%), an increase of 43%. Seventy one participants had pre- and post-intervention scores for the standardized patient exam. Fifty eight (82%) of the students improved, and 8% demonstrated no improvement as determined by the number of areas correctly examined. The most common deficiencies observed in the clinical breast exam were not supporting the arm when examining the axillary nodes, failure to search all breast tissue, and failure to examine the supraclavicular nodes.

<u>Test scores on Written Exam (% correct)</u>	<u>Number of students</u>	
	<u>Pre test</u>	<u>Post test</u>
>90	6	32
75-90	31	37
50-74	35	5
<50	2	0

Overall, 62 participants improved their individual numeric score, it was unchanged in 6, and decreased in 6. Those with lower test scores usually answered a single additional question incorrectly.

Twelve healthcare providers have returned for retesting 12 months or more after completion of the intervention. This sample is too small to allow any conclusions to be drawn, but test results are provided below for informational purposes.

<u>Student</u>	<u>% Correct on Written Exam</u>		
	<u>Pre</u>	<u>Post</u>	<u>1-year</u>
1	65	95	75
2	85	95	80
3	85	95	80
4	60	95	85
5	85	90	75
6	65	90	75
7	75	75	65
8	85	95	80
9	80	85	60
10	80	90	85
11	90	95	70
12	85	90	75

A comparison of testing on the standardized patient revealed that 5 students improved proficiency compared to that demonstrated at the completion of the course, 4 were unchanged, and 3 had a worse performance.

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, and all ratings were again in the upper 2 categories.

## B. Curriculum Revision

An ongoing evaluation of the course content and syllabus is a part of this project. Course evaluations are reviewed by Kay Pearson RN, Course Coordinator, and all course instructors at the completion of each 4-week session. Initial evaluations indicated that the genetics curriculum was too complex and not well understood by participants. These lectures were simplified and since that revision have been favorably received. Kathleen O'Connell MSW participated in an NCI program on recruitment of patients to clinical trials, and this material has been incorporated into the course. Curriculum revision for the 1998/99 courses is ongoing and will include new information on the use of antiestrogens for breast cancer prevention, as well as information on eligibility criteria and recruitment sites for the National Surgical Adjuvant Breast Project P2 trial (STAR) of tamoxifen versus raloxifene for breast cancer prevention.

## Conclusions

The results of this study clearly indicate that a low cost, 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. Written testing and standardized patients are complementary methods of evaluation. Data on the long-term retention of skills and knowledge will be particularly important to obtain. In year 2 of this project, we have resolved the problem of the high dropout rate of course registrants prior to the beginning of the course. This has allowed us to meet the accrual goals in our statement of work for year two. Some reluctance of participants to return for the 1-year follow-up examination has been observed. We are addressing this problem by offering incentives such as a buffet luncheon, and a flexible time schedule for retesting.

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## APPENDICES

- 1) Letters from participants
- 2) Submitted abstract

## PROJECT 4. INCREASING ADHERENCE TO PHYSICIAN'S SCREENING MAMMOGRAPHY RECOMMENDATIONS: A RANDOMIZED CONTROLLED CLINICAL TRIAL

### INTRODUCTION

Screening mammography has been shown to decrease breast cancer mortality in women age 50 years and older.<sup>1-3</sup> The benefits of breast cancer screening to reduce mortality in the population can be achieved only if screening guidelines are followed and a large proportion of women receive screening examinations regularly. While recent data show that the proportion of women reporting recent mammography has substantially increased from 1998 to 1995, 30 to 40% of women age 40 and older report that they have not had a mammogram within the past two years.<sup>4-6</sup> Although lack of a physician's recommendation is an important cause of under utilization,<sup>7-12</sup> among women seen a physician's office who have not had a recent mammogram, adherence rates to a doctor's recommendation are only 45% - 60%.<sup>13-15</sup>

In a pilot study conducted in Northwestern Medical Faculty Foundation 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 its own barriers.<sup>15</sup> 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 on inconvenience. As a follow up to this study we conducted a randomized clinical trial in the same practice site to test an intervention aimed to reduce barriers of the adherence process. Specifically we tested; 1) whether targeted educational messages increase acceptance and subsequent adherence to screening mammography recommendations among non-acceptors, and 2) whether offering same day mammography increases adherence to screening mammography recommendations among acceptors. We completed the study in year one of the grant. The results will be reported in an upcoming issue of Archives of Internal Medicine.<sup>16</sup> Two hundred and forty-one patients were assigned to the control group and 210 to the intervention group. Seventy (30%) of the intervention group received a same-day mammogram. Their mean satisfaction level with the experience was high; 96% stated they would take advantage of this opportunity in the future if it were available. Three months after the recommendation was made, 58% of those in the intervention group had obtained the mammogram compared to 46% of those in the control group ( $p < .001$ ), increasing to 61% and 49% respectively at six months ( $p = < .001$ ). 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 is to test the generalizability of above results to other practice settings. Specifically, the study is testing the effectiveness of this two-intervention strategy of targeted educational messages and same day screening mammography in a private practice and a public health clinic.

Year 2 Objectives were:

1. Train research assistants and orient practice sites regarding study logistics.
2. Start enrollment of patients in each of the practice sites; it is the goal that by December, 1998 one hundred and twenty participants from the private practice site and three hundred and fifty participants from the public health clinic will be enrolled.

Study enrollment was scheduled to take place from July 1997 to December 1998. Data collection at the public health clinic experienced a slight delay and began August 1997. This was due to the employment procedures for hiring a research assistant. The start of data collection at the private practice site was delayed until December of 1997. This delay was due to two factors. One factor was awaiting the completion of a new mammography center that could handle the same-day

screenings. A second factor was a relocation and expansion of the private practice site that was behind schedule. The move was complete in October, and the office manager requested that the practice be given a month to get adjusted. This request was honored.

The study population consists of female patients age 40-79 presenting for appointments at one of three practice sites, each located in Chicago. Three clinical practice sites initially agreed to participate in the study: 1) a geriatric evaluation practice with four physicians; 2) a private practice site with 7 physicians; and 3) a city of Chicago public health clinic. Same-day mammography screening is available to patients at each of these practice sites. For reasons detailed below, the geriatric evaluation practice will not be included as a study site.

In accordance with objectives for year 2 forms for data collection were developed and refined; a physician enrollment form, patient consent form, patient questionnaire, and research protocol. A research assistant was trained in methods of chart review. Physicians, practice managers, and receptionists at each site have been oriented with regard to study logistics, patient enrollment, and data collection. These forms and methods were sampled on a small group of patients. Based on this sampling of 212 patient records, a number of refinements were made to the study protocol.

Three changes from the originally outlined plan have been made. First; initially it was planned that the receptionists at each site would enroll patients and administer questionnaires. Early on, it became apparent that the already demanding responsibilities of the receptionists would make it impossible for the receptionists to collect data effectively. Therefore, a research assistant assumed responsibility for data collection at the sites.

Second; after a period of three months of data collection, it was decided to not utilize the geriatric evaluation practice. Due to the specialized nature of services provided at this clinic, patients on the whole presented with more severe medical complications. Physician appointments focused primarily on acute care and/or treatment on ongoing and severe medical complications. In addition, patient scheduling was very fluid, with patients showing for appointments hours and sometimes days after their scheduled appointment. After two months of patient enrollment only six patients were enrolled in the study. Based on this low number and the problems listed above it was decided that data collection would be too timely and labor intensive, and that efforts could be more effectively utilized at the private practice site.

The third change involves enrollment age for women. In line with the revised mammography screening guidelines of the American Cancer Society and National Cancer Institute recommending regular screening mammograms for women starting at age 40, we have lowered enrollment from age 50 to age 40. Therefore, the target population is now women age 40-79 who have not had a mammogram within the past year.

### PRELIMINARY RESULTS

To date, 97 patients have been enrolled from the public health clinic and 74 from the private practice. The following table summarizes demographic data on the study population.

### Characteristics of Intervention and Control Groups

<u>Characteristics</u>	<b>Study Participants</b>
<b>Group Assignment (%)</b>	
Intervention	47.4% (n=74)
Control	52.6% (n=82)
<b>Mean age <math>\pm</math> SD, years</b>	<b>62.9 <math>\pm</math> 11</b>
<b>Education, years (%)</b>	
<12	33%
12	25%
>12	43%
<b>Race (%)</b>	
<u>Caucasian</u>	36%
African American	61%
other	3%
<b>Primary Insurance (%)</b>	
Medicare	58%
Private	5%
PPO	16%
HMO	8%
Medicaid	3%
Self-pay	10%
<b>Marital Status (%)</b>	
Single	19%
Married	23%
Widowed	30%
Divorced / separated	28%
<b>Intend To Get Mammogram Within 3 Months (%)</b>	
No	14%
Yes, definitely	74%
Considering	12%

### CONCLUSION

The objectives of year two have been met. There have been a few changes to the study protocol, which are discussed in detail above. The interventions are being tested at a private practice as well as a city of Chicago health clinic, two very different practice sites with unique patient populations. Study enrollment and data collection are ongoing and will continue until December of 1998. We are anticipating a possible need for extension of the patient enrollment period in the public health clinic as numbers have been lower than anticipated. Currently, the patients from the public health clinic are accrued from the internal medicine clinic. Starting in August, patients from the family practice clinic at the same site will also be included, which should increase the number of patients enrolled. Analysis of the primary outcome measures of mammography adherence will be summarized in the next annual report.



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## **PROJECT 5 - MUJERES FELICES POR SER SALUDABLES: HAPPY HEALTHY WOMEN. A BREAST CANCER RISK REDUCTION PROGRAM FOR PREMENOPAUSAL HISPANIC WOMEN**

### INTRODUCTION

Breast cancer incidence and mortality rates vary widely among different racial and ethnic groups.<sup>1</sup> Specifically, the incidence of breast cancer is consistently higher among non-Hispanic whites than Hispanics.<sup>2,3</sup> However, data suggest that between 1969 and 1987, the incidence of breast cancer increased more rapidly among Hispanic (57%) compared to non-Hispanic white women (15%).<sup>2</sup> This change in Hispanics may be due, at least in part, to increased screening and/or to temporal changes in lifestyle factors such as diet.

Hispanics are the fastest growing ethnic minority in the United States,<sup>4</sup> and they are expected to become the largest minority group by the year 2000. This rapid growth in the Hispanic population of the United States makes the health needs of this population a growing public health priority. We believe there is an important window of opportunity that must be captured among low-acculturated Hispanics, particularly young women, to foster the link between their traditional dietary lifestyle factors with disease prevention and early detection behaviors.

Mujeres Felices por Ser Soludables is a randomized intervention project designed to assess breast cancer risk reduction behavior among 300 premenopausal women living in Chicago. The specific aims of the study are: a) to conduct an 8-month active intervention that promotes a low-fat and high fruit and vegetable diet, and provides instruction about breast self-exam (BSE) and other aspects of early breast cancer detection and breast cancer risk.; and b) to measure changes from baseline in dietary intake based on nutrient data assessed from three 24-hour dietary recalls, and to measure changes from baseline in serum carotenoids and fatty acid levels, frequency of BSE, and anxiety related to BSE at 8 months and 20 months post randomization.

The major accomplishments during Year 1 of the study were hiring and training personnel, conducting the focus groups, finalizing the design of the project, developing the instruments, the data management systems, and the intervention curriculum. In addition, during Year 1 we established an agreement with Erie Family Health Center to designate and build space for this project at this community-based center. Our integration into the environment of the Health Center has helped to foster a sense of trust with prospective and current participants.

### METHODS AND PROCEDURES

#### A. Overall Study Design:

The design of the study has not changed; 300 eligible women will be recruited to participate in the study. Data are collected at each of three health center visits: baseline, 8 months, and 20 months post-randomization. After the baseline health center visit, eligible and willing participants are randomized to either the classroom group or to a mail control group. During the first 8 months (i.e., active intervention), the women in the classroom group attend 16 sessions in which the curriculum integrates dietary and breast health education. The goal is to achieve adherence to a low-fat/high-fiber diet and to increase behaviors consistent with good breast health. After the 8-month health center visit, four booster sessions are conducted during a one-year follow-up. The final data are collected at the 20-month health center visit.

#### B. Participant recruitment:

Our primary recruitment efforts have focused on Hispanic/Latina women who utilize services at Erie Family Health Center. Hispanics account for 83% percent of the population who use their services. In addition, Latina women who attend the Women, Infant and Children Program at the Chicago Nutrition Center near Erie Family Health Center are invited to participate.

Recruitment for the project began in June 1997. Through July 18, 1998, 674 women have been contacted either by telephone or in person. Approximately, 22% (n = 145) met the initial screening eligibility criteria and agreed to complete the baseline health center visit. Pre-eligibility criteria include: a) aged 20-40 at baseline; b) not currently pregnant or lactating; c) not planning a pregnancy within the next two years; d) no personal history of diabetes or cancer; e) Hispanic; f) >28% calories from fat intake.

#### C. Baseline Health Center Visit:

Of the 145 women who were eligible for the Baseline Health Center Visit, 124 completed the visit (including all three baseline 24-hour diet recalls). After exclusions (i.e., body mass index >35 kg/m<sup>2</sup>, eating disorder or serum cholesterol >260 mg) and dropouts, 79 women have been randomized to the intervention. Once a woman is randomized, retention is high. Through July 18, 1998, seven of the 79 women randomized completed the 8-month health center visit, and only one participant has dropped out of the project.

At each health center visit, a blood sample is drawn for measuring serum cholesterol, carotenoids, and fatty acids. Serum for the carotenoid and fatty acid levels are stored at -70° until all three health center visits have been completed so that all three samples from each woman can be analyzed within an analytic batch. Laboratory analysis for these serum markers will begin during Year 3 of the study. One serum sample is sent to a commercial laboratory for cholesterol measurement; these data are used for eligibility. Using breast models, a nurse rating is conducted to assess the woman's technique of BSE (circular vs. not a circular motion) and to find lumps. A health and behavior questionnaire is administered to assess occupation, education, smoking status, medical history, reproductive history, social desirability, aberrant eating patterns and depression, current behaviors and knowledge related to breast health, and acculturation. In addition, height, weight, and waist and hip circumference are measured. At the health center visit, the first of three 24-hour diet recalls are conducted, and the other two recalls are collected within two-weeks of the health center visit. A brief description of the baseline data from women who have been randomized to the intervention is provided in results.

#### D. Data Management:

When data from the eligibility form are entered into the database, all potential participants are assigned a 6-digit study ID. Prior to the health center visit, labels indicating study ID, visit, and form or biologic sample are preprinted on sheets. All the forms associated with that visit are assembled and placed into a folder that accompanies the participant from station to station during the visit.

MS Access data entry screens have been created for all data entry and updating purposes. These screens filter invalid data using range, skip pattern, and logic checks. To insure quality in the data entry step, all data, except biological samples, are entered twice. The data form is first entered, and one week later it is re-entered (verified) into a program that blinds the entry clerk from the original data values. 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 was entered differently during the verification step, the data entry clerk uses careful judgment to insure that the final value entered is the correct value. After verification, all forms are filed in the participant's final folder. A menu system allows the data entry person to select between data entry and data verification, and then which form(s) to enter. The program determines the "state" of the form (partially entered, completely entered, verified). The databases are managed in MS Access and stored on a network computer. Daily backups (Monday through Friday) are made onto two separate computers. At the end of each week, one copy of the data is transferred to diskette and taken off site.

#### E. Quality Control:

Prior to the participant leaving the center, all forms are first edited by a health interviewer so that any missing or incomplete data can be obtained. 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. When editing forms, all changes are made in a different colored marker, annotated, initialed and dated by the editor.

Quality control of the dietary data involves several steps. First, the nutrition interviewer reviews the printed report to verify the correct participant study ID and clarify missing foods. The interviewer also reviews the Nutrients per Food Item Report for outliers on total calories, protein, total fat and total dietary fiber. In addition, every record is reviewed by an expert nutritionist to clarify hard to code items and to determine the appropriateness of the diet. Finally, every four months, interview tapes (Spanish and English) from each nutrition interviewer are reviewed by experts for appropriateness of the interview process.

Quality control of the anthropometric measurements are monitored on a monthly basis by comparing repeated measurements between the health center visit technicians taken on two-three participants. Currently, two technicians are responsible for all anthropometric measurements. Overall, the intra-individual between-technician coefficients of variation are less than 4% (n=12 participants) for height, weight, and waist and hip circumference.

To monitor potential laboratory drift, the within-day and between-day reliability of the laboratory assays for serum cholesterol levels are assessed using blinded split samples on approximately 10% of the women screened. Overall, the intra-individual within-day coefficient of variation is 1.3% (n=24 samples), and the intra-individual between-day coefficient of variation is 1.9% (n=8).

#### F. Intervention:

Table 1 describes the number of women randomized to the classroom intervention group and to the mail control group through July 1, 1998. The women randomized to the classroom intervention have been divided into five groups, and the intervention is delivered in either English, Spanish, or for group 5 both English and Spanish.

Starting January 1998, the first classroom group began intervention sessions. Subsequently, a new group starts intervention sessions approximately every six weeks. The comparable mail control group receives health-related material (e.g., safety belt use) at intervals equal to those the classroom group attends the intervention sessions. These health-related materials do not include any information related to diet or breast health.

Table 1. Distribution of women by intervention and control group.

Group number	Number of women		Number of intervention sessions completed	Spanish/English
	Classroom	Control		
1	7	7	15	Spanish only
2	4	6	14	English only
3	4	6	12	Spanish only
4	7	5	10	Spanish only
5	7	8	4	Spanish and English

**RESULTS** (please note that these results are unpublished, and based on few numbers)

#### A. Baseline Descriptive Data:

Of the participants who have been randomized, complete data were entered and verified for 71 women through July 10, 1998. Table 2 shows the sociodemographic, cultural and anthropometric characteristics of these women. The age of the women ranged from 20.9–40.9 years. The majority of the women were not born in the United States, and the data indicate that

most of women who have been randomized were born in Mexico (data not shown). Using the acculturation index developed by Marin & Marin (scale of 1-5, with 1 as low acculturated), the average acculturation level of these women is low, the majority of women reported having a high school education or less. A high proportion of the women were currently married and only two women were nulliparous. The average body mass index of the women is 27.9 kg/m<sup>2</sup> indicating a high proportion of these women are overweight despite our cut-off of 35 kg/m<sup>2</sup> for eligibility. In addition, these data suggest that motivation to participate in the project does not result from a positive family history of breast cancer, as only one women reported a family history of breast cancer. The average serum cholesterol for these participants is within acceptable range for this age group of women. Finally, only 14% of the women reported current oral contraception use, and 11% are currently smoking cigarettes on a regular basis.

Table 2. Baseline sociodemographic, and anthropometric characteristics of the randomized participants (n = 71)

Characteristic		Characteristic	
Age; mean ± SD	32 ± 5.4 years	Body mass index; mean ± SD	27.9 ± 3.9 kg/
Country of birth; n (%)		Family history if breast cancer; n (%)	
United States	10 (14%)	Yes	1 (1.4%)
Other	61 (86%)	No	70 (98.6%)
Acculturation index; mean ± SD	1.8 ± 1.1	Serum total cholesterol; mean ± SD	176 ± 29 mg/
Education; n (%)		Current oral contraception use; n (%)	
≤ High school	51 (73%)	Yes	10 (14%)
> High school	20 (27%)	No	61 (86%)
Marital status; n (%)		Cigarette smoking; n (%)	
Single, never married	12 (17%)	Never smoker	59 (83%)
Currently marries	55 (77%)	Past smoker	4 (6%)
Separated/divorced	4 (6%)	Current smoker	8 (11%)
Number of live births			
Nulliparous	2 (3%)		
1-2	31 (44%)		
3-4	34 (48%)		
> 5	1 (1%)		
missing	3 (4%)		

#### B. Baseline dietary intake and breast health:

The average daily dietary intake as assessed by three 24-hour diet recalls is reported in Table 3. These data were computed for 51 participants in whom all three recalls were completed and examined for quality control. Average total daily calorie intake ranged from a minimum of 1082 kcal to a maximum of 2873 kcal, and average total daily fat intake ranged from 28.5-130 grams. It is interesting to note that total fiber intake is high (21 grams per day). Furthermore, using a measure of stage-of-change for fruit and vegetable intake, the data indicate that more than 75% (n=55) of the women were motivated to make preliminary changes in their fruit and vegetable consumption. This level of motivation is ideal for compliance with the dietary intervention.

In addition, Table 3 shows data regarding BSE proficiency and utilization of breast care in the 71 women randomized. No woman correctly performed a breast exam on the breast models. In addition, the model contained 5 lumps and only 4% of the participants were able to detect at least 5 lumps. One woman reported finding 6 lumps; however, she may have counted one lump twice. The proportion of women who ever practiced BSE was 67%. In addition, according to the stage-of-change scale, slightly more than 50% (n=36) of the women are considering beginning BSE, whereas 28% are routinely practicing BSE on a monthly basis.

Table 3. Baseline dietary (n=51) and breast health (n=71) characteristics of the randomized participants.

<u>Characteristic</u>		<u>Characteristic</u>	
Average daily intake	mean ± SD	Ever practiced BSE;	n (%)
Total energy)	1925 ± 446 kcal	Yes	47 (67%)
Total fat	65 ± 22 g	No	19 (27%)
Total carbohydrate	272 ± 64 g	Not sure/missing	4 (6%)
Total protein	69 ± 18 g		
Total fiber	21 ± 7.2 g		
Average daily percent calories	mean ± SD	Ever had a clinical breast exam	n (%)
Fat	30 ± 5.3 %	Yes	52 (74%)
Carbohydrate	57 ± 6.4 %	No	15 (22%)
Protein	14 ± 2.4 %	Not sure/missing	3 (4%)
Breast self-exam technique	n (%)	Ever had a mammogram	n (%)
Not circular motion	27 (38%)	Yes	11 (16%)
Circular motion/lose contact	44 (62%)	No	51 (73%)
Circular motion/constant contact	0 (0%)	Not sure/missing	8 (11%)
Number of lumps found	n (%)		
0	33 (47%)		
1-2	23 (32%)		
3-4	12 (17%)		
5-6	3 (4%)		

### C. Intervention:

As described earlier, five groups of women have been randomized to receive the intervention. The timing and presentation of the material varies as a function of the language spoken. This may be due, in part, to the level of acculturation of the groups. The Spanish-speaking groups tend to be lower in acculturation, and the women verbalize more concerns related to immigration, transitional living difficulties, child rearing problems, and other stressors. These concerns often are brought up during group discussions, and appear to affect the ability of some participants to attend to the material. This leads to changes in the timing of the delivery of the curriculum material. We realize life stressors can make both dietary and other health changes more difficult. Although we have a set curriculum, we believe that each group tends to develop its own identity. We have found it necessary to modify the curriculum because of stressors that the women need to talk about during group time.

We also found that although our program was developed for a lower literacy population, some of the material was still too complex. During Year 1, the focus groups gave us feedback about the importance of simplifying the intervention material. When conducting the intervention, however, we have found the need to simplify our messages even further. Many of the participants respond most positively to one or two direct and simple take-home messages. This is equally true for both the more direct, didactic part of the sessions as well as the more "hands on" cooking demonstrations. When the material becomes too complex, the interventionists lose the

attention of participants. For example, one session was initially devoted to finding fat in the diet and ways to reduce overall saturated fat intake. It was necessary to devote three sessions to this topic in order to deliver the material in smaller pieces. In other words, it is necessary to tailor the delivery of the intervention to the needs of the group. We have built in a great deal of repetition into the curriculum to underscore our primary aims, so we can be flexible in the delivery and be assured that groups are receiving the same information.

The integration of the breast health and nutrition curriculum has proved a challenging task, but we feel that ultimately it has been beneficial for the women. Our initial impression was that women might feel more anxious discussing and learning about breast health than they would be about a nutrition focused curriculum. It is interesting to see that the women seemed to become more animated about the nutrition curriculum. They related stories about food preparation, particularly about food from their native countries. However, they were also enthusiastic to learn more about breasts and the structure of the normal breast. This, at times, seems more interesting to them than discussing the development of possible diseases related to the breasts. More specifically related to our specific aims, it is apparent that most of our participants had heard of BSE but really did not know what they were looking for when performing it. They also had little experience talking with their health care provider about the subject. Even women who had clinical breast exams were unsure what questions to ask. Our session with Dr. Oviedo (breast surgeon) gave the women the opportunity to ask questions that they might not otherwise have asked a health care provider.

Although it is too early in the intervention to assess the quantitative changes among the women in the active intervention, there is anecdotal evidence that the intervention is having a positive impact. Some of the women experienced breast symptoms prior to joining the Mujeres project. This may have been an impetus to join the study. Some women randomized to the classroom group use the class time to verbalize concerns about breast symptoms. For example, one woman had a mammogram soon after randomization. Another woman complained of fibrocystic breasts and stated that her condition improved after her physician recommended that she stop drinking caffeine. Another woman complained of a large and painful cyst in one breast. Over the course of the first intensive 8-week intervention, she was able to talk about her fears with the interventionist and a breast cancer survivor. She finally scheduled an exam with her physician who told her that there was no need for concern. It is questionable if she would have been able to do this without the support and education of the program. The verbalization of these concerns has also helped to develop connections between the women in the group and the interventionists.

The group sessions seem to be a forum for women to discuss their family's reactions to their participation in a program to change health behavior. Women have voiced some concerns about conducting BSE in their home because of difficulty finding time, but also the reaction of their partners. Some women report that their husbands are uncomfortable discussing BSE. To provide the women with more adequate information on how to engage the support of family members, we showed a video entitled, "Una Vez al ano: Para Toda Una Vida." This video depicts a Latina woman diagnosed with breast cancer and the reaction of her family and friends, and it led to a lively discussion about family reaction to illness as well as their reaction to their wives or partners involvement in a program to decrease health risks. Overall, it appeared there was mixed support among the women's families. Some of the women said that their partners and other family members were curious and supportive. In addition, some family members seemed to lack an understanding of why the sessions needed to be so frequent and questioned the repetition of the material.

Our experience thus far strongly suggests that the delivery of the intervention needs to be tailored to the level of literacy and acculturation of the participants. We have observed that the lower the acculturation level, the more life stressors seem to impact the participants' ability to

attend to the material. A strong connection with the interventionists is essential if women are going to feel a bond with the group. Although group members become friendly with each other, the more important connection is the one with the interventionists. It has been important for each member to be called each week and reminded of the availability of child-care, and this helps insure ongoing attendance. This cannot be stressed enough; when child-care is available the participants are more apt to come to the sessions and focus on the material.

Overall, the participants are enthusiastic and motivated to learn more about healthy ways to eat and take care of their bodies. We have made great strides in our challenge to build strong ties with the community. We now more clearly understand the time and consistent effort it requires to build the foundation that is necessary to develop and implement this type of program.

#### STATEMENT-OF-WORK (TIMELINE):

As mentioned previously, our goal is to recruit 300 women into Mujeres Felices por Ser Saludables, and retain these women for at least 20 months. We have made great strides towards achieving this goal. First, during Year 1, we established our affiliation with Erie Family Health Center where we recruit participants, conduct all health center visits and conduct the intervention classes in a room designated for this project. Because this room is used for nearly all aspects of the study, a high level of organization in the conduct of the study is required. Over the last year, the study coordinator, recruitment coordinator and interventionists have worked closely to develop a schedule which will meet this demand. Second, based on the data collected over the last year, we have demonstrated the ability to collect high-quality data of a unique nature (epidemiologic, behavioral, nutritional and laboratory) from this hard-to-reach population. The health and nutrition interviewers undergo periodic monitoring to assure the high quality of the data collection. Moreover, the assistant study coordinator, data manager and programmer have developed sophisticated methods for monitoring the data to assure its quality and completeness.

The primary limitation in achieving our goals has been the frequency with which potential participants reach randomization. In the original design, we would have recruited 3 groups (cohorts) of 100 participants. Within a cohort, the women would be randomized to intervention or to control. In the original proposal, however, recruitment efforts were underestimated. During Year 1, we were delayed in beginning recruitment because of the need to formalize our the agreement with the Erie Health Center, and the need to secure alternative recourses for providing the infrastructure to occupy our space at the Health Center, as well as the time to build that infrastructure. In addition, current recruitment efforts are limited because of the focus on reaching individuals rather than large groups of women. As discussed previously, for every 700 contacts made, we are able to randomize approximately only 80 women into the study. The effort required to recruit these women cannot be understated, and over the last year we have increased our recruitment staff in order to achieve our final sample size of 300. In fact, from September through December of 1997, the average number of weekly contacts was approximately 11, and this number has increased to nearly 30 per week. If this level of recruitment is maintained, then we anticipate being able to recruit the required number of participants by January 2000 and we will complete the final health center visit in August 2001.

#### CONCLUSIONS

The major accomplishments of this study during the last year includes the recruitment and randomization of 78 Hispanic women into Mujeres Felices, and the conduct of sessions in five groups of women randomized to the intervention. Once women are randomized, retention in the study is high. Following our focus groups, we more finely tuned our integrated curriculum and have adapted the intervention to the education and acculturation levels of the participants. To our knowledge, this is the first randomized trial to deliver an integrated nutrition and early detection curriculum focusing on breast cancer. The feedback we have received from the participants has been extremely positive.



We recognize that our recruitment goal has not been consistent with our original timeline. However, in Year 1 it was necessary to build the groundwork for the study, including the hiring and training of bilingual and bicultural staff, the development of instruments, the development of a data management system, and an infrastructure at the Erie Family Health Center. These efforts provided the support for a streamlined and effective recruitment and randomization process, and have contributed to our high retention.

A goal, which we have accomplished, was to become fully integrated into the day-to-day operations of the Health Center. In this way, the aims of our study are consistent with the mission of the Health Center. The importance of building and nurturing trust between academic institutions and the community-based intervention sites cannot be underestimated when conducting this type of research.

#### PRESENTATIONS AND PUBLICATIONS:

Fitzgibbon MF, Knight SJ, Prewitt E (SBM, 1998). Minority communities: are they really hard to reach?

Fitzgibbon MF (1997). Interventions in minority communities. Grand Rounds, NUMS

Knight SJ (APA, 1997). Group strategies in breast cancer risk reduction for Hispanic women. (see attached).

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#### APPENDIX

Abstract of Society of Behavioural Medicine Seminar

## PROJECT #6: MULTIDISCIPLINARY NETWORKED BREAST CANCER CONFERENCE

### STATEMENT OF WORK

#### INTRODUCTION

The modern multidisciplinary management of breast cancer requires input from a variety of specialties, as well as interpretation of pathologic material and imaging studies within the context of the patients' clinical problem. This allows the creation of a unified treatment plan for local and systemic therapy. At Northwestern Memorial Hospital (NMH), the mechanism for this sharing of information is a weekly conference which is held in the Vanderwicken Library of the Lurie Comprehensive Cancer Center.

The goals of the Multidisciplinary Conference are to optimize patient care by utilizing multiple resources to determine a therapeutic recommendation, and to increase accrual into available research studies. Since the study investigators and data managers are present at the conference, an individual patient's eligibility for a study can be determined and the merits of study participation debated. The final purpose of the conference is educational. The regular interaction among different disciplines allows participants to be cognizant of advances in fields outside their own area of expertise. The conference also serves as a model of multidisciplinary care for the students and trainees in attendance.

Technology is now available by which information, and even surrogate presence, can be shared by multiple persons at disparate locations at acceptable costs. Patients at all hospitals in the Northwestern Network could be served by health care teams in full communication under acceptable logistical conditions. The purpose of this project is to design, specify, set up, operate and measure the performance of a comprehensive Networked Breast Cancer Conference (NBCC). This system will allow exchange of data including images, audio and video as well as personal interaction.

Successful implementation of the Networked Breast Cancer Conference is intended to achieve two specific aims:

1. Making available to Network hospital practitioners the expertise of an Academic Multidisciplinary Breast Cancer Management Team for discussion of difficult breast cancer cases.
2. Provision to Network hospital practitioners of information regarding investigational studies in which their patients would be eligible for participation; ultimately the NBCC may provide the mechanism to increase accrual to cooperative group studies and Northwestern University-sponsored investigational studies.

At the completion of year 2 the following objectives were to have been completed:

1. Networked system fully operative at all hospitals -- **completed**
2. Collect treatment, clinical trial statistics and attitude survey -- **underway**

#### SCOPE

The installation of teleconferencing hardware has been completed in all of the participating organizations: Evanston Hospital, Ingalls Memorial Hospital, the Lurie Cancer Center at Northwestern, Highland Park Hospital, Northwest Community Hospital, Silver Cross Hospital, and Swedish Covenant Hospital. The organizations participate, at assigned times, in the Multidisciplinary Breast Cancer Conferences each Monday afternoon. The final phase of the subcontract will be the collection of data from those participatory sessions and assessment of the impact upon patient treatment.

## WORK TO DATE

Installation and initial operation of the teleconferencing systems took a considerably longer time than had been anticipated. This was not due to any deficiencies in the technology, but rather to infrastructure-related factors. For example, each hospital had to determine who would be the likely participants in the conferences and, accordingly, the best location at which to place the equipment. This varied considerably, because of differences among the hospital. In one case the system is located within the offices of an individual physician while in another it is in a general conference room area that is used for a number of different activities. The location at the Lurie Center was the only one predetermined at project onset because of the established site of the weekly Multidisciplinary Breast Cancer Conference.

In all the hospitals it was also necessary to coordinate the activities of the medical, administrative and operation personnel who were involved with the project. For example, the Information Technology Department at each hospital had to interact with the medical staff once the site for the equipment was chosen and the Communications Department became involved because of the need to install the special ISDN telephone lines. In most cases, it took considerable time to meet with each group, explain the research project, obtain approval, and get put on the appropriate operational schedule. Internal coordination was then needed before the final installation activities could take place. The fact that this is a research activity rather than an operational function may also have played a significant part in the amount of internal and external coordination required, especially since the research project is centered at one organization and the others are participants. We found that the early identification of an internal "champion" within each organization to facilitate communications helped considerably in the installation process.

The final component of installation activity was external: the local telephone company. ISDN lines require special circuitry. It takes some time to order then, arrange for installation and have the installation completed by the telephone company. During the course of the project, this process changed considerably. For our first installations we had to provide a great number of details to the telephone company regarding the equipment to be used, the switching needed, etc. By the time of the last installations, the telephone company had established standard packages and we just had to specify the appropriate one, greatly reducing the complexity of getting ISDN lines in place. ISDN lines are now becoming commonplace and we expect that future expansion of this system, or deployment of similar systems, will not be subject to many of the difficulties we experienced with these installations.

The hardware chosen has proved to be reliable and to perform well. In fact, recent improvements in the software used to operate the systems has made the quality of transmission considerably better than original design specifications provided. The continued development of standards has also made the utility of the selected hardware greater. Though we chose systems from a single manufacturer, Vtel, for this project we required that those systems adhere to interconnectibility standards. Accordingly, this equipment can be used to communicate with that of other manufacturers. While that is not a consideration for this particular research project, it is important for future expansion. The overall consensus of Conference participants is that the audio and video quality provided by the systems is good to excellent and fully adequate to permit real-time participation in the Conferences.

ISG personnel operate the equipment at the Lurie Cancer Center during each Conference. Initially, ISG personnel assisted the representatives at the other hospitals when they participated, but most of those organizations operate their systems without any assistance. The hospitals each have Vtel SmartStation (individual workstation) systems, with a single camera, microphone and speakers. At the Lurie Center, the Vtel Team Conferencing system is used. This systems is more complex. It incorporates a pan/zoom camera with preset location capability, as well as a document camera for the presentation of mammograms and ultrasound images, plus a microscope camera for the

presentation of the pathology data. A "Director" is needed to move among the input sources, select the person speaking at a given time, etc. ISG is defining the parameters of that process so that Lurie personnel can be trained to direct the Conference activities.

### Experience with the System

Operationally, the Conferences have been very successful. Personal confidentiality is maintained by referring to patients only by number. Each participant, both remote and local, has a summary sheet for the patients to be discussed at each meeting. The Lurie Center coordinates the collection and distribution of relevant documentation. Participating hospitals send radiology and pathology information in advance of each meeting via express delivery, and the Lurie Center faxes out the summary sheets just before each meeting begins. The use of the teleconferencing system has not negatively impacted the flow of the meetings, and after the first several sessions were held, became a normal and completely accepted part of the Conferences. Participants from the remote hospitals feel that they are an integral part of the meeting. Because of the technology chosen, only point-to-point communication is possible. Not all hospitals can participate simultaneously. Each therefore gets a scheduled time to present its patients. This has worked quite well within this application, where the major value is the participation of the remote hospitals with the multidisciplinary group at the Lurie Center. In educational settings, simultaneous participation may be required.

Though the data collection activity has just been begun in earnest, the initial results of the efficacy of the use of this technology are encouraging. Some changes in treatment plan have resulted for more than half of the patients discussed via teleconference. In some cases those changes were considerable, such as the decision to most from a mastectomy to a lumpectomy for one patient, chemotherapy and radiation treatment regimen modifications for several patients, and recommendation of two patients to clinical trials.

### Remaining Tasks

The infrastructure to support the Networked Conference is now in place at all hospitals. Two challenges remain for the project meet all of its original goals

1. Participation in the Conference: Hospitals participating in this project are, with the exception of Evanston Hospital, non-academic, non-tertiary care community based hospitals. Evanston Hospital is a much larger, academically oriented, community based hospital. Members of the medical staff of Evanston Hospital have academic appointments at Northwestern University Medical School. Evanston Hospital also has an established multidisciplinary breast program that evaluates approximately 500 new breast patients/year.

Both types of hospitals and their respective medical staff present unique problems for the project. At the typical community-based hospitals, the medical staff is in private practice and there has been some difficulty getting a commitment from them to break away from seeing patients to participate in the conference. To reap the full benefits of the Networked Conference, outside participants must send the pathology slides and mammograms to the Lurie Cancer Center ahead of time so that they can be reviewed and projected during the Conference. The Conference leaders are willing to discuss cases that are not accompanied by supporting material (i.e., path, mammograms), but this is viewed as suboptimal. Since the conference can only accommodate one external site at a time, the participating institutions have a pre-designated date of the month when they have a slot to present cases. The time constraints of the conference (1 hour) and the limitations of the technology (one site at a time) may have limited participation.

Solution: The PI will personally meet with the key medical staff at the participating institutions and encourage their participation. We will make an effort to contact the participating hospitals one week before "their turn" so that they can gather cases and supporting material for the Conference. This will serve as a reminder to them.

Evanston Hospital conducts a Breast Conference every Monday at 7 am. As indicated above Evanston Hospital has a full complement of breast cancer experts and as such is unlikely to seek outside input for the management of their cases.

Solution: The PI and one or two other faculty from Northwestern will make an effort to attend the Breast Conference at Evanston Hospital on a rotating basis as a means of improving cooperation to complete this project. Evanston Hospital accrues significant numbers of patients to clinical trial at the present time.

2. Participation in Clinical Trials and Changes in Treatment Plan:

One of the principal goals of this project was to determine if the management of individual breast cancer patients would change following discussion at the Networked Conference. Increasing the number of patients from outside hospitals that are presented at the Conference will allow us to make a determination of how treatment was effected. Of equal importance, with the exception of Evanston Hospital, accrual to clinical trials at the other participating hospital is almost nonexistent. Every patient that is discussed at the Breast Conference is considered for a clinical trial if appropriate. If an increase in clinical trial accrual were detected at the outside hospitals, this would be interpreted as a direct result of the Networked Conference.

CONCLUSION

The infrastructure to support full implementation of the project has been completed. Efforts are now being directed to increasing participation of outside hospitals in the Conference and to objectively measuring the whether the care of individual patients are altered by discussion at the Conference and whether patient accrual to clinical trials increases.

## **PROJECT #7: COST-EFFECTIVENESS OF STEREOTACTIC BIOPSY VERSUS SURGICAL EXCISIONAL BIOPSY FOR WOMEN WITH ABNORMAL MAMMOGRAMS.**

### INTRODUCTION

Stereotactic biopsy has been advocated as an alternative to open surgical biopsy for the diagnosis of mammographically detected breast lesions. Stereotactic biopsy is a reasonable substitute but there is uncertainty about the accuracy of the procedure, the ability to completely characterize malignancies and allow for definitive surgical treatment, and the consequences of missing a diagnosis of early breast cancer. Although a stereotactic biopsy is less invasive and less costly than a surgical biopsy initially, it is uncertain whether the procedure is less costly overall when the above-mentioned concerns are factored in.

A few studies can be found in the literature investigating this question. In one study, stereotactic core biopsies were performed on 182 patients with mammographically evident lesions and data from clinical follow-up were collected. Of these patients 42 required re-excision. The study determined a cost savings of 52-55% by performing the stereotactic as opposed to the surgical biopsy. This study only considered the costs of diagnosis, did not follow-up patients to determine if there were "missed" diagnoses and did not breakdown the cost differences by severity of diagnosis.[1] A retrospective study of 52 consecutive patients diagnosed with invasive cancer, comparing costs for those with stereotactic core biopsies to those having surgical biopsies, determined that patients in the surgical biopsy group more often had positive margins and required re-excision more frequently. Total costs through the time of definitive procedure determined a median cost of \$1000 less per patient for the stereotactic core biopsy group.[2] But this study was very small, included only patients diagnosed with invasive cancer (60-90% of biopsy procedures are typically diagnosed as benign) and did not account for patient selection bias. While both of these studies have approached this question, neither has had the sample size or study design to appropriately conclude which of the procedures is more cost-effective.

The purpose of this study is to evaluate the cost-effectiveness of these procedures and determine the sensitivity and specificity of these procedures in the clinical setting. A decision analytic model of the outcomes (diagnosis through definitive treatment) of all biopsy patients seen at the Lynn Sage Breast Center during a two year period will be stratified by suspicion and utilized to determine the cost of diagnosis and treatment.

### METHODS

A decision analysis model was formulated to represent the flow of decisions and chance events related to the consequences of an abnormal mammogram, as practiced in our institution. These assumptions were utilized to develop a decision tree which will be used to perform the cost analysis.

The two main branches of the tree, core biopsy or surgical biopsy, have the possibility of four diagnoses: invasive cancer, ductal carcinoma in situ, benign, or missed. Missed diagnoses will be classified as those DCIS or invasive cancer diagnoses determined either via a second biopsy procedure within one month (technical miss) or by a biopsy procedure resulting from a suspicious mammogram within one year of a benign diagnosis.

The third tier of the tree represents the treatment possibilities for each diagnosis. For invasive cancer they are mastectomy or lumpectomy (with or without lymph node dissection). Patients receiving a lumpectomy will have tumor margins evaluated as negative or positive. The lumpectomy is definitive when the margins are negative, or further re-excision or mastectomy is performed when the margins are positive. Patients with a diagnosis of DCIS under go either a lumpectomy or mastectomy without lymph nodes. Patients with confirmed DCIS and negative margins require no further surgery. Those patients whose disease is determined to be invasive will have axillary node

dissection, and if the biopsy margins were positive, re-excision or mastectomy. Benign patients are followed for follow-up mammogram results at 6 months and one year post biopsy.

Information is to be collected on all patients seen at the Lynn Sage Breast Center for a surgical or core biopsy from September 1, 1996 through August 31, 1998. Data were received from the mammography staff at the Lynn Sage Breast Center. A monthly printout of each patients age, biopsy procedure, lesion type, degree of suspicion, and pathological diagnosis was supplied to researchers and entered into a data base. Follow-up information on surgery performed was obtained from the cancer database in Dr. Monica Morrow's office suite. The combined database was reviewed by Drs. Venta and Morrow for clinical relevance. Any further required information on treatment will be obtained by chart review. Follow-up mammogram information for benign patients will be obtained from the mammography staff. For patients not receiving mammograms at Lynn Sage, information will be requested from the original referring physician. Cost data will be obtained from Northwestern Memorial Hospital in the form of detailed patient bills, including the biopsy procedure through definitive treatment. Cost data will be collected for randomly selected patients from each definitive arm of the decision tree and a mean cost per procedure determined. Resources utilized will be reviewed by Drs. Venta and Morrow to assure that patients selected are representative of "typical" diagnostic and treatment procedures. The mean costs will then be applied to the probability of each procedure and a total cost per biopsy type computed. Univariate sensitivity analyses and Monte Carlo analyses will be performed to determine the robustness of the estimates.

#### RESULTS TO DATE

Data have been collected on all patients for the Year 1 time period, September 96-August 97. A total of 476 core biopsies and 335 surgical biopsies were performed during this time period. Table 1 outlines the basic characteristics of each of these groups.

	Core Biopsy	Surgical Biopsy
Procedures	476	335
Mean Age (+/-SD)	53 +/- 12	55 +/- 11
Degree of Suspicion (%)		
Prob Benign	18.9	16.1
Low	39.3	27.3
Intermediate	23.0	25.2
High	12.4	22.7
Sugg Malignancy	6.3	8.8
Diagnosis (%)		
Benign	76.7	66.6
DCIS	6.1	11.3
Invasive	17.2	22.1

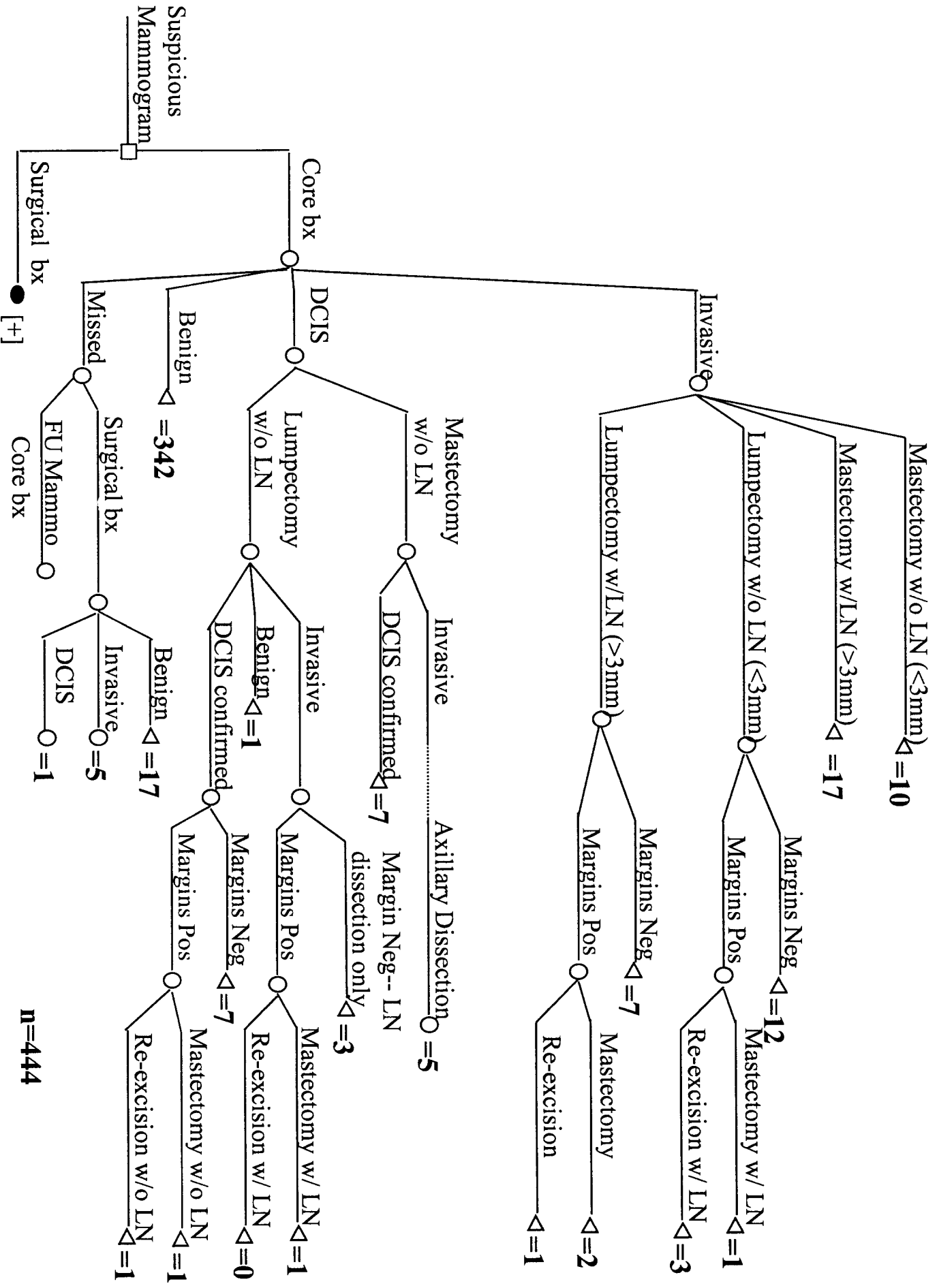
The mean age of patients in both groups is the same, 53-55 years of age at the time of biopsy. There are more patients with a "high" or "suggestive of malignancy" suspicion in the surgical biopsy group, as well as more DCIS and invasive diagnoses. Surgical follow-up information has been collected for the patients receiving treatment at Northwestern Memorial Hospital. Of the 111 core biopsy patients with a DCIS or invasive diagnosis there was one death and one patient refusal. Surgical follow-up data are not yet available for 28, or 25.2% of the patients. At this time, there are missing surgical follow-up data on 39 of the 112 (34.8%) DCIS or invasive patients. For the core biopsy patients with a benign diagnosis, results of the follow-up mammograms have been collected on 196 of the 365 patients. For the remaining core biopsy patients and surgical biopsy patients with a benign diagnosis, the referring physician will be contacted to collect this information.

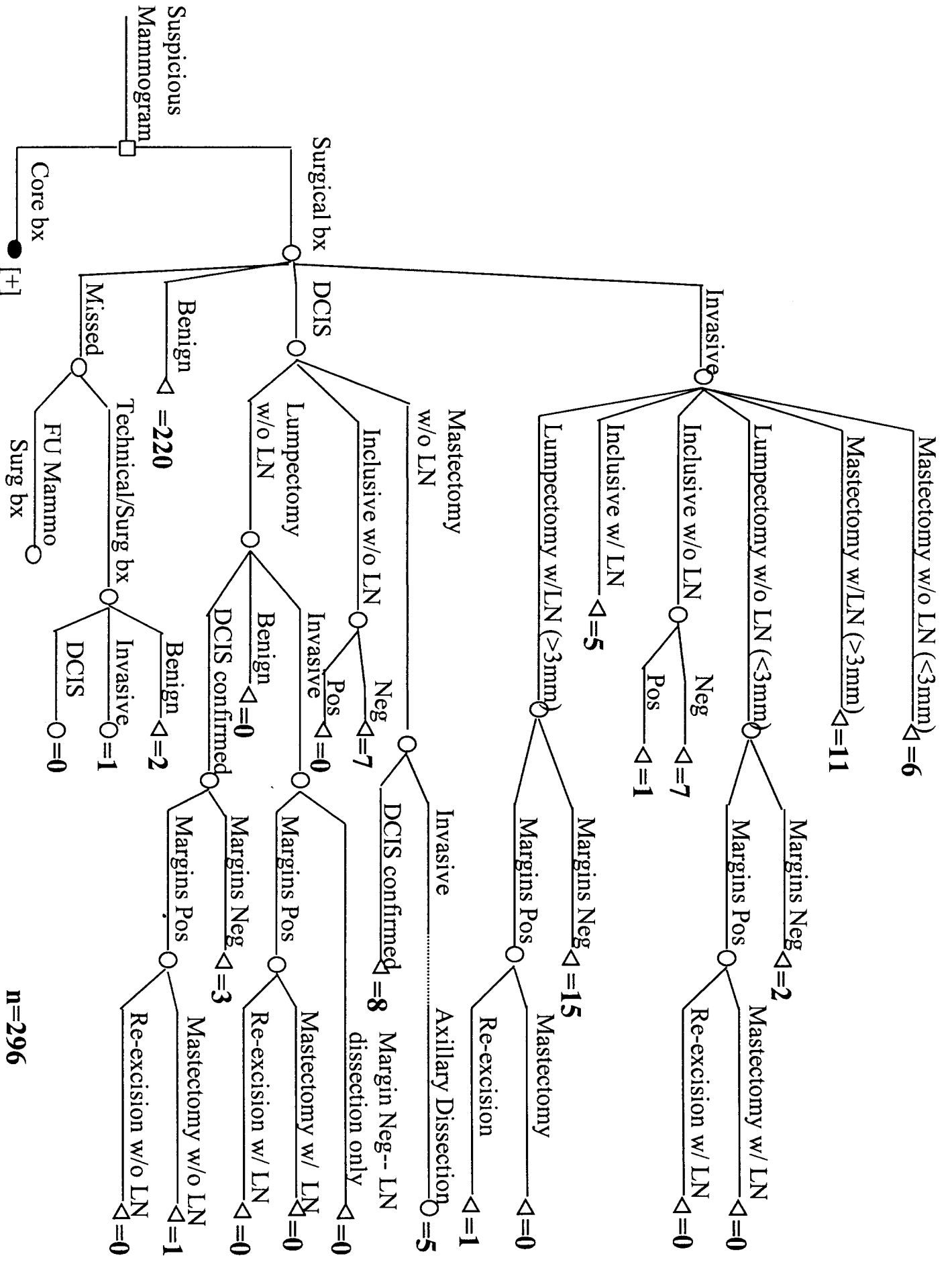
A copy of each main branch of the decision tree with the number of patients at each terminus is included as Figures 1 and 2. It has been determined by the investigators that there is adequate clinical information to begin collecting billing data and performing preliminary cost analyses. A data request for this information is currently being prepared and forwarded to the billing department at Northwestern Memorial Hospital.

#### REFERENCES

1. Liberman L, Fahs MD, Dershaw, DD, et al. Impact of stereotaxic core breast biopsy on cost of diagnosis. *Radiology* 1995;195(3):633-37.
2. Yim JH, Barton P, Weber B, et al. Mammographically detected breast cancer. Benefits of stereotactic core versus wire localization biopsy. *Ann Surg* 1996;223(6):688-97.







n=296

Core Biopsy Diagnoses by Degree of Suspicion (%)

	Prob B9	Low	Intermediate	High	Sugg Malig
Apocrine Metaplasia	0.00	2.78	1.96	0.00	0.00
Atrophic Tissue	4.60	3.89	1.96	1.75	0.00
Atyp Duct Hyperplasia	3.45	1.67	3.92	3.51	0.00
Atyp Lob Hyperplasia	0.00	0.56	0.98	0.00	0.00
Benign Cyst	3.45	2.22	0.98	1.75	0.00
Ductal Ectasia	1.15	1.67	0.00	0.00	0.00
Fat Necrosis	1.15	0.00	0.98	0.00	0.00
Fibroadenoma	35.63	35.56	26.47	5.26	0.00
Fibrocystic Disease	16.10	8.89	7.84	7.02	6.90
Focal Adenoma	0.00	1.11	0.00	0.00	0.00
Focal Fibrosis	13.79	12.22	13.73	3.51	0.00
Foreign Body	0.00	0.00	0.98	0.00	0.00
Large Duct Papilloma	0.00	1.67	1.96	3.51	0.00
LCIS	1.15	1.67	0.00	0.00	0.00
Lipoma	0.00	1.67	0.00	0.00	0.00
Lobular Hyperplasia	1.15	0.56	0.98	0.00	0.00
Lymph Node	1.15	0.56	0.00	0.00	0.00
Papilloma	0.00	1.11	0.98	0.00	0.00
Phylloides Tumor	0.00	0.56	0.00	0.00	0.00
Radial Scar	0.00	3.33	0.98	0.00	0.00
Sclerosing Adenosis	3.45	5.56	4.90	3.51	3.45
Usual Duct Hyperplasia	9.20	5.56	9.80	3.51	3.45
Total Benign	95.42	92.82	79.40	33.33	13.80
DCIS	1.15	2.78	9.80	15.79	6.90
Total DCIS	1.15	2.78	9.80	15.79	6.90
Apocrine Ca	0.00	0.00	0.00	1.75	0.00
Colloid Ca	0.00	0.56	0.98	0.00	0.00
Infil Ductal Ca	1.15	0.00	1.96	10.53	34.48
Infil Lobular Ca	0.00	0.56	0.00	0.00	3.45
Infil Medullary Ca	0.00	0.00	0.98	0.00	3.45
Infil Tubular Ca	1.15	1.11	0.00	5.26	6.90
Inv Duct Ca	0.00	1.11	4.90	29.82	31.03
Inv Lob Ca	0.00	0.00	0.00	3.51	0.00
Lymphoma	0.00	0.00	0.98	0.00	0.00
Papilloma Ca	0.00	0.00	0.98	0.00	0.00
Phylloides Tumor	0.00	1.11	0.00	0.00	0.00
Primary Malignant	1.15	1.11	0.00	0.00	0.00
Total Malignant	3.45	5.56	10.78	50.87	79.31

Surgical Biopsy Diagnoses by Degree of Suspicion (%)

	Prob B9	Low	Intermediate	High	Sugg Malign
Apocrine Metaplasia	0.00	2.22	2.25	0.00	0.00
Atrophic Tissue	0.00	2.22	2.25	0.00	3.45
Atyp Duct Hyperplasia	5.66	5.56	4.49	10.81	6.90
Atyp Lob Hyperplasia	1.89	0.00	0.00	0.00	0.00
Benign Cyst	0.00	1.11	2.25	0.00	0.00
Ductal Ectasia	1.89	1.11	0.00	0.00	0.00
Fat Necrosis	0.00	0.00	0.00	0.00	0.00
Fibroadenoma	28.30	22.22	4.49	2.70	3.45
Fibrocystic Disease	22.64	22.22	21.35	9.46	0.00
Focal Adenoma	0.00	0.00	0.00	0.00	0.00
Focal Fibrosis	9.43	8.89	6.74	4.05	0.00
Foreign Body	0.00	0.00	0.00	0.00	0.00
Large Duct Papilloma	3.77	1.11	1.12	0.00	0.00
LCIS	3.77	2.22	4.49	1.35	0.00
Lipoma	0.00	0.00	0.00	0.00	0.00
Lobular Hyperplasia	0.00	0.00	0.00	0.00	0.00
Lymph Node	0.00	0.00	0.00	0.00	0.00
Papilloma	0.00	2.22	2.25	1.35	3.45
Phylloides Tumor	0.00	0.00	0.00	0.00	0.00
Radial Scar	1.89	2.22	7.87	6.76	6.90
Sclerosing Adenosis	5.66	12.22	2.25	0.00	3.45
Usual Duct Hyperplasia	3.77	4.44	7.87	1.35	0.00
Total Benign	88.67	89.98	69.67	37.83	27.60
DCIS	3.77	6.67	13.48	16.22	20.69
Total DCIS	3.77	6.67	13.48	16.22	20.69
Apocrine Ca	0.00	0.00	0.00	0.00	0.00
Colloid Ca	0.00	0.00	0.00	0.00	3.45
Infil Ductal Ca	5.66	2.22	5.62	18.92	20.69
Infil Lobular Ca	0.00	0.00	0.00	1.35	0.00
Infil Medullary Ca	0.00	0.00	0.00	0.00	0.00
Infil Tubular Ca	0.00	0.00	2.25	5.41	6.90
Inv Duct Ca	1.89	1.11	9.00	20.27	17.24
Inv Lob Ca	0.00	0.00	0.00	0.00	3.45
Lymphoma	0.00	0.00	0.00	0.00	0.00
Papilloma Ca	0.00	0.00	0.00	0.00	0.00
Phylloides Tumor	0.00	0.00	0.00	0.00	0.00
Primary Malignant	0.00	0.00	0.00	0.00	0.00
Total Malignant	7.55	3.33	16.87	45.95	51.73

## PROJECT #8: INPATIENT VERSUS OUTPATIENT HIGH-DOSE THERAPY

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,<sup>1</sup> and the numbers of patients seeking such therapy nationally has grown exponentially. Recent concerns over health care costs have led to increasing interest in outpatient transplant. The use of growth factors and peripheral blood progenitor cells have made outpatient transplant a possibility. Early reports have demonstrated reductions in the length of hospital stay without compromising short-term outcomes.<sup>2-4</sup> Although there is the perception that outpatient therapy is less expensive than inpatient treatment, this has yet to be fully considered. Meisenberg et al showed a reduction in costs from \$39,700 for inpatient treatment to \$29,400 for outpatient treatment (from first day of chemotherapy to 30 days post transplant).<sup>4</sup> This study measured only the direct medical costs, or cost to the third party payer. When one considers the efforts and resources required by the patient and the round-the-clock caregiver for an outpatient transplant, it is feasible that a considerable portion of the total costs were excluded. Another argument used to justify outpatient transplant over the traditional inpatient stay is the perception that 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 investigate and compare the societal costs (direct medical, indirect medical and indirect personal) of outpatient versus inpatient autologous transplant for a prospective, case-matched cohort of patients with breast and hematologic malignancies. Also, quality of life assessment and comparison of inpatient and outpatient quality of life will be analyzed both descriptively and quantitatively to determine if outpatient transplant is associated with an enhanced quality of life.

### WORK TO DATE

#### Patient Accrual

Every new transplant candidate evaluated by the Northwestern University/Northwestern Memorial Hospital stem cell transplant program is screened for eligibility by the program research coordinator (P. Frey, RN) who discusses the option of participation with each patient individually. Data is being collected regarding the various reasons that patients are unable to proceed to outpatient transplant (Table 1). Additionally, each patient is discussed as a possible candidate for outpatient bone marrow transplant at the weekly bone marrow transplant team meeting. If patients are interested in pursuing outpatient transplant, the coordinator works closely with them to find a suitable caregiver. The research coordinator/nurse continues to be involved in educating insurance companies and case managers about the outpatient transplant process.

As of July 27, 1998, ninety-six individuals have been screened. Table 1 gives the percentages and reasons why patients were unable to have an outpatient transplant.

Table 1

	Number (%) Total N = 96
Proceeded to outpatient bone marrow transplant	14 (14.5)
Did not have transplant at institution (went elsewhere, disease progression, decided against transplant)	15 (15.6)
No caregiver available	53 (55.2)
Medical or psychosocial issues	3 (3.1)
Insurance issues	8 (8.3)
Refused and no reason given	3 (3.1)

A total of 26 patients have been enrolled on this study. Fourteen of these have been outpatients and twelve have been inpatient controls. The disease site breakdown is demonstrated in Table 2.

Table 2

<u>DISEASE</u>	<u>INPATIENT</u>	<u>OUTPATIENT</u>
	N (%)	N (%)
Breast Cancer	9 (75.0)	4 (28.6)
Lymphoma (Hodgkin's and non Hodgkin's)	2 (16.7)	3 (21.4)
Multiple Myeloma	1 (8.3)	7 (50.0)

Table 3 shows further descriptive statistics for the patients enrolled on the study. Two patients' data are not included since they are currently in progress.

Table 3

<u>DESCRIPTION</u>	<u>INPATIENT</u>	<u>OUTPATIENT</u>
Sex Male/Female	0/11	4/9
Age (years) Mean(Range)	47 (24 - 64)	48 (28 - 63)
Total length of stay Mean(Range) Number of inpatient days Mean(Range)	20.9 (17 - 31)	17.2 (14 - 22)
Caregiver types Number(%)		
Parent	N/A	3 (21.4)
Extended family	N/A	3 (21.4)
Spouse	N/A	6 (42.9)
Children	N/A	2(14.3)

#### Quality of Life

Quality of life instruments are administered verbally by the research coordinator/nurse to all patients and to caregivers of outpatients on a weekly basis beginning just prior to high dose chemotherapy and

continuing for one month post-discharge. Data is complete on 22 patients. The other 4 patients are not yet one month after discharge. The research coordinator/nurse is responsible for scoring the quality of life instruments and assists in entering the data into the data base. An PSS data base has been established to collect quality of life data. A case report form has been developed to assist in compiling necessary information (Appendix 1). Data is entered into the data base by two people to help insure accuracy.

### Cost Comparison

Clinical information for each enrolled patient was obtained from specifically designed case report forms, including dates of procedures, age, sex, disease and stage, treatment regimen, hospitalization and use of supportive care agents. Detailed financial records were obtained from the following sources: inpatient records including hospital bills and professional fees, outpatient records included home health bills, hospital bills (which include outpatient pharmacy charges and fees for the use of the outpatient cancer treatment facility), and professional fees. Data were collected from the time of transplant through discharge from the appropriate facility. Charges related to high-dose chemotherapy, stem cell harvest and pretransplant evaluations were excluded. Case report forms were used to cross-check the financial records and determine possible missing information. As the study proceeds, chart review will be used for quality assurance as well. All outpatients were housed in a Northwestern Memorial Hospital owned apartment at a rate of \$100/day. All outpatients and their caregivers were asked to complete a diary during the stay that collected information on out of pocket costs for medical care and meals, indirect costs due to the patient's or caregiver's absence from home (babysitting, home cleaning, lawn mowing, etc.), insurance deductibles, and time from work (paid or unpaid).

## RESULTS

### Quality of Life

There have not yet been enough patients with complete data to analyze differences in quality of life.

### Cost Analysis

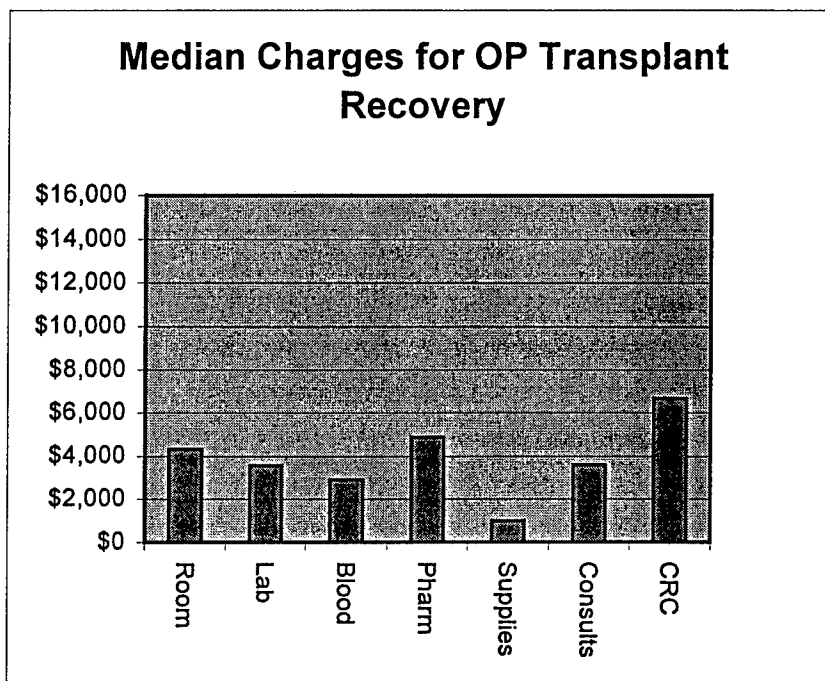
Retrieval and preliminary analysis of financial data for the first five inpatients and five outpatients has been completed. Data are reported as charges, as the cost to charge ratios for home health care are yet to be determined. The total charges for each arm of the study (analyzed beginning day 0) are:

	Inpatient* (n=5)	Outpatient** (n=5)
Median (Range)	\$44,336 (36,694-85,060)	\$26,404 (22,493-47,487)
Mean (SD)	\$53,276 (19,423)	\$30,159 (10,357)

\* Diagnoses included: 3 breast cancer, 2 lymphoma

\*\* Diagnoses included : 3 breast cancer, 1 lymphoma, 1 multiple myeloma

Data are reported as both means and medians. Median values for costs are often preferred for data that are highly-skewed, such as the cost data analyzed here, to decrease the significance of the outliers in the estimate. A breakdown of these charges for each treatment arm is shown in the following figures.



#### FUTURE DIRECTIONS

Accrual to this study continues. In future analyses an estimate of the opportunity cost for the time the caregiver is required to spend attending to the outpatient will be added to the total costs.

#### REFERENCES

1. Bennett CL, Armitage JL, Armitage GO, et al. Costs of care and outcomes for high-dose therapy and autologous transplantation for lymphoid malignancies. *J Clin Oncol* 1995;13:969-973.
2. Meisenberg BR, Miller WE, McMillan R, et al. Outpatient high-dose chemotherapy with autologous stem cell rescue for hematologic and non-hematologic malignancies. 1997; *J Clin Oncol* 15:11-17.
3. Jagannath S, Vesole D, Tricot G, et al. Outpatient autotransplants in multiple myeloma. *Blood* 1994;84:832 (abst).
4. Meisenberg BR, Ferran K, Hollenback K, et al. Reduced charges and costs associated with outpatient autologous stem cell transplantation. *Bone Marrow Transplant* 1998;21:927-32.

#### APPENDICES

Appendix 1 Quality of life case report form

Appendix 2 Abstract submitted for presentation at United Resource Network Transplant Symposium



## Appendices Project 2

### Revised Forms

1. Health Belief Questionnaire (revised)  
Health Belief Questionnaire (original)  
Sample translated form (Korean)
2. Decisional Balance Scales (revised)  
Decisional Balance Scale (original)  
Sample translated form (Hindi)
3. Breast Facts (original)  
Breast Facts (revised)  
Sample translated form (Amharic)
4. Stage of Adoption PHE Contact log  
Sample translated (Bosnian)

**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 Neutral      2-Disagree      1-Strongly Disagree Rarely or Never

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

33. I always follow medical orders because I believe they will benefit my state of health.      5      4      3      2      1

*Engl. sk*

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

*English  
Long Form*

CHICAGO ETHNIC COMMUNITIES BREAST CANCER EDUCATION PROJECT

시카고 소수민족사회의 유방암 교육·연구계획

HEALTH BELIEF QUESTIONNAIRE

건강신념에 대한 설문사항

Name (성명) \_\_\_\_\_ Agency (소속단체) \_\_\_\_\_ Date (날짜) \_\_\_\_\_

Pre test \_\_\_\_\_ Post test \_\_\_\_\_

5-Strongly Agree or Always 강한 동의함 혹은 항상	4=Agree or Sometimes 동의함 혹은 때때로	3=Neither Agree or Disagree Neutral 동의함도 동의안함도 아님 혹은 중간	2=Disagree or Rarely 동의안함 혹은 드물게	1=Strongly Disagree or Never 강한 동의안함 혹은 전혀
--	--	--	---	---

4. There is a high possibility that I will get breast cancer.  
(나는 유방암에 걸릴 높은 가능성이 있다.)

5 4 3 2 1

7. The thought of breast cancer scares me.  
(유방암에 대한 생각이 나를 두렵게 한다.)

5 4 3 2 1

9. If I had breast cancer my daily home activities or career would be endangered.  
(내가 유방암이라면 나의 가정사와 경력이 위태로울 것이다.)

5 4 3 2 1

18. If I had breast cancer, my whole life would change.  
(내가 유방암이라면, 나의 인생이 달라질 것이다.)

5 4 3 2 1

20. I have a lot to gain by doing self breast exams.  
(나는 유방자가검진을 함으로써 많은 것은 얻게 된다.)

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.  
(만일 내가 매달 유방자가검진을 한다면 정기건강검사에서 발견되기전에 '종양'을 찾을 수 있을 것이다.)

5 4 3 2 1

23. I would not be so anxious about breast cancer if I did monthly exams.  
(만일 내가 매월 자가검진을 했다면 유방암에 대해서 걱정하지 않을 것이다.)

5 4 3 2 1

33. I always follow medical orders because I believe they will benefit my state of health.  
(나는 항상 의사의 지시에 따른다. 왜냐하면 그들이 나의 건강상태를 이롭게 할 것이라고 믿기 때문이다.)

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 |
| <hr/> |   |   |   |   |   |   |
| 4.    | I would probably not have a mammogram unless I had some breast symptoms or discomfort.                      | 5 | 4 | 3 | 2 | 1 |
| <hr/> |   |   |   |   |   |   |
| 6.    | Once you have a normal mammogram, you don't need to have any more mammograms.                               | 5 | 4 | 3 | 2 | 1 |
| <hr/> |   |   |   |   |   |   |
| 8.    | I would be more likely to obtain a mammogram if a doctor told me how important it was.                      | 5 | 4 | 3 | 2 | 1 |
| <hr/> |   |   |   |   |   |   |
| 11.   | Mammograms are now a very common medical test.  | 5 | 4 | 3 | 2 | 1 |
| <hr/> |   |   |   |   |   |   |
| 12.   | My family will benefit if I have a mammogram.   | 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

*English Long Form*

CHICAGO ETHNIC COMMUNITIES BREAST CANCER EDUCATION PROJECT  
MAMMOGRAPHY QUESTIONNAIRE

नाम \_\_\_\_\_ एजन्सि \_\_\_\_\_ तारीख \_\_\_\_\_

परि टेस्ट \_\_\_\_\_ पोस्ट टेस्ट \_\_\_\_\_

5= पूरी तरह सहमत या कभी कभी 4= सहमत या कभी कभी 3= पता नहीं 2= सहमत नहीं 1= एकदम गलत या कभी नहीं

- |  |   |   |   |   |   |
|--|---|---|---|---|---|
| 1. अगर मैं स्वस्थ आकार वाली हूँ, तो मेरे को कैंसर होने की सम्भावना कम हो जाएगी और मुझे मैमोग्राम (mammogram) करवाने की ज़रूरत नहीं है। | 5 | 4 | 3 | 2 | 1 |
| 4. जब तक मुझे पृष्ठ में तकलीफ़ के लक्षण नहीं होते, मुझे मैमोग्राम (mammogram) करवाने की ज़रूरत नहीं है।                                | 5 | 4 | 3 | 2 | 1 |
| 6. यदि एक बार आप का मैमोग्राम (mammogram) सामान्य हो जाता है, तो आपको और मैमोग्राम (mammogram) करवाने की ज़रूरत नहीं है।               | 5 | 4 | 3 | 2 | 1 |
| 8. अगर मेरा डाक्टर कहे कि मैमोग्राम (mammogram) बहुत ज़रूरी है, तो मेरे लिए मैमोग्राम (mammogram) करवाने की सम्भावना बढ़ जाएगी।        | 5 | 4 | 3 | 2 | 1 |
| 11. अब मैमोग्राम (mammogram) एक बहुत साधारण चिकित्सा टेस्ट है।   | 5 | 4 | 3 | 2 | 1 |
| 12. मेरा परिवार का लाभ होगा, अगर मैं मैमोग्राम (mammogram) करवाती हूँ।   | 5 | 4 | 3 | 2 | 1 |

मैमोग्राम = mammogram

English

# CHICAGO ETHNIC COMMUNITIES BREAST CANCER EDUCATION PROJECT BREAST CANCER FACTS

Name: \_\_\_\_\_ Agency \_\_\_\_\_ Date \_\_\_\_\_

Pre test \_\_\_\_\_ Post test \_\_\_\_\_

READ OR LISTEN TO EACH STATEMENT. IF SOMEONE YOU KNOW SAID THIS TO YOU, WOULD YOU THINK, "YES, I AGREE, THIS COULD BE TRUE"; OR WOULD YOU THINK "NO, I DISAGREE. I DON'T THINK THIS IS TRUE". IF YOU AGREE WITH THE FOLLOWING STATEMENTS, WRITE A LARGE "Y" NEXT TO THE LINE. IF YOU DO NOT AGREE, WRITE A LARGE "N" NEXT TO THE LINE.

1. Breast cancer is the most common cancer in women. \_\_\_\_\_

2. Doctors know what causes breast cancer. \_\_\_\_\_

3. If no one in my family ever had breast cancer, then I cannot get it. \_\_\_\_\_

4. Breast pain is a sign of breast cancer. \_\_\_\_\_

5. Breast cancer is more likely to happen to old women than to young women. \_\_\_\_\_

6. Breast cancer is contagious. \_\_\_\_\_

7. Breast cancer can be cured. \_\_\_\_\_

8. Old women SHOULD have mammograms. \_\_\_\_\_

9. The best way for me to find a lump that might be cancer is to do breast self exam, have a doctor or nurse examine me and get a mammogram. \_\_\_\_\_

10. AT WHAT AGE SHOULD MOST WOMEN GET A MAMMOGRAM FOR THE FIRST TIME?

\_\_\_\_\_ 20      \_\_\_\_\_ 30      \_\_\_\_\_ 40      \_\_\_\_\_ 50      \_\_\_\_\_ 60

11. HOW OFTEN SHOULD YOU DO A BREAST SELF EXAM?

\_\_\_\_\_ Once a WEEK      \_\_\_\_\_ Once a MONTH      \_\_\_\_\_ Once a YEAR

12. HOW OFTEN SHOULD YOUR DOCTOR CHECK YOU FOR BREAST LUMPS?

\_\_\_\_\_ Once a MONTH      \_\_\_\_\_ Twice a YEAR      \_\_\_\_\_ Once a YEAR

15. WOMEN WHO ARE OLDER THAN 50 SHOULD GET A MAMMOGRAM

\_\_\_\_\_ Every 6 MONTHS      \_\_\_\_\_ Every YEAR      \_\_\_\_\_ Every 2 YEARS      \_\_\_\_\_ Every 5 YEARS

THANK YOU FOR TAKING OUR BREAST FACTS QUIZ.

REV. 8/14/97



English  
Old Form

### 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.

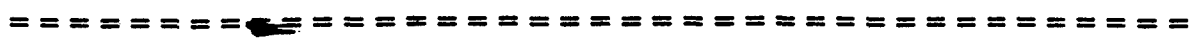
የችካጎ ኤትኒክ ኮሚቴ የጡት ካንሰር ትምህርትና ምርመራ ማስፋፊያ የሴቶች ለሴቶች ፕሮጀክት

የጡት ካንሰር እውነቶች ቅድመ ትምህርትና የትምህርት ማጠቃለያ ፈተና

በዓረፍተነገሩ መጨረሻ ባለው ባዶ ቦታ እውነት ወይም ሀሰት በማለት መልስ ይስጡ

- 1 በአሜሪካን አገር ከዘጠኝ አንድ ሴት የጡት ካንሰር ይይዛቸዋል። \_\_\_\_\_
- 2 ዶክተሮች የጡት ካንሰር ከምን አደሚመጣ ያውቃሉ። \_\_\_\_\_
- 3 የጡት ካንሰር በጣም በልጅነት እድሜያቸው ልጅ መውለድ የጀመሩ ሴቶችን የበለጠ ያጠቃል። \_\_\_\_\_
- 4 በቤተሰቤ የጡት ካንሰር የያዘው ሰው ከሌላ እኔም ሊይዘኝ አይችልም። \_\_\_\_\_
- 5 የጡት ካንሰር ከያዘዎት በሽታው በርስዎ ላይ መኖሩን በቀላሉ ያውቃሉ። \_\_\_\_\_
- 6 ከ 15 እስከ 20 ዓመት ዕድሜ ውስጥ ያለች ወጣት ሴት በጡቷ ውስጥ እጢ ካገኘች የተገኘው እጢ የጡት ካንሰር የመሆን እድሉ ከፍተኛ ነው። \_\_\_\_\_
- 7 ዕድሜያቸው ጠና ያለ ሴቶች በጡት ካንሰር የመያዝ ዕድላቸው አነስተኛ ነው። \_\_\_\_\_
- 8 የጡት ካንሰር ካያዘዎት ያለዎት ዕድል መሞት ብቻ ነው። \_\_\_\_\_
- 9 የጡት ካንሰር ሊድን ይችላል። \_\_\_\_\_
- 10 የጡት ካንሰር ገና ትንሽ እያለ ለማግኘት መንገዱ ያግል የጡት ምርመራ ማድረግ፣ የዶክተር የጡት ምርመራ ማደርግና ማሞግራም ማድረግ ነው። \_\_\_\_\_
- 11 በ 30 ዓመትዎ የመጀመሪያ የማሞግራም ምርመራ ማድረግ አለብዎት። \_\_\_\_\_
- 12 ዕድሜያቸው ጠና ያለ ሴቶች ማሞግራም ማድረግ አያስፈልጋቸውም። \_\_\_\_\_
- 13 በጡትዎ ውስጥ እጢ መኖር አለመኖሩን መመርመር ያለብዎት በስንት ጊዜ ነው?  
\_\_\_\_\_ በየሣምንቱ \_\_\_\_\_ በየወሩ \_\_\_\_\_ በዓመት አንድ ጊዜ
- 14 በጡትዎ ውስጥ እጢ መኖር አለመኖሩን በዶክተር ማስመርመር ያለብዎት በስንት ጊዜ ነው?  
\_\_\_\_\_ በየስድስት ወር \_\_\_\_\_ በዓመት \_\_\_\_\_ በሁለት ዓመት \_\_\_\_\_ በምስት ዓመት
- 15 ከሀምሳ ዓመት በላይ ከሆኑ ማሞግራም ማድረግ ያለብዎት በየስንት ጊዜ ነው?  
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Name: \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_  
Ethnic Group: \_\_\_\_\_

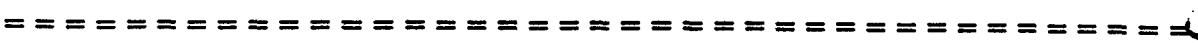


**MAMMOGRAPHY QUESTIONS**

- 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? \_\_\_\_\_
- D. Stage of Adoption for Mammography (circle one): 1 2 3 4

**STAGES OF ADOPTION FOR MAMMOGRAPHY**

- 1. No prior mammogram and no plan for one in the coming year.
- 2. EITHER: (a) No prior mammogram, but planning for one in the coming year.  
OR: (b) One or more prior mammograms, 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.

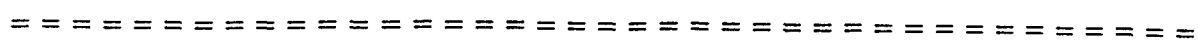


**BREAST SELF EXAM QUESTIONS**

- 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? \_\_\_\_\_
- D. Stage of Adoption for breast self exam (circle one): 1 2 3 4

**STAGES 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 for one in the next month.  
OR: (b) One or more prior breast self exams, but no plan for 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.



**Log of Contacts  
Women's Health Project**

Name \_\_\_\_\_ Telephone Number \_\_\_\_\_

Age \_\_\_\_\_ Ethnicity \_\_\_\_\_

**Initial Contact**

Date of Intervention \_\_\_\_\_

Stage of Adoption for Mammography \_\_\_\_\_

Stage of Adoption for Breast Self-Exam \_\_\_\_\_

Check if Pre-Test was administered \_\_\_\_\_

**Follow-Up #1**

Date of Intervention \_\_\_\_\_

Stage of Adoption for Mammography \_\_\_\_\_

Stage of Adoption for Breast Self-Exam \_\_\_\_\_

**Follow-Up #2**

Date of Intervention \_\_\_\_\_

Stage of Adoption for Mammography \_\_\_\_\_

Stage of Adoption for Breast Self-Exam \_\_\_\_\_

Check if Post-Test was administered \_\_\_\_\_

**Log of Contacts  
Women's Health Project**

Ime \_\_\_\_\_ Tel. Broj \_\_\_\_\_

Godine \_\_\_\_\_ Narodnost \_\_\_\_\_

Prvi Kontakt

Datum \_\_\_\_\_

Ocjena Ucesca u Mamografiji \_\_\_\_\_

Ocjena Ucesca u Samokontroli Grudi \_\_\_\_\_

Da li ste imali Pre-Test \_\_\_\_\_

Kontrolni Kontakt #1

Datum \_\_\_\_\_

Ocjena Ucesca u Mamografiji \_\_\_\_\_

Ocjena Ucesca u Samokontroli Grudi \_\_\_\_\_

Kontrolni Kontakt #2

Datum \_\_\_\_\_

Ocjena Ucesca u Mamografiji \_\_\_\_\_

Ocjena Ucesca u Samokontroli Grudi \_\_\_\_\_

Da li ste imali Post-Test \_\_\_\_\_

Ime: \_\_\_\_\_ Datum: \_\_\_\_/\_\_\_\_/\_\_\_\_  
Narodnost: \_\_\_\_\_

---

### MAMMOGRAPHY QUESTIONS

- A. Kada ste imali zadnji mamogram? \_\_\_\_\_  
B. Koliko ste dosad imali mamograma? \_\_\_\_\_  
C. Planirate li imati mamogram u ovoj godini? \_\_\_\_\_  
D. Ocjena Ucesca u mamografiji (zaokruzi):      1      2      3      4

### OCJENE UCESCA ZA MAMOGRAFIJU

1. Nije imala mamogram, i ne planira imati u slijedećoj godini.
2. a) Nije imala mamogram, ali planira jedan u slijedećoj godini.  
b) Jedan ili više prethodnih mamograma, ne planira jedan u slijedećoj godini.
3. Imala je jedan mamogram, i planira jedan u slijedećoj godini.
4. Imala je više od jednog mamograma, i planira jedan u slijedećoj godini.

---

### BREAST SELF EXAM QUESTIONS

- A. Kada si zadnji put sama pregledala dojke? \_\_\_\_\_  
B. Koliko puta si pregledala dojke? \_\_\_\_\_  
C. Planiras li samopregled dojki u slijedećem mjesecu? \_\_\_\_\_  
D. Ocjena Ucesca u samopregledu dojki (zaokruzi):      1      2      3      4

### OCJENE UCESCA ZA SAMOPREGLED DOJKI

1. Nikad se nije pregledala, i ne planira u slijedećem mjesecu.
2. a) Nije imala samopregled nikad, ali planira da pocne slijedećeg mjeseca.  
b) Imala je jedan ili više samopregleda, ali ne planira imati u slijedećem mjesecu.
3. Imala je jednom samopregled dojki, i planira jedan u slijedećem mjesecu.
4. Više od jednog samopregleda, i planira i slijedeći mjesec.

Appendices Project 3

1. Sample letters from participants
2. Submitted abstract

11-21-97.

Dear Kay + Cathy,  
I can't begin to  
tell you how much I enjoyed  
your informative class.  
Keep up the excellent work.  
Happy Holidays  
Deborah, RN

5500 North River Road • Rosemont, Illinois 60018  
(847) 678-4000 • For Reservations (800) 542-0912



Dear Kay & Cathy

3/6/98

The breast health course we completed last week was very complete and informative. Thank you so much for giving us such a structured course. I even shared some of my new information during my breast exam & mammogram take yesterday. I'm still enthusiastic.

Thanks again  
Evelyn Burns.

Kay & Cathy,

Thanks a million for your breast health course. The experience was very pleasant. I learned so much, - I was never bored with the ongoing teaching. I'm still trying to convince my mother and with the extra training, it made it easier for me to explain the mammogram. I think she's coming around because she's asked me more questions.

Thanks  
Janita Caine

Dear Kay & Cathy, Thanks a lot for a job well done. Keep up the good work!!!

Sharon Cook

Chicago Dept. of Public Health  
Woodlawn Outpost staff.



**ABSTRACT DEADLINE IS  
JUNE 1, 1998.**



21st Annual  
San Antonio  
Breast Cancer  
Symposium  
December 12-15, 1998

FOR OFFICE USE ONLY				
CK	CC	C	O	NP
Abst. #	Prog. #			

**ABSTRACT WILL BE PRESENTED BY**

Pearson Kay RN, BSN  
Family Name First Name MI Degree

**PRESENTER'S MAILING ADDRESS**

Northwestern Univ. Med. Sch.  
Institution, Department/Division (if applicable)  
333 E. Superior St. , #250  
Street Address or PO Box  
Chicago, Illinois 60611  
City, State, Postal Code  
USA  
COUNTRY

(312) 926-0858 / (312) 926-9039  
Telephone No.

(312) 926-1722  
FAX No.

kpearson@nmh.org  
E-Mail Address

**PRESENTATION PREFERENCE**

Poster  
 Slide  
 No preference

3 SUBJECT CATEGORY: Insert the number of the most appropriate subject category for your abstract. (Refer to list on reverse side.)

INSTRUCTIONS: Specific instructions are provided on the reverse side of this form. Be sure to note No-Show Penalty on page 2.

PAYMENT: \$25 each abstract. Pay by check or money order (must be in US Dollars and drawn on US bank), or credit card.

**In order to attend the meeting, you must also register. A Meeting Registration Form is included in this packet.**

**PRESENTER DISCLOSURE DECLARATION** (Required on ALL abstracts): It is the policy of The University of Texas Health Science Center at San Antonio School of Medicine that the presenter must disclose any real or apparent conflict of interest that may have a direct bearing on the subject matter of the program. This pertains to relationships with pharmaceutical companies, biomedical device manufacturers, or other corporations whose products or services are related to the subject matter of the presentation topic. The intent of this policy is merely to identify openly any potential conflict so that listeners may form their own judgments about the presentation with full disclosure of the facts. IF NONE, WRITE "NONE."

I have a financial interest/arrangement or affiliation with one or more organizations, named below, that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

List of Organization(s) (IF NONE, WRITE "NONE"): NONE

Signature (REQUIRED) Kay L Pearson Date 5/29/98

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Signature Kay L Pearson Exp. Date (MMYY) 11/98

**ABSTRACT**  
Do not fold • Type inside blue space below

Short-term Results of a Program of Breast Health Education for Minority Care Providers: K. Pearson, C. Bucci, K. O'Connell, and M. Morrow. Lynn Sage Breast Program. Northwestern University Medical School, Chicago, IL 60611

Many minority/low income women receive health care from non-MD's. This study was undertaken to assess the level of breast health knowledge of primary care nurse providers and determine the effect of a short-term educational intervention. The intervention included 16 hours of small group lectures and breast self-exam (BSE) instruction with Mammocare models. Evaluation was by a pre and posttest and evaluation of clinical breast exam (CBE) on a standardized patient. A total of 69 nurses from city health clinics and 2 minority clinics participated. Mean age of participants was 46 years (range 23-64 years) and the number of years in practice was 3 months-43 years (62% > 10 years). Sixty-one percent were African American, 16% Hispanic, 17% Caucasian, 3% Asian and the remainder unknown. Although 84% instructed women in BSE and 83% taught screening guidelines, only 56% scored in the 75<sup>th</sup> percentile or above on a pretest of basic breast health facts. Post test scores improved for both the written test and CBE. Scores of 75% or better were recorded for 94% of participants, an increase of 38%. Only 66 participants had pre and post CBE testing, and 82% improved, with the remainder showing no change. Although a majority of participants did improve on the CBE, 48% were not examining supraclavicular nodes, 74% were not supporting the arm when checking axillary lymph nodes and 64% did not search all breast tissue. We conclude that a brief, low-cost educational intervention improves both knowledge and CBE skill in the short term. Written testing and standardized patients are complimentary methods of evaluation. Participants will be retested in 1 year to determine the long-term effect of this program.

Supported by DAMD 17-96-2-6013

Appendix Project 5

Society of Behavioural Medicine abstract

## SEMINAR MINORITY COMMUNITIES: ARE THEY REALLY HARD TO REACH ?

Marian L. Fitzgibbon, Ph.D., Sara Knight, Ph.D., Northwestern  
University Medical School, Elaine, Prewitt, R.D., Dr. Ph. Loyola  
University Medical School

This is a seminar for a broad range of health care providers and scientists, including psychologists, physicians, dieticians, nurses, epidemiologists, and public health professionals who conduct or plan to conduct health risk reduction interventions in minority populations.

This seminar will address recruitment, development, and implementation strategies across and unique to ethnic group, age, gender, socioeconomic status, and disease. We will also focus on choice of setting, community relations, incorporation of neighborhood peer leaders, training of staff, development of culturally relevant material, and the use of incentives for program enhancement. Specifically, Dr. Prewitt will examine these issues as they relate to a cardiovascular disease (CVD) risk reduction intervention with over 400 adult households in a working class suburban Black neighborhood. Dr. Fitzgibbon will describe a CVD risk reduction program for 300 inner city Black families. She and Dr. Prewitt will compare and contrast strategies as a function of SES, gender, and unit of recruitment. Dr. Knight will address these same issues in a population of low-acculturated, inner city Hispanic women participating in a breast cancer risk reduction intervention. Additionally, information gathered from focus groups conducted with these populations will be presented.

The seminar will be presented through slides, videos, and discussion. We encourage participants to call or contact the corresponding author in advance about their specific project prior to the seminar so that we may examine several projects in depth over the course of the seminar.

Corresponding Author: Marian L. Fitzgibbon, Ph.D.,  
Department of Psychiatry and Behavioral Sciences, 303 E. Ohio, Suite  
550, Chicago, IL 60611.

Appendix Project 8

1. Quality of life case report form
2. Abstract submitted for presentation at United Resource Network Transplant Symposium

**PROJECT #8**  
**APPENDIX 1**  
**95H5 DATA SHEET**

**NAME:** \_\_\_\_\_

**ID #:** \_\_\_\_\_

**SEX:**           \_\_ male           \_\_ female

**DATE OF BIRTH:** \_\_\_\_\_

**DISEASE:**           \_\_ Breast Cancer  
                  \_\_ NHL  
                  \_\_ HD  
                  \_\_ MM  
                  \_\_ Leukemia  
                  \_\_ Other

**HIGH DOSE CHEMOTHERAPY:**           \_\_ Busulfan, cytoxan  
  \_\_ Cytoxan, thiotepa, taxol  
  \_\_ Cytoxan, thiotepa  
  \_\_ Melphalan  
  \_\_ Cytoxan, TBI

**GROWTH FACTOR TYPE:**           \_\_ GMCSF  
  \_\_ GCSF  
  \_\_ Experimental

**RADIATION THERAPY:**           \_\_ yes           \_\_ no

**IN OR OUTPATIENT:**           \_\_ inpatient           \_\_ outpatient

**DATE OF DIAGNOSIS:** \_\_\_\_\_

**TIME SINCE DIAGNOSIS:** \_\_\_\_\_

**NUMBER OF PREVIOUS CHEMO  
TYPES IN PT. HISTORY:** \_\_\_\_\_

**RELAPSE:**           \_\_ relapse disease  
  \_\_ original disease

**STAGE OF DISEASE:**           \_\_ local

metastatic  
 not applicable

DATE OF ADMISSION: \_\_\_\_\_

# OF ICU DAYS: \_\_\_\_\_

LENGTH OF STAY: \_\_\_\_\_

NUMBER OF INPATIENT DAYS: \_\_\_\_\_

DATE OF START OF CONDITIONING: \_\_\_\_\_

DATE OF REINFUSION: \_\_\_\_\_

DATE OF DISCHARGE: \_\_\_\_\_

DAYS WITH ANC UNDER 500: \_\_\_\_\_

TYPE OF GRAFT: \_\_\_\_\_

NUMBER OF CAREGIVERS: \_\_\_\_\_

MARITAL STATUS:  married  
 separated  
 divorced  
 widowed  
 single

RACE:  caucasian  
 African American  
 Hispanic  
 Asian  
 Middle Eastern  
 other

EMPLOYMENT STATUS:  full time  
 part time  
 not employed

DISABILITY:  yes  
 no

**EDUCATION LEVEL:**

- elementary school
- partial high school
- high school diploma
- some college
- college graduate
- graduate or professional school

**TYPE OF INSURANCE:**

- HMO
- PPO
- fee for service
- free care
- medicare
- medicaid
- other

**HOUSEHOLD INCOME:**

\_\_\_\_\_

**CAREGIVER CONFIDENCE:**

- TEMP
- INTAKE
- PHYSICIAN CONTACT
- GROWTH FACTOR INJECTIONS
- DIET RESTRICTIONS
- MEDICATIONS
- CATHETER
- TEMP2
- INTAKE2
- PHYSICIAN CONTACT 2
- GROWTH FACTOR2
- DIET RESTRICTIONS2
- MEDICATIONS
- CATHETER 2
- EXERCISE
- OVERALL CONFIDENCE

**FACT FOR CAREGIVER TIME 1**

- PHYSICAL
- SOCIAL
- DOCTOR
- EMOTIONAL
- FUNCTIONAL
- BMT
- TOTAL

**POMS FOR CAREGIVER TIME 1**

- NEGATIVE
- POSITIVE



IES FOR CAREGIVER TIME 1

\_\_\_ TOTAL  
\_\_\_ INTRUSION  
\_\_\_ AVOIDANCE

PERCEIVED INVOLVEMENT IN CARE  
TIME 1

\_\_\_  
\_\_\_  
\_\_\_

FACT FOR CAREGIVER TIME 2

\_\_\_ PHYSICAL  
\_\_\_ SOCIAL  
\_\_\_ DOCTOR  
\_\_\_ EMOTIONAL  
\_\_\_ FUNCTIONAL  
\_\_\_ BMT  
\_\_\_ TOTAL

POMS FOR CAREGIVER TIME 2

\_\_\_ NEGATIVE  
\_\_\_ POSITIVE

IES FOR CAREGIVER TIME 2

\_\_\_ TOTAL  
\_\_\_ INTRUSION  
\_\_\_ AVOIDANCE

PERCEIVED INVOLVEMENT IN CARE  
TIME 2

\_\_\_  
\_\_\_  
\_\_\_

FACT FOR CAREGIVER TIME 3

\_\_\_ PHYSICAL  
\_\_\_ SOCIAL  
\_\_\_ DOCTOR  
\_\_\_ EMOTIONAL  
\_\_\_ FUNCTIONAL  
\_\_\_ BMT  
\_\_\_ TOTAL

POMS FOR CAREGIVER TIME 3

\_\_\_ NEGATIVE  
\_\_\_ POSITIVE

IES FOR CAREGIVER TIME 3

\_\_\_ TOTAL  
\_\_\_ INTRUSION  
\_\_\_ AVOIDANCE

PERCEIVED INVOLVEMENT IN CARE  
TIME 3

\_\_\_  
\_\_\_  
\_\_\_

FACT FOR CAREGIVER TIME 4

\_\_\_ PHYSICAL  
\_\_\_ SOCIAL  
\_\_\_ DOCTOR  
\_\_\_ EMOTIONAL  
\_\_\_ FUNCTIONAL  
\_\_\_ BMT  
\_\_\_ TOTAL

POMS FOR CAREGIVER TIME 4

\_\_\_ NEGATIVE  
\_\_\_ POSITIVE

IES FOR CAREGIVER TIME 4

\_\_\_ TOTAL  
\_\_\_ INTRUSION  
\_\_\_ AVOIDANCE

PERCEIVED INVOLVEMENT IN CARE  
TIME 4

\_\_\_  
\_\_\_  
\_\_\_

FACT FOR CAREGIVER TIME 5

\_\_\_ PHYSICAL  
\_\_\_ SOCIAL  
\_\_\_ DOCTOR  
\_\_\_ EMOTIONAL  
\_\_\_ FUNCTIONAL  
\_\_\_ BMT  
\_\_\_ TOTAL

POMS FOR CAREGIVER TIME 5

\_\_\_ NEGATIVE  
\_\_\_ POSITIVE

IES FOR CAREGIVER TIME 5

\_\_\_ TOTAL  
\_\_\_ INTRUSION  
\_\_\_ AVOIDANCE

PERCEIVED INVOLVEMENT IN CARE  
TIME 5

\_\_\_  
\_\_\_  
\_\_\_

**ECOG PERFORMANCE STATUS:**

- BASELINE
- TIME 2
- TIME 3
- TIME 4
- TIME 5
- TIME 6
- TIME 7

**CAREGIVER TYPE:**

- spouse or significant other
- parent
- sibling
- extended family
- friend
- not applicable

**FACT TIME 1**

- physical well being time
- social
- doctor relationship
- emotional
- functional time
- bmt additional concerns
- total

**POMS TIME 1**

- negative
- positive

**IES TIME 1**

- total
- intrusion
- avoidance

**MONITORING TIME 1**

\_\_\_\_\_

**BLUNTING TIME 1**

\_\_\_\_\_

**PREVIOUS CHEMOTHERAPY  
TOTAL NUMBER OF CYCLES:**

\_\_\_\_\_

**PROTOCOL NUMBER FOR  
HIGH DOSE REGIMEN:**

- 96B1
- 87H5
- 87H6
- 93H2
- ECOG 2190
- 94H1

**FACT TIME 2**

\_\_\_physical well being time  
\_\_\_social  
\_\_\_doctor relationship  
\_\_\_emotional  
\_\_\_functional time  
\_\_\_bmt additional concerns  
\_\_\_total

**POMS TIME 2**

\_\_\_negative  
\_\_\_positive

**IES TIME 2**

\_\_\_total  
\_\_\_intrusion  
\_\_\_avoidance

**FACT TIME 3**

\_\_\_physical well being time  
\_\_\_social  
\_\_\_doctor relationship  
\_\_\_emotional  
\_\_\_functional time  
\_\_\_bmt additional concerns  
\_\_\_total

**POMS TIME 3**

\_\_\_negative  
\_\_\_positive

**IES TIME 3**

\_\_\_total  
\_\_\_intrusion  
\_\_\_avoidance

**FACT TIME 4**

\_\_\_physical well being time  
\_\_\_social  
\_\_\_doctor relationship  
\_\_\_emotional  
\_\_\_functional time  
\_\_\_bmt additional concerns  
\_\_\_total

**POMS TIME 4**

\_\_\_negative  
\_\_\_positive

**IES TIME 4**

\_\_\_total  
\_\_\_intrusion  
\_\_\_avoidance

**FACT TIME 5**

\_\_\_ physical well being time  
\_\_\_ social  
\_\_\_ doctor relationship  
\_\_\_ emotional  
\_\_\_ functional time  
\_\_\_ bmt additional concerns  
\_\_\_ total

**POMS TIME 5**

\_\_\_ negative  
\_\_\_ positive

**IES TIME 5**

\_\_\_ total  
\_\_\_ intrusion  
\_\_\_ avoidance

**FACT TIME 6**

\_\_\_ physical well being time  
\_\_\_ social  
\_\_\_ doctor relationship  
\_\_\_ emotional  
\_\_\_ functional time  
\_\_\_ bmt additional concerns  
\_\_\_ total

**POMS TIME 6**

\_\_\_ negative  
\_\_\_ positive

**IES TIME 6**

\_\_\_ total  
\_\_\_ intrusion  
\_\_\_ avoidance

**FACT TIME 7**

\_\_\_ physical well being time  
\_\_\_ social  
\_\_\_ doctor relationship  
\_\_\_ emotional  
\_\_\_ functional time  
\_\_\_ bmt additional concerns  
\_\_\_ total

**POMS TIME 7**

\_\_\_ negative  
\_\_\_ positive

**IES TIME 7**

\_\_\_ total  
\_\_\_ intrusion  
\_\_\_ avoidance

**FACT TIME 8**

- \_\_\_ physical well being time
- \_\_\_ social
- \_\_\_ doctor relationship
- \_\_\_ emotional
- \_\_\_ functional time
- \_\_\_ bmt additional concerns
- \_\_\_ total

**POMS TIME 8**

- \_\_\_ negative
- \_\_\_ positive

**IES TIME 8**

- \_\_\_ total
- \_\_\_ intrusion
- \_\_\_ avoidance

PROJECT #8  
APPENDIX 2  
**INPATIENT VERSUS OUTPATIENT HIGH-DOSE CHEMOTHERAPY  
WITH STEM CELL RESCUE**

Patti Frey, Kathy O'Gara, Tammy Pajeau, Halina Rubin, Alfred Rademaker, Sara Knight, Charles Bennett, Jane Winter  
Robert H. Lurie Cancer Center, Division of Hematology/Oncology, Northwestern University/Northwestern Memorial Hospital/Northwestern Home Health Care, Inc., Chicago, Illinois.

The cost of high dose therapy with stem cell rescue for the treatment of malignant disease has escalated over recent years and the numbers of patients seeking such therapy nationally has grown exponentially. This has led to extraordinary scrutiny by payors, requiring that transplanters look at ways to reduce the overall cost of treatment. There is the perception that outpatient therapy is less expensive than inpatient treatment, but this may not be the case. In addition to the direct costs involved, substantial out-of-pocket and indirect costs may be incurred by the required round the clock caregiver.

Currently we are conducting a study to determine if the cost of high dose chemotherapy, with or without radiotherapy, with autologous peripheral blood progenitor cell reinfusion is reduced through the use of intensive outpatient support without causing a decrease in the quality of life. This research supported by the Department of Defense. It involves a cost comparison of patients who receive their transplants as inpatients versus those who receive transplant as outpatients. This study includes a prospective comparison of quality of life between the two groups. Patients are matched according to disease and transplant protocol. At the completion of the study, a total of 72 patients will be enrolled, 36 inpatients and 36 outpatients. Secondly, we have found that outpatient transplant is not appropriate for all patients and are collecting information on the varied reasons patients do not qualify to receive an outpatient stem cell transplant. We will discuss the instruments and sources that we are using to collect direct and indirect cost information; the tools that are being used to assess quality of life, caregiver readiness, and caregiver burden; and the data we have collected on patients unable to undergo stem cell transplant as an outpatient.



DEPARTMENT OF THE ARMY  
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND  
504 SCOTT STREET  
FORT DETRICK, MARYLAND 21702-5012

REPLY TO  
ATTENTION OF:

MCMR-RMI-S (70-1y)

21 Feb 03

MEMORANDUM FOR Administrator, Defense Technical Information  
Center (DTIC-OCA), 8725 John J. Kingman Road, Fort Belvoir,  
VA 22060-6218

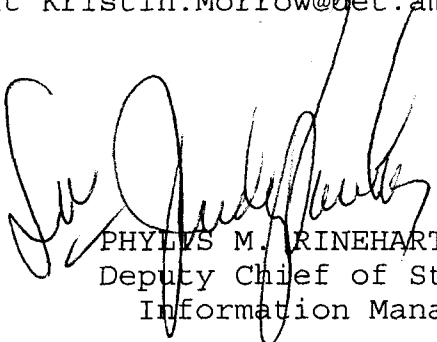
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1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for this Command. Request the limited distribution statement for the enclosed accession numbers be changed to "Approved for public release; distribution unlimited." These reports should be released to the National Technical Information Service.

2. Point of contact for this request is Ms. Kristin Morrow at DSN 343-7327 or by e-mail at Kristin.Morrow@det.amedd.army.mil.

FOR THE COMMANDER:

Encl

  
PHYLLIS M. RINEHART  
Deputy Chief of Staff for  
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